CAMS Relational Agent System (CAMS-RAS) for Suicide Prevention

Emergency Department Treatment Study & Telehealth Virtual Care Study

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Summative Evaluation Protocol
Emergency Department Treatment Study | Telehealth Study

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3. Introduction

Suicide Remains a Significant Public Health Problem. With 44,965 U.S. suicides in 2016 (one suicide every 11.7 minutes), suicide remains the 10th leading cause of death among all ages and the second leading cause of death among those 10-44 years old. Despite considerable effort, U.S. suicide rates have remained unchanged for over two decades. In 2012, 483,596 people were treated in Emergency Departments (EDs) for suicide attempts and non-suicidal self-injury; 332,833 were hospitalized. The U.S. cost of suicides and suicide attempts in 2013 was $58.4 billion – of this 97% was due to lost productivity; adjusted for underreporting, $94.5 billion or $298 per capita. While it might be hoped that hospitalization may resolve suicide risk, it significantly increases (up to as much as 200 times) for individuals recently discharged.

EDs face formidable challenges in treating these patients that ultimately result in significantly longer lengths of stay compared to those for medical emergencies, lower satisfaction, and unnecessary hospitalizations. Jaspr is an evidence-based patient, and provider facing tablet application that has been funded through a National Institute of Mental Health (NIMH) SBIR grant (R44MH108222) and built by suicide experts and people with lived suicide experience. Jaspr is designed to reduce unnecessary hospitalization, length of stay (LOS) in the emergency department (ED), and ED/hospital readmissions while also improving patient satisfaction. Jaspr enables delivery of four of the five brief interventions recommended by the Suicide Prevention Resource Center (SPRC) including brief patient education, safety planning, lethal means counseling, and caring contacts post-discharge.

For the patient, Jaspr has four primary sections:

1. Suicide Risk Assessment: Through the use of a virtual guide, Jaspr walks the patient through the Collaborative Assessment and Management of Suicidality (CAMS) - an evidence-based suicide risk assessment that includes crisis and lethal means safety planning. Data from the assessment will be provided to the provider as a decision support tool in report form and the crisis safety and lethal means safety plans will be available for the patient to take home. CAMS was developed by David Jobes, PhD for use by clinicians to engage, assess, and treat suicidal patients.

   CAMS was developed by David Jobes, PhD for use by clinicians to engage, assess, and treat suicidal patients. CAMS is a non-prescriptive, atheoretical therapeutic framework for patients drawn to suicide as a way of coping. CAMS is a highly flexible treatment that can be used as a brief intervention, as an add-on to an existing treatment, or as a short-term (6-8 session) treatment. CAMS is a highly collaborative method for understanding and treating patient-defined “drivers” for suicide. CAMS is guided by the “Suicide Status Form” (SSF) which is used to assess the patient’s own ratings of suicide risk, including reasons for living and dying (Section A), along with key suicide risk and warning signs relevant to imminent risk (Section B), which lead to stabilization planning, suicide-specific treatment, and a better-informed disposition for care (Section C). CAMS Stabilization Plan includes: reducing access to lethal means, developing specific behavioral strategies to enhance coping with future suicide crises, and identifying people to call for help, which is supplemented by specific treatment goals and driver-specific interventions. Three published RCTs (Comtois et al., 2011; Andreasson et al., 2016; Jobes et al., 2017), eight non-randomized trials (Jobes, Jacoby, Cimbolic, & Hustead, 1997; Ellis, Rufino, Allen, Fowler, & Jobes, 2015; Ellis, Green, Allen, Jobes, & Nadorff, 2012; Arkov, Rosenbaum, Christiansen, Jonsson, Munchow, 2008; Jobes, Kahn-Green, Greene, & Goeke-Morey, 2009; Nielsen, Alberdi, & Rosenbaum, 2011; Jobes, Wong, Conrad, Drozd, & Neal-Walden, 2005; Ellis, Rufino, & Allen, 2017), and two not yet published RCTs across multiple treatment settings provide replicated evidence that CAMS reliably outperforms control conditions in reducing suicidal ideation, overall symptom distress, and depression, while increasing hope, patient satisfaction, and care retention. Recent RCTs provide promising evidence that CAMS reduces self-harm and suicide attempts (Andreasson et al., 2016) and that standard CAMS significantly decreases ED visits among

suicidal military sub-samples (Jobes et al., 2005; Huh et al., 2017).

2. Shared Stories: The app contains a robust collection of videos from people who have lived experience with suicide sharing their personal stories to inspire hope and connectedness that the patient can browse either by topic category or by the individual story teller.

3. Comfort and Skills: Through a variety of activities and videos, the app teaches the patient coping skills to manage their imminent distress in the moment and reduce their suicide risk post-discharge.

4. Take Away Kit ("Jaspr-at-Home"): A companion mobile app accompanies the patient home for continued use during the highest period of suicide risk post-discharge. The patient has the ability to save activities and videos from the app to their crisis safety plan which is then available to them post discharge. Additionally, there are more advanced skill building tools and activities available to the patient post discharge that can be customized by the provider.

For the provider:

- Jaspr will generate a provider decision support report based on the CAMS interview that can be printed or faxed to the provider. In the future (but not during the length of this study), the patient data will be integrated into the EMR.
- Allow the provider to select additional skills and activities that will be available to the patient post discharge.
- Create custom "Caring Contacts" that will be delivered to the patient at definable intervals post discharge

This NIMH-funded research involves two research phases: a **formative evaluation** and a **summative evaluation**.

The formative evaluation (SIRB #7097) occurred first and will continue throughout the length of the research project. Its purpose is to gather invaluable information as we design and improve all features for patient and provider users of the technology to ensure its acceptability, ease of use, and clinical relevance to achieve the intended outcomes, such as: decreasing suicidal behavior, length of stay in the ED, unnecessary hospitalization, readmission, liability, and increasing ability to manage suicidal crises and satisfaction with ED experience.

The focus of this summative evaluation is to evaluate Jaspr (N=120) and JAH (N=60) in clinical trials. The ED clinical trial compares Jaspr to Care-as-Usual (CAU) in EDs nationwide; the Telehealth clinical trial compares JAH to CAU + crisis safety plan. Patient participants meeting study criteria for the ED study will be randomly assigned to receive Jaspr (in addition to their usual care; n=60) or CAU only (the treatment that is standardly provided to suicidal patients in the ED; n=60). Patients participants in the ED study who are assigned to the Jaspr condition will receive access to JAH for use throughout the follow up period as they see fit. Outpatient participants meeting study criteria for the Telehealth study will be randomly assigned to receive JAH (in addition to their usual care; n=30) or CAU (in addition to crisis safety planning; n=30). We will also conduct a small (N=15) ED study pilot trial to make necessary adjustments to both study procedures and Jaspr before conducting the ED study RCT. The research procedures for the pilot and full RCT will be identical unless the research team identifies areas for improvement during the pilot to incorporate into the full RCT. All modifications will be submitted to IRB prior to implementation.

Patient participants in the ED study will be asked to complete study sessions (interview and online surveys) at four time points: at the time of ED admission, and at 7-days, 30-days, and 90-days after ED admission. Outpatient participants in the Telehealth study will be asked to complete study sessions at three time points: baseline, 30- and 90-days after the initial session. The initial session of the ED study will be conducted in-person in a private space provided by the organization/hospital (e.g., the patient's room or another private environment); the initial session of the Telehealth study will be conducted remotely. Each follow up assessment will be conducted remotely consisting of a brief phone

interview and a set of surveys administered online.

The ED study will also include provider participants who will be asked to complete a demographics survey and a brief interview about each of their index study patients after their intervention with the patient is complete. The brief interview will be administered in-person and assess the provider's feeling of preparedness for the assessment, the patient's degree of distress at the time of encounter, helpfulness of Jaspr's clinical support tool in discharge disposition determination, and risk assessment (if applicable).

ED study primary outcome variables include: suicidality (death by suicide, suicide attempts, suicidal ideation), ED/hospital admissions, discharge disposition, use of restraints while in ED (chemical, physical), intensity ratings of acute distress, self-efficacy in coping with distress, use of imminent distress intervention and coping skills, and helpfulness of their ED encounter. Jaspr condition-specific outcomes will be examined and reported descriptively. These include tools accessed during and after the ED visit, perceived usefulness and satisfaction of Jaspr brief intervention components, and usage of provider/patient apps and their features.

Telehealth study primary outcome variables include: suicidality (death by suicide, suicide attempts, suicidal ideation); Crisis-related healthcare utilization (ED visits, psychiatric hospitalization, calls to crisis line; crisis calls to therapist; Outpatient Satisfaction; Use of evidence-based interventions to reduce suicide risk (safety planning, lethal means management, behavioral skills). Secondary outcomes include: Reasons for living; Psychological distress (depression, anxiety, stress); Cognitions associated with suicide risk (hope, optimism, pessimism).

The primary hypotheses include:

1. Jaspr patients will report significantly greater decrease in suicidality and ED/hospital admissions than CAU patients from the initial session to follow-up assessments.
2. Jaspr patients will report significantly greater increases in self-efficacy in coping with acute distress, use of acute crisis tolerance skills, and perceived helpfulness of the care they receive compared to CAU patients.
3. Jaspr patients will report high levels of satisfaction with Jaspr.

Secondary hypotheses for the ED study include that medical providers will rate the Jaspr clinical support tools as helpful in preparing for and assessing suicide risk and patient's degree of distress at the time of their encounter and aiding in discharge disposition plan. We will also examine if providers rate themselves as more confident in their suicide risk assessment with patients assigned to the Jaspr condition compared to those assigned to the CAU condition.

The procedures defined within this document pertain *only* to the procedures performed during the summative evaluation.

A. Type of Research

The studies involves behavioral research. Our goal is to digitize and automate a number of scientifically validated processes to ensure that suicidal patients in the emergency department receive them. The focus of the studies is to compare the effects of Jaspr versus CAU with suicidal patients in the ED as well as JAH versus CAU with outpatients experiencing suicidality, with the former having particular interest in suicidality, ED/hospital admissions, self-efficacy, and treatment satisfaction.

B. Purpose/Objective of the Study

The overall purpose of the ED study is to evaluate the app we recently developed, called Jaspr, that can be used on a tablet and/or smartphone by suicidal patients in the ED and their care providers. Jaspr also includes a companion mobile app patients may use after discharge on their smartphone. Jaspr is designed to reduce unnecessary hospitalization, length of stay in the ED, and ED/hospital readmissions while also improving patient satisfaction and providing support to

ED providers (e.g., nurses, social workers, physicians). The overall purpose of the Telehealth study is to evaluate the effectiveness of the companion mobile app, called Jaspr-at-Home, that can be used by outpatients experiencing suicidality, when implemented in a telehealth context.

C. Background of the Study

In our Phase I preliminary research for this project, we developed and tested the feasibility of a Jaspr prototype (called Virtual CAMS) for "proof of concept". The prototype, for use with suicidal ED patients and medical providers was based on a nurse avatar ("Louise") that reduced readmissions through enhanced medical discharge planning, included "Dr. Dave" (based on CAMS treatment developer, David Jobes, PhD) to administer a CAMS-oriented Suicide Status Interview (SSI; based on the Suicide Status Form, SSF) and a clinical decision-making support tool for providers that summarizes the patient's suicide risk based on the SSI.

Proof of concept was determined in two stages: (1) a formative evaluation during the iterative development of Jaspr where feedback was obtained from target end-users, and (2) a summative evaluation consisting of a feasibility test (usability, acceptability, satisfaction) of "Dr. Dave" with suicidal ED patients. During this preliminary study, we visited Mayo Clinic, HealthPartners' and four Allina Health EDs to understand their workflow and discuss with administrators to understand their challenges treating suicidal ED patients. We met with over 25 Allina administrators and ED directors to discuss how innovative technologies like Jaspr might improve ED services. We developed and tested all Jaspr elements proposed for Phase I: (1) a tablet-based avatar ("Dr. Dave") performing a 15-minute segment of the CAMS SSI; (2) the discharge disposition clinical decision support tool that distills Jaspr SSI content into an easy-to-review provider report (content and graphics only); and (3) "Caring Contacts" post-discharge messages. We also developed two videos of peer specialists with lived experience with suicide (generating hope) and videos of Dr. Jobes introducing patients to the SSI for later testing of whether suicidal ED patients preferred videos to an avatar.

In Phase II preliminary research, we conducted extensive research and analysis of competitor apps to analyze market competition and gathered ideas about designs and content to include in Jaspr. Design summit meetings were held to further refine the initial design of the app. In collaboration with systems stakeholders, various personas were created to better understand the workflow in the ED. Personas for different patient journeys in the ED were created, as well as personas for loved ones accompanying the patient, business development leaders, masters-level assessors, ED physicians, and stakeholders. Patient personas were informed by interviews with 15 people with lived experience (PLE) who previously sought ED services during their suicide crises. During this phase, user-centered research was conducted to obtain feedback about Jaspr's patient-facing features. Patients in the ED and inpatient unit were interviewed at Harborview Medical Center, Mayo Clinic, and Allina Health. With consultation from suicide experts, we received validation and enhanced understanding to develop Caring Contacts content for the app. We also created 3.5 hours of video content of PLEs discussing various topics including relationship to suicide now, experience in the ED, skills to stay well and manage difficult emotions, personal stories, first day/week out of hospital, and "my wish for you". These video clips were culled and tested within the NowMattersNow.org collection of behavioral skills to include in Jaspr-at-Home a companion mobile app patients may use on their own smartphone after discharge.

Preliminary Findings: Four important findings emerged through our initial Phase I, 80+ hours of testing and interviews. First, administrators and providers universally viewed tablets as acceptable technology to deliver Jaspr as patients are always under observation – either directly monitored in open-spaces or with cameras when in a closed room. Second, they excluded only psychotic and/or severely agitated patients as inappropriate to use Jaspr. Third, all participants liked the hope-instilling videos by consumer/peer specialists and viewed them as a nice counterbalance to the "Dr. Dave" SSI. Finally, patient participants preferred a simple avatar (like "Nurse Louise") using a computer-generated voice instead of video delivery of CAMS or use of Dr. Jobes' actual voice for "Dr. Dave." Stated plainly by one participant, "It's clear that the avatar is a computer and not a person trying to get into my head." While not all suicidal

patients felt strongly in their preference, all found the simple avatar acceptable and valuable to use.

Preliminary study results from the Phase II user-centered research are similarly positive, with 95% of participants endorsing that they would save the content they encountered for use after leaving the ED, 100% identified the features as "helpful", and 100% indicated they would like to see the app available for use in EDs for suicidal individuals.

4. Participant Selection

A. Inclusion and Exclusion Criteria

All participants must be 18 years or older and English-speaking (Jaspr is currently only available in English. A Spanish version will be developed after the English version of Jaspr is successfully commercialized).

Patient Participants:
ED Study Inclusion Criteria: Patient participants must: 1) currently be in the ED seeking treatment for suicidal behavior; 2) be medically and clinically[1] stable as deemed by ED medical personnel or other treatment provider on patient's care team; 3) have access to a computer or other device (smartphone, tablet) with Internet connection; 4) have access and regularly use an Apple or Android smartphone; 5) have a stable address and housing for the last 30 days.

Telehealth Study Patient Inclusion Criteria: 1) Currently receiving outpatient treatment services for suicidality; 2) have access to a computer or other device (smartphone, tablet) with Internet connection; 3) currently has and regularly uses an Apple or Android smartphone; 4) has a stable address and housing.

Patient Exclusion Criteria: Patients who are 1) acutely psychotic, severely agitated;[2] patients with significant intoxication or other impairment that may interfere with providing consent and meaningful feedback (as determined by their medical provider); 2) have no access or way to access phone or computer (or other device) with Internet connection; and 3) homeless or have unstable housing in the past 30 days will be excluded from the study.

Additional Exclusion Criterion (Telehealth Study only): Prior use of Jaspr/Jaspr-at-Home.

Provider Participants (ED study only):
Inclusion Criteria: Providers must be currently serving in the ED as a medical provider who treats patients with suicidal behaviors. There are no exclusion criteria.

B. Gender

The research team will maintain a focused effort on ensuring that the percent of women participants recruited for this study are representative of the broader group of target end-users. Women as well as men will be eligible for participation in this study. Because of the overrepresentation of men who present to emergency departments as suicidal, it is expected men will represent approximately 60% of our sample population. Pregnant women will not be excluded from this study and method of birth control will not be measured as this research will impose no risk to the fetus.

C. Racial/Ethnic Origin

Our goal is to achieve a minimum of 25% involvement by ethnic and racial minority participants among patient and provider participants. Dr. Dimeff has successfully employed a number of approaches in her previous research to reach recruitment targets, in particular 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, and 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. This approach may involve visiting (either virtually or directly) the hospital and may involve providing an in-service, as requested by the director. We can easily provide these services through our online community format.

Should we continue to encounter difficulty meeting our targets for recruitment of ethnic and racial minority participants after applying these methods, we will form an ethnic and racial minority recruitment advisory committee, chaired by Steven Lopez, PhD, an expert on cross-cultural clinical research and a close colleague of Dr. Koerner's. The task force will then examine recruitment efforts to date in an effort to identify potential problems or barriers to access that may account for the continued low enrollment. Solutions will then be generated, implemented, and reevaluated. We will seek input from this advisory board as needed to ensure we have fulfilled our stated aims described here.

D. Vulnerable Populations

The risk to participants in this research is minimal when applying NIMH risk standards and designations. According to these NIMH 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 acutely suicidal and/or recently hospitalized because of suicidality. 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. Preliminary data from our non-randomized observational research has demonstrated that suicidal patients feel less distressed following contact with our research team and use of Jaspr. Our research to date has demonstrated a 30% reduction in overall self-report ratings of distress for suicidal ED patients engaged in our research. Given the minimal risk nature of this study, the likely causes of such adverse events are likely to be factors related to their ED experience (e.g., nicotine withdrawal while in ED, fear/anxiety about what to expect, restrained on gurney, etc.) that co-occur or overlap with their engagement in our research, particularly during their ED stay. Unique research factors may include one or more of the following: length of the assessment, or interrupted use of Jaspr to attend to medical providers' interventions.

E. Age

Participants under the age of 18 will be excluded from participating in the study as suicide interventions and assessments for adolescents and children differ significantly from those for adults. While it is, in theory, conceivable that a portion of our provider participants will include older adolescents between the ages of 18 and 21, it is expected that these individuals will all be adults over the age of 21.

F. Total Number of Participants to be Enrolled

Participants will be recruited from healthcare systems and hospital EDs nationwide. For the ED RCT (and ED pilot RCT), we will gather data from approximately 135 suicidal ED patients (no fewer than 90 patients) and their health care

providers in the ED. We will recruit approximately 20 suicidal ED patients from each project site. To reach our recruitment goals for the RCT, we expect to spend an average of eight days at each site, with capacity to increase our time at each if needed. For the Telehealth study, we will gather data from approximately 60 outpatients experiencing suicidality. Outpatient participants will be recruited from clinics represented in the Dialectical Behavioral Therapy (DBT) Clinics Consortium (including Portland DBT Institute, Tampa Bay Center for Cognitive Behavioral Therapy, DBT Institute of Michigan) and, if needed, through an online distribution list of providers serving suicidal patients (ZeroSuicide, AAS, and DBT listservs).

5. Study Design / Method / Procedures

A. Summary of the Research Design

EBPI is partnering with several large healthcare systems to conduct this research to ensure that Jaspr meets the needs and workflow of multiple large healthcare systems and persons who seek ED services for their suicidal behavior. Research with participants will occur onsite or remotely (via telephone and computer). For the ED study, each project performance site will decide if they prefer EBPI researchers to conduct all study procedures at their site or if they prefer to engage a qualified researcher to conduct the research in conjunction with EBPI researchers. EBPI will develop and maintain all the research protocol and procedures to be followed by EBPI and all site researchers. If applicable, EBPI will provide training to the site researchers (virtually or in-person) in the ED study research protocol and procedures prior to commencing research at each site, including training in approaching potential participants without coercion and the informed consent process. Moreover, all individuals engaging in research will be required to complete training in protection of human subjects in research, HIPAA training, and Good Clinical Practices education. Course completion certificates will be kept up to date during the study and stored by EBPI in their records.

Formal screening and the informed consent process will be performed by the researchers prior to commencing participation. Informed consent procedures will be fully and thoroughly conducted by a researcher (e.g., orienting prospective participants to the study details, highlighting that they are under no obligation to participation in the study, and that a decision to decline participation will not affect their care, in the case of patients, or employment, in the case of providers) onsite or remotely.

ED Study

Patient Participants: Because the patient's medical treatment is of foremost importance and to accommodate the fluid, unpredictable environments in the ED and to work within their usual flow, the researchers will pause all research procedures whenever necessary to allow for the patient's medical care and resume should there be additional periods of waiting. Once enrollment is complete (i.e., consent is obtained), the researchers will request a release of information from the participant for information we would like to gather from a member of their care team after the patient's discharge. Specifically, we are interested in collecting data about the patient's length of stay, if physical or chemical restraints were used and if so for how long, their final discharge disposition (e.g., if the patient was admitted to inpatient, residential, or substance abuse treatment or discharged to home), and if the patient was admitted whether it was involuntary or voluntary. This data will be obtained orally by speaking with a member of the patient's care team; medical records will not be accessed by the researchers. Permission (or not) for this release of information will not impact the patient's participation in the study (i.e., if they decline to provide permission for this release, they may still participate in the study). If the patient agrees to provide permission for the researcher to collect this information, they will be asked to sign a release of information form.

The researcher will then conduct the baseline assessment and the researcher will randomize the patient to condition while the participant is completing baseline measures. The researcher will inform the patient of the condition they have

been assigned after they have completed the baseline assessment.
If the patient is assigned to the CAU condition, the researcher will conclude the session and tell the patient that they will return in two hours to complete the post treatment interview and online surveys. If the patient is assigned to the Jaspr condition, the researcher will walk the patient through a supplement consent form to provide further information about the app and obtain their electronic or paper/pencil signature. The researcher will orient the patient to the app on the study tablet, help them to set up their account, and let them know they may use Jaspr however they choose for up to two hours, not including breaks they may request or that may be needed in order to receive their standard medical care. The researcher will remain with the patient at all times while using Jaspr to answer any questions that the patient may have about Jaspr or the study; the researcher will not engage with the patient otherwise. After two hours of Jaspr use, the researcher will ask the patient to pause their use of Jaspr and conduct the post treatment interview and online surveys. If the patient indicates they are finished using Jaspr prior to the two hour timeframe, the researcher will conduct the post treatment interview and online surveys at that time. After the post treatment surveys are completed, researchers will orient the patient to installing the Jaspr-at-Home mobile app on their smartphone and ask them to use it however they see fit after being discharged. If the patient does not have access to their smartphone or if they prefer to install the app after they leave the ED, the researcher will provide email instructions for accessing and installing Jaspr-at-Home.

Patient participants will be asked to contact the researcher in the unlikely event that they are going to be discharged or transferred prior to completing the post treatment surveys so that the patient may complete the study procedures prior to leaving. Time spent completing the initial session (i.e., eligibility, consent, randomization, baseline, scheduling, and post assessment) is estimated to take approximately 2 – 4 hours depending on the number of breaks the patient is required or elects to take.

After the post-treatment interview and surveys are completed in the ED, the onsite researcher will explain the purpose of blinding researchers to participants' condition and then virtually introduce (e.g., via Zoom, FaceTime) the patient participant to the (blinded) EBPI research assistant who will be responsible for conducting the post-discharge follow-up assessments[3]. This research assistant will remain blind to the patient's condition during this discussion and the 7- , 30, and most of the 90-day follow up assessment time points. At the very end of the 90-day assessment, the research assistant will be asking condition-specific questions (e.g., usability questions about the patient's experience with the Jaspr app) and thus cannot be blind during this assessment time point. In an effort to ensure a warm hand-off from the ED-based researcher to the follow-up blinded assessor, the blinded research assistant will schedule the three follow up assessments and administer the Participant Information Form.

Because the site contact or their designee will determine sufficiently stable participants to refer to the research, we do not anticipate that participation in the study will lead to significant distress. However, the researchers will be attentive to changes in mood states and, if indicated, will check in verbally with the participant about whether they wish to continue. If a participant becomes more distressed during the meeting for whatever reason (e.g., due to length of waiting in the ED, an upsetting conversation with medical personnel, or some aspect of the research procedure), the researchers will again ask if they prefer to discontinue the study. We prefer not to automatically discontinue the study in cases where their distress is caused by an aspect of their ED experience for the reason that participation in the study may actually be helpful to them in distracting them from the actual cause of their upset. We will however inquire about their preference to discontinue. We will also inform the site contact or their designee and a member of the patient's care team that the patient appears more upset than at the start of the research procedure. In cases where the patient appears more distressed than they were at the start of the procedure and displays difficulty redirecting to research tasks, we will discontinue the study procedure and notify the site contact or their designee and a member of the patient's care team.

Follow up assessments will occur remotely via phone and internet 7-, 30-, and 90-days after baseline. At the pre-

arranged time, the researcher will call the patient to conduct the study follow up assessment. The researcher will first send the patient a link to the online surveys via email and verbally remind the participant of their study ID. The researcher may also text the study ID to the patient if they prefer. The researcher will mute their phone and remain on the line as the patient completes the surveys. The researcher will unmute their phone and address any questions the patient may have as needed. Upon completion of the surveys, the researcher will then conduct the semi-structured interview.

The researcher will conclude the assessment by asking the patient to rate their level of stress, urge to self-harm, intent to kill self, intent to physically harm self using a 7-point Likert scale (based on Dr. Marsha Linehan's UWRAMP protocol). If the patient endorses a score of 5 or greater on urges to harm self or others or if a patient participant becomes distressed during or immediately after the follow up assessment, the researcher will do a warm hand off to Boys Town and inform the study PI immediately. Boys Town Hotline is staffed by a specialized team of crisis counselors trained in providing suicide risk assessments by telephone in accordance with the National Suicide Prevention Lifeline's Suicide Risk Assessment Standards. Boys Town Hotline will provide telephone crisis intervention services and will provide the research staff documentation, including information given during the call, the nature of the call, responses given, and other evaluative data elements, to the study PI within 24 hours. Boys Town will utilize their national internal database of service referrals to provide further action for the participant if deemed necessary. If the crisis counselor determines the participant's situation as life threatening, they will notify a senior counselor who will determine the level of assistance needed (i.e., if another party should be contacted, facilitation of contact with third party, and monitor the call while crisis counselor endeavors to remain actively engaged with the participant).

***Provider Participants**:* The ED providers and other hospital staff of each participating site will be knowledgeable about the study. The researchers will provide further information as needed for providers to refer patients to the study. Interested provider participants will enroll in the study prior to referring potential patient participants. After enrollment is complete, the researcher will set up the provider's Jaspr account and provide a brief introduction to the app.

After their index patient is enrolled in the study, the researchers will inform the provider of their patient's study condition via the method preferred by the provider as indicated during their consent process (e.g., verbally in person, via page or text message; no identifying information will be included by text or other electronic communication). Providers will be asked to treat their enrolled patient participants utilizing either the care they typically provide or the care they typically provide supplemented with Jaspr, depending to which condition the patient is assigned (CAU or Jaspr, respectively). While providers are treating a patient participant assigned to the Jaspr condition, they will be asked to utilize the provider summary reports and other tools within Jaspr as they see best, guided by their clinical judgement. Once the disposition discharge report is available from the patient participant's use of Jaspr, the researcher will print it out and provide this report to the provider participant to use as they see fit. After their index patient has used Jaspr for up to two hours (not counting breaks) or received usual care for two hours, all providers will be asked to complete a brief post treatment interview. They may also choose to complete the survey on paper or online if they prefer. In the case of a patient participant having multiple providers (e.g., social worker), the researcher will gather feedback from the ED physician or main provider and then from the other providers who also treated the patient participant given these other providers also have enrolled in the study. Participation time for providers per patient is approximately 5 minutes including enrollment procedures.

Telehealth Study

Outpatient individuals experiencing suicidality will learn of the study opportunity from their outpatient provider. Interested outpatients will complete the enrollment process with a researcher over computer screenshare and/or telephone. This includes eligibility screening, informed consent, and randomization to JAH or CAU. The baseline and follow-up assessments will be scheduled at the end of the call. Participants will be paid $25 for each completed assessment

The baseline assessment will be conducted remotely via Zoom, a HIPAA-compliant video conference site. A brief semi-structured telephone interview and online survey measures will be administered to collect data including the participant's experience with suicidality, depressive and anxiety symptoms, stress, coping with acute distress, satisfaction with outpatient care and JAH. Participants assigned to the JAH condition will be oriented to the Jaspr Health app through Zoom screenshare, and will complete (via telehealth) a comprehensive suicide assessment within Jaspr. Based on the Suicide Status Interview (SSI) from the CAMS approach, the JAH chatbot will also conduct lethal means counseling and assist the participant in building a stability plan as part of the comprehensive assessment. Participants will also be able to select behavioral skills from Jaspr Health to include in their stabilization plan as well as videos of people with lived experience to provide insight, wisdom, and hope. To mimic a telehealth workflow, the researcher will provide access to Jaspr Health via Zoom and guide the participant's engagement with different components of the platform until they have completed the SSI and fully built out their stability plan. Once completed, the Jaspr Health platform will provide the participant with access to JAH. Before concluding the call, the researcher (functioning as a mental health technician) will ensure the participant is able to download, register, and reliably use JAH on their PC, phone, tablet, or other hardware.

We will schedule three brief (5-10 minutes) support check in calls with each participant to take place at 72 hours, one week, and three weeks after they receive access to their study materials (JAH or safety planning packet). During these calls, a researcher will answer any questions about the app or the safety planning materials, inquire if they are using the materials, and assess any barriers to use. These calls are similar to getting a call from a medical provider's office (not from the provider themselves, but office staff) to check in on their patient after surgery or other procedure to check in on pain, comfort, got what they need; our staff will be checking in on the participants. Just as the office staff member making the call doesn't delve into the specifics of the medical problem, we also won't delve into their suicidality or other problem behaviors. If the participant needs, warm handoff procedures will be used to connect them with a crisis counselor at Boys Town.

The follow-up assessments conducted at 30- and 90-days after the baseline assessment will include the online survey measures and a semi-structured interview. The researcher will send a reminder the day before each appointment using the method of contact preferred by the participant (i.e., email or text). At the time of the scheduled follow-up appointment, the researcher will call the participant's primary phone and subsequently attempt to reach them via text and email if there is no answer. During the follow-up assessments, the researcher will send the participant a link to complete the online surveys and verbally provide their study ID number. After the surveys are completed, the researcher will proceed to the semi-structured interview which will include questions collecting information such as the participant's thoughts and experience with suicide since the prior study session and their use of resources (JAH and the crisis stability plan, if applicable). The debrief interview from the UWRAMP will be conducted following each assessment. In the event that the participant meets or exceeds the distress threshold, we will utilize the Warm Handoff procedure and connect the participant to a crisis counselor at Boys Town, as described above.

All participants will be given access to use JAH for 30-days should they wish to do so following the completion of their final study assessment.

B. Analysis of Study Results

During the summative evaluation, data gathered is qualitative and quantitative in nature. Online survey measures will be administered at four time points (baseline, post treatment, 7-day follow up, 30-day follow up, and 90-day follow up) to all ED study patient participants and three time points (baseline, 30-day, and 90-day follow up) to all Telehealth study participants. For the ED study, provider participants will complete study procedures via interview with the researcher (on paper or online if they prefer) at post treatment for all patients they treat as part of this study. Measures for patient

participants will include demographics, questions about suicidality, depressive symptoms, use of acute crisis tolerance skills, coping with acute distress, and satisfaction with ED experience. Measures for provider participants will include demographics, questions about preparedness for clinical interview, patient distress, provider confidence in suicide risk assessment, and helpfulness of Jaspr. Semi-structured interviews will be conducted with patient participants at each time point after baseline to obtain feedback about the participant's experience in the ED, experience with suicide symptoms, and/or Jaspr tools and features. For the Telehealth study, measures for patient participants include demographics, questions about suicidality, depressive and anxiety symptoms, stress, coping with acute distress, satisfaction with outpatient care and JAH. Semi-structured interviews at each follow-up assessment will be conducted to obtain feedback about the participant's experience with suicide and use of their resources since the prior study session.

Data will be entered online using an encrypted, secure online assessment tool such as SurveyMonkey. Missing values are coded as to reason missing (e.g., 'participant unable to be located,' 'participant refused to answer,' etc.). All data will be cleaned for logic and other types of errors using SPSS. 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 Jaspr or JAH. This will allow us to conduct primary analyses on the intent-to-treat sample. To minimize missing data, we have included built-in incentives (i.e., bonus payments for completing all assessments) and training by Dr. Kate Comtois in methods to decrease attrition. To the extent that there is question about skipped or missed assessments, the software and analysis method we have chosen provides 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 parameters.

Analysis Strategy. We will use SPSS Version 23. For patient data, we will use Hierarchical Linear Modeling (HLM). HLM provides greater flexibility in that it can analyze a variety of commonly encountered outcome distributions (e.g., continuous, binary count), test the fit of different covariance matrix assumptions; and include participants who are missing data at some time points. We will account for nesting of patients under providers by including providers as a random effect; we will account for nesting within sites by including dummy coded fixed effects predictors representing site in all analyses. For each outcome, we will specify the correct distribution and compare fit indices to identify the covariance matrix best fitting the data. Many hypotheses relate to change over time, and so the multiple time-points will be treated as nested within the individual. Also, we will treat the intervention conditions (Jaspr and JAH) and time as categorical, dummy-coded predictors; the control conditions and baseline scores will serve as the reference category. 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. Regression coefficients will indicate at which follow up time points the conditions showed differential change from baseline. For patient satisfaction as well as the secondary hypotheses concerning medical providers ratings of helpfulness, we will compute descriptive statistics and consider ratings to be favorable using the *a priori* established criteria that 80% or more respondents rate program components as favorable or highly favorable. For the remaining secondary hypotheses, which are based on provider data about patients from both conditions at one time point, we will compute between-condition means. Since it is possible that not all providers will be able to provide data given time constraints inherent in their job, we may not have the statistical power to conduct probability tests. Hence, we will examine the data descriptively to provide preliminary information about efficacy and compute effect sizes to inform future research.

Statistical Power Considerations. For Hypotheses 1 and 2, we conducted power analyses focused on the ability to detect statistical significance on the key parameter of interest, the Time X Condition interaction. Power analyses assumed equal size groups, $p \leq .05$, power of .80, and two-tailed tests. Using GPower's utility for the General Linear Model, we found that a total sample size of 24 patients would allow detection a medium effect ($f > = 25$). However, this assumes no design effects (DE) that occur due to the nesting of patients under physicians. In the likely event that design effects exist, a sample of 72 participants will allow sufficient power to detect a medium effect with DEs as great as 3.0). Adjusting this number for possible 20% attrition, we would need to enroll at least 90 patients, but will strive to include 120 patients total in this research to ensure we have sufficient statistical power for all outcome variables.

C. Monitoring

This study will include a Data and Safety Monitoring Board (DSMB). Relying on Dr. David Jobes' (CAMS Treatment Developer) familiarity with the top clinicians and researchers within the field, we selected Gregory Brown, PhD, as the chair of our DSMB. Dr. Brown currently serves as a Research Associate Professor at of Clinical Psychology and Psychiatry at the University of Pennsylvania, where his research efforts focus on developing, evaluating, and disseminating interventions for individuals at high risk for suicide. Jeffrey Sung, MD has agreed to serve in the role as our DSMB ED Psychiatrist. Dr. Sung has experience in the clinical treatment of suicidal patients and has also focused on training in suicide risk assessment, management, and treatment. Our third DSMB member is Craig Bryan, PsyD. Dr. Bryan is a board-certified clinical psychologist and current Executive Director of the National Center for Veterans Studies at the University of Utah. Dr. Bryan has a lengthy history of successful treatment development, research, and treatment of suicide.

The specific goals of this DSMB are:

1. To review procedures for maintaining the confidentiality of data, and quality of data collection, management, and analysis.
2. Provide consultation and procedural recommendations for working with suicidal patients when necessary.
3. Review progress toward meeting enrollment goals.
4. When appropriate, serve as final arbiters of whether a participant should be removed from the protocol.
5. To recommend continuation, discontinuation, modification, or termination of a study based on emerging data (in the study and/or literature) and evaluation of risk/benefit ratio.

Given the nature of this project, we expect the likelihood of items 3 and 4 to be extremely low. However, the formation of the DSMB ensures that we are taking steps to protect the welfare of the study participants. The DSMB will periodically review any modifications to the research design and conduct of the study, and make recommendations according to the NIH policies for data and safety monitoring. An initial meeting of the DSMB and Research Team will be scheduled prior to the start of the research, thereafter members of the DSMB will meet approximately quarterly. If the need arises, the board will schedule additional meetings. At the initial DSMB meeting, the board's criteria for an immediately reportable severe adverse event (SAE) will be established and subsequent reporting will follow this guideline. The study will use the procedures of the NIMH Data Safety Monitoring Board to determine triggers for stopping the study and the DSMB will discuss if additional specific stopping rules should be developed prior to commencing the trial. As per NIMH DSMB procedure, the raw numbers of suicidal events and level of suicidal ideation will be provided in the DSMB reports to allow the DSMB to determine if stopping the study needs to be considered. We will also send recruitment progress updates, participation rates, a detailed summary of all potentially adverse events, as well as a summary of those situations that may not meet the threshold of a potentially adverse event but that nonetheless may be important for the DSMB to consider in advance of their scheduled meetings. In the event that a SAE occurs (e.g., suicide, homicide, physical attack on staff, indication of clinical worsening), the PI will notify the IRB and DSMB within 24 hours of learning of the event. All suicide attempts and emergency department are also reported in the annual IRB and DSMB reports. In trials of acutely suicidal participants, suicide attempts and emergency department are classified as expected events and immediate reporting is required only when clinical worsening is indicated (e.g., a suicide attempt in a patient who has not done so before).

Following each meeting of the DSMB, the DSMB Chair will prepare and send a brief summary report to the PI. The report will document that: (1) a review of recruitment, data, and outcomes has occurred; (2) the number, nature, and outcome of any adverse events occurring during the review period; and (3) reflect the date the review took place. The report will also inform the PIs of the board's conclusion with respect to study progress, any need for modification of the study

protocol or operating procedures, and determination for the study to continue. Upon receipt of the report, the PIs will be responsible for transmitting a copy of the report to the IRB.

Dr. Dimeff will be responsible for managing, storing, and protecting data at the primary study research site. She will work closely with the research staff to maintain continuous, close monitoring and promptly report adverse events to the site PIs, the DSMB, and the IRB. The study coordinators (i.e., EBPI RAs, site PIs, site RAs) will notify Dr. Dimeff of any adverse events within 24 hours of occurring and notification will be forwarded to the DSMB and IRB immediately.

D. Storage of Data

Study data, including qualitative notes from follow up interviews and survey-based data, are stored in a password protected area within a cloud-based encrypted server (Box)[4] that is accessible only to the research team. The data files are coded with the participant's study identification number and time point. The files do not contain identifying information such as the participants' names, but will again contain the participant's study identification number. 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 SurveyMonkey, where responses are transmitted using a Secure Sockets Layer (SSL) connection and is also encrypted.[5] Like the qualitative notes from the follow up assessments, the Survey Monkey data sources use only the study identification number to identify the participant.

In most cases, participants will complete the surveys directly in SurveyMonkey and/or the data are entered directly by the RA into Survey Monkey. In the rare event that a participant prefers to complete a paper-pencil measure, the data will be immediately entered into SurveyMonkey by a study RA 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 electronic research files is limited to research staff, who are required to log in to Box with a unique user name 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 password protected and stored separate from study data on a cloud-based encrypted server (Dropbox)6 accessible only to the research team trained in the ethical conduct of human subjects' research. No other data is included in the MPD. Out of an abundance of caution and to ensure HIPAA protections, all electronic files that include patient names or other identifying information (even though not associated with the patient's study ID), will be stored on Dropbox. EBPI has a BAA in place with Dropbox and only assigned researchers (e.g., PI, Research Assistants) will have access to EBPI's Dropbox account.

When applicable (e.g., follow up assessments) study staff will send email and/or text 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 or via paper/pencil). 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 will be protected and stored as described above in Storage of Data. In addition, we will destroy all files that have any names or other identifying information five years after the study is finished, including the file that links participant names to study IDs.

Information provided to Boys Town counselors, when applicable, will be sent via secure email transfer using Microsoft

365 Message Encryption that is built on the Azure Information Protection platform. Emails will be sent directly to a dedicated Boys Town email address. All identifying information will be destroyed after the call and reports provided by Boys Town counselors to the study PI will be scrubbed of identifying information. Boys Town will use the patients study ID instead of their name or other identifying information, such as initials.

6. Risk/Benefit Assessment

A. Risks

The risk to participants in this research is minimal when applying NIMH risk standards and designations.[7] According to these NIMH 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 includes patients and health care provider participants. Not all potential study risks listed here will be relevant for all participants.

This study seeks to include patients currently acutely suicidal and/or recently hospitalized because of suicidality. By definition, these patients are inherently high-risk participants; however, the question to consider for this research is whether the study procedures, including the clinical intervention, is likely to make the participants more suicidal. We believe the answer is no. Some patient participants may feel distressed while completing study procedures and survey measures because of the content, which includes questions about suicidality, use of acute crisis tolerance skills, and coping with acute distress. Some patient participants may find these questions distressing as they could remind them of the reason for their hospitalization. On the other hand, the assessments could potentially be helpful to the patient participants as they reflect over their recent experiences and view the bigger picture of their treatment. Even with this sensitive population, we believe the risk to be low, particularly because the Site Contact or a designee or outpatient provider will determine who is sufficiently stable to engage in the research and will rule out those who are considered to be at considerable psychotic and/or so agitated that engagement in the study could cause harm. Nevertheless, this concern will be first and foremost in our minds as we implement the study procedures, and in our discussions with our suicide expert advisors and DSMB members.

Physical, social, economic, or legal risks from participating for patients and providers 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.

Other potential study risks include:

- discomfort sharing personal experiences and opinions
- discomfort providing negative feedback on the tool or responding to questionnaires
- feeling pressure to participate because they are being referred to the study by their treatment provider (in the case of patients) or their supervisor (in the case of professional participants)
- impact on treatment
- data charges
- There is also the potential risk of loss of confidentiality

There are no known alternative procedures to assess this information. The primary alternative to participating in the

research is to elect not to participate in the research, which participants may do at any time without change to any current or future medical care, benefits, or employment.

B. Prevention of Risks

The primary focus of this summative evaluation will be to gather qualitative and quantitative data regarding the patient participant's suicidality, use of coping skills and acute crisis tolerance skills, ED or outpatient experience, and feedback about the app (in the case of patients in the Jaspr [ED study] or JAH [Telehealth study] conditions). To address potential discomfort in sharing personal experiences, opinions, and criticism about the app and/or negative experiences during the follow up interviews and surveys, the interviewer will assure the participant that any and all feedback is helpful and that they may choose how much or little they wish to share. For the ED study, the baseline assessment with patient participants will occur in the ED in where medical and clinical staff are available to provide assistance in the unlikely event that the patient becomes upset during the study procedures. During in-person testing, the study assessment will take place in a quiet, private room provided by the hospital or in the patient's private ED room. All follow up assessments (and baseline assessment for the Telehealth study) will be conducted remotely via phone and internet, and the participant will be advised to schedule the call at a time when they can be in a private, quiet area.

Other potential risks for patient participants assigned to the Jaspr condition include the provider's overreliance on Jaspr, superseding their own independent analysis and/or an incomplete or faulty imminent distress brief intervention, which could ultimately cause harm. Providers will be encouraged to use their own clinical judgment when deciding how/when to incorporate Jaspr and the reports it provides. Regarding the patient's use of Jaspr-at-Home, the app is meant to be used only after discharge and research staff and/or Boys Town crisis counselors are available to support patients in any way they need.

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 supervisors (in the case of providers), or their providers (in the case of patients), it will be made clear to all potential participants that the study is completely voluntary and will not affect their standing with their agency, provider, or treatment (i.e., that they will receive treatment regardless of their participation) in any way. Organizations and providers will be informed that there should be no coercion of potential participants to take part in the research. In addition, we will provide partnering organizations with detailed instructions and scripts on how to provide information about this study to potential participants.

Should adverse events occur during the study, we will thoroughly assess factors that contributed to the adverse event, including use of Jaspr or JAH, and will seek resolution of those problems related to the study. We will notify the IRB and our DSMB of adverse events, seek their recommendations, modify the protocol, and seek IRB approval for the modification.

Dr. Dimeff will collaborate closely with the IRB and DSMB throughout the study to ensure proper management of high-risk situations. Dr. Jobes will be consulted for concurrence with the plan on imminent-risk situations as well. If the participant becomes distressed during the baseline session, the study staff initiates a warm hand off to a provider on the spot so that the patient may receive assistance in mood improvement or safety planning from their clinical team or other trained professional. During follow up assessments, if the participant sounds distressed or indicates suicidality or self-harm intentions, the researcher conducting the follow up interview will initiate a warm hand off at the end of the interview to a Boys Town counselor to conduct risk assessment and provide resources as necessary. Boys Town will provide study staff with call documentation by the next business day and the study PI will determine actions to take; if

the DSMB and/or IRB need to be informed.

Steps will be taken to ensure that participation is voluntary and that participants' privacy and the data collected from the participants are protected.

Protection from Feeling Discomfort
The primary focus of the summative studies is to evaluate Jaspr and JAH, respectively. To address potential discomfort in sharing criticism during the study session, the interviewer will assure the participant that any and all feedback is helpful and the main reason for conducting the study.

Protection from Coercion
Participants will be told that their participation is completely voluntary, and that they may change their minds and withdraw at any time. Participants will be told that their choice to participate or not will in no way affect their relationship with their treatment providers, the usual care they are eligible to receive, and/or their colleagues.

Protection from Potential Delayed Treatment
The participants' medical care is the most important thing. Study procedures will be paused if a member of the care team needs to talk with or proceed with other medical care with the patient participant, and resume when the patient is available again.

Protection from Potential Data Charge
This is applicable only to participants in the Jaspr and JAH conditions. Participants will be told that they may choose to use the app at any time and they may choose to use it only when on Wi-Fi connection. They may also log out of the app and only log back in when they are comfortable doing so. We will also recommend checking with their smartphone data provider to ensure they know how much data they may use each billing period without incurring extra charges.

Protection from Loss of Confidentiality
Data will be protected and stored as described above in Protection of Study Data. In addition, we will destroy all files that have any names or other identifying information five years after the study is finished, including the file that links participant names to study IDs.

C. Adverse Events

For this study, we define an adverse event as any untoward or unfavorable occurrence, including significant increases in distress during the study interview, or symptom associated with the participant's participation in the research, *whether or not considered related to their participation in the research*.[8] Serious adverse events include suicide attempt, non-suicidal self-injury, significant increase in suicidal ideation, and/or significant increase in agitation while participating in the study, as reported by the participant, or observed and/or reported by their healthcare provider, and/or a member of the research team. Given the minimal risk nature of this study, likely causes of such adverse events may include one or more of the following factors: frustration with the extensive length of stay in the ED (frequently considerably longer than the usual length of stay for patients with a medical crisis); nicotine withdraw caused from long lengths of stay in patients addicted to nicotine; and dissatisfaction with the care they are receiving while in the ED or with the discharge disposition provided by their physician.

Should adverse events occur during the study, we will thoroughly assess factors that contributed to the adverse event, including use of Jaspr or JAH, and will seek resolution of those problems related to the study. Regardless of the cause of the adverse event, we will notify the IRB and our DSMB of adverse events within 10 business days, should they occur, and seek their recommendations. Fatal or life-threatening events, should they occur, will be reported to the IRB

immediately.

All participants will be provided with information about how to report Potential Adverse Events. In addition, patient participants will be encouraged to report any Potential Adverse Events directly to the provider who is in charge of their care. Potential Adverse Event reports will be monitored daily by study staff. 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 PI will be notified immediately. The PI 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 promptly report adverse events. The study coordinators will notify Dr. Dimeff of any adverse events within 24 hours of occurring and notification will be forwarded to the DSMB and IRB within ten business days; fatal or life-threatening events will be reported to Dr. Dimeff immediately and she will notify the IRB and DSMB right away.

D. Benefits

There are no direct benefits from participating in this study; however, there are several indirect benefits for participation. Some participants may feel personal reward by engaging in testing to help further develop and polish the Jaspr tool designed to support medical personnel and suicidal patients in ED settings. Findings from this study will be used to develop a product that is intended to increase quality of care for patients who recently made a suicide attempt or are struggling with suicidal ideation. Participants directly interacting with Jaspr may benefit from perceived improved care as a result of their direct interaction and their provider's interaction with the tools. Provider participants may benefit from using Jaspr while providing risk assessments and management while also learning CAMS. Providers may also experience less distress when assessing, treating, and deciding disposition for their suicidal patients. We believe the potential benefits to science and standard of care for suicidal patients outweigh the risks associated with participation in this research.

The proposed research contributes to the goal of improving quality of care for suicidal patients, particularly in EDs where there is often a lack of sufficient time and mental health resources. Developing a successful and efficient relational agent based on the CAMS approach means that suicidal patients will receive evidence-based assessment and treatment delivered in a more timely, effective, and efficient manner than is typical in EDs and other settings.

7. Participant Recruitment and Informed Consent

A. Recruiting

Suicidal patients and their providers will be recruited from hospitals/organizations nationwide. Interested providers from each site will be recruited and enrolled on a first-come, first-served basis. Patient participants will similarly be recruited on a first-come, first-served basis.

ED Study: Each designated project site that has agreed to participate will designate a person within the ED to serve as our "site contact" when conducting research with patient participants. We will specifically coordinate who the onsite contact would like to initially approach as potential participants and proceed as they prefer at each site. Because our access is linked to the onsite contact's authority and oversight of the ED, our intention is to ensure we proceed in a way that is consistent with their preferred approach. In the case where the site contact or their designee prefers to inform sufficiently stable (according to usual hospital procedures and using their own clinical judgment) suicidal patients about

the study and ask if they are interested in talking to the researchers about the project. The purpose will only be to briefly mention that they may qualify for a research study taking place at their site for patients who are in the ED because of suicidal behaviors and to ask the patient if they would be interested in speaking with a member of the research team to find out more. While not required, site contacts or their designee may choose to also mention that: a) the study is completely voluntary; they do not need to participate; b) their decision – whatever it is – will in no way affect relationship with their treatment team and that they will receive care regardless; and c) study involvement that day may include using an app as part of their care or receiving the care the provider/hospital normally provides, completing a brief interview, and completing survey measures online today and at three time points over the next 90 days. While all these components will be repeated as part of the Informed Consent process by the researchers, we anticipate that some onsite contacts may prefer to briefly mention the study to their patients personally before a stranger enters the room or have a member of the care team do so on their behalf.

Telehealth Study: Outpatient individuals experiencing suicidality will learn of the study from their outpatient provider. Interested individuals will contact the researchers via email or phone to determine eligibility and subsequently the informed consent process if eligible.

While all informed consent procedures will be fully and thoroughly conducted by the researchers (e.g., orienting prospective participants to the study details, highlighting that they are under no obligation to participate in the study, and that a decision to decline participation will not affect the fact that they will receive treatment; the research will be paused whenever necessary so as not to interfere with the patient's medical treatment), the onsite contact may *informally* mention that the study is optional and that it will not impact their care in any way. Onsite contacts will be knowledgeable about the study's inclusion/exclusion criteria only to the degree that they can help identify which patients to speak with about the study. They will not be expected to formally screen the patient for study eligibility; this will instead be performed by a researcher prior to commencing with the informed consent procedures.

In the event that the site contact prefers to have the researchers initially approach a prospective patient, the onsite contact will then inform the researchers how to determine which patients we are permitted to approach based on study inclusion/exclusion criteria and/or other ED or outpatient policies and procedures. For example, it may involve looking at the status on a patient whiteboard and/or asking the charge nurse if the suicidal patient is sufficiently stable to talk about the study.

ED Study only: Once a prospective patient participant is identified, before proceeding further, if the patient isn't already in a private room, the researchers will proceed with the patient to a private area designated by the site contact. The researchers will enter the private room with the patient, introduce him/herself, and request permission to describe briefly the study using the following script or a close proximity that allows for natural conversation with the patient: *"Hello. My name is <name>. I am a researcher here at <site name>. I know you're going through a lot right now but I'm wondering if it would be okay to talk to you about a research study we have going on right now and see if you might want to take part in it? If not, that's absolutely fine."* (Intention is to get verbal permission to proceed). If patient indicates a preference to not speak with the researchers, then the researchers will simply say: "*That is of course totally fine. Should you change your mind while you're here, just let the staff know and I'll come back."* If the patient indicates interest in learning more about the study, then the researchers will thank the patient and proceed to eligibility screening and (if eligible) the Informed Consent process. In consultation with the site PI, treatment providers of patient participants will be recruited from each participating ED. When possible the study PI (Dr. Dimeff) or her designee will conduct an informational meeting about the study (conducted informally or during grand rounds or brown bag lunch sessions while onsite) for the purposes of orienting potential provider participants to the study and participation. Given the minimal risk nature of their engagement in this research and for efficiency, informed consent will be reviewed in this group format and questions will be addressed. Providers may opt to provide their consent at that time, or opt to complete the consent online at a later date (i.e., not during a group context). Providers may choose to contact the

research team at a later time to ask questions individually, learn more about the study, and/or provide consent at that later time. In all cases, researchers will connect via phone/email or in-person with the prospective provider participants and provide a high-level overview of the study.

Although potential participants may be informed of the study by their provider (in the case of patients) or their supervisor (in the case of providers), it will be made clear to all participants that the study is completely voluntary and will not affect their employment or treatment services. Partnering agencies and providers will be informed that there should be no coercion of potential participants to take part in the study.

B. Informed Consent

Patients and providers who are interested in participating will complete a screen for eligibility. As part of the screening process, the potential participants will also answer demographic questions to assess whether our recruitment efforts are reaching a diverse group and to assess the characteristics of participants in the research. Eligible participants will then proceed to the Informed Consent procedure with a researcher, though participants may choose to review the consent form on their own if they prefer. All participants will be provided with an overview of the study and disclosure regarding what will be asked of them using Informed Consent procedures. The Informed Consent form will describe the study procedures and clarify that the study is completely voluntary and that participants may decline to participate at any time. For the ED study, the information provided to patients about Jaspr will be limited until after randomization to guard against disappointment or other negative feeling if assigned to the CAU condition. Once randomized, patients assigned to the Jaspr condition will be provided with the supplemental consent form with complete disclosure of the study procedures and information about Jaspr. These patient participants will have the chance to ask questions about Jaspr and the Jaspr study condition and decide if they want to continue their participation in the study. 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. The Informed Consent process will take place in person with a member of the research team. The Informed Consent process will take place remotely via telephone and/or internet with a member of the research team.

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, 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. The researchers may use a high-level overview PowerPoint on their laptop computer to verbally and/or visually walk patients through the informed consent form and HIPAA Authorization (patients only). Study staff will be available to answer any questions or concerns the participants may have prior to signing and returning the consent form. For the ED study, patient participants assigned to the Jaspr condition will be walked through a supplement consent form with more information about the app, their signature will be collected for final consent, and they will receive an electronic or hard copy of the supplement consent form for their records.

C. Obtaining and Documenting Consent

Participants will provide consent by signing the paper Informed Consent form or electronically by typing their name in an online version of the Informed Consent form. We will provide a copy of the Informed Consent form, and supplement consent form if applicable, for the participant to keep for their records. All signed consent forms will be stored in our secure server on Dropbox. The researchers will scan signed hard copies of consent forms and save electronic copies as PDFs on Dropbox; the paper copies will be destroyed after they are filed on Dropbox.

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 process, the researchers will ask if the participant has any questions.

As in the formative evaluation, members of the research team who conduct the Informed Consent process with suicidal ED patient participants, will present a brief PowerPoint presentation or video that outlines the main points of the Informed Consent in smaller "chunks" of information in the ED RCT. We have worked with our consultants, DSMB, and IRB to ensure the language and length of the consent form is appropriate for this population. The patient will have the opportunity to ask questions throughout the process.

E. Costs to Participants

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

F. Compensation to Participants

For the ED study, patient participants will be paid up to $225 for their participation. They will receive $25 for completing their baseline assessment and $50 for each follow up study assessment they complete. Patients who complete all three follow up assessments will earn an additional $50. There is no payment for provider participants. For the Telehealth study, patient participants will be paid $25 for each completed assessment for a total of up to $75 for their participation and access to JAH for up to 30 days upon their completion of the study. Payment will be distributed by check in the mail within 30 days of their participation. If a participant decides to withdraw or end participation prior to completing their trial, they will be compensated the total amount for the assessments they have completed.

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