Informed Consent Form

Brief Title: Comparing Suicide Prevention Interventions to Guide Follow-up Care (SPRING Trial)

Official Title: Comparing the Effectiveness of Two-Way Caring Contacts Texts vs One-Way Caring Contacts Texts vs Enhanced Usual Care to Reduce Suicidal Behavior in Youth and Adults Screening At-Risk for Suicide in Primary Care or Behavioral Health Clinics: The SPRING Trial

PI: Anna Radin

Date ICF Approved by IRB: 10/18/2023

NCT #: not yet assigned

SPRING Informed Consent Form

[Version date: 08/01/2023]

The SPRING Study

Comparing Suicide Prevention Interventions to Guide Follow-up Care

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If you are in crisis, please call or text 988 anytime.

Introduction to the Study

You, or your child, are being invited to join a research study. If you are a parent of a child, who is being asked to participate in the study, the word "you" or "your" used throughout this form refers to your child. If you are an adult being asked to participate in the study, the word "you" or "your" refers to you. Minors aged 12-17 years will also be asked to provide their permission to participate.

You are being asked to join a research study because during your clinic visit there were some signs that you may be at risk for suicide. This form provides you with information about the study and at the end of the form you will be asked if you would like to be part of this study. Ask as many questions as you need to about the study. You will have as much time as you need to make your choice. As you think about being in this study you should know:

- Taking part in this research study is your choice. You can choose to not be in the study. If you decide not to be in this study it will not affect your medical care.
- You may still receive support from the Idaho Crisis and Suicide Hotline (988) without being in this study.
- The goal of this study is to determine which of three types of follow-up care are most helpful to people at risk for suicide. All of the follow-up care will be delivered by text, phone, or email.
- This study involves filling out surveys online or over the phone four times over one year.
- About 849 participants ages 12 and up will be in this study.
- This study may involve receiving text messages, emails, and phone calls. It will be important that you receive messages from the research team and complete all surveys yourself.
- There are some risks with being in this study. Some questions may make you feel uneasy or you may decide you do not like the follow-up care. You may stop taking part at any time.
- Your information will be kept private but there is a small risk in any study that some information may be released. Great care will be taken to keep your data secure.
- If you participate in this study, you will help us learn more about ways to improve care for people with suicide risk. You will also receive Amazon eGift cards as compensation for your time.

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If you think that you want to be in this study, you should read the rest of this form to learn more. If you decide to not sign this form, you will not be able to take part in this study.

Are you still interested in learning more about this study?

- □ **Yes** *[Informed consent discussion continues]*
- □ **No** *[If this is selected, Research Coordinator will end the informed consent conversation]*

What will I have to do in the study?

You will be randomly assigned to one type of phone or text-based follow-up care. That means by chance, like a flip of a coin you will be placed in one of three types of follow-up care. No one will be able to choose or change which type of care you are assigned to, and you will not know the details about the other types of follow-up care being provided in the study.

You will be asked to complete surveys about your:

- background, including:
  - housing,
  - gender identity,
  - sexual orientation,
  - education and income,
  - religion, and
  - drug and alcohol use;
- quality of life;
- mental health and suicide risk;
- mental health treatment; and/or
- how well you like the care you receive during the study.

If you are under the age of 18, you may need to ask your parent/guardian to help you answer questions related to housing, education and income, and other background questions, but you will answer most of the survey questions yourself.

You will be asked to complete surveys today, then again in 3 months, 6 months, and 12 months. You will be asked to provide various forms of contact information so the study team can follow-up with you.

The surveys will be completed online by a link sent to you through email or text, or by phone call with study staff who can enter your information in the online form for you. You will be able to choose the survey method that you prefer. If you agree to participate in the study, the first survey (baseline) will be completed today after signing this consent form.

Researchers will also review data in your St. Luke's health record such as your demographic and contact information, safety plan, insurance claims data, mental and physical health data including medications, reasons and number of clinic visits, Emergency Department visits, and hospitalizations while you are in the study, and cause of death (if applicable) for up to 10 years following your study participation.

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Schedule of Events				
	Baseline Visit	3 Month Outcome Survey	6 Month Outcome Survey	12 Month Outcome Survey
Consent Signed	x			
Baseline Survey	x			
Outcome Survey		x	x	x
Compensation (Amazon Gift Card)	$30	$30	$30	$40

If researchers learn during the study that one type of follow-up care is better than the others, study staff will notify you, and you will be switched to the better option. The researchers may also remove you from the study if they are unable to contact you, if they feel it is in your best interest or in the best interest of the study team for you to be withdrawn from the study, or if your circumstances change and you are no longer eligible to participate.

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.

Are there any benefits to joining the study?

There may not be any direct benefits to you for taking part in this research. If you take part, you will help us learn more about improved ways to care for people at risk for suicide.

Will it cost anything to participate?

There is no cost to participate in this study. Wireless carriers may charge you fees for receiving calls and texts related to your participation in this study. The study will not pay for these charges.

Will you get paid for joining the study?

You will be paid for the time you spend on this study. The table above shows when and how much you will be paid. Compensation will be in the form of an electronic Amazon gift card that will be sent to you after you complete the survey at each timepoint. We need to collect tax information such as your social security or tax ID number before we can give you gift cards. If you do not provide tax information, you may still be in the study, but we will not be able to give you gift cards. If you do not have your tax information available today, you can provide it to our study team later and then we can send your gift cards.

What are the risks if I decide to join the study?

There are some known risks to participating in this study. There may be other risks which are not known at this time. The study team will notify you if any new, unforeseen risks arise beyond what is discussed below.

This study does not protect you from suicide, nor does it put you at greater risk of suicide.

Potential loss of privacy is a known risk to this research. If you share a phone or email with someone else, there is a chance that they will have access to messages intended for you. If you are under the age of 18, your texts or emails may be accessible by your parents or legal guardian.

Also, some questions may make you feel uneasy. You may stop taking part in the research at any time. You may take a break or stop taking a survey at any time if you become distressed.

If you think you have an injury or illness because you took part in this study, contact the study staff at spring@slhs.org. If you ever have thoughts of harming yourself, please call 911 or the Idaho Crisis and Suicide Hotline at 988. If you get an unexpected injury or illness that St. Luke's determines is because you took part in this study, you will get emergency medical care at no cost. An unexpected injury or illness is one not talked about in the consent form or talked about by the doctor or the study staff. An injury or illness cannot be unexpected if it is caused by a disease or a problem you already have. An attempted suicide or completed suicide is not a study related injury. You do not give up any of your legal rights if you sign this consent form.

You may decide to stop being in the research study at any time by contacting the study staff at spring@slhs.org. There is no penalty or loss of benefits that you would normally receive if you choose to stop participating or if you choose to not participate at all in the study. If you decide to withdraw from the study, the information already collected will be kept as part of the research.

How will my information be protected?

St. Luke's has an electronic health record system so providers and staff can access your records on a need to know basis. Your record may include studies you take part in, including this study. People who view your medical record may see that you participated in this study.

The study uses a secure system called REDCap to capture survey information. Information that directly identifies you will be kept confidential. Results that are published or discussed will not use your name or identify you in any way.

Information collected as part of this research project may be shared with other researchers. This study is being led by St. Luke's in partnership with the Idaho Crisis and Suicide Hotline and the University of Washington. Your information may be shared with our study team at these partner organizations. This study is funded by the American Foundation for Suicide Prevention. Any data shared outside of the research team will be anonymous and will not identify you in any way. Information will be stored in REDCap or another secure database for up to 10 years and will then be destroyed according to St. Luke's Health System policies.

What if I have questions?

You have a right to receive a copy of this form after you have signed it. If after you have signed this form you have any study-related questions, please contact the Principal Investigator using the contact information listed on the first page. If you have questions about your rights as a research participant, you may contact the St. Luke's Health System Institutional Review Board at SLHSIRB@slhs.org or 208-381-1406.

If you ever have thoughts of harming yourself, please **call 911** or the Idaho Suicide Prevention Hotline at (208) 398-4357.

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National Institute of Mental Health Data Archive

De-identified data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where de-identified study data from many NIH studies are stored and managed. Sharing your de-identified study data helps researchers learn new and important things about brain science more quickly than before.

De-identified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The St. Luke's study staff will collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study staff will never send your personal information to NDA.

It is possible that you may participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your de-identified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study staff will send de-identified study data about your health and behavior to the NDA. Other researchers across the world can then request your de-identified study data for different research projects. Every researcher (and the institution to which they belong) who requests your de-identified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. Every attempt will be made to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

Are you still interested in being in this research study?

- □ **Yes**
- □ **No**

[If "Yes", instructional language will ask participants to wait while Research Coordinators initiate the REDCap randomization of participants into one of 3 intervention arms]

You have been randomly assigned to the treatment group receiving:

[*For Group 1 (one-way caring messages):] Caring text messages. At the end of this call, I will share a list of resources that you may find helpful, and we can try calling 988, the mental health crisis and suicide hotline together if you'd like. You will receive caring text messages from our study team over the course*

of the year. You will not be able to reply to these text messages, but you may call or text 988 anytime you'd like support.

[For Group 2 (two-way caring messages):] Caring text messages. At the end of this call, I will share a list of resources that you may find helpful, and we can try calling 988, the mental health crisis and suicide hotline together if you'd like. You will receive caring text messages from a follow-up specialist on our study team over the course of the year that you can reply to if you would like. If you decide to reply, your follow-up specialist will be on the other end to review and respond to your messages. You may also call or text 988 anytime you'd like extra support.

[For Group 3 (usual care):] Resources and phone or text support anytime from 988, the mental health crisis and suicide hotline. At the end of this call, I will share a list of resources that you may find helpful, and we can try calling 988 together if you'd like. You may call or text 988 anytime you'd like support.

Key Takeaways & Next Steps

I understand that I have been assigned to:

- [Treatment Group 1: One-way Caring Contacts only]: Receive supportive texts. I know that I cannot reply to the texts I receive. I know that I can call or text 988 anytime 24/7 for extra support.
- [Treatment Group 2: Two-way Caring Contacts only]: Receive supportive texts and I can decide whether or not I want to reply. I understand that the follow-up team may not see texts I send late at night or on weekends, but they will respond once they are available. I know that I can call or text 988 anytime 24/7 for extra support.
- [Treatment Group 3: Enhanced Usual Care only]: Receive a list of resources at the end of this call, and I can call or text 988 anytime 24/7 for extra support.

- I understand that there are some risks with being in this study. Some questions may make me feel uneasy. I may stop taking part at any time. My information will be kept private but there is a small risk that some information may be released. Strict procedures will be followed to keep my data secure.
- I understand that St. Luke's Health System is leading this study in partnership with the University of Washington and the Idaho Crisis and Suicide Hotline, and my information may be shared with the Idaho Crisis and Suicide Hotline, my emergency contact, and/or my St. Luke's provider if my responses suggest I may be at immediate risk for self-harm.
- I understand that online study surveys will be sent to me in about 3 months, 6 months, and 12 months from now. For each survey I complete, I will receive an electronic Amazon e-gift card.
- [Minor participants only] I understand that if the study team is concerned for my safety, they may share information related to my suicide risk with my parents, guardians, or my St. Luke's doctor, or therapist. The study team will not share other survey responses.
- I understand that if I participate in this study, I will help the study team learn more about ways to improve mental health care. I will also receive compensation for my time through Amazon e-gift cards.
- I understand that the study team may send me the results of the study when it is complete.

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- I understand that if I have study-related questions, I can contact the Principal Investigator at spring@slhs.org. I also understand that I may stop being in the research at any time by emailing the study team at spring@slhs.org.

Have all of your questions about participating in this study been answered?

- Yes
- No

If "no", please talk with the Research Coordinator about any remaining questions you may have.

Informed Consent Statement and Authorization

I have read or had read to me all the information in this consent form. I have been given the chance to discuss it and ask my questions. All my questions have been answered to my satisfaction. I voluntarily consent to take part in this study.

By signing this form, I have not given up any of my legal rights that I otherwise would have as a subject in a research study.

By signing this form, I agree to the use, creation, and/or release of my PHI as explained in this form.

Signing this form electronically is the same as signing a paper document. A copy of this signed document will be emailed to the address you provided. You may keep this copy for your records.

Do you consent to participate in this study?

- Yes
- No
    - *If no: You have opted not to participate in this research study. This will in no way affect the care you receive at St. Luke's or through 988. Thank you for your time today!*

There may be additional studies in the future related to this one. May we retain your name and contact information to reach out to you about future research opportunities? You may still be in this study whether you choose yes or no.

- Yes
- No

Adult Study Participants only
Please provide your full legal name below:
First Name: _____
Last Name: _____

For Parents or Legally Authorized Representatives of Minor Study Participants only
Please provide the full legal name of the **parent or legally authorized representative** of the minor below:
First Name: _____

Last Name: _____
Relationship of the parent or legally authorized representative to the minor: _____

[SIGNATURE BLOCK with date and time]

[For Minor Study Participants only:]
Assent for Minor Participants (Age 12-17)
Please read and complete if you are 12-17 years of age.

This research has been explained to me. I understand what will happen while I am in this research study. I have asked the questions about the study that I wanted to ask, and they have been answered. If I change my mind about being a part of this study, I know I can talk to my parents or email study staff at spring@slhs.org to quit the study. I understand that no one at St. Luke's will be angry with me if I decide not to be in this research. I know if my survey responses indicate I may be at significant risk for suicide, the researchers may contact my parents or guardians with or without my permission. I also understand that even if I decide not to participate in the study, I will not be treated any differently. I agree to be in this research study.

Do you agree to be in this study?
Please provide your full legal name below:
Minor's First Name: _____
Minor's Last Name: _____

[SIGNATURE BLOCK with date and time]

Please enter your primary email address where we can email you a copy of the consent form and your Amazon gift card.

Email address: _____

Confirm email address: _____

[After submitting a signed, completed ICF, this is an example of the type of certification that will appear (actual version will vary slightly and will say SPRING instead of MHAPPS)]

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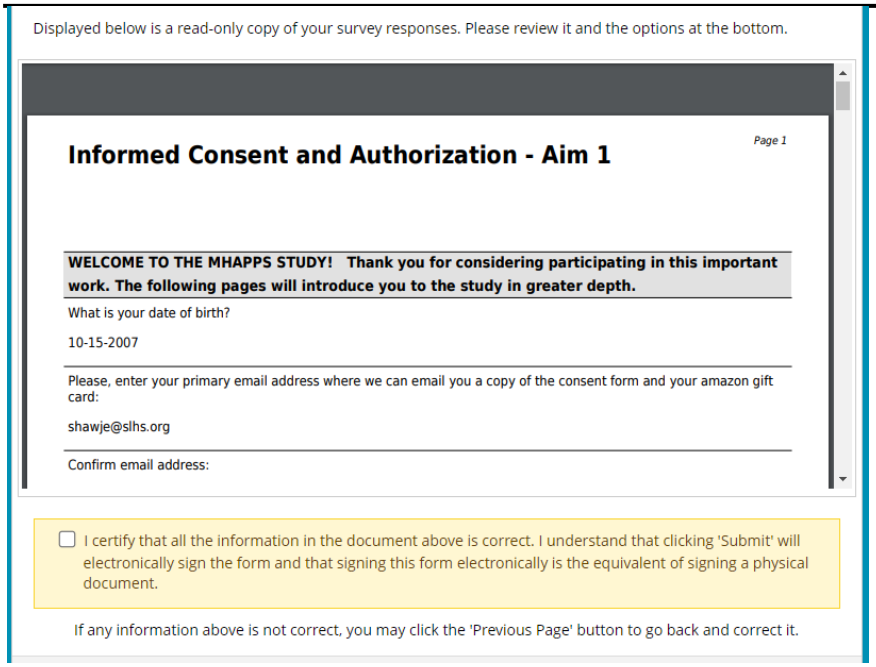
SPRING Informed Consent Form



Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

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Informed Consent and Authorization - Aim 1

WELCOME TO THE MHAPPS STUDY! Thank you for considering participating in this important work. The following pages will introduce you to the study in greater depth.

What is your date of birth?

10-15-2007

Please, enter your primary email address where we can email you a copy of the consent form and your amazon gift card:

shawje@slhs.org

Confirm email address:

☐ I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.