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

Emergency Department Treatment Study & Telehealth Virtual Care Study

Sterling IRB Protocol Number: 7446

National Clinical Trial (NCT) Identified Number: NCT03584386

Principal Investigators: Linda Dimeff, PhD & David Jobes, PhD

Sponsor: Evidence-Based Practice Institute, Inc.

Grant Title: CAMS Relational Agent System (CAMS-RAS) for Suicide Prevention

Grant Number: R44MH108222

Funded by: National Institute of Mental Health

ED Treatment Study | Version 3 | 26 July 2020

ED Treatment Study Supplement | Version 2 | 30 December 2019

Telehealth Virtual Care Study | Version 2 | 20 October 2020

PARTICIPANT INFORMED CONSENT FORM

STUDY TITLE: Emergency Department Treatment Study

PROTOCOL NO: R44MH108222S

STUDY DOCTOR: «First_Name» «Middle_Name» «Last_Name», «Suffix»

STUDY SITE: «Company_Name»
«Address»
«City_State_ZIP»

TELEPHONE: «Telephone»
«Telephone_2_if_applicable»

SPONSOR: Jaspr Health

24-HOUR EMERGENCY TELEPHONE NUMBER: Crisis Hotline
(800) 448-3000

- Being in a study is voluntary – **your choice**.
- If you join this study, you can still **stop at any time**.
- **No one** can **promise** that a study will help you.
- Do not join this study unless all of your **questions** are **answered**.

After reading and discussing the information in this consent form, you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

This consent form contains important information to help you decide whether to participate in a research study. Please read this consent form carefully.

A. PURPOSE AND BACKGROUND

- You are being asked to volunteer for a research study
- The goal of the study is to evaluate a mobile app that may be helpful to people who are suicidal
- The research is funded by the National Institute of Mental Health (NIMH)
- The Principal Investigators of this study is Dr. Linda Dimeff and Dr. David Jobes. Both are clinical psychologists who want to help people who are suicidal.

- This study will include approximately 135 men and women, age 18 years and older currently in the emergency department with suicide behaviors and their treatment providers

B. PROCEDURES

If you agree to be in this study, this is what will happen:

- You will be asked to complete a set of surveys including questions about your age, gender, emotions, and thoughts or feelings you may have about suicide.
  - This will take approximately 30 minutes, but with interruptions from your care team, may take longer.
  - In the event that you are called away during this initial research session to talk with a member of your care team or to receive medical care, the interview will be paused and resume, if you wish and are able, at a later time when you are again available.
- You will be randomly assigned (like flipping a coin) to one of two study conditions: the app, known as the "study condition" or the usual care provided by your care team along with completing several study surveys.
  - If you are randomly assigned to the study condition, you will be provided with more details about the app itself so you can decide whether you want to participate and use it.
  - You will receive treatment in the emergency department regardless of which study condition you are randomly assigned to.
  - Your treatment and your participation in this study are separate activities. You will receive treatment from your medical provider in this emergency department regardless of whether or not you decide to participate in this research study.
- You will be asked to complete another set of surveys and a brief interview with one of our researchers after about two hours. You will be asked about your emotions, thoughts or feelings you may have about suicide, and your impressions of the treatment you received today. Answering these questions may again take about 30 – 45 minutes to complete, but may take longer depending on the number of times the process is interrupted for you to receive care from your medical team and whether you wish to take any breaks.
- Three follow up study appointments will be scheduled to take place after today. The first will take place after 7 days, then 30-days, and finally 90-days from today. These follow up appointments will be over the phone and using a computer or other device (like a cell phone or tablet) that has Internet.
  - Each study appointment will include a set of surveys (about 30 minutes) you complete online and a brief phone interview (about 5 minutes) with a member of the research team.
  - For each follow up appointment, you will receive a phone call from a researcher and then be emailed a link to complete the surveys online during the call.
  - Each of the follow up assessments will take about 40 – 45 minutes.

During each study appointment, we want to make sure you are in good shape as you answer the questions and before the appointment ends. For this study, mental health professionals who are specially trained to assess and help in these types of situations are available. For each of the follow up appointments, a dedicated phone line has been set up to connect you with a mental health counselor if needed. You will be connected you with one of these counselors during the study appointment if:

- You tell us you are feeling highly distressed or currently suicidal;
- You made a recent suicide attempt without seeking health care;
- You report feeling at risk of hurting yourself or others or if the researcher believes you are at risk of hurting yourself or others; or
- You seem to need additional resources, even if you are not currently at risk of hurting yourself or others at this time.

If the researcher believes it is important to connect you to one of the counselors, you will be told directly that we wish to connect you with a counselor. The researcher will then call the counselor in to our call and tell them that you are a participant in this research project. The researcher will also provide them with the following information so that they can best help you:

- Your name, address, phone number, and email address
- Your study identification number
- Your emergency contact information
- The reason we are connecting you with the counselor

If you get disconnected, the counselor will try several times to get back in contact with you. They will use a different phone number than the one our researcher used to call you for the research session. It is important you answer their call if you get disconnected. If they are unable to reach you for any reason, they may try several other methods to reach you including contacting your emergency contact or sending out emergency services to check on you if they have reason to believe you are at immediate risk for dying by suicide.

The counselors are available to you at any time if you need it. If you are feeling unsafe or suicidal, you should contact your primary care provider, go to the nearest emergency room, or call 911.

C. STUDY LENGTH

Your study participation will last 3 months. You can tell the study staff at any time if you would like to stop sooner.

D. RISKS/DISCOMFORTS

The possible risks to you from being in this study include:

- Feeling discomfort providing negative feedback about your treatment and/or your personal experiences.
- Feeling pressured to participate because you are being referred to the study by your treatment provider or another member of your care team.
- Your treatment may be delayed or take longer than is typical if you participate in this study.
- Feeling embarrassment or discomfort responding to the survey questions or while talking with a researcher for a follow up appointment from a public location or when around people you know who may not know that you are in a research study.
- The other kind of risk has to do with privacy and security of your answers to study questions

To reduce the chance of you feeling uncomfortable sharing your personal experiences and opinions:

- We will check in with you throughout the study to see how you are feeling. If, at any time, you are too upset or uncomfortable, we will ask if you would like to take a break or stop the study.
- We will encourage you to tell us both negative and positive thoughts about your participation and other research activities so you can feel comfortable telling us even if you don't like something. Both positive and negative feedback is equally important to us.
- During the study, you decide how much or little to share.
- Your name will not be associated to the responses you provide, so no one will know who provided what feedback except for members of the research team

To reduce the risk of feeling pressured to participate:

- We will ask you in private if you would like to participate in the study or not.
- We will not inform anyone outside of the research team and your care team if you choose to be in the study or not.
- If you choose not to be in the study, your relationship with your doctors and care team will not change in any way.
- If you decide you do want to be in the study, you may change your mind at any time, and this will also not change your relationship with your doctors and care team in any way.

To reduce the risk of your treatment being impacted by this study:

- Your medical care is more important than these study procedures. We will pause study procedures if a member of your care team wants to talk with you or if it is time for you to receive other medical care. Study procedures will resume when you are available again.
- You may stop or pause your participation at any time.

To reduce the risk of feeling embarrassment because of this study:

- You are encouraged to observe your own limits in how you use the app (if applicable) and when answering the survey questions.
- We will never require you to do anything for the study when you do not want to.
- As an added protection, all app-generated information and study survey answers will be stored on a server without your name. No data will be stored on your phone or computer.

To protect your privacy:

- We will not share your information with anyone outside the research team or your doctors and care team except as required by law.

  These happen only if:
  - There is a court order or subpoena of the study records
  - If you tell us that you have thoughts of harming yourself or others. In this case, we are required by state laws to share that information with a doctor or treatment provider to help keep you and others safe.
  - You have a plan or have made a suicide attempt that you have not shared with a treatment provider. In this case, we are required by state laws to share that information with a doctor or treatment provider to help keep you safe.

To protect the information that you share with us:

- Your answers will be saved in a secure, password-protected file on an encrypted server that only the research staff can access.
- Your answers will not have your name in the same file; your answers will be associated only with a research study ID number.
- The list linking your name to your research study ID number will be kept in a separate, secured location, also password protected that only the study staff can access.
- To protect your privacy even more, we will destroy all files that have any names or other identifying information 5 years after the study is finished, including the file that links your name to your research study ID.

If you think you experienced an Adverse Event:

For this study, an adverse event is defined as any unfavorable occurrence (such as significant increase in your distress during the study interview resulting from your involvement in the research) associated with your participation in the research, whether or not you consider it to be related to your participation.

If you think you have experienced an Adverse Event from this study, please report it as soon as possible in one of the following ways:

- Complete the Secure Online Form: https://www.surveymonkey.com/r/JBSHNZV
- Contact the Study PI by Phone: Dr. Linda Dimeff at 206-455-7934
- Contact the Study IRB by Phone: Sterling IRB at 888-636-1062

E. HOW BEING IN THE STUDY CAN BENEFIT YOU

There are no direct benefits to your from participating in this study.

Potential indirect benefits from being in this study are:

- You may feel good knowing that you are helping others like you who are feeling suicidal. Your involvement in this research will help for us to detect how to help people who are feeling suicidal when they are in crisis and at the ED.

F. COSTS

There are no costs to you for participating in this study.

G. PAYMENT TO PARTICIPANTS

You may receive up to a total of $225.00 for participating in this study. You will receive $25.00 after completing your first day's study session and $50.00 after completing each of the three follow up study appointments. You will receive an additional $50.00 if you complete all three follow up appointments within 72 hours of each scheduled appointment.

Each payment for your study appointments and the bonus payment for completing all your follow up appointments (if applicable) will be sent by check within 30 days after you complete the follow up survey. Checks will be sent directly from Chase Bank and will arrive in a Chase Bank envelope.

H. ALTERNATIVES

The alternative to being in this study is not being in the study.

I. OTHER STUDY INFORMATION

The information you give us will be used to develop, improve, and test an app we recently developed. This information may be published, but we will not use any names and no one reading it will ever know you were in the study. Information that can lead someone to know you were in the study will be kept confidential to the extent possible within State and Federal law (as described above).

Only the investigators running this study, the National Institute of Mental Health (NIMH), Sterling Institutional Review Board, and Boys Town hotline (if applicable) will have access to identifying study information. All records in Oregon, Washington, and Michigan are subject to subpoena by a court of law.

It is completely your choice if you want to be in this study or not. You can choose not to do the study if you prefer. Even if you decide you do want to do it, you can choose to stop it at any time. If you decide to do that, you should tell the researcher. If you decide not to do this study, that will not change any of your current or future medical care or benefits.

The researchers and/or NIMH may decide you should stop being in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the researcher's instructions.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Participant Statement

- I have had a chance to ask questions about this study.
- I am satisfied with the answers I was given.
- If I have any more questions about being in this study, would like to withdraw from the study, or become distressed from being in the study, I may contact Dr. Linda Dimeff (Principal Investigator) at 206-455-7934.
- If I have any questions, problems, or worries, or want more information or want to give my feedback about the study, I may contact Sterling Institutional Review Board at 888-636-1062. This includes any questions about my rights as a research participant in this study.
- I agree to participate in this study.

I will receive a signed copy of this form, which has 11 pages.

I have not waived any of my legal rights by signing this document.

If you wish to participate, you should sign here:

Signature of Participant Date	Printed Name of Participant
Signature of Person Obtaining Consent Date	Printed Name of Person Obtaining Consent

Please provide your contact information:

First Name _____

Last Name _____

Email address _____

Secondary email address: _____

Physical Address _____

_____

Mailing Address (if different from above) _____

_____

Primary phone number _____

Okay for research team to leave a message at this number? _____ Yes _____No

Alternative phone number _____
Okay for research team to leave a message at this number? _____ Yes _____No

Who else may we contact if we cannot locate you for your study appointments?

First Name _____

Last Name _____

Relationship to you _____

Email address _____

Physical Address (optional) _____

_____

Primary phone number _____

Alternative phone number _____

Please provide emergency contact information:

Permission to contact Emergency Contact if we have difficulty to locating you for the follow-up calls? ____Yes ____ No

First Name _____

Last Name _____

Relationship to you _____

Email address _____

Physical Address (optional) _____

_____

Primary phone number _____

Alternative phone number _____

LOCATING CONSENT

As part of your participation in this study, we will be contacting you on three occasions for your follow-up study appointments over the next 90 days. It is not uncommon for participants in research studies to move or change phone numbers between assessment periods. In the event that we are unable to reach you, we would like your permission to follow the locating procedures listed below for the duration of your time in the study.

Remember, at the 90-day assessment, you will be paid an additional $50.00 if you complete all 3 follow-up interviews on time. These procedures will help us keep in contact with you so that you remain eligible for this bonus payment.

PARTICIPANT STATEMENT | LOCATING PROCEDURES

The follow-up locating procedures described below have been explained to me, and I voluntarily consent to permit the indicated activities. I have had the opportunity to ask questions and understand each locating procedure.

Please indicate which of the following activities you give permission for the researchers to use if we need to locate you for study appointments.

Permission to search for me on social networking sites that I specifically list on the *Participant Information Form* (such as Facebook, LinkedIn). I agree the research team can send a message to the site(s) I name.

O I give permission for this locating procedure

O I **do not** give permission for this locating procedure

Authorization of governmental agencies (for example, post office, Social Security, DSHS) to release my current address and phone number to the study. This is the only information the agencies would be authorized to give the study, and the information would be used by the study only in order to contact me.

O I give permission for this locating procedure

O I **do not** give permission for this locating procedure

Permission to search for me if the study is unable to locate me for follow-up by calling friends, relatives, and other contacts I give the study on the Participant Information Form to see if they know where I am. If contacted by the study, these people are under no obligation to give out information.

O I give permission for this locating procedure

O I **do not** give permission for this locating procedure

Permission for treatment providers/emergency services I have named to release contact information to the study. Specifically, addresses and phone numbers I have given them as well as other ways they have used for contacting me.

O I give permission for this locating procedure

O I **do not** give permission for this locating procedure

Please also list below any person or organization **you would not** like for the research study to contact. You may add to or change this list at any time by contacting the research office.

The study will **not** contact anyone I name here:

_____
_____
_____

Printed name of Participant	Signature	Date

Printed Name of Researcher	Signature	Date

Data Repository

As part of this research, we will add your study data to a de-identified research database, called a data repository. *The data repository will not include your name, address, or any other information that could identify you.* To transfer data into the data repository, we will remove information that would make it possible to identify you and transfer the anonymous data into a research database, the data repository. The database will be used for scientific research about topics such as suicide, options for medical and mental health treatment for mental health problems, and use of technology in mental health treatment. The de-identified data may be shared with other researchers also studying these and similar research topics.

You do not have to give permission for your data to be used in this way unless you want to. Declining to give permission will not affect your participation in this research in any way. Because no identifying information will be added to the data repository, data cannot be withdrawn from the data repository once they are placed there because we will have no way of knowing which data are yours. Your information will not be added to the data repository unless you provide permission below.

Please initial one of the following options:

____ **(initial)** I give permission for my study data that does not identify me to be entered into the Data Repository.

____ **(initial)** I do NOT give permission for my study data that does not identify me to be entered into the Data Repository.

Signature of Participant	Date	Printed Name of Participant
Signature of Researcher	Date	Printed Name of Researcher

SUPPLEMENT TO PARTICIPANT INFORMED CONSENT FORM
Patient Participants Randomly Assigned To Jaspr Study Condition

STUDY TITLE: Emergency Department Treatment Study

PROTOCOL NO: R44MH108222S

STUDY DOCTOR: «First_Name» «Middle_Name» «Last_Name», «Suffix»

STUDY SITE: «Company_Name»
«Address»
«City_State_ZIP»

TELEPHONE: «Telephone»
«Telephone_2_if_applicable»

SPONSOR: Jaspr Health

You are currently taking part in the above-named research study and have been assigned to the Jaspr study condition. The purpose of this document is to provide further information about study participation, possible risks, and indirect benefits specifically for participants in the Jaspr study condition who will be using the mobile app during the study. This information is supplemental to Informed Consent Form and does not replace or change any information contained in the Informed Consent Form.

A. ADDITIONAL STUDY PARTICIPATION INFORMATION

The goal of the study is to evaluate a mobile application, called Jaspr, that can be used on a tablet and/or smartphone and may be helpful to people who are suicidal. There are a number of helpful interventions for people who are suicidal, that may be helpful to them while they are in the emergency department. The challenge is making these interventions regularly available to people when they need them. Jaspr was created to help. Jaspr includes different tools for your use. For example, a Virtual Guide will walk you through a comprehensive suicide risk assessment that may be helpful to you and your care team. You will hear stories, insights, and the wisdom from people with lived experience who have walked in your shoes. You have an opportunity to learn behavioral skills that many people have found helpful when coping with distress. The Virtual Guide will help you build a safety plan and think about how to make your environment more safe.

You have been randomly assigned to the Jaspr study condition, which means your treatment today will include the use of Jaspr in addition to the usual care your care team would usually provide. To summarize, you can expect the following as part of your study participation:

- We will provide you with a brief introduction to Jaspr and then ask you to use it for up to two hours (not including any breaks you may take) in whatever way you want.
    - In the event that you wish to take a break or are called away during your use of Jaspr to talk with a member of your care team or to receive medical care, we will simply pause

the study and your counted time with Jaspr then resume, if you wish and are able, at a later time when you are again available.

- We will then ask you to complete another set of surveys and a brief interview with a researcher after the two hours (not including any breaks you may take) or when you are done using Jaspr, whichever comes first. You will be asked about your emotions, thoughts or feelings you may have about suicide, and your impressions of the treatment you received today, specifically using Jaspr.
- You will have the option to receive access to the Jaspr-at-Home, a companion web app you can access on your smartphone or other device after your discharge and throughout your follow up period as you see fit.
    - After you complete the study procedures today, we will provide you with information about how to access Jaspr-at-Home once you are discharged. Our researchers are also available now or when you are ready to help you with this process and answer any questions you may have.
- We will schedule your three follow up study appointments that will take place at 7-days, 30-days, and 90-days from today

B. RISKS/DISCOMFORTS

The possible risks to you from being in this study as related to the Jaspr condition

- Feeling discomfort providing negative feedback about Jaspr
- Feeling embarrassed or discomfort using the app in a public place
- Possibility of incurring data charges while using Jaspr/Jaspr-at-Home
- Provider overreliance on Jaspr

To reduce the change of you feeling uncomfortable providing negative feedback about the app:
We will encourage you to tell us both what you like and what you don't like about the app, so you can feel comfortable telling us even if you don't like something. Both positive and negative feedback are equally important to us so we can improve upon things you don't like and do more of the kind of things you do like in the app.

To reduce the risk of feeling embarrassed because of the app:

- You are encouraged to observe your own limits in how you use the app
- You can use the app whenever and wherever you feel comfortable. We will never require you to use it in a place or at a time when you do not want to.
- All app-generated information will be stored on a server without your name. No data will be stored on your smartphone or computer.
- Finally, as an added safeguard, we recommend you password-protect your smartphone (such as using a pin to unlock the phone) while you are in the study.

To avoid the possibility of incurring data charges:

- You may choose to use the app only when on a Wi-Fi connection.
- Check with your smartphone's provider to ensure you know how much data you are allowed to use each billing period without incurring extra charges.

- If needed, only access Jaspr-at-Home when you are comfortable doing so.

To avoid the possibility of provider overreliance on Jaspr

- Providers will be encouraged to use their own clinical judgment when deciding how and when to incorporate Jaspr in your care and the reports it provides.

C. HOW BEING IN THE STUDY CAN BENEFIT YOU

There are no direct benefits to participating in this study. A potential indirect benefit from being in the study as related to the Jaspr condition:

- You may enjoy using the app and feel like you received better care.

D. QUESTIONS

Who do I contact for questions about this study?

For more information about the study or the study procedures or treatments, or to withdraw from the study, contact: Dr. Linda Dimeff at 206-455-7934.

SIGNATURES

By participating in the study and signing this supplement consent form, you are providing full consent to participate in this study.

Research Participant's Consent:
By signing the line below, I am voluntarily agreeing to take part in this study and agreeing to accept the information as outlined in this supplement consent form regarding my study condition, Jaspr. I am aware that if I choose to take part in this study, I may withdraw at any time. I am not giving up any of my legal rights by signing this form. By signing and dating below, I indicate that I have read this entire consent form supplement and have had all of my questions answered.

I will receive a signed copy of this form, which has 4 pages.

I have not waived any of my legal rights by signing this document.

Please sign here if you wish to continue with participation:

Signature of Participant Date	Printed Name of Participant
Signature of Person Obtaining Consent Date	Printed Name of Person Obtaining Consent

PARTICIPANT INFORMED CONSENT FORM

STUDY TITLE: Emergency Department Treatment Study | Telehealth Study

PROTOCOL NO: R44MH108222S

STUDY DOCTOR: Linda Dimeff, PhD

STUDY SITE: Jaspr Health
3222 64th Avenue SW
Seattle, WA 98116

TELEPHONE: 206-455-7934 (24 hours)

SPONSOR: Jaspr Health

CRISIS HOTLINE: 531-355-0618 / 1-800-448-3000 (toll-free)

- Being in a study is voluntary – **your choice**.
- If you join this study, you can still **stop at any time**.
- **No one** can **promise** that a study will help you.
- Do not join this study unless all of your **questions** are **answered**.

After reading and discussing the information in this consent form, you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

This consent form contains important information to help you decide whether to participate in a research study. Please read this consent form carefully.

KEY INFORMATION

Things you should know:

- The purpose of the study is to evaluate a method of delivering virtual care, including use of a mobile app, called Jaspr-at-Home that may be helpful to people experiencing thoughts or behaviors of suicide or a suicide crisis.

- If you choose to participate, you will be asked to take part in three interviews over the phone and complete surveys online. You will be assigned to use the mobile app or a standard safety plan study group.
- Risks or discomforts from this research include feelings of discomfort or embarrassment or loss of privacy or confidentiality.
- There may be no direct benefit to you from participating in this study.
- Your alternative to participating in this study is not to participate.

A. PURPOSE AND BACKGROUND

- You are being asked to volunteer for a research study
- The goal of the study is to evaluate a mobile app that may be helpful to people who are suicidal
- The research is funded by the National Institute of Mental Health (NIMH)
- The Principal Investigators of this study are Dr. Linda Dimeff and Dr. David Jobes. Both are clinical psychologists who want to help people who are suicidal.
- This study will include approximately 60 people, age 18 years and older currently receiving outpatient care for suicide behaviors.

B. PROCEDURES

If you agree to be in this study, this is what will happen:

- You will first be asked to complete a set of surveys and a brief telephone interview, including questions about your age, gender, emotions, and thoughts or feelings you may have about suicide. We expect this set of surveys and the interview to take about 20 minutes to complete.
- You will then be randomly assigned (like flipping a coin) to one of two study groups: the mobile app or standard safety planning.
- If you are randomly assigned to the mobile app study group, you will be asked to use the app on your smartphone as you wish during your study participation.
    - We will schedule an additional meeting with you to set up your account and the mobile app on your smartphone. During this meeting that will last about 1 hour, you will first use the parent app called Jaspr Health to answer some questions about your thoughts and experiences with suicide. A Virtual Guide will walk you through a suicide risk assessment and help you build a safety plan.
- If you are assigned to the standard safety planning group, we will provide you with a packet of information that may help you build a safety plan to use in times of experiencing a suicide crisis. We encourage you, if you think it would be helpful, to also review the plan you create with your provider.
- Your treatment and your participation in this study are separate activities. You may continue your outpatient care regardless of your decision to participate in this study or not. Similarly, you may continue your participation in this study whether or not you continue your care or change providers.
- We will then schedule your two follow up study appointments and three quick support check in calls.
    - Study appointments will take place in 30 days and 90 days. These follow up appointments will be over the phone and using a computer or other device (like a cell phone or tablet)

that has Internet. Each study appointment will be about 20 minutes and include a set of surveys you complete online and a brief phone interview.

- Support check in calls will take place in 3 days, 1 week, and 3 weeks. During these 5 to 10 minute phone calls, we will help with any questions you might have about your assigned safety planning or the app, if you are in that study group

During each study appointment, we want to make sure you are in good shape as you answer the questions and before the appointment ends. We have set up a dedicated phone line to connect you with a mental health counselor if needed. You will be connected with one of these counselors during the study appointment if:

- You tell us you are feeling highly distressed or currently highly suicidal;
- You recently had a suicide attempt without seeking care;
- You report feeling at risk of hurting yourself or others or if the researcher believes you are at risk of hurting yourself or others; or
- You seem to need additional resources, even if you are not currently at risk of hurting yourself or others at this time.

If the researcher believes it is important to connect you to one of the counselors, you will be told directly that we wish to connect you with a counselor. The researcher will then call the counselor in to the call and tell them that you are a participant in this research project. The researcher will also provide them with the following information so that they can best help you:

- Your name, address, phone number, and email address
- Your study identification number
- Your emergency contact information
- The reason we are connecting you with the counselor

If you get disconnected, the counselor will try several times to get back in contact with you. They will use a different phone number than the one our researcher used to call you for the research session. It is important you answer their call if you get disconnected. If they are unable to reach you for any reason, they may try several other methods to reach you including contacting your emergency contact or sending out emergency services to check on you if they have reason to believe you are at immediate risk for dying by suicide.

The counselors are available to you at any time if you need it by calling 531-355-0618 / toll free: 1-800-448-3000. If you are feeling unsafe or suicidal, you should contact your care provider, go to the nearest emergency room, or call 911.

C. STUDY LENGTH

Your study participation will last 3 months. You can tell the study staff at any time if you would like to stop sooner.

D. RISKS/DISCOMFORTS

The possible risks to you from being in this study include:

- Feeling discomfort providing negative feedback about your treatment, your personal experiences, and/or the app or standard safety planning materials.
- Feeling pressured to participate because you heard about this study from your treatment provider.
- Feeling embarrassment or uncomfortable responding to the survey questions or while talking with a researcher.
- Feeling uncomfortable using the app or incurring data charges while using the app (if you are assigned to use the mobile app).

The other kind of risk has to do with privacy and security of your answers to study questions.

To reduce the chance of you feeling uncomfortable sharing your personal experiences and opinions:

- We will check in with you throughout the study to see how you are feeling. If, at any time, you are too upset or uncomfortable, we will ask if you want to take a break or stop the study.
- We will encourage you to tell us both negative and positive thoughts about your participation and other research activities, including about the app and your experiencing using it, so you can feel comfortable telling us even if you don't like something. Both positive and negative feedback is equally important to us.
- During the study, you can decide how much or little to share.
- Your name will not be associated to the responses you provide, so no one will know who provided what feedback except for members of the research team.

To reduce the risk of feeling pressured to participate:

- We will ask you in private if you would like to participate in the study or not.
- We will not inform anyone outside of the research team without your permission if you choose to be in the study or not.
- If you choose not to be in the study, your relationship with your provider will not change in any way.
- If you decide you do want to be in the study, you may change your mind at any time, and this will also not change your relationship with your provider in any way.

To reduce the risk of feeling embarrassment because of this study:

- You are encouraged to observe your own limits in how you use the app and when answering the survey questions.
- We will never require you to do anything for the study when you do not want to.
- If you are assigned to use the app, you can use the app whenever and wherever you feel comfortable. We will never require you to use it in a place or at a time when you do not want to. As an added protection, we recommend you password-protect your smartphone (such as using a pin to unlock the phone) while you are in the study.
- All app-generated information and study survey answers will be stored on a server without your name. No data will be stored on your phone or computer.

To avoid the possibility of incurring data charges while using the app:

- You may choose to use the app only when on a Wi-Fi connection.
- Check with your smartphone's provider to ensure you know how much data you are allowed to use each billing period without incurring extra charges.

To protect your privacy:

- We will not share your information with anyone outside the research team or your doctors and care team except as required by law.

  This happens only if:
  - There is a court order or subpoena of the study records
  - If you tell us that you have thoughts of harming yourself or others. In this case, we are required by state laws to share that information with a doctor or treatment provider to help keep you and others safe.
  - You have a plan or have made a suicide attempt that you have not shared with a treatment provider. In this case, we are required by state laws to share that information with a doctor or treatment provider to help keep you safe.

To protect the information that you share with us:

- Your answers will be saved in a secure, password-protected file on an encrypted server that only the research staff can access.
- Your answers will not have your name in the same file; your answers will be associated only with a research study ID number.
- The list linking your name to your research study ID number will be kept in a separate, secured location, also password protected that only the study staff can access.
- To protect your privacy even more, we will destroy all files that have any names or other identifying information 5 years after the study is finished, including the file that links your name to your research study ID.

If you think you experienced an Adverse Event:

For this study, an adverse event is defined as any unfavorable occurrence (such as significant increase in your distress during the study interview resulting from your involvement in the research) associated with your participation in the research, whether or not you consider it to be related to your participation.

If you think you have experienced an Adverse Event from this study, please report it as soon as possible in one of the following ways:

- Complete the Secure Online Form: https://www.surveymonkey.com/r/JBSHNZV
- Contact the Study PI by Phone: Dr. Linda Dimeff at 206-455-7934
- Contact the Study IRB by Phone: Sterling IRB at 888-636-1062

E. HOW BEING IN THE STUDY CAN BENEFIT YOU

There are no direct benefits to your from participating in this study. You may feel good knowing that you are helping others like you who are feeling suicidal. Your involvement in this research

will help us test an app developed to help people who are feeling suicidal and when they are in crisis.

F. COSTS

There are no costs to you for participating in this study.

G. PAYMENT TO PARTICIPANTS

You may receive up to a total of $75.00 for participating in this study. You will receive $25.00 after completing each of the three study appointments. Each payment for your study appointments will be sent by check within 30 days after you complete the follow up survey. Checks will be sent directly from Chase Bank and will arrive in a Chase Bank envelope.

You will also have access to the Jaspr-at-Home mobile app for 30 days following your completion of the study.

H. ALTERNATIVES

The alternative to being in this study is not being in the study.

I. OTHER STUDY INFORMATION

The information you give us will be used to develop, improve, and test an app we recently developed. This information may be published, but we will not use any names and no one reading it will ever know you were in the study. Information that can lead someone to know you were in the study will be kept confidential to the extent possible within State and Federal law (as described above).

Only the investigators running this study, the National Institute of Mental Health (NIMH), Sterling Institutional Review Board, and Boys Town hotline (if applicable) will have access to identifying study information. All records in Oregon, Washington, and Michigan are subject to subpoena by a court of law.

It is completely your choice if you want to be in this study or not. You can choose not to do the study if you prefer. Even if you decide you do want to do it, you can choose to stop it at any time. If you decide to do that, you should tell the researcher. If you decide not to do this study, that will not change any of your current or future medical care or benefits.

The researchers and/or NIMH may decide you should stop being in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the researcher's instructions.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

PARTICIPANT STATEMENT

- I have had a chance to ask questions about this study.
- I am satisfied with the answers I was given.
- If I have any more questions about being in this study, would like to withdraw from the study, or become distressed from being in the study, I may contact Dr. Linda Dimeff (Principal Investigator) at 206-455-7934.
- If I have any questions, problems, or worries, or want more information or want to give my feedback about the study, I may contact Sterling Institutional Review Board at 888-636-1062. This includes any questions about my rights as a research participant in this study.
- I agree to participate in this study.

I will receive a signed copy of this form, which has 9 pages. I have not waived any of my legal rights by signing this document.

If you wish to participate, you should sign here:

Signature of Participant	Date	Printed Name of Participant
Signature of Researcher	Date	Printed Name of Researcher

Please provide your contact information:

First Name _____

Last Name _____

Email address _____

Secondary email address: _____

Physical Address _____

_____

Mailing Address (if different from above) _____

_____

Primary phone number _____
Okay for research team to leave a message at this number? _____ Yes _____ No

Alternative phone number _____
Okay for research team to leave a message at this number? _____ Yes _____ No

Please provide emergency contact information:

Permission to contact Emergency Contact if we have difficulty to locating you for the follow-up calls? ____Yes ____ No

First Name _____

Last Name _____

Relationship to you _____

Email address _____

Physical Address (optional) _____

_____

Primary phone number _____

Alternative phone number _____

Who else may we contact if we cannot locate you for your study appointments?
As part of your participation in this study, we will be contacting you on two occasions for your follow-up study appointments over the next 90 days. It is not uncommon for participants in research studies to move or change phone numbers between study appointments. In the event that we are unable to reach you, we would like to have the contact information for another person you feel comfortable we contact who will know how to get a hold of you.

First Name _____

Last Name _____

Relationship to you _____

Email address _____

Physical Address (optional) _____

_____

Primary phone number _____

Alternative phone number _____

DATA REPOSITORY

As part of this research, we will add your study data to a de-identified research database, called a data repository. *The data repository will not include your name, address, or any other information that could identify you.* To transfer data into the data repository, we will remove information that would make it possible to identify you and transfer the anonymous data into a research database, the data repository. The database will be used for scientific research about topics such as suicide, options for medical and mental health treatment for mental health problems, and use of technology in mental health treatment. The de-identified data may be shared with other researchers also studying these and similar research topics.

You do not have to give permission for your data to be used in this way unless you want to. Declining to give permission will not affect your participation in this research in any way. Because no identifying information will be added to the data repository, data cannot be withdrawn from the data repository once they are placed there because we will have no way of knowing which data are yours. Your information will not be added to the data repository unless you provide permission below.

Please initial one of the following options:

____ (initial) I give permission for my study data that does not identify me to be entered into the Data Repository.

____ (initial) I do NOT give permission for my study data that does not identify me to be entered into the Data Repository.

Signature of Participant	Date	Printed Name of Participant
Signature of Researcher	Date	Printed Name of Researcher