Treating Drivers of Suicide in Primary Care using Jaspr Health

Informed Consent Form & Informed Consent Form Addendums

Sterling IRB Protocol: 12603

National Clinical Trial (NCT) Identified Number: NCT05427734

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

Sponsor: Evidence-Based Practice Institute, Inc.

Grant Title: Treating Drivers of Suicide in Primary Care using Jaspr Health

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PARTICIPANT INFORMED CONSENT FORM
SUMMATIVE EVALUATION: RANDOMIZED CONTROLLED TRIAL

STUDY TITLE: Drivers of Suicide Mobile App Study

PROTOCOL NO: R44AA029868S

STUDY INVESTIGATOR: Linda Dimeff, PhD

STUDY SITE: Evidence-Based Practice Institute, Inc.
7241 36th Avenue SW
Seattle, WA 98126

TELEPHONE: 206-455-7934

SPONSOR: Evidence-Based Practice Institute

- 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.

Please read this consent form carefully.

KEY INFORMATION

Things you should know:

- We are doing this study to test a mobile app designed to help people with a history of suicidal behaviors (thoughts, actions, self-injury) and other concerns such as sleep/mood problems and/or misuse of alcohol.
- Taking part in this study will last 3 months. You will be asked to complete 4 sets of online surveys and phone interviews with our researchers.
- There are no physical risks from participating in this study, but you may feel uncomfortable answering some of the questions.
- There is no direct benefit to you from participating in this study.

PURPOSE AND BACKGROUND

We are testing a mobile app for adults with suicidal and non-suicidal self-injury who may also struggle with other concerns such as depression, sleep problems, and alcohol misuse.

You are being asked to participate in a research study. Participation will involve using a mobile phone app for 3 months, sharing your experience using it, and whether and how it may have been helpful. This study includes four study appointments that will take place remotely over video-conferencing (like Zoom). Each appointment will include an interview and an online survey. We will ask about barriers you might experience to using the app, suicidal behaviors, non-suicidal self-injury, mood concerns, sleep issues, and about your use of alcohol and other drugs. We are also interested in learning about how the study app is working for you, what you like and dislike, and your suggestions for how to make it better.

PARTICIPANTS

The study will include about 130 people aged 22 and older.

PROCEDURES

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

- You will be randomly assigned to install and use one of two mobile apps on your Android or Apple smartphone. Participants in this study will be equally divided between the two mobile apps. After you are assigned to an app, we will tell you more about it and help you set up the app on your phone. After we tell you more about the app you will be using, you will have the chance to decide if you want to continue being in this study.
- You will each be asked to complete four study appointments by computer and/or phone. These will be at the start of your participation (also called “baseline”) and during weeks 4, 8, and 12. Each study appointment will include an interview and a set of surveys to complete online. We expect the study appointments will take about 1 hour each: 30 minutes for an interview on the phone/computer and 30 minutes to complete the surveys online.

We recommend making sure you are in a quiet, private place during the study appointments. The interviews and surveys may include questions about feelings you may be having about suicide and other concerns.

- You will be paid up to $240.00 for your time in this study. For each study appointment you complete on time, you will also earn one ticket for entry into a drawing for a chance to win an additional $100.00 Amazon gift card.

STUDY CRISIS / HELPLINE

While you are in this study, we want to make sure you are safe. Our researchers are able to provide extra support if you need it or we may connect you with a counselor from the 988 Suicide Prevention & Crisis Lifeline if needed. **The counselors at 988 are available to you at <u>any</u> time if you need it by texting or calling 988.** If you are feeling unsafe or suicidal, you should contact your care provider, go to the nearest emergency room, or call 911.

You may be connected with a counselor during this study if:

- You tell us you are feeling very upset or at risk of hurting yourself or others
- You recently had a suicide attempt without seeking professional care
- You seem to need additional resources, even if you are not currently at risk of hurting yourself or others

If the researcher believes it is important to connect you to one of the counselors at 988, we will tell you. The researcher will then call the counselor to join the call and tell them that you are a participant in this research study. The researcher will also provide them with the following information so that they can best help:

- Your name, address, phone number, and email address
- Your emergency contact information
- The reason we are calling the counselor in

STUDY RISKS / DISCOMFORTS

There are several kinds of potential risks to you for participating in this study, such as embarrassment sharing your opinions (likes and dislikes) of the app with us in an interview, feeling uncomfortable using the app in public, possible data charges, and/or feeling upset when answering survey questions.

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

- We will check in throughout our appointments with you to see how you are feeling. If, at any time, you are too upset or uncomfortable, we will stop the study appointment right away.
- Both positive and negative feedback are equally important to us so we can improve upon things participants don't like and do more of the kinds of things participants like.
- During the study, you decide how much or little to share.

- Your name will not be associated with answers you provide during the interview or on the study surveys, 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 without your permission if you choose to be in the study or not.
- If you decide to participate in the study, you may change your mind at any time.

To reduce the risk of feeling embarrassed when using the app in a public place or when around people who may not know you are participating in a research study:

- You are encouraged to only use the app when it feels comfortable to do so.
- We will never require you to use the app in a place or at a time when you do not want to.
- The app's server is as secure as possible; similar to those used in banking or other commercial websites. This will help protect your information stored in the app.
- As an added protection, all identifying information will only be connected to your study ID (not your name or email address) when downloaded from the server.
- Using the app requires a login, and you can log out of the app at any time.
- As an added safeguard, we recommend you password-protect your smartphone (such as using a pin to unlock the phone) while you are in this study.

To avoid the possibility of getting charged extra fees for data charges while using the app:

- Check with your smartphone's data provider to know how much data you are allowed to use each billing period without extra charges.
- If needed, log out of the app and only log back in when you are comfortable doing so.

To protect your privacy and the information that you share with us:

- Your answers to interview and survey questions will be saved on an encrypted server that only the researchers can access.
- Your answers will not be associated with your name; data will be associated only with a study ID number. The list linking participant names to study ID numbers will be kept in a separate, secured location that only the researchers can access.
- We will destroy all files that have any names or other identifying information 6 years after the study is finished, including the file that links participant names to study IDs.
- We will not share information with others outside our team that identifies you except as required by law. This would happen only if:
    - You tell us that you have thoughts of harming yourself or others or a plan that you have not shared with a treatment provider.

IF YOU THINK YOU EXPERIENCED AN ADVERSE EVENT

For this study, we define an Adverse Event as any bad or uncomfortable event (such as you feeling very upset during a study interview, visiting the hospital for a suicide attempt), whether or

not you think it is related to being in this study. If you think you have experienced an Adverse Event, please report it as soon as possible in one of the following ways:

- Complete the Secure Online Form: https://jasprhealth.qualtrics.com/jfe/form/SV_8qss8BYDCVbtlP0
- Email our research team at research@ebpi.org
- Contact the Study Investigator by phone: Dr. Linda Dimeff at 206-455-7934
- Contact the Sterling IRB at 888-636-1062

No money has been set aside to pay for expenses related to treatment of an adverse event. You do not waive any of your legal rights by signing this form.

STUDY BENEFITS

There are no direct benefits to participating in this study. However, you may experience potential indirect benefits such as help from the app you are using or feeling good knowing that you are helping to improve an app that may someday help others who experience thoughts and behaviors of suicide and other behavioral concerns.

STUDY COSTS

There are no costs to be in this study.

STUDY PAYMENT TO PARTICIPANTS

You will be paid for your time in this study, up to $240.00. You will receive the following amount for completing each of the following study appointments:

- 4-week appointment: $60.00
- 8-week appointment: $60.00
- 12-week appointment: $60.00
- BONUS for completing all study appointments: $60.00

You may choose at the end of this form whether you want to receive your payment by check or gift card. All payments will be sent as soon as possible, no longer than within 30 days of completion.

At the end of the study, we will conduct a random drawing for twelve $100.00 Amazon gift cards. For each study appointment you complete on time (baseline, 4-week, 8-week, 12-week), you will receive an entry into the drawing. After all participants complete the study, we will randomly draw 12 entries for the gift cards. For any drawing, the odds of winning a prize depend on how many people are entered in the drawing. As we do not know how many drawing entries each participant will receive, we cannot predict what the odds of winning a prize will be.

Financial rules require us to have your name and address in order to process and send payments. That information, payment amount, and the name of the study will be kept secure and confidential in our offices by our team, including our bookkeepers and accountants. We will use bookkeeping

software tools to pay you. These tools will have your name and address in order to issue and send payments. We will enter your name, address, and/or email address into the associated websites to send payment by check (Chase Bank) or gift card (Amazon, Kroger, Target).

OTHER STUDY INFORMATION

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

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified.

Information collected during this research that can identify you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the institutional review board(s) overseeing this research will have access to identifying information.

The study investigator is the CEO and on the Board of Directors for the sponsor company and could benefit financially from products developed based on this research study. If you have any concerns about this financial relationship, please ask the research staff.

Your participation in this study is voluntary. You may refuse to be in this study now or at any time. You should tell a researcher if you decide you don't want to be in the study anymore. Your decision to be in the study or not will not affect any benefits to which you are entitled.

The researchers may stop your participation 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.

You will be told if there is any new information that might affect your decision to participate in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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.

QUESTIONS

If you have questions, concerns or complaints about the research study, please contact Dr. Linda Dimeff at 206-455-7934.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department at telephone number 1-888-636-1062 (toll free) or info@sterlingirb.com.

PARTICIPANT STATEMENT

- I have had a chance to ask questions about this study. I am satisfied with the answers I was given.
- I will receive a signed copy of this form.
- I have not waived any of my legal rights by signing this document.
- I agree to participate in this study.

If you wish to participate, please sign below.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

Please indicate how you would like to receive your payment for participation in this study (please choose only one):

- Check: ☐ by Mail
- Gift card from Amazon: ☐ by Mail
- Gift card from Kroger: ☐ by Mail
- Gift card from Target: ☐ by Mail

Please place your initials next to your choice below.

____ (initial) I would like to be contacted if there is a chance to participate in future research.

____ (initial) I do not want to be contacted if there is a chance to participate in future research.

CONTACT INFORMATION

Please provide your contact information:

First Name _____

Last Name _____

Email address _____

Physical Address _____

Mailing Address (if different) _____

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 locating you for your study appointment? _____Yes _____No

First Name _____

Last Name _____

Email address _____

Mailing Address _____

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 for your study appointments over the next 3 months. 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 _____

Primary phone number _____

Alternative phone number _____

_____ _____
Signature of Researcher Obtaining Consent Date Printed Name

DATA REPOSITORY

As part of this research, we will add your study data to a research database, called a Data Repository. The database will be used for scientific research about topics such as suicide, self-harm, options for mental health treatment for mental health problems, and use of technology in mental health treatment. The information in the data repository may be shared with other researchers also studying these and similar research topics. *The Data Repository will not include your name, address, or any other information that could identify you.* We will remove identifying information before transferring the anonymous data into the Data Repository. You do not have to give permission for your data to be used in this way unless you want to. If you do give permission to add your study information to the Data Repository, it cannot be withdrawn once added 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.*

Studies, like this one, that are funded by National Institute on Alcohol Abuse and Alcoholism (NIAAA) are required to add study data into the NIAAA Data Archive. Information added to this study's Data Repository may also be added to the NIAAA Data Archive. This helps sharing and use of study data by the entire research community. The NIAAA Data Archive also includes data collected by researchers funded by other NIH Institutes and Centers.

Please initial <u>one</u> 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	
Signature of Researcher	Date	Printed Name of Researcher	

ADDENDUM TO THE PARTICIPANT INFORMED CONSENT FORM WISEPATH STUDY CONDITION

STUDY TITLE: Drivers of Suicide Mobile App Study

PROTOCOL NO: R44AA029868S

STUDY INVESTIGATOR: Linda Dimeff, PhD

STUDY SITE: Evidence-Based Practice Institute, Inc.
7241 36th Avenue SW
Seattle, WA 98126

TELEPHONE: 206-455-7934

SPONSOR: Evidence-Based Practice Institute

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- Do not join this study unless **all of your questions are answered**.

Please read this form carefully.

ADDITIONAL STUDY INFORMATION

You are currently taking part in this research study. The purpose of this document is to tell you more about the app you were assigned to use during this study.

We are testing a mobile app called WisePath that is designed to help support individuals during challenging moments and while experiencing behavioral concerns. The app is designed for people who struggle with depression, sleep problems, have feelings of wanting to die, or want to harm themselves, and/or misuse alcohol. WisePath includes specific tools for those who are experiencing suicidality, including creating a safety plan and teaching skills and strategies to get through distressing moments. You have been assigned to use the WisePath app while you are in this study.

We will help you install and set up the app on your smartphone. As part of setting up your use of the app, we may share your email address and full name to Apple (if you have an iPhone) or Google Play (if you have an Android-based phone) in order for the app to be installed on your smartphone.

While you are using the app, you will be asked to provide phone permissions for it to work properly, and agree to our terms of use, privacy policy, and data keeping policies. You may also be asked to enter a valid email address, your name, or other identifying information. You may use

an alias or create a new, anonymous email address for this purpose. Our researchers can help you with this if you need.

While using the app, we will be able to access the information collected about you by the app. This information, like all information in this study, will be coded with your study ID number when downloaded from the server and combined with the other participants' data. We will use this information to learn how participants are using WisePath.

PARTICIPANT STATEMENT

Please indicate if you agree to continue participating by signing below. If you do not want to continue taking part in the study, please tell the researcher.

- I have had a chance to ask questions about this additional information. 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 at 206-384-7371 or the research team at research@ebpi.org.
- 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 will receive a signed copy of this form.
- I have not waived any of my legal rights by signing this document.
- I agree to the changes outlined in this form and to use the WisePath app during my time in this study.

If you wish to participate, please sign below:

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

ADDENDUM TO THE PARTICIPANT INFORMED CONSENT FORM VIRTUAL HOPE BOX STUDY CONDITION

STUDY TITLE: Drivers of Suicide Mobile App Study

PROTOCOL NO: R44AA029868S

STUDY INVESTIGATOR: Linda Dimeff, PhD

STUDY SITE: Evidence-Based Practice Institute, Inc.
7241 36th Avenue SW
Seattle, WA 98126

TELEPHONE: 206-455-7934

SPONSOR: Evidence-Based Practice Institute

- 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**.

Please read this form carefully.

ADDITIONAL STUDY INFORMATION

You are currently taking part in this research study. The purpose of this document is to tell you more about the app you were assigned to use during this study.

You have been assigned to use an app called Virtual Hope Box while you are in this study. The Virtual Hope Box app contains tools to help with coping, relaxation, distraction, and positive thinking. You can personalize the app content on your phone according to your specific needs and preferences and continue to add or change your app's content as needed. For example, you can include family photos, videos and recorded messages from loved ones, inspirational quotes, music you find especially soothing, reminders of previous successes, positive life experiences and future aspirations, and affirmations. You can also create coping cards to use in response to personal problem areas you experience. Virtual Hope Box also provides access to positive activity planning, distraction tools, and interactive relaxation exercises including guided imagery, controlled breathing and muscle relaxation.

While you are using the app, you will be required to provide phone permissions for it to work properly, and agree to their terms of use, privacy policy, and data keeping policies. You may also be asked to enter a valid email address, your name, or other identifying information. You may use an alias or create a new, anonymous email address for this purpose. Our researchers can help you with this if you need.

As part of this study condition, we will also text or email you a packet of resources that may help to learn more about suicide and suicide prevention, helpful skills to practice during difficult times, and other resources such as finding support for misuse of alcohol.

PARTICIPANT STATEMENT

Please indicate if you agree to continue participating by signing below. If you do not want to continue taking part in the study, please tell the researcher.

- I have had a chance to ask questions about this additional information. 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 at 206-384-7371 or the research team at research@ebpi.org.
- 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 will receive a signed copy of this form.
- I have not waived any of my legal rights by signing this document.
- I agree to the changes outlined in this form and to use the Virtual Hope Box app during my time in this study.

If you wish to participate, please sign below:

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