Treating Drivers of Suicide in Primary Care using Jaspr Health

Study Protocol & Statistical Analysis Plan

Sterling IRB Protocol: 12603

National Clinical Trial (NCT) Identified Number: NCT05427734

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3. INTRODUCTION

Suicide remains a serious public health problem in the United States (U.S.) as rates have risen nearly each year since 2005, from 11.0 per 100,000 to 14.8 per 100,000 in 2018, totaling 48,344 in 2018; 1.4 million U.S. adults made a suicide attempt, and another 12 million thought seriously about killing themselves that same year. Alcohol use disorder (AUD) exponentially increases suicide risk and can also interfere with suicide prevention intervention efforts. Digital technologies can efficiently and reliably help deliver suicide prevention evidence-based practices and increase the confidence and competence of providers in treating suicide, including when AUDs and other behavioral problems ("drivers of suicide;" e.g., anxious/depressed mood, sleep problems) may interfere with these efforts.

This project will test the newly developed *WisePath for Adults* ("WisePath"), a robust digital technology developed under NIAAA SBIR Fast-Track award (R44AA029868; Drs. Dimeff & Jobes, Co-PIs) that is developed to efficiently and reliably aid delivery of recommended best-practices for the treatment of suicidal ideation in adults, including suicidal individuals who also misuse alcohol. WisePath includes techniques for prevention of suicidal behaviors (ideation, planning, attempts) while providing support *in the moment* via a mobile app. WisePath will include evidence-based practices for suicide prevention, including for those who are suicidal and also experience other behavioral health concerns such as depressed mood, sleep problems, and misuse of alcohol. This study will test WisePath with individuals who are experiencing these problems and recently sought treatment from a primary care provider. WisePath includes: psychoeducation, behavioral skills training, crisis stabilization planning, lethal means management, brief interventions for the treatment of suicidal ideation, depressed mood, sleep problems, alcohol misuse, and messages of hope, wisdom, and insights from people with lived experience (PLE).

We will conduct a randomized controlled trial (RCT; N=120) comparing WisePath (n=60) to an active control condition (Virtual Hope Box and electronic wellness resources brochure; n=60) in adults experiencing suicidal ideation. To ensure a sufficient sample of individuals who misuse alcohol, no fewer than 35% (n=42) of the sample will be comprised of individuals who experience a harmful or hazardous level of alcohol use. Participants will be randomly assigned to a condition utilizing a minimization randomization procedure to match participants across condition on suicide severity, depression severity, and alcohol misuse. Participants will be assessed at baseline, 4, 8, and 12 weeks. Participants will be compensated $60 for completion of each of the follow-up assessments (4-, 8-, and 12-week); no payment will be provided for completion of the baseline assessment, however participants will receive a $60 bonus for completing all assessments. Participants who complete each assessment (including baseline) within 72 hours of the scheduled appointment will earn a chance to win one of 13 $100 Amazon gift cards (1 provided to pilot test participants, 12 to RCT participants) that will be raffled at the end of the study (i.e., those who complete all four assessments on time will have four raffle entries). If a participant decides to withdraw or end participation prior to completing their trial or if they are administratively withdrawn by the researchers, they will be compensated the total amount for the assessments they have completed.

Prior to commencing the RCT, we will conduct a small pilot trial with target end-users (N=20), using identical procedures (including inclusion and exclusion criteria) that will be applied in the RCT. The purpose of the pilot is to make necessary adjustments to both study procedures and WisePath before the RCT is conducted. We will address problems and barriers during the pilot trial. The RCT will begin after all issues that could adversely impact the study are resolved during the pilot. As a final check of WisePath, we will over-recruit for the WisePath condition, comparing WisePath (n=15) to the active control (n=5). In contrast to the proposed 12-week RCT, the pilot study will last 6 weeks and will include 3 assessments (baseline, 3 and 6 weeks). Participants taking part in the pilot trial will receive $60 each for the 3- and 6-week assessment points they complete, as well as a chance to win the Amazon gift cards as described above (up to 3 entries, depending on how many assessments completed within 72 hours of the scheduled assessment).

A. Type of Research

This study involves behavioral research. The focus of this summative evaluation study is to compare WisePath to an active control condition to test its effectiveness. Our goal is to test the newly developed WisePath app designed to deliver evidence-based interventions that directly treat a person's reasons for wanting to die (their "drivers" for suicide) while simultaneously addressing alcohol misuse and other co-occurring behavioral health problems (e.g., mood, sleep problems) when relevant.

B. Purpose/Objective of the Study

The central purpose of this project is to evaluate and facilitate evidence-based best practices for individuals struggling with suicidal ideation and co-occurring behavioral problems, including alcohol misuse, and provide assistance to the patients while they are waiting to receive care, as they are receiving care, and after they return home. While WisePath is highly innovative in *how* it delivers these best practices, the content is well-established and known to reduce suicidality and alcohol misuse.

We will conduct a 12-week intent-to-treat RCT with 120 suicidal adults 22 years and older who may also be experiencing alcohol misuse. Participants will be randomly assigned to WisePath (n=60) or an active control condition (n=60) including Virtual Hope Box, a well-regarded suicide prevention self-help app, plus an electronic wellness resources brochure containing links to health and wellness materials, psychoeducation about suicide, depression, self-help recovery-focused resources (e.g., Alcoholics Anonymous and other 12-Step programs, Moderation Management, etc.), and phone/text information for the 988 Suicide & Crisis Lifeline. Participants will be assessed at baseline, 4, 8 and 12 weeks.

We hypothesize that in comparison to the active control condition, WisePath participants will show significantly better outcomes from baseline to the 4-, 8-, and 12-week assessment points such that:

1. WisePath participants will report significantly greater decreases in suicidal and alcohol misuse behaviors compared to controls
2. WisePath participants will report greater increases in self-efficacy and coping with suicidal thoughts and distress, as well as use of suicide prevention strategies compared to study controls
3. WisePath participants will report a higher degree of satisfaction with their respective app compared to controls

Prior to commencing the RCT, we will first conduct a pilot trial to ensure clarity of research protocol instructions, to validate time estimates to complete research measures, and to ensure that all aspects of the research protocol are sensitive to the needs and experiences of suicidal individuals, applying the same recruitment strategy, participant criteria, research procedure, and outcome measures as will be applied in the RCT. As a final check of WisePath app, we will over-recruit for the WisePath condition, comparing WisePath (n=15) to the active control (n=5). In contrast to the proposed 12-week RCT, the pilot study will last 6 weeks and will include three assessments (baseline, 3 and 6 weeks).

C. Background of the Study

Globally, suicide is a significant public health problem accounting for approximately 800,000 deaths annually.[1] Death by suicide is the second leading cause of death for people ages 15 to 24 worldwide[2] and the second leading cause of death for people ages 10-34 in the United States.[3] In addition to the lives lost annually to suicide, far more people seriously think about (12.3 million), make a serious plan (3.5 million), or make an attempt annually (1.7 million).[4] In addition to the devastating impact of suicide on those left behind,[5] the economic annual cost of suicide between 2015 and 2020 averaged $484 billion.[6]

Individuals struggling with self-injurious thoughts and behaviors need access to evidence-based resources, but often do

not receive it. For communities with limited behavioral health resources, referrals to behavioral health specialists for management of problems contributing to suicidality are problematic for a variety of reasons including lack of clinical resources, emphasis on stabilization during a crisis rather than ongoing care, and barriers to patient treatment access and engagement.

There is a well-established gap between the prevalence of mental health disorders and availability of behavioral health providers in general,[7,8] and for suicide in particular.[9] For instance, currently only 11 states mandate suicide focused training for counselors, therapists, etc. and majority of behavioral health providers do not receive any training in suicide assessment and intervention.[10] Moreover, many providers are reluctant to treat suicidal ideation in patients because they do not know what to do, fear they may make the patient worse, or be sued for malpractice. These issues can contribute to complete lack of availability (particularly in rural communities), long waitlists, and treatment delivery from well-meaning, but untrained providers that may lack empirical support.

When providers are available, there continue to be challenges in the delivery of care for individuals struggling with suicidality and co-occurring behavioral health problems. The emphasis in many settings is often on reducing acute crises (e.g., The Joint Commission (TJC) requirement of safety planning, lethal means assessment). While these efforts are critical, they may not effectively address the issues contributing to the individual's suicidality, including commonly co-occurring behavioral health problems (e.g., alcohol misuse, depressed mood, sleep problems). It can also be rare that providers are trained in evidence-based practices for both suicidality and the array of co-occurring behavioral health problems.

Alcohol use disorder (AUD) is consistently implicated in suicidal behaviors and death by suicide[11–18] and is associated with a tenfold increase in risk for suicide.[19–21] According to the CDC, alcohol intoxication is involved in approximately 22% of suicides and in approximately 30-40% of all suicide attempts.[22] Among persons seeking treatment for alcohol dependence, about 40% have made at least one suicide attempt in their lifetime.[19,23–25] In one study of 50 suicides, AUD was the primary diagnosis in 23% of cases, and co-occurred in another 37% of cases.[26] In another study, 56% of those who died by suicide had a lifetime history of AUD.[27] While the behavioral mechanisms for the relationship are complex, alcohol may increase the risk of suicide by decreasing inhibitions and increasing depressed mood.[11] Other factors for suicide may include alcohol's ability to: (1) increase psychological distress and agitation; (2) propel suicidal ideation into action through suicide-specific alcohol expectancies (e.g., provides "liquid courage" to act and/or makes the act itself painless); and (3) constrict cognition, which in turn impairs problem-solving and use of adaptive coping strategies.[28]

In addition, there are very frequently significant other barriers to treatment access and engagement even when evidence-based intervention delivery is available. Such barriers include structural barriers related to patient resources (e.g., cost, childcare, transportation costs, ability to take time off work), as well as greater perceived stigma, particularly within lower income communities[29] and among minoritized racial/ethnic communities.[30]

Digital technologies can help address unmet treatment needs. Meta-analytic efforts support the delivery of self-guided computerized cognitive-behavioral therapy (CCBT) for numerous mild to moderate behavioral health problems, including depression, panic, and anxiety as well as alcohol and substance use,[50,51] Additionally, nine meta-analyses conducted worldwide have found that such interventions outperform wait-list controls and treatment as usual, producing small to medium effect sizes, and can perform comparably to traditional face-to-face therapy.[37,38, 83–88] Moreover, digital support tools offer many advantages that can help improve access to evidence-based care, including availability for use whenever and wherever they are most needed (e.g., 24-hours a day, rural areas), delivery in areas with behavioral health shortages (e.g., rural and low-income communities), all without inattention, drift, burnout, or compassion fatigue. As such they can be a powerful tool in stepped care models (i.e., healthcare models that match intervention strategy to severity and course of the problem).[60,61] Although some mobile apps targeting these individual mental and behavioral health problems have been developed for adults with promising outcomes,[62,63] no mobile

technologies currently exist that address both suicidal ideation and co-occurring behavioral health concerns. Mobile technology support tools are scalable, low-cost, and liked by consumers[64] when they are used.

4. PARTICIPANT SELECTION

A. Inclusion and Exclusion Criteria

Potential participants will first complete an eligibility screen to ensure they meet study criteria:

Inclusion Criteria:

- Resides in the United States
- 22+ years of age
- English speaking
- At risk for suicide, as evidenced by at least one of the following:
    - One or more lifetime suicide attempts (ASQ item 4)
    - Endorsement of any ASQ items 1 -3 (expanded from "past few weeks" in ASQ to "past 30 days" in our measures)
        - Item 1: In the past 30 days, have you wished you were dead?
        - Item 2: In the past 30 days, have you felt that you or your family would be better off if you were dead?
        - Item 3: In the 30 days, have you been having thoughts about killing yourself?
- Currently has a primary care provider and sought care from them in the past year
- Possesses and is the primary user of an Android- or iPhone-based smartphone with a data plan

Given that alcohol misuse exponentially increases the risk of death by suicide, can exacerbate other problems, and interfere with effective treatment, we will over-recruit individuals who misuse alcohol to ensure relevance of the tool for them. No fewer than 35% of the sample will be comprised of individuals who score 8 or more on the Alcohol Use Disorders Identification Test (AUDIT), indicating a harmful or hazardous level of drinking.

Exclusion Criteria:

- Severe depression (PHQ-9 score of 20 or greater)
- Alcohol dependence (AUDIT score of 32 or greater)
- Acutely suicidal (affirms item 5 of the Ask Suicide Screening Questions; *Are you having thoughts of killing yourself right now*? Followed by endorsing intent; *Have you intended to act on urges to kill yourself in the past 30 days?* or planning within the past 30 days; *Have you made a plan to kill yourself in the past 30 days?*)
- Significant drug abuse problems (scores 6 or greater on the DAST-10)
- Previous participation in NIAAA formative research (i.e., used or was exposed to WisePath app)
- Current use of the Virtual Hope Box app

Individuals who are excluded because of the severity of their depression, suicide acuity, and/or degree of substance use disorder will be provided with resources (i.e., the Suicide and Crisis Lifeline (988), SAMHSA's National Helpline) and encouraged to reach out to their primary care or mental/behavioral health provider.

Because we have experienced a number of participants in other studies recruited from social media faking their identities (and thus likely faked clinical symptoms, history) to participate in the study (i.e., said they resided in the US, but later we found they actually were located in Africa or other countries), we would like the option to verify the identity and/or residency of prospective participants. This may include requiring prospective participants to turn their cameras on during

virtual meetings and/or asking the individual to verify they are in the US by showing either their state-issued driver's license/ID card or a piece of mail showing their name and a US mailing address. Any individual who cannot demonstrate their residency will be told that the session cannot proceed, and they will not be enrolled in the study.

B. Gender

This study will not limit inclusion of any group by sex/gender, race, and/or ethnicity. Women as well as men will be eligible for all phases of this study. The research team will maintain a focused effort on ensuring that the percent of women and minority participants recruited for this study are representative of the broader group of target end-users. In addition to recruitment from care clinics (e.g., outpatient clinics, primary care), listservs, and other groups serving providers who treat individuals experiencing suicidality, we will utilize social media platforms (e.g., Facebook, Instagram) and referrals from our professional network to ensure we reach a diverse participant population.

C. Racial/Ethnic Origin

To ensure that the sample demographic represents the racial/ethnic make-up of the U.S. population, we may augment our recruitment efforts to include recruitment using social media and/or third-party recruitment companies. This allows us to recruit from ethnically and racially diverse regions of the country to ensure a match between the U.S. ethnic/racial demographic make-up with the diversity of our research sample or targeted recruitment from groups on social media platform that include individuals that may be interested/eligible to participate in this research.

Dr. Dimeff has successfully employed a number of approaches in her previous research to reach recruitment targets with respect to ethnic and racial minorities. If needed, we will pursue these approaches including: Significantly expanding recruitment efforts in ethnically and racially diverse geographic locations, to agencies serving ethnic and racial minorities, and taking a much more active, personal approach throughout the recruitment effort. This latter approach often involves identifying what matters to the organization in advance and seeking ways to link our request to their needs/interests/mission.

D. Vulnerable Populations

The risk to participants in this research is minimal when applying NIH risk standards and designations. According to these NIH guidelines, "minimal risk to subjects means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and that confidentiality is adequately protected. This category includes protocols that pose "no greater than minimal risk" according to federal regulations."

This study does include patients who are currently suicidal. By definition these patients are inherently high-risk participants; however, the question to consider for this research is whether the study procedures are likely to make the participants more suicidal. We believe the answer is no. Past research found that many of the patient participants enjoyed providing their feedback during the interview sessions and having their opinion/perspective valued. Some also described that for the moments they were interacting with the research team, their mind was off their worries.

However, as a precaution, all participants will complete the debrief protocol and, in the unlikely event that a participant experiences high distress during or after an interview, a member of our clinical staff (e.g., PI Dr. Linda Dimeff or Co-Investigator Dr. Allison Ruork) will immediately join the call with the participant and provide crisis support, including teaching behavioral skills and/or connection with 988 crisis hotline.

E. Age

Participants under the age of 22 will be excluded from participating in the study as suicide interventions and assessments for adolescents and children differ significantly from those for adults.

F. Total Number of Participants to be Enrolled

Anticipated total number of participants is 150. We will over-recruit for the RCT to ensure at least 120 participants complete the study.

5. STUDY DESIGN / METHOD / PROCEDURES

A. Summary of the Research Design

The summative evaluation includes a 6-week pilot test and a 12-week intent-to-treat RCT with adults who have current or past history with suicidality and/or alcohol misuse. Participants will be randomly assigned to WisePath (n=15/n=60, respectively) or Virtual Hope Box plus electronic wellness resources brochure containing links to health and wellness materials, psychoeducation about suicide, depression, self-help recovery-focused resources (e.g., Alcoholics Anonymous and other 12-Step programs, Moderation Management, etc.), and phone/text information for the 988 Suicide & Crisis Lifeline (n=5/n=60, respectively). Participants will be assessed at baseline, 4, 8 and 12 weeks. (Those in the pilot test will only be assessed at baseline, 3, and 6 weeks).

Primary outcome variables include: suicidal behaviors (ideation, planning), self-efficacy and coping with suicidal thoughts and distress, and use of evidence-based strategies to cope with distress (behavioral skills, use of a crisis stability plan). Secondary outcome variables will include alcohol misuse, severity of depressed mood, sleep quality, and suicide attempts (considered secondary outcome due to the low base rate). App satisfaction and use of technology outcomes (i.e., degree of usage, features used) will be examined and reported descriptively.

PILOT STUDY				
	Eligibility Screening	**Baseline**	**3 Week Assessment**	**6 Week Assessment**
Eligibility Screen	X			
Ask Suicide Screening Questions (ASQ); modified to ask about past 30 days	X			
Drug Abuse Screening Test (DAST)-10	X			
Alcohol Use Disorders Identification Test (AUDIT)	X			
Patient Health Questionnaire-9 (PHQ-9)	X	X	X	X
Demographics Questionnaire		X		
Suicide-Related Coping Skills Scale / Coping Skills Use		X	X	X
Suicide Cognitions Scale		X	X	X
Self-Injurious Thoughts and Behaviors Interview-Short Form (SITBI-SF)		X	X	X
PROMIS Sleep Disturbance-Short Form		X	X	X

PROMIS Sleep-Related Impairment-Short Form		X	X	X
PROMIS Social Isolation-Short Form		X	X	X
PROMIS Alcohol Use-Short Form		X	X	X
PROMIS Alcohol: Negative Consequences-Short Form		X	X	X
PROMIS Self-Efficacy to Manage Emotions-Short Form		X	X	X
PROMIS Global Mental Health-Short Form		X	X	X
PROMIS Psychosocial Illness Impact – Negative		X	X	X
PROMIS Global Health Scale		X	X	X
Difficulties in Emotion Regulation Scale-Short Form (DERS-SF)		X	X	X
App Satisfaction Survey				X

FULL RCT

	Eligibility Screening	Baseline	4 & 8 Week Assessment	16 Week Assessment
Eligibility Screen	X			
Ask Suicide Screening Questions (ASQ) ; modified to ask about past 30 days	X			
Drug Abuse Screening Test (DAST)-10	X			
Alcohol Use Disorders Identification Test (AUDIT)	X			
Patient Health Questionnaire-9 (PHQ-9)	X	X	X	X
Demographics Questionnaire		X		
Suicide-Related Coping Skills Scale / Coping Skills Use		X	X	X
Suicide Cognitions Scale		X	X	X
Self-Injurious Thoughts and Behaviors Interview-Short Form (SITBI-SF)		X	X	X
PROMIS Sleep Disturbance-Short Form		X	X	X
PROMIS Sleep-Related Impairment-Short Form		X	X	X
PROMIS Social Isolation-Short Form		X	X	X
PROMIS Alcohol Use-Short Form		X	X	X
PROMIS Alcohol: Negative Consequences-Short Form		X	X	X
PROMIS Self-Efficacy to Manage Emotions-Short Form		X	X	X
PROMIS Global Mental Health-Short Form		X	X	X
PROMIS Psychosocial Illness Impact – Negative		X	X	X

PROMIS Global Health Scale		X	X	X
Difficulties in Emotion Regulation Scale-Short Form (DERS-SF)		X	X	X
App Satisfaction Survey				X
MEASURES ADMINISTERED DAILY VIA WISEPATH APP				
Depression Anxiety & Stress Scales-21				
Daily Ratings				

Participants will be recruited through word-of-mouth, existing professional networks, primary care and outpatient counseling clinics, and through 3rd party recruitment platforms (e.g., CINT, User Interviews). We may also use targeted social media ads (e.g., Facebook, Instagram) posted in closed groups. A recruitment flyer will be available to prospective patients by their provider and/or in clinic lobbies or via email/online; it will contain an email address and phone number that individuals can contact if interested in participating and links directly to the eligibility survey.

To ensure a sufficient sample of individuals who misuse alcohol, no fewer than 35% of the sample will be comprised of individuals who score eight or more on the Alcohol Use Disorders Identification Test (AUDIT), indicating a harmful or hazardous level of drinking.

After learning of the study, those wishing to participate will go to an online eligibility screen to determine eligibility then, if eligible, set an appointment for informed consent and their baseline assessment; they will be reminded of the appointment in advance. If the prospective participant prefers, the eligibility screening may take place with the researcher verbally asking the eligibility questions and inputting the participant's answers in the survey system. At the first appointment, the researcher will conduct the informed consent procedures. After informed consent, the researcher will provide a link to the baseline survey measures. Appointments will occur virtually, using HIPAA-compliant screensharing (e.g., Zoom). Participant involvement is voluntary.

After completion of the baseline surveys, the participant will then be randomly assigned to receive access to either WisePath or the active control condition (Virtual Hope Box & electronic brochure). We will use a minimization random assignment procedure, where youth are matched on: (1) suicide severity (1=ideation only; no suicide attempt history; 2=1 suicide attempt; 3=2+ attempts; items from the SITBI-SF); (2) depression severity (1=minimal to mild; 2=moderate; 3=moderate to severe; using the PHQ-9), (3) alcohol misuse (1=low risk; 2=risky use; 3=harmful; using the AUDIT), and current mental/behavioral health treatment at baseline (1=not in treatment; 2=receiving light (less than 2 hours a week) treatment; 3=more than 3 hours of treatment a week or comprehensive DBT. This randomization method aims to obtain equal numbers of participants in each condition at different levels of the matching variable and is superior to both simple and stratified randomization in producing balance for separate prognostic variables, particularly when the number of strata is large in comparison with the number of subjects. The end result will be 60 WisePath participants (15 in the pilot) and 60 control participants (5 in the pilot).

1. A researcher will provide instruction for downloading and setting up the assigned app and schedule all follow up study assessments. Participants will be told to use their assigned app however they wish over the course of the study. For those participants assigned to the control arm of the study, each participant will be emailed (or sent a text message with an attachment, according to preference) the suicide prevention and other resources, which will include phone/text infor
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At each follow up assessment point, participants will be asked to complete a set of survey measures online and complete a semi-structured interview with a researcher. The researcher will stay on the line with the participant while

they are completing survey measures. The researcher will limit their involvement to only a) reading survey questions to the participant if requested, and b) answering clarifying questions about survey items. Researchers will be trained to not coach or guide participants in how to respond to survey items (e.g., with standard responses such as, "Just select the answer that you feel best matches your situation/feelings") and will not know how participants are responding. Participants will be encouraged to complete their assessments even if they are no longer using their assigned app.

All participants will receive compensation for their time and effort in the study by check or gift card via mail, depending on the preference of the participant.

Assessment Point	Payment Per Participant
Pilot Test	
Baseline	N/A
3-Week Follow-Up	$60
6-Week Follow-Up	$60
Raffle Entries	Up to 3
	TOTAL: $120
Randomized Controlled Trial	
Baseline	N/A
4-Week Follow-Up	$60
8-Week Follow-Up	$60
12-Week Follow-Up	$60
Bonus	$60
Raffle Entries	Up to 4
	TOTAL: $240

We will use the debrief protocol developed by Marsha M. Linehan, PhD for use in studies involving suicidal patients to assess distress and imminent suicide risk at end of each session. (Please see Appendix 1). Participants in high distress or reporting high suicidal ideation will be walked through behavioral skills with a trained researcher and mood assessed again. If the distress/risk has been alleviated after utilization of the behavioral skills, no further action will be taken. If the participant's distress/risk does not alleviate, or when further support or risk assessment is required, we will proceed to a warm handoff procedure and connect the participant, if needed, to a crisis counselor from 988 Suicide & Crisis Hotline.

B. Analysis of Study Results

With regards to dropouts and missing data, we plan to gather data for all participants at all time points (including from those who stop using their assigned app). This will allow us to conduct our primary analyses on the intent-to-treat sample. To minimize missing data, we have included built-in incentives (i.e., raffle entries for completing study assessments on time). To the extent that there is question skipping or missed assessments, the software and analysis

method we have chosen provides several options for the handling of incomplete data. Preference will be given to those methods for which the assumptions (e.g., Missing at Random) are plausibly met and that have the least biased parameter estimates.

Analysis Strategy. We will use the Generalized Linear Model (GLM), a regression-based approach. It addresses limitations of ANOVA in that it can analyze a variety of commonly encountered outcome distributions (e.g., continuous, count) and can calculate robust standard errors which are less sensitive to skewness. Specifically, we will conduct our repeated-measures analyses using a version of GLM called Generalized Estimating Equations (GEE), which does not rely on the overly restrictive (and often incorrect) assumptions made by Repeated Measures ANOVA about the covariance matrix that can lead to misspecification. Like Hierarchical Linear Modeling (HLM), GEE can test the use of different assumptions of the covariance matrix to determine the one that best fits the data; it can also include participants who are missing data at certain time points. We will use the SPSS and GEE for all hypotheses concerning outcomes for parents and youth. For each outcome, we will specify the correct distribution and compare fit indices to identify the covariance matrix that best fits the data. All hypotheses relate to change over time, and so the multiple time-points will be treated in the GEE analyses as nested within the individual. Also, we will treat intervention condition and time as categorical, dummy-coded predictors; the control condition and baseline scores will serve as the reference points. The parameter of interest will be the Time X Condition interaction, and the Type III statistic will serve as an omnibus test of whether the two conditions differed in change over time.

C. Monitoring

We have formed a Data and Safety Monitoring Board (DSMB) to provide oversight of this study. The committee will periodically review any modifications to the research design and conduct of the study, and make recommendations according to the NIH/NIAAA policies for data and safety monitoring. Members of the DSMB have no financial stake with any member or organization involved with this project and are free of existing or potential conflicts of interest.

Drs. Dimeff and Jobes will be responsible for managing, storing, and protecting study data. They will work closely with the research staff to maintain continuous, close monitoring and promptly report adverse events to each other, the DSMB, and the IRB.

D. Storage of Data

All data collection and storage will follow Good Clinical Practice and HIPAA guidelines. Electronic data will be maintained in a secured, password protected site with firewall and other security protections. The data files are coded with the participant's study identification number. We will assign each participant a unique study identification number, which will be attached to data, including all qualitative data and online surveys. No names or personal identifying information will be included with participants' data. Only one record connecting identification numbers with names will be kept, and that will be stored separately from the data on a secure server with a password required to access the record. This record will be destroyed after six years. After the record is destroyed, there will be no way to link participant names to their responses. The de-identified data will be retained indefinitely. Hard copies of Informed Consent forms will be stored in a locked cabinet separate from the data or scanned and saved electronically in an electronic database separate from the data, which is secure, password protected, HIPAA-compliant, and includes firewall and other security protections. Informed Consent forms filled out electronically will be stored in an electronic database separate from the data, which is secured, password protected, HIPAA-compliant, and includes firewall and other security protections. Only the study staff will have access to the electronic and hard copy records.

Survey-based data, including the screening and demographics questionnaire, as well as a brief questionnaire to assess acceptability and clinical relevance, are also stored in our HIPAA-compliant survey system (i.e., Qualtrics), where responses are transmitted using a Secure Sockets Layer (SSL) connection and is also encrypted. Survey data use only the

study identification number to identify the participant. In most cases, participants will complete the surveys directly in the survey system and/or the data are entered directly by a researcher into the system. In the unlikely event of a paper-pencil measure being preferred or necessary, the data will be immediately entered into the survey system by a researcher then the paper copy will be destroyed within 24 hours via shredding or secure disposal in a secure shredding bin for later secure disposal. Access to all electronic research files is limited to research staff, who are required to log in with a unique username and password for access.

E. Confidentiality of Data

To protect participants from loss of confidentiality, the following procedures will be employed: Each participant will be assigned a study identification number that does not contain number elements that could be linked back to their identity. Only one document, known as the Master Participant Document (MPD), will link the patient's identity to their study identification number. The MPD file is stored separate from study data on a cloud-based encrypted server (SharePoint) accessible only to the research team trained in the ethical conduct of human subjects' research.

When applicable study staff will send email reminders to participants completing survey measures online that includes a link to the online survey questionnaires. Participants will enter their unique study identification number rather than identifying information when completing survey measures online. Data gathered via online surveys will be securely transmitted and stored according to the site's security policy, accessible only to the research staff via a password-secured account.

Data will be protected and stored as described above in Storage of Data. In addition, we will destroy all files linking participant names or other identifying information to study identification numbers six years after the study is finished.

6. RISK/BENEFIT ASSESSMENT

A. Risks

We believe the risks of harm caused by the study to be low and we estimate the risk to study participants is minimal. All aspects of the research protocol and WisePath have been carefully reviewed by our advisors with lived experience to ensure their acceptability for individuals experiencing suicidality and other concerns such as sleep/mood problems, alcohol misuse. To note, no known adverse events have occurred during our research to date. Rather, feedback from target end users (e.g., those like the participants in this study) has been universally positive. However, should adverse events occur during the study, we will thoroughly assess factors that contributed to them and will seek resolution of those problems related to the study and make notify the appropriate parties as specified in our Data Safety Monitoring Plan.

Some participants may nonetheless feel uncomfortable completing questionnaires about non-suicidal self-injurious behaviors, and suicidal behaviors, alcohol and/or other substance misuse, or about their mood. We will address this by informing participants that they have the right to refuse to answer any question during the study.

Another potential risk for participants is that of embarrassment or discomfort if a friend or colleague sees and inquires about the app and/or discovers its purpose. Participants will be encouraged to use their assigned app only when and where they are comfortable doing so. Researchers will also encourage participants to password protect their phone to prevent others from seeing the app they are assigned to or its notifications.

Another risk is the possibility that data from the mobile device may be intercepted during transmission or accessed by

others should the participant misplace or lose their phone; this is a risk that applies to the use of mobile devices overall. We have elicited the consultation of healthcare administrators and primary care and other clinic administrators to ensure that the data collected by WisePath cannot be used against the participants in any way. The server is secured and password protected and only accessible to EBPI engineers and select research staff. The protections for the server are similar to those used in banking or other commercial websites and as an added precaution, all app-generated data is stored on the secure server, not on the mobile phone itself.

Some participants may feel pressure to participate because they are being referred to the study by their service provider (i.e., primary care physician, mental health counselor). There is also the potential risk of loss of confidentiality. Steps will be taken to ensure that participation is voluntary and that participants' privacy and the data collected from the participants are protected. Participants will be informed that refusal to participate will not affect the services they currently receive and that we will not inform their service provider or other professional who may have provided study information of their participation (or not) in this study. To further decrease this risk, study staff will be trained never to pressure participants to take part in the research or express disappointment if consent to participate in the study is not provided. All participants will be informed that they have the right to refuse to participate or discontinue participation at any time.

No deception will be used in this research. Because participants will have history of recent or current suicidal ideation, there is a possibility that some patient participants may experience emotional distress during the study procedures. However, we have not received any reports of adverse events in our previous research that included suicidal outpatients and patients in the emergency department or inpatient unit completing similar study procedures.

Thus, despite the fact that this study includes participants from a sensitive population, we believe the risks of the study to be low and we estimate the risk to study patients is minimal; however, should adverse events occur during the study, we will thoroughly assess factors that contributed to the adverse event, including use of WisePath, and will seek resolution of those problems related to the study. We will notify the IRB and our DSMB about any adverse events, should they occur, and seek their recommendations. Further, after each study meeting, researchers will conduct a debrief protocol developed by Marsha M. Linehan, PhD for use in studies involving suicidal patients to assess distress and imminent suicide risk at end of each session. (Please see Appendix 1). Participants in high distress or reporting high suicidal ideation will be walked through behavioral skills with a trained researcher and mood assessed again. If the distress/risk has been alleviated after utilization of the behavioral skills, no further action will be taken. If the participant's distress/risk does not alleviate, or when further support or risk assessment is required, we will proceed to a warm handoff procedure and connect the participant, if needed, to a crisis counselor from 988.

Other potential risks are minimal. Some participants may feel discomfort providing negative feedback on the study app as they answer the questionnaires because they are hesitant to criticize. Some participants may feel pressure to participate because they are being referred to the study by their service provider.

Physical, social, economic, or legal risks from participating for patients and non-patients are expected to be low to non-existent; however, it is conceivable that a data breach could lead to work/insurance discrimination based on a patient's history of suicidal behavior.

There are no known alternative procedures to assess this information. The primary alternative to participating in the research is to decline to participate in the research, which participants may do at any time without change to any study benefits they have earned.

B. Prevention of Risks

All researchers interacting with participants will be trained in protection of human subjects, HIPAA, and will complete a course in Good Clinical Practices. All information will be treated as confidential material and will be available only to staff.

All participants will be provided with complete disclosure regarding what explicitly will be asked of them using an Informed Consent procedure. The Informed Consent form will describe the procedures of the study and clarify that the study is completely voluntary and that they may decline to participate at any time. Although potential participants may be informed of the study by their service providers, it will be made clear to them that the study is completely voluntary and will not affect the services they are receiving in any way or will the researchers inform their provider if they decide to participate in the research or not. Providers and agencies who agree to provide the study information to their patients or waitlist clients will be informed that there should be no coercion of potential participants to take part. In addition, we will train staff and provide all staff in partnering agencies with detailed instructions and/or scripts on how to provide information about this study to potential participants.

As described previously, if researchers conducting the follow up assessments perceive any indication of the participant being at imminent risk for suicide or in need of extra support, a warm handoff procedure will be used to help the participant by teaching skills and the researcher will connect them with 988 Suicide & Crisis Lifeline if needed (e.g., mood ratings do not improve after skills, participant requests additional support) or in cases of extreme distress or if the participant requests to talk with a crisis counselor at 988. Dr. Dimeff will collaborate closely with the IRB and DSMB throughout the study to ensure proper management of high-risk situations, should they occur.

Further, no identifying information will be associated with data collected from participants. Data gathered via online surveys will be securely transmitted and stored according to the site's security policy, accessible only to the PIs and research staff via a password-secured account. Data being uploaded from WisePath will be transmitted on a secure, encrypted channel. App-generated data exported from WisePath will be de-identified during download and provided to researchers without identifying information. When downloaded by the Engineering Team, data is exported and de-identified to scrub the data of personally identifiable information. Only the staff trained in HIPAA and procedures for conduct of ethical human subjects research will have access to study data. The identity of participants will be kept separate from records of their research data.

Steps will be taken to ensure that participation is voluntary, and that participants' privacy and the data collected from the participants are protected. Participants will be told that their participation is completely voluntary, and that they may change their minds and withdraw at any time. Data will be protected and stored as described above in Protection of Study Data.

To address potential discomfort in sharing criticism or other opinions about the app during the study interview, the interviewer will assure the participant that any and all feedback, positive and negative, is helpful. Participants will be informed that they may decide how much or little to share.

C. Adverse Events

For this study, we define an adverse event as any undesirable experience associated with the use of a medical device or engagement in the research procedure, including:

Suicide-related Adverse Events

- Suicide attempts that do not require medical attention or hospital-based care

- Warm handoff to 988
- Significant increase in suicidal ideation, defined by:
    - Frequency: A two-fold increase in SI in the past 30 days based on the Self Injury Thoughts and Behaviors Interview (SITBI); or
    - Intensity: A two-point increase in SI in past 30 days based on SITBI

Alcohol-related Adverse Events

- Self-report of blackouts
- Self-report of injuries to themselves or others related to alcohol
- ≥5-point raw score increase on PROMIS Alcohol Use (item 7a) OR PROMIS Alcohol Negative Consequences Measure (≤1.3 SD change in T-scores)

Serious Adverse Events

- Suicide attempt that leads to acute hospital-based care (e.g., visit to emergency department) and are directly related to the study procedures and/or use of study-assigned app
- Alcohol poisoning that leads to acute hospital-based care resulting from the study procedures or study-assigned app usage
- Death of participant

In the event that a participant has experienced an adverse event, the research team, under the direction of study investigators (Dimeff, Jobes, Ruork), will assess situation giving rise to and consequence of (e.g., associated medical treatment) an adverse event. Effort will be made to determine whether and the extent to which the digital apps used in the research study or study procedure caused or contributed to the adverse event. Complete information gleaned from this assessment will then be shared with the DSMB, in addition to our determination regarding the involvement of the digital app and/or study procedure in the adverse event. The DSMB will be the final arbiter in determining whether the adverse event was caused or exacerbated by the study app or study protocol. If a serious adverse event occurs, it will be reported to DSMB and IRB within 72 hours.

All participants will be provided with information about how to report potential adverse events and information about potential adverse events will be gathered from participants via surveys and semi-structured interviews.. In addition, participants will be encouraged to report any potential adverse events directly to the researchers immediately. Potential adverse event reports will be monitored by study staff; the survey system automatically notifies study staff when a report is completed. Because the risks to participation are low, the likelihood of adverse events related to the proposed research is judged to be low. In the event that a potential adverse event is reported, the investigators (Drs. Dimeff, Jobes, and Ruork) will be notified immediately. They will then assess the situation and determine an appropriate clinical and ethical course of action, including report of an adverse event to the IRB and DSMB. Dr. Dimeff will work closely with the research staff to maintain continuous, close monitoring and prompt report reporting.

Stopping Criteria

There are three standard stopping rules: evidence of harm, futility, and benefit. Given the brief duration of this study and small sample size, we have elected to apply the stopping rule only to harm caused by the research procedures or study-assigned app, and not futility and benefit.

This type of stopping rule is typically established by estimating expected adverse event rates based on previous studies and/or clinical data. If the actual rate of those events exceeds your anticipated rate by some prespecified amount, the stopping rule is triggered. Approximately 20-40% of patients with recent suicidal ideation or attempts will attempt suicide during a one-to-two-year study period. During this same study period, an estimated 10% of patients with similar suicidal ideation and attempt history will be hospitalized. Therefore, if the device is safe, these would be the estimated

expected rates for suicide attempts and hospitalizations we could expect to encounter during the study. Based on natural variability, random error, potentially higher risk samples, and a caution to not overestimate level of risk, the stopping rule is set at 50% higher than these rates. The same principles have been applied for alcohol-related problems.

If it is determined that the threshold for stopping, based on the study criteria, has been met for one or more of the criteria, the DSMB would examine the data to decide whether the study should be stopped.

If any of the following criteria are met, data will be sent to DSMB to determine if study should be stopped and a report will be sent to IRB within 72 hours of DSMB decision:

- 60% of participants attempt suicide
- 15% of participants are hospitalized
- 90% of participants experience blackouts or injuries due to alcohol use
- 4% of participants experience alcohol poisoning that leads to hospital-based care

D. Benefits

The overarching purpose of this research is to design a highly effective, easy-to-use digital technology for use by individuals who are suicidal and may also experience co-occurring concerns (e.g., sleep/mood problems, alcohol misuse) to help facilitate access to evidence-based care at the point of need. By participating in this project, people can help ensure that those who are suicidal have access to robust suicide-specific care.

7. PARTICIPANT RECRUITMENT AND INFORMED CONSENT

A. Recruiting

Participants will be recruited on a first-come, first-served basis though some participants will be strategically recruited to ensure the relevance of WisePath for individuals who misuse alcohol; no fewer than 35% of the sample will be comprised of individuals who report a harmful or hazardous level of drinking (score 8 or more on the AUDIT). Further, to ensure cultural relevance, recruitment efforts will also prioritize ethnic and racial diversity over first-come, first served recruitment.

Participants will be recruited through word-of-mouth, referrals from organizations, primary care clinics, mental health and outpatient clinics, other professional connections, and through 3rd party recruitment platforms (e.g., CINT, User Interviews). We may also use targeted via social media advertisement (e.g., Facebook, Instagram) posted in closed groups. We will request that administrative staff and providers at partnering clinics and organizations distribute study recruitment materials (flyer) directly to patients and/or have it accessible in clinic lobbies. Recruitment materials will contain an email address and phone number that prospective participants can contact if interested in participating, and a link and/or QR code to a website or directly to the online eligibility screen. Potential participants will indicate their interest in learning more about the study by contacting study staff directly via phone, text, or email or by directly proceeding to the online eligibility screen. Providers and others distributing research recruitment materials will be instructed to emphasize the voluntary nature of the research for all participants and to describe the research opportunity in ways that minimize actual and perceived coercion. Study staff will be trained never to pressure potential participants to take part in the research or express disappointment if consent to participate in the study is not provided.

As described above, we may also ask prospective participants to verify their identity and/or residency, including requiring prospective participants to turn their cameras on during virtual meetings and/or asking the prospective participant to verify they are in the US by showing either their state-issued driver's license/ID card or a piece of mail showing their name and a US mailing address. Any individual who cannot demonstrate their residency will be told that the session cannot proceed, and they will not be enrolled in the study.

B. Informed Consent

All participants will be provided with complete disclosure regarding what explicitly will be asked of them for participation using Informed Consent procedures. The Informed Consent forms will describe the study procedures and clarify that the study is completely voluntary and that participants may decline to participate at any time.

Once initial eligibility is determined, potential participants will be given a brief description of the study and asked for their verbal consent to proceed with the Informed Consent discussion. Participants will first complete an omnibus consent form that describes the study in detail, including that they will be asked to use a mobile app during the study, but does not include detailed information about the mobile apps used in the study. After the participant is randomized to condition, they will be asked to sign an informed consent form addendum with information about the study condition (i.e., the mobile app) to which they were allocated.

The Informed Consent process will take place in person or remotely (e.g., Zoom, telephone, email) with a researcher. All potential participants are informed during the Informed Consent procedure that participation is completely voluntary and that they may withdraw from the study at any time with no negative consequences. Eligible participants will receive a copy of the Informed Consent Form (via hard copy, online, or email). Participants will have the opportunity to read and review the consent form with the research staff, on their own, and/or review it with friends and family if desired. Study staff will be available to answer any questions or concerns the participants may have prior to signing and returning the consent form.

C. Obtaining and Documenting Consent

Participants will provide consent by signing the paper Informed Consent Form or electronically by typing their name or adding their electronic signature to an online version/PDF of the Informed Consent Form. We will provide a copy of the Informed Consent Form for the participant to keep for their records. The signed consent forms will be stored on HIPAA-compliant SharePoint. If a participant signs a paper copy of the Informed Consent Form, a researcher will scan signed hard copies and save electronic copies (e.g., as a PDF) on SharePoint.

D. Participant Comprehension and Capacity

All efforts will be made to ensure potential participants understand the information presented in the Informed Consent Form. Throughout the Informed Consent processes, the researcher will ask if the participant has any questions. Participants will have the opportunity to read and review the consent/assent form on their own and review it with friends and family if desired. Dr. Dimeff and the study staff will be available to answer any questions or concerns the participants may have prior to signing the consent form.

E. Costs to Participants

There are no costs to participants for taking part in this study.

F. Compensation to Participants

All payments will be distributed within 30 days after participation is complete. Participants may choose to receive payment in the form of a check in the mail or a gift card (Amazon, Kroger, Target) by mail. If a participant decides to withdraw or end participation prior to completing their trial (or if they are administratively withdrawn by the researchers), they will be compensated the total amount for the assessments they have completed.

All payments will be distributed via mail after appointment completion and no later than within 30 days. Financial rules require us to record participants' names and addresses in order to process and send payments. That information, payment amount, and the name of the study will be kept secure and confidential with access only by our team, including our bookkeepers and accountants. We will use bookkeeping software tools to pay participants. These tools will have participants' names and addresses in order to issue and send payments. If a participant chooses to receive payment by gift card, we will enter their name, address, and/or email address into the associated websites to send payment.

Participants who complete each assessment (including baseline) within 72 hours of the scheduled appointment will earn a chance to win one of 13 $100 Amazon gift cards that will be raffled at the end of the study (i.e., those who complete all four assessments in the RCT on time will have four raffle entries).

Assessment Point	Payment Per Participant
Pilot Test	
Baseline	N/A
3-Week Follow-Up	$60
6-Week Follow-Up	$60
Raffle Entries	Up to 3 entries
	TOTAL: $120
Randomized Controlled Trial	
Baseline	N/A
4-Week Follow-Up	$60
8-Week Follow-Up	$60
12-Week Follow-Up	$60
Bonus	$60
Raffle Entries	Up to 4 entries
	TOTAL: $180

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APPENDIX 1

Mood Assessment & Debrief Protocol

Adapted from Marsha Linehan's Suicide Risk/Distress Assessment Protocol

PURPOSE:

While the risk is deemed low for this research, the intent of this Mood Induction Protocol is to ensure that participants are not in greater distress than at the start of the interview due to the interview process.

PROCEDURE:

The intent of this procedure is to ensure that participants who may become emotionally distressed during or after the interview receive helpful support following completion of the interview and encouragement to reach out for support, if needed.

Two versions of the basic procedure are described below: the first focuses on supporting the participant during the course of the study appointment should they become distressed; the second focuses on assessing and providing as-needed support following the completion of the interview.

During Study Appointment:

If **participant appears emotionally distressed during the course of the interview or online surveys, ask:** *"Just wanted to take a moment to check in and see how you are doing. Sometimes just talking about or reflecting on a really upsetting time in your life can bring stuff up."* Pause and listen.

- If participant communicates they are okay: *"Okay. We'll keep moving along then. But if you want to pause or stop at any point, just let me know. Sound good?"* Pause, allow response, and proceed.

- If the **participant states they are distressed** and/or it is apparent to interviewer that they could benefit from a short break and/or practicing a behavioral skill, ask: "*Would it be helpful to take a mini break? Or if you're up for it, we could also do a little deep breathing or walking (or another skill the patient readily uses with success) together.*

  The interviewer should then do what is needed and/or asked for: practicing a skill (such as paced breathing or distraction technique, TIPP) and/or taking a short break.

Following a brief break, ask: *"Is it okay to continue, or would you prefer to take a pause or call it a day?"* Interviewer should then proceed in requested way.

- If participant wishes to proceed, remind participant that they are free to take a break whenever they wish.
- If they wish to end the interview, thank them and ask them what will be helpful for them to do to reduce their emotional distress after they leave. Encourage connection with a 988 Suicide & Crisis Lifeline counselor and perform a warm handoff if they agree to be connected, ask: *"Is there someone you call for support should you need it later today? Or I can connect you with the counselors providing support for this research."*
  - If the participant is extremely upset and/or experiencing an acute crisis, the interviewer will immediately perform a warm handoff to 988 (See Managing an Acute Crisis Section

below) and contact Dr. Dimeff 206-384-7371, Dr. Ruork 707-888-7292, and Angela Kelley-Brimer 253-279-8659 (text and email).

End of Study Appointment:

Unless terminating the appointment mid-session at participant's request (see above), complete the mood assessment below even if you have already checked in with the participant. In other words, the mood assessment must be completed at the end of all study appointments.

If the participant reports a score of 3 or greater on the mood assessment question, the interviewer will move on to the Mood Induction Protocol.

If the participant is extremely upset and/or experiencing an acute crisis, the interviewer will perform a warm handoff to 988 immediately and contact Dr. Dimeff 206-384-7371, Dr. Ruork 707-888-7292, and Angela Kelley-Brimer 253-279-8659 (text and email).

MOOD ASSESSMENT:

Open the Mood Assessment and Debrief Protocol Survey for Researchers to complete and record all participant answers and actions taken during the mood assessment and debrief protocol.

Script:

Thank you so much for sharing with us today. Before we end our session, I just want to check in to make sure you are in good shape once you leave.

On a scale of 0-7, how would you rate your emotional distress right now, where 0 is Low/non-existent and 7 is the highest imaginable?"

On that same scale, what is your urge to use drugs or alcohol right now?

On the scale of 0-7, what is your urge to harm yourself right now?

On that same scale, what is your intent to kill yourself right now?

<<If participant answers 0-4 on all questions, thank participant again and end the session here.>>

<<If participant answers 5 or higher, continue to the remaining protocol.>>

MOOD INDUCTION:

1. Validate experience: *You mentioned on that mood rating that you are feeling* <<insert what person endorsed, e.g., "like killing yourself" or "like harming yourself">>. *I just want to make sure that you're in good shape before we hang up. Would it be okay with you if we take a few moments to see if we can get your mood up a bit before we hang up?* (if really distressed, skip to Managing an Acute Crisis section)
2. Invite Assistance: *Do you feel at all like you could benefit from additional support at the moment, or is it one of those things that you can expect will pass with time? If it would be helpful to you, we could think through a few skills you might find helpful to bring down your distress or sort of distract from details that are upsetting* (listen). The interviewer should then do what is needed and/or asked for: see Practicing a Skill section below, if participant is interested.

   If Participant Is Reluctant to Engage in Problem Solving Efforts to Change Mood: *I do want to make sure you're okay before we hang up. Is there something else that might be going on for you right now that might be helpful to talk about for a few minutes? I can help you connect with helpful counselors at the 988 Suicide & Crisis Lifeline or would it be helpful to try out a skill?* If they do not wish to, move to Identify Support They Can Call if Needed.
3. OPTIONAL: Identify Support They Can Call if Needed: If relevant/applicable (e.g., distress is high and not fully resolving, refusing transfer to 988), ask: *"I wonder if it might be helpful to identify a person who you might call after you leave here if you're still feeling pretty distressed and just need a bit of support? Or I can connect you know with a counselor dedicated to supporting others in these situations."*
   a. Listen and inquire if they have that person's number easily available.
4. Coping Ahead After Hanging Up:
   - Identify a Plan. *Before we end this call, I want to make sure you're set and in good shape. Would that be okay?* (Pause)

     <<If participant wants to terminate call before completing this step, skip to Step 5>>
     What ideas do you have for what you might do if you start feeling distressed again?
     <<If no ideas, remind participant of skills practiced today or if no skills, suggest one or two skills they could use and offer to practice together. Also remind participant that they can call or text 988 at any time>>
   - Identify Who they Can Call if Needed. *Would it be helpful for us to figure out whom you might call if you need a bit more support later? Do you have someone you usually call when you're feeling down?* (Pause)

     <<if needed>> *What about the suicide lifeline at 988? Is that someone you might reach out to?*
5. Concluding the Call: *Thank you for working with me today. I think we've got a good plan in place. Do you want to just say back to me what the plan is just to make sure you have it?* If important details omitted, fill in.

   <<If needed, summarize the plan>>
   That's okay. Let me summarize it for you. Would you like to write it down just so you have it? Did I get it right? (Pause) *Great. So can we agree that's what you're going to do if it's needed after we hang up?*
   Conclude the Call. *Thank you again for taking the time. All my best to you. Goodbye.*

MANAGING AN ACUTE CRISIS

For use when participant is extremely upset.

I can tell you are still having a hard time. I want to make sure that you are okay and safe after we hang up. I am worried about you and I'd like to get help from a counselor at the 988 Suicide & Crisis Lifeline. I am going to conference us into the 988 hotline and have them join our call. Please hold on while I get them on the line with us. It's important you don't hang up while I am getting the counselor on the line.

Once participant is on with 988, mute your phone and Zoom and turn your camera off on Zoom then contact Dr. Dimeff 206-384-7371, Dr. Ruork 707-888-7292, and Angela Kelley-Brimer 253-279-8659 (text and email).

Should an emergency occur, do not hesitate to call Dr. Dimeff after initiating a warm handoff or at any time.

PRACTICING A SKILL

Choose a skill to practice with the participant or describe the skill and let the participant choose:
TIPP Skills
Self-Soothe
Distract: Wise Mind ACCEPTS
IMPROVE the Moment
Thinking of Pros & Cons

After teaching 1 or 2 skills, reassess mood.

If mood ratings are below threshold (0-4), continue to Step 4: Coping Ahead.

Email Linda Dimeff (linda.dimeff@jasprhealth.com) and Angela Kelley-Brimer (angela.brimer@jasprhealth.com) that extra support was provided to the participant.

If mood ratings are still above threshold (5-7), ask participant if they want to try another skill (then reassess mood) or proceed to warm handoff to 988 Suicide & Crisis Lifeline.

>> If warm handoff: *I want to make sure that you are okay and safe after we hang up. I am worried about you and I'd like to get help from a counselor at the 988 Suicide & Crisis Lifeline. I am going to conference us into the 988 hotline and have them join our call. Please hold on while I get them on the line with us. It's important you don't hang up while I am getting the counselor on the line.*

Once participant is on with 988, mute your phone and Zoom and turn your camera off on Zoom then contact Dr. Dimeff 206-384-7371, Dr. Ruork 707-888-7292, and Angela Kelley-Brimer 253-279-8659 (text and email).

TIPP Skills

Teach Skills below or watch linked video together with participant

- **T**EMPERATURE CHANGE:

Video to watch with participant: https://nowmattersnow.org/skill/cold-water

Immerse your face in Ice or Cold Water. Taking a hot bath or shower may also be effective.

Fill a sink with cold water and add some ice. If you don't have ice, be creative. Add a pack of cold peas or something icy that will lower the temperature of the water even more. If you don't have a sink, fill a big mixing bowl. Now you're going to hold your breath and dunk your face and head in for as long as you can hold your breath. Then come up, exhale, inhale and dunk again. Repeat as many times as you need to until you feel quite a bit calmer. *DO NOT USE THE ICE TECHNIQUE IF YOU HAVE A HEART CONDITION OR HAVE HAD A HEART ATTACK*

- **I**NTENSE PHYSICAL EXERCISE:

Video to watch with participant: https://www.youtube.com/watch?v=RcIXkeG90t0

Running around the block, doing jumping jacks, turning on a song and dancing around for a little while…all of these things can use up some of the energy that is fueling distress.

- **P**ACED BREATHING:

Video to watch with participant: https://nowmattersnow.org/skill/paced-breathing

Breathe in and out normally, slightly lengthening the out breath. Starting with 9 and decreasing to 0, label each of the out breaths with a number, *i.e. In.. Out (9)…. In.. Out (8)…. In.. Out (7)….* If you notice your mind wandering, gently bring your attention back to the counting of the breaths. Try to focus on the numbers and breathing, and nothing else. When you reach zero, start counting down again. This time don't start with the number 9; start with the number 8. Work your way down to 0 again. When you reach 0, continue starting the counts again, each time decreasing the starting number by one, until you have reached zero again. When you have finished, if you need to, start again at 9, and repeat until you are feeling more regulated.

- **P**ROGRESSIVE MUSCLE RELAXATION:

Video to watch with participant: http://www.youtube.com/watch?v=ihO02wUzgkc

There are many ways of doing progressive relaxation, but in a nutshell, you are going through your body and mindfully relaxing one area at a time. If your distress is very high, you may want to squeeze all the muscles in each area very tightly for a few seconds and then release. Don't forget your face! Scrunch it up tightly, and release. Don't give up on it if it doesn't work once - try it a few times. You can also find guided progressive relaxation videos on YouTube.

Self-Soothe

Think of soothing each of your five senses

Video to watch with participant: https://www.youtube.com/watch?v=CwnHez9TC6c

- **VISION**: Buy one beautiful flower, make one space in a room pretty, light a candle and watch the flame. Set a pretty place at the table, using your best things for a meal. Go to a museum with beautiful art. Go sit in the lobby of a beautiful old hotel. Look at nature around you. Go out in the middle of the night and watch the stars. Walk in a pretty part of the town. Fix your nails so they look pretty. Look at beautiful pictures in a book. Go to a ballet or other dance performance, or watch one on TV. Be mindful of each sight that passes in front of you, not lingering on any.
- **HEARING**: Listen to beautiful or soothing music, or to invigorating and exciting music. Pay attention to sounds of nature like waves, birds rainfall, rustling leaves. Sing your favorite songs, hum a soothing tune, learn to play an instrument. Call 800 or other information numbers to hear a human voice. Be mindful of any sounds that come your way, letting them go in one ear and out the other.
- **SMELL**: Use your favorite perfume or lotions, or try them on in the store, spray fragrance in the air, light a scented candle. Put lemon oil on your furniture. Put potpourris in a bowl in your room. Boil cinnamon, bake cookies, cake or bread. Smell the roses. Walk in a wooded area and mindfully breathe in the fresh smells of nature.
- **TASTE**: Have a good meal, have a favorite soothing drink, such as herbal tea or hot chocolate (but no alcohol). Treat yourself to a dessert. Put whipped cream on your coffee. Sample flavors at an ice cream store. Suck on a piece of peppermint candy. Chew your favorite gum. Get a little bit of special food you don't usually spend the money on, such as fresh squeezed orange juice or organic vegetables. Really taste the food you eat, eating one thing mindfully and focusing on its taste.
- **TOUCH**: Experience whatever you are touching, notice that the touch is soothing. Take a bubble bath, put clean sheets on the bed, pet your dog or cat, have a massage, soak your feet, put creamy lotion on your whole body. Put a cold compress on your forehead, sink into a really comfortable chair in a hotel lobby or in your home, put on a silky blouse, dress, or scarf. Try on fur-lined gloves. Brush your hair for a long time. Hug someone.

Distract

Wise Mind ACCEPTS

Video to watch with participant: https://nowmattersnow.org/skill/distraction

- **A**CTIVITIES:

Activities helps you to feel better, and as you feel better and productive, your self esteem rises and endorphin's are released. Do something physical like exercise, hobbies, cleaning, go to a community event, call or visit a friend, go walking, work, play, participate in sports, go out to a meal, have decaf coffee or tea, go fishing, chop wood, do gardening, play pinball. Do whatever works for you.

- **C**ONTRIBUTING:

Contribute to someone, do volunteer work; give something to someone else, make something nice for someone else, do a surprising, thoughtful thing.

- **C**OMPARISONS:

Watch disaster movies, watch soap operas, visit an ER waiting room, or a hospital waiting room, compare yourself to people coping the same as you or less well than you.

- **E**MOTIONS

(Opposite Emotions): Be sure what you do will create the opposite emotion to what you are feeling. You could watch comedies like "I Love Lucy" or "Carol Burnett" or watch emotional movies or listen to emotional music. Read emotional books or stories.

- **P**USHING AWAY

(use this skill last - as a tuning out): Push the situation away by leaving it for a while, leave the situation mentally. Build an imaginary wall between yourself and the situation or push the situation away by blocking it out of your mind. Censor ruminating. Refuse to think about the painful aspects of the situation. Put the pain on a shelf. Box it up and put it away for a while.

- **T**HOUGHTS

(other thoughts): Count to 10; count colors in a painting or tree or out the window. Do anything, work puzzles, watch TV, read.

- **S**ENSATIONS

(other intense sensations): Hold ice in your hand, squeeze a rubber ball very hard, take a hot shower, listen to loud music, sex, snap a rubber band on your wrist, suck on a lemon.

IMPROVE the Moment

Video to watch with participant: https://www.youtube.com/watch?v=nw5moYAEjY8

- **I**MAGERY:
  Imagine very relaxing scenes or soldiers fighting and winning. Imagine a secret room within yourself, seeing how it is decorated. Go into the room whenever you feel threatened. Close the door on anything that can hurt you. Imagine everything going well. Imagine coping well. Make up a fantasy world that is calming and beautiful and let your mind go with it. Imagine hurtful emotions draining out of you like water out of a pipe.

- **M**EANING:
  (create a track record of endurance) Find or create some purpose, meaning or value in physical or emotional pain. Remember, listen to, or read about spiritual values. Focus on whatever positive aspects of a painful situation you can find. Repeat them over and over in your mind. Make lemonade out of lemons.

- **P**RAYER:
  (walk & talk out loud or kneel and pray to your higher power, to God, Goddess, whoever) Open your heart to a supreme being with great wisdom, whatever that means to you. It could be God or your own wise mind for instance. Ask for the strength to bear the pain in this moment. Turn things over to God or a higher being.

- **R**ELAXATION:
  Find humor and laugh. Try relaxing each large muscle group, starting with your hands and arms, going to the top of your head, and then working down. Listen to a relaxation tape, exercise hard, take a hot bath, or sit in a hot tub. Drink hot milk, massage your neck and scalp, or your calves and feet, get in a tub filled with very cold or hot water and stay in it as long as you can tolerate. Breathe deeply, half-smile, change your facial expression

- **O**NE THING IN THE MOMENT:
  Focus your entire attention on just what you are doing right now. Keep yourself in the very moment you are in in the present. Focus your entire attention on physical sensations that accompany nonjudgmental tasks. (e.g. walking, washing, doing dishes, cleaning, fixing). Be aware of how your body moves during each task. Do awareness exercises.

- **V**ACATION:
  Give yourself a brief vacation. For instance, from 2 p.m. to 4 p.m., get in bed and pull the covers over your head for 20 minutes. Rent a motel room at the beach or in the woods for a day or two. Unplug your phone for a day, or let your answering machine screen your calls. Take a 1 hour breather from work that needs to be done. Look at a magazine, bundle up in a chair, eat slowly. Allow yourself to be a kid again - take a break from adulthood.

- **E**NCOURAGEMENT:
  Cheer lead yourself. Repeat over and over: “I can stand it. This won't last forever. I will make it out of this. I'm doing the best I can. I can do it. I am OK.”

Thinking of Pros & Cons

Video to watch with participant: https://vimeo.com/836262227/893b06d063?share=copy

Make a list of the pros and cons of tolerating the distress.

Make another list of the pros and cons of not tolerating the distress - that is, of coping by doing something impulsive.

Focus on long-term goals, the light at the end of the tunnel. Remember times when your discomfort has ended.

Think of the positive consequences of tolerating the distress. Imagine in your mind how good you will feel if you achieve your goals, if you don't act impulsively.

Think of all of the negative consequences of not tolerating your current distress. Remember what has happened in the past when you have acted impulsively to escape the moment.

Ask yourself, "*Will this event that is distressing me going to matter in 5 years?*"

APPENDIX 2

WisePath for Adults Device Overview

Consistent with other countries where digital tools are widely used as a first intervention in a stepped care model,[1] the intent of this product is to increase access to evidence-based resources for suicidal ideation (SI) while also addressing other behavioral health problems that can co-occur and/or exacerbate risk of suicide. We focus specifically on depressed mood, alcohol misuse, and sleep problems. While apps exist for some of these behavioral health problems individually, we know of no digital app available on the market that is designed to address SI along with the other co-occurring problems. Furthermore, we know of no app for these conditions that is currently approved by the FDA.

WisePath is not for use in emergency situations (e.g., acute suicide risk) and labeling within the app will make this clear and include referral to 911 or 988 if crisis care is indicated.

WisePath will provide the essential key performance elements for each recommended evidence-based practice in Table 1: crisis stability planning, lethal means safety, as well as standardized assessment and progress monitoring, and other recommended resources: psychoeducation with behavioral skills training, stories by people with lived experience, and activities for managing alcohol misuse, depressed mood, and sleep problems.

Table 1: Recommended Evidence-Based Practices (EBPs) that WisePath Digitizes for the User

Recommended EBP	Roadmap to Digitization in the WisePath Application
Lethal Means Safety	WisePath digitizes self-report of assessing and planning for lethal means safety including identifying lethal means the patient currently has available to them (including firearms); orienting the patient to the concern about having access to lethal means during a period of heightened suicidality; and developing a plan for managing access to lethal means.
As Described In Bryan, C. J., Stone, S. L., & Rudd, M. D. (2011). A practical, evidence-based approach for means-restriction counseling with suicidal patients. *Professional Psychology: Research and Practice*, *42*(5), 339-346. doi:10.1037/a0025051 References Mann, J. J., & Michel, C. A. (2016). Prevention of Firearm Suicide in the United States: What Works and What Is Possible. *American Journal of Psychiatry*, *173*(10), 969-979. doi:10.1176/appi.ajp.2016.16010069 Betz, M. E., Kautzman, M., Segal, D. L., Miller, I., Camargo, C. A., Jr, Boudreaux, E. D., & Arias, S. A. (2018). Frequency of lethal means assessment among emergency department patients with a positive suicide risk screen. *Psychiatry Research*, *260*, 30–35. doi:10.1016/j.psychres.2017.11.038	
Crisis Safety/Stability Planning	WisePath digitizes the development of a crisis safety plan. Patients are guided through identifying their warning signs, people they can call when in a suicide crisis, behavioral skills they can use to get through emotional distress, practical ways they make their environment safe, and their reasons for living.
As Described In Stanley, B., & Brown, G. K. (2012). Safety Planning Intervention: A Brief Intervention to Mitigate Suicide Risk. *Cognitive and Behavioral Practice*, *19*(2), 256–264. doi:10.1016/j.cbpra.2011.01.001	

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Jobes, D. A. (2017). Clinical assessment and treatment of suicidal risk: A critique of contemporary care and CAMS as a possible remedy. *Practice Innovations*, *2*(4), 207-220. doi:10.1037/pri0000054
TJC, Patient Safety Goal EP6 - Evidence-based resources for safety planning, and follow up care upon discharge https://www.jointcommission.org/resources/patient-safety-topics/suicide-prevention/

Assessment and Progress Monitoring	WisePath digitizes the delivery of self-report assessment measures relevant to SI and its drivers as well as providing visualizations of these data and interpretation information.

As Described In

Kazdin, A. E. (2008). Evidence-based treatment and practice: new opportunities to bridge clinical research and practice, enhance the knowledge base, and improve patient care. *American psychologist*, *63*(3), 146.
Langkaas, T. F., Wampold, B. E., & Hoffart, A. (2018). Five types of clinical difference to monitor in practice. *Psychotherapy*, *55*(3), 241.
Wampold, B. E. (2015). Routine outcome monitoring: Coming of age—With the usual developmental challenges. *Psychotherapy, 52*(4), 458–462. https://doi.org/10.1037/pst0000037

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de Jong, K., Conijn, J. M., Gallagher, R. A., Reshetnikova, A. S., Heij, M., & Lutz, M. C. (2021). Using progress feedback to improve outcomes and reduce drop-out, treatment duration, and deterioration: A multilevel meta-analysis. *Clinical Psychology Review*, *85*, 102002.
Harmon, C., Hawkins, E. J., Lambert, M. J., Slade, K., & Whipple, J. S. (2005). Improving outcomes for poorly responding clients: The use of clinical support tools and feedback to clients. Journal of clinical psychology, 61(2), 175-185.
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Intervention Pathways for Multi-problem Presentations	WisePath digitizes the individual pathways for patients struggling with SI and multiple drivers of suicide. Pathways in WisePath are derived from principles regarding how target hierarchies are developed in Dialectical Behavior Therapy (DBT) in the treatment of SI and multiple co-occurring problems.

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Hofmann, S. G., & Hayes, S. C. (2019). The future of intervention science: Process-based therapy. *Clinical Psychological Science*, *7*(1), 37-50.
Persons, J. B. (2022). Case formulation. *Cognitive and Behavioral Practice*, *29*(3), 537-540.
Riper, H., Andersson, G., Hunter, S. B., de Wit, J., Berking, M., & Cuijpers, P. (2014). Treatment of comorbid alcohol use disorders and depression with cognitive-behavioural therapy and motivational interviewing: A meta-analysis. *Addiction*, *109*(3), 394-406.

Psychoeducation/ Behavioral Skills Training	WisePath digitizes and consolidates a wide range of behavioral skills intended to improve emotion regulation and distress tolerance. Behavioral skills are derived from Dialectical Behavior Therapy (DBT). WisePath orients patients to what the skill is, why it is useful, and how to use it.

As Described In

Linehan M. (2015). *DBT Skills Training Manual*. Guilford Publications.

Barlow, D.H., Ellard, K.K., & Fairholme, C.P. (2010) *Unified protocol for transdiagnostic treatment of emotional disorders: Workbook.* Oxford University Press.

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Anestis, M. D., Pennings, S. M., Lavender, J. M., Tull, M. T., & Gratz, K. L. (2013). Low distress tolerance as an indirect risk factor for suicidal behavior: Considering the explanatory role of non-suicidal self-injury. *Comprehensive Psychiatry*, *54*(7), 996-1002. doi:10.1016/j.comppsych.2013.04.005

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Grepmair, L., Mitterlehner, F., Loew, T., Bachler, E., Rother, W., & Nickel, M. (2007). Promoting Mindfulness in Psychotherapists in Training Influences the Treatment Results of Their Patients: A Randomized, Double-Blind, Controlled Study. *Psychotherapy and Psychosomatics*, *76*(6), 332–338. doi:10.1159/000107560

Luxton, D.D, June, J.D., & Chalker, S.A. (2015). Mobile Health Technologies for Suicide Prevention: Feature Review and Recommendations for Use in Clinical Care. *Current Treatment Options in Psychiatry*, *2*(4), 349-362. doi:10.1007/s40501-015-0057-2

McCaul, K. D., Solomon, S., & Holmes, D. S. (1979). Effects of paced respiration and expectations on physiological and psychological responses to threat. *Journal of Personality and Social Psychology*, *37*(4), 564–571. doi:10.1037//0022-3514.37.4.564

Zeifman, R. J., Boritz, T., Barnhart, R., Labrish, C., & McMain, S. F. (2020). The independent roles of mindfulness and distress tolerance in treatment outcomes in dialectical behavior therapy skills training. *Personality Disorders: Theory, Research, and Treatment*, *11*(3), 181–190. doi:10.1037/per0000368

Psychoeducation/ People with Lived Experience	WisePath includes videos by people with lived experience (suicide attempt survivors and others who have lived with suicidal ideation) who provide practical information (e.g., the importance of seeking and engaging in treatment, strategies for managing intense emotions) and hope for the future.

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Pisani, A.R., Wyman, P. A., Gurditta, K., Schmeelk-Cone, K., Anderson, C. L., & Judd, E. (2018). Mobile Phone Intervention to Reduce Youth Suicide in Rural Communities: Field Test. *JMIR Mental Health*, *5*(2), e10425. doi:10.2196/10425

Naslund, J. A., Grande, S. W., Aschbrenner, K. A., & Elwyn, G. (2014). Naturally Occurring Peer Support through Social Media: The Experiences of Individuals with Severe Mental Illness Using YouTube. *PLoS ONE*, *9*(10): e110171. doi:10.1371/journal.pone.0110171

Gay, Barb. (2015, August 15). *Engaging Suicide Attempt Survivors* [Video]. Suicide Prevention Resource Center. https://www.sprc.org/video/attempt-survivors

Activities for Managing Depressed Mood	WisePath digitizes the delivery of therapy activities intended to improve depressive symptoms. Activities are derived from Behavioral Activation (BA), including identification of previously enjoyed activities, values-consistent activities, and subsequent activity scheduling.

As Described In

Lenuez, C.W., Hopko, D.R., Acierno, R., Daughters, S.B., & Pagoto, S.L. (2011). Ten year revision of the brief behavioral activation treatment for depression: Revised treatment manual. *Behavior Modification. 35*(2), 111-161.

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Addis, M. E., & Martell, C. R. (2004). *Overcoming depression one step at a time: The new behavioral activation approach to getting your life back*. New Harbinger Publications, Incorporated.
Cuijpers, P., van Straten, A., & Warmerdam, L. (2007). Behavioral activation treatments of depression: A meta-analysis. *Clinical Psychology Review*, *27*(3), 318–326. doi:10.1016/j.cpr.2006.11.001
Ekers, D., Webster, L., Van Straten, A., Cuijpers, P., Richards, D., & Gilbody, S. (2014). Behavioural activation for depression; an update of meta-analysis of effectiveness and sub group analysis. *PloS one*, *9*(6), e100100.
Ribeiro, J. D., Huang, X., Fox, K. R., & Franklin, J. C. (2018). Depression and hopelessness as risk factors for suicide ideation, attempts and death: meta-analysis of longitudinal studies. *The British Journal of Psychiatry*, *212*(5), 279-286.
Stein, A. T., Carl, E., Cuijpers, P., Karyotaki, E., & Smits, J. A. (2021). Looking beyond depression: A meta-analysis of the effect of behavioral activation on depression, anxiety, and activation. *Psychological Medicine*, *51*(9), 1491-1504.

Activities for Managing Alcohol Use	WisePath digitizes the delivery of therapy activities intended to reduce problems related to alcohol use. Particularly strategies related to moderating alcohol use and reducing intoxication.

As Described In

US Department of Health and Human Services. Rethinking Drinking: Alcohol and Your Health. Tips to Try. https://www.rethinkingdrinking.niaaa.nih.gov/thinking-about-a-change/strategies-for-cutting-down/tips-to-try.aspx
Epstein, E. E., & McCrady, B. S. (2009). *Overcoming alcohol use problems: A cognitive-behavioral treatment program*. Oxford University Press.
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Isaacs, J. Y., Smith, M. M., Sherry, S. B., Seno, M., Moore, M. L., & Stewart, S. H. (2022). Alcohol use and death by suicide: A meta-analysis of 33 studies. *Suicide and Life-Threatening Behavior*, *52*(4), 600-614.
Kuehn, B. M. (2009). Rethinking Drinking. *JAMA*, *301*(16), 1647-1647.
Witt, K., Chitty, K. M., Wardhani, R., Värnik, A., De Leo, D., & Kolves, K. (2021). Effect of alcohol interventions on suicidal ideation and behaviour: A systematic review and meta-analysis. Drug and alcohol dependence, 226, 108885.

Activities for Managing Sleep	WisePath digitizes and delivers psychoeducation and activities to improve sleep hygiene. Content is derived from Cognitive Behavioral Therapy for Insomnia (CBT-I).

As Described In:

Edinger JD, Means MK: Cognitive-behavioral therapy for primary insomnia. Clin Psychol Rev. 2005, 25: 539-558. 10.1016/j.cpr.2005.04.003.

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Bernert, R. A., & Joiner, T. E. (2007). Sleep disturbances and suicide risk: a review of the literature. *Neuropsychiatric disease and treatment*, *3*(6), 735-743.

WisePath digitizes already-existing evidence-based resources and activities to make it easier for adult users to access tools to facilitate management of their suicidal thoughts, depressed mood, alcohol misuse, and sleep problems, as well as supporting them with psychoeducation/behavioral skills training and insight from people with lived experience (shared stories), see Table 2. This is important because these recommended activities are oftentimes not delivered due to geographical limitations (e.g., rural areas), staff shortages, insufficient training in the necessary evidence-based protocols to address multiple problems, lack of resources to access treatment, and community stigma regarding mental health treatment. Wise Path facilitates delivery of EBPs by automating self-report measures and access to other helpful resources.

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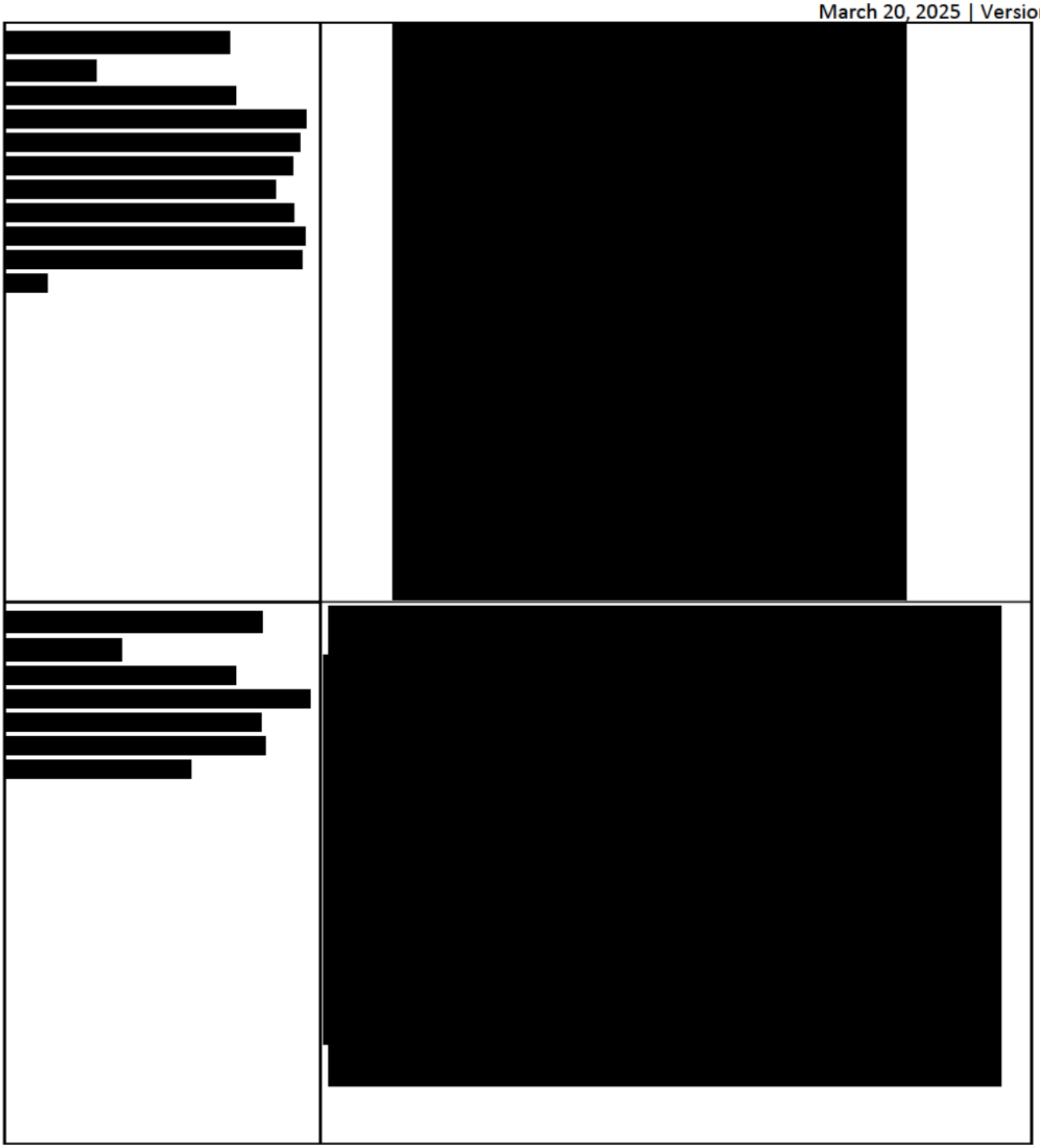

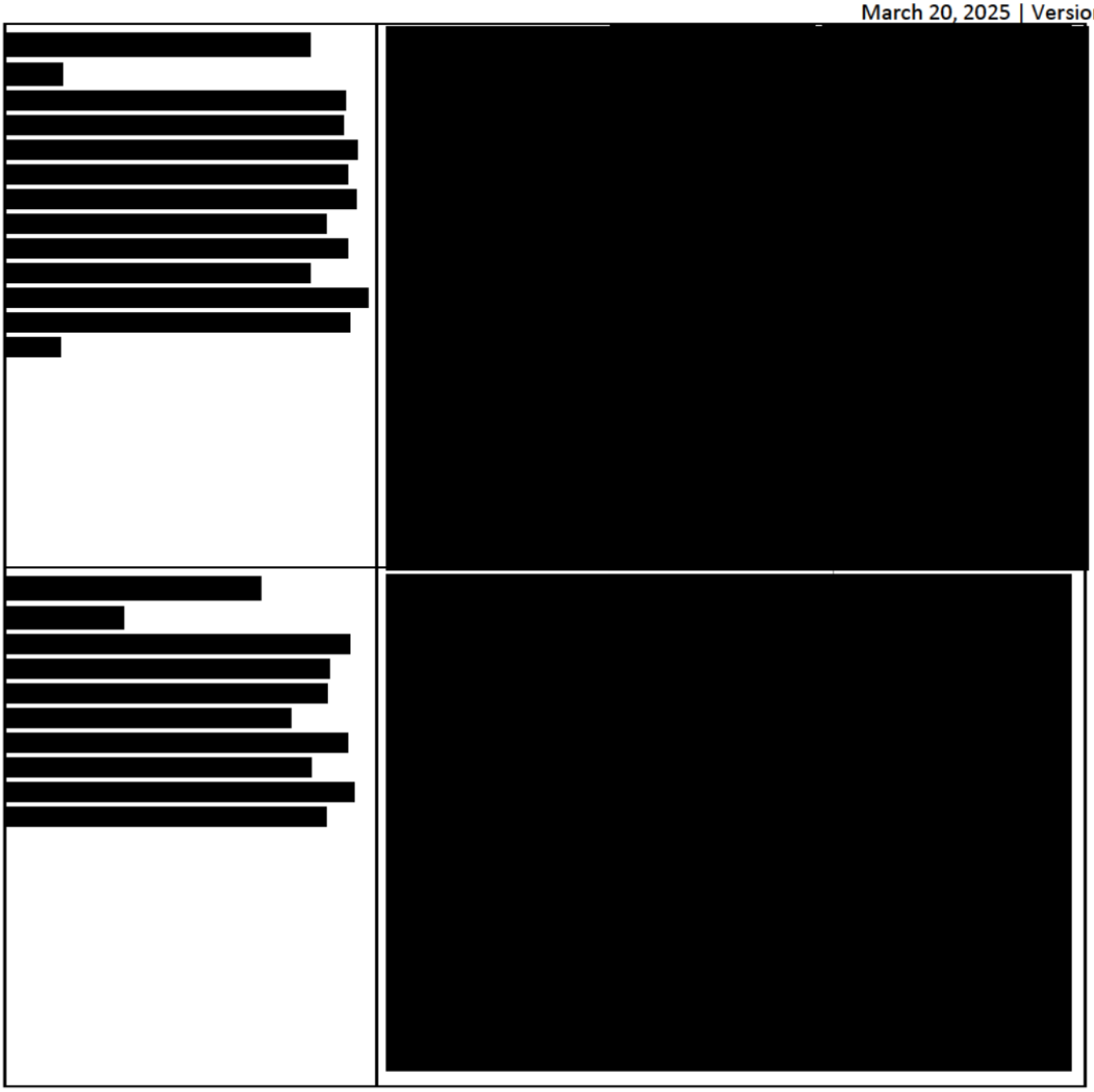

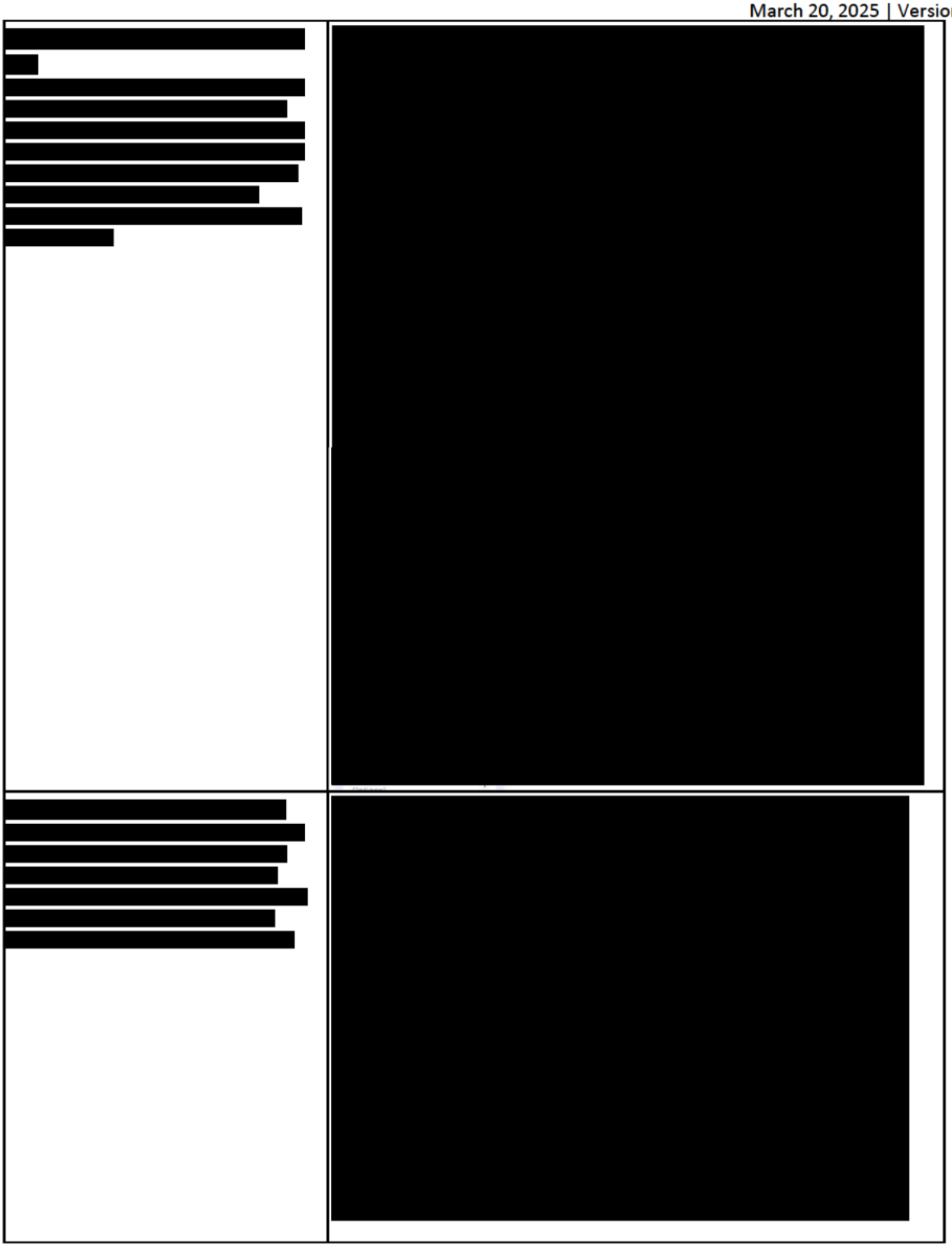

Psychoeducation/Shared Stories

WisePath provides access to peer videos. While the state of science is nascent, evidence shows that listening to people with lived experience with suicide on electronic media has been helpful for individuals to explore feelings and topics that they might otherwise be uncomfortable with. Such content represents a largely untapped resource that can be leveraged to improve outcomes for users.

Statistical Analysis Plan

We will use the Generalized Linear Model (GLM), a regression-based approach. It addresses limitations of ANOVA in that it can analyze a variety of commonly encountered outcome distributions (e.g., continuous, count) and can calculate robust standard errors which are less sensitive to skewness. Specifically, we will conduct our repeated-measures analyses using a version of GLM called Generalized Estimating Equations (GEE). Like Hierarchical Linear Modeling (HLM), GEE can include participants who are missing data at certain time points and test assumptions about the covariance matrix to determine the one that best fits the data. We will use the SPSS statistical package version 31 and GEE for all hypotheses concerning repeated measures outcomes. All hypotheses relate to change over time, and so the multiple time-points will be treated in the GEE analyses as nested within the individual. Also, we will treat intervention condition and time as categorical, dummy-coded predictors; the control condition and baseline scores will serve as the reference points. We will analyze hypothesis 3 (satisfaction with the WisePath app) descriptively and compare to the control app using t-tests.

Overall Plan

1. Chi-Square and t-tests to Confirm Group Equivalency between Control and WisePath Conditions for demographics and randomization variables
2. Demographic Frequencies
3. Descriptives for All Analytic Variables
4. Data Structuring for GEE
    a. Examine correlation and covariance, along with variable distribution to inform model parameters
5. GEE Models (see below) and t-tests

<u>Measures and items to be included in analyses</u>

1. H1: WisePath participants will report significantly greater decreases in suicidal and alcohol misuse behaviors compared to study controls.
    a. Suicidal behaviors
        i. Intensity and duration most likely to be sensitive to change
        ii. Still look at Past 30-day frequency, with understanding that it is less sensitive to change in other studies
        iii. Forecasting variables (e.g., perceived likelihood of future attempts)
    b. PROMIS Alcohol Use, Negative Consequences

2. H2: WisePath participants will report significantly greater increases in self-efficacy and coping with suicidal thoughts and distress, as well as use of suicide prevention strategies compared to study controls.
    a. Suicide Related Coping Scale
    b. PROMIS Self-Efficacy of Managing Emotions
3. H3: Satisfaction will be evaluated using descriptives for individual items and t-tests for overall satisfaction and average item satisfaction
4. Covariates
    a. No a priori covariates planned
    b. Will determine final list of covariates after examining demographics, group equivalency chi-square, and any other baseline variables descriptives of interest