

Informed Consent and Authorization - Aim 2

12/15/2020

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| Study Title: | Mental Health Among Patients, Providers, and Staff (MHAPPS): Investigating the Mental Health Impact of COVID-19 and Comparing the Effectiveness of Two Caring Contact Interventions |
| Principal Investigator: | Anna Radin, DrPH, MPH |
| Idaho Suicide Prevention Hotline (24/7): | (208) 398-4357 |

Introduction

You, or your child, are being asked 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. Children and teenagers, ages 12-17 years, will also be asked to provide their assent (agreement) to participate.

You are being asked to join the second part of this research study because you participated in the first part of this study, and there are signs that COVID-19 has impacted your mental health. This form asks if you would like to be part of this research. 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 the information below:

- Taking part in this research study is your choice. You can choose to not be in the study. Your decision to not be in this study will not affect your medical care (if patient) or employment (if SLHS employee).
- The goal of this study is to compare two interventions to improve mental health and determine which is better.
- This study involves filling out a survey after you enroll and another survey in six months.
- About 660 participants ages 12 and up will be in this study.
- You may receive a phone call and you will receive text messages on your phone. If you do not have your own phone, you will need access to a phone that can receive these messages. If you share a phone or email, it will be important that you receive the messages and complete the surveys yourself.
- There are some risks with being in this study. Some questions may make you feel uneasy. You may stop taking part at any time. Your information will be kept private but there is a small risk that some information may be released.
- Strict procedures will be followed to keep your data secure. Your information may be shared with the Idaho Suicide Prevention Hotline if your responses suggest you may be at immediate risk for self-harm.

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- If you do participate in this study, you will help us learn more about ways to improve mental health care. You may also receive compensation for your time.

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 not to sign this form, you will not be able to take part in this study.

What will I have to do in the study?

As part of the research, you will be randomly placed in one of two treatment groups. The study staff will not be able to choose or change which group you are assigned to. The treatments used in both groups are recommended by experts. You will receive caring text messages (which you may choose or choose not to respond to) from the Idaho Suicide Prevention Hotline over six months.

[For Group 1:] You will be in Group 1. You will receive text messages from the Idaho Suicide Prevention Hotline.

[For Group 2:] You will be in Group 2. You will receive a phone call from the Idaho Suicide Prevention Hotline sometime in the next two weeks. You will also receive text messages from the Hotline.

You will be asked to complete surveys about your:

- background (including employment, sexuality, religion, and substance use)
- mental health (including loneliness, stress, depression, anxiety, and thoughts of suicide)
- COVID-19 beliefs and practices

There will be two different times you will be asked to complete surveys. If you agree to participate in the study, the first surveys will be completed today after signing the consent form; the second survey will be completed at 6 months. Information from the survey you already completed in part 1 of this study will be used as well.

The follow-up surveys will be completed online by a link sent to you through email or text. You will be able to choose the follow-up method that you prefer.

You will be asked to provide various forms of contact information so the study team can follow-up with you. Additional contact information is optional.

The study investigators may remove you from the study if they are unable to contact you or if they feel it is in your best interest to be withdrawn from the study or your circumstances change and you are no longer eligible to participate.

Are there any benefits to join the study?

There may be no 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 whose mental health may be impacted by the COVID-19 pandemic.

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.

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Will I get paid for joining the study?

You will be paid for the time you spend on this study. The table below shows when and how much you will be paid. Compensation for your time is provided through the MHAPPS study and will be in the form of an electronic Amazon gift card that will be emailed to you after you complete the surveys at each timepoint. You will only receive the gift card if you complete the entire survey and provide your email address and information necessary for tax purposes. If you choose not to provide tax information, you may still participate in the study but will not receive gift cards. Please remember if you are a St. Luke's employee, the surveys should be completed on your own time, not as part of your workday.

| | Initial Survey | 6 Month follow up: Email, Text, or Phone |
|---------------------------------|----------------|--|
| Compensation (Amazon Gift Card) | \$35 | \$35 |

If you are paid a total of \$600 or more as a research participant in a calendar year, St. Luke's Health System is required to report the payment to the Internal Revenue Service as miscellaneous income. You will be required to provide your social security number, and St. Luke's will send you a form (IRS form 1099) in January documenting the payment total. You can use the form with your income tax return, if appropriate.

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

There are some known risks 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.

The purpose of this study is to better understand how to support people struggling with mental distress, but the study does not protect you nor does it put you at a greater risk for mental distress.

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 a minor, 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 by emailing study staff at mhapps@slhs.org. If you think you have an injury or illness because you took part in this study, contact the study staff right away at 208-388-7701 and/or St. Luke's Health System IRB at 208-381-1406. **If you have thoughts of harming yourself, please call 911 or the Idaho Suicide Prevention Hotline at (208) 398-4357.** If your responses to the surveys suggest you may be at immediate risk for harming yourself, the Idaho Suicide Prevention Hotline will reach out to you.

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. You do not give up any of your legal rights if you sign this consent form.

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You may decide to stop being in the research study at any time by contacting the study staff at mhapps@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?

If you are a patient with St. Luke's Health System, your medical record may indicate that you participated in this study. The results of your survey will not become part of your medical record.

The study is using a secure system called REDCap to capture the survey information. Only the study team will have access to information that directly identifies you. Results that are published or discussed will not use your name or identify you in any way. Information will be stored in REDCap or another secure data base for up to 10 years and will then be destroyed according to St. Luke's Health System policies.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. 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.

Authorization to release protected health information (PHI)

Health information that we gather about you is personal. St. Luke's researchers are required by a law called the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to keep your **protected health information (PHI)** private. All reasonable efforts will be made to protect the confidentiality of your PHI.

What is protected health information?

- **Protected health information** is health information combined with information that identifies you.
 - **Health information** is any information that relates to the past, present, or future physical or mental health or condition of an individual or the provision of health care to an individual.
 - **Information that identifies individuals** includes name, date of birth, dates of service, address, or medical record numbers.

What protected health information may be accessed, used, created, and/or released?

If you sign this form, you give permission for the release of the PHI needed to complete the research study. The PHI will be accessed, created, used and released as described in this authorization. Information may include:

- Information that identifies you such as your name, address, health plan number, birth date, Social Security Number, and your phone number; or survey results

Why will this information be accessed, used, created, and/or released to others?

- To do the research,

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- To study the results,
- To ensure your safety, and
- To make sure that the research was properly performed.

Who will my protected health information be released to?

The Investigator may release your PHI to the following entities or agents associated with or responsible for monitoring this research:

- Research staff and representatives of the Patient Centered Outcomes Research Institute (PCORI)
- St. Luke's Health System Institutional Review Board and/or St. Luke's Health System employees and contractors, and partner organizations, including the Idaho Suicide Prevention Hotline, and the University of Washington.
- If you are a minor, survey results related to suicide risk may be released to parents or legally authorized representative.

There is a chance your PHI may be re-disclosed (re-released) by the entities or agents receiving it listed above. That information may no longer be protected by the HIPAA Privacy Rule. However, other laws that keep your information private may apply.

Will I be able to access my research information?

You have the right to see a copy of the health information collected from you in the course of the research study for as long as that information is maintained by the study personnel and other entities subject to federal privacy regulation. Research data including survey responses will be kept confidential between the research team and the participant (including minor participants) unless your survey responses indicate you may be at significant risk for suicide.

If I choose not to sign this form, may I still be in the study?

If you do not sign this form, you will not be able to be in the research study, but you will still be able to receive normal medical care from St. Luke's Health System (if patient), and your employment will not be affected (if SLHS employee). You can still use the standard services offered by the Idaho Suicide Prevention Hotline.

How long will my permission be valid?

Unless you revoke (take back) your permission, this form will expire 10 years after the study closes.

May I revoke (take back) my permission?

You may take back your permission for the study at any time, but it must be done in writing and sent to:

Principal Investigator Anna Radin, DrPH, MPH
mhapps@slhs.org

- If you take back your permission for the study, then you may not continue to participate in the study.

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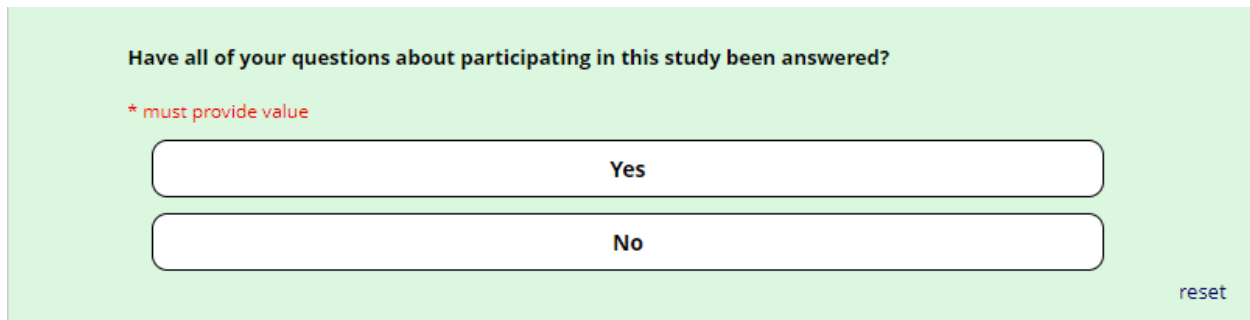
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When you take back your permission, no new PHI will be used, created, and/or released after that date. Information that has already been gathered may still be used for the purposes of this research.

What if I have questions?

If after you have signed this form you have any study-related questions, please contact the Principal Investigator at mhapps@slhs.org. If you have questions about your rights as a research participant, you may contact the St. Luke's Health System Institutional Review Board at 208-381-1406.

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



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

* must provide value

Yes

No

reset

Screen shot from RedCap, if the participant selects "no" then the following will appear:

"Please talk to the research coordinator about any remaining questions you might have."

If "yes" is selected then the appropriate authorization will appear for the age of the participant:

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. I understand that I will receive an emailed copy of this form.

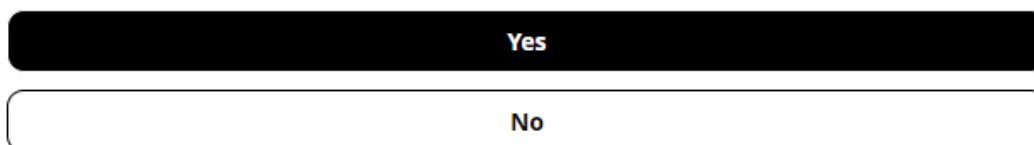
By signing this form, I have not given up any of my legal rights that I otherwise would have as a participant in a research study.

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?

* must provide value



Yes

No

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If the participant selects "no" then "We appreciate your time and consideration for the MHAPPS Study, thank you!" will appear. If the participant selects "yes" in REDCap then the following will appear:


Name of Study Participant (adult) or Legally Authorized Representative

* must provide value

Signature of Study Participant (adult) or Legally Authorized Representative:

Click or tap on the green comment that says "Add signature."


* must provide value

 [Add signature](#)

You can use your finger or mouse to draw your signature.

Date signed:

* must provide value

 M-D-Y

Click on the 'Today' button.

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If participant is 12-17 years of age, the following will appear:

Relationship of Legally Authorized Representative (if applicable)

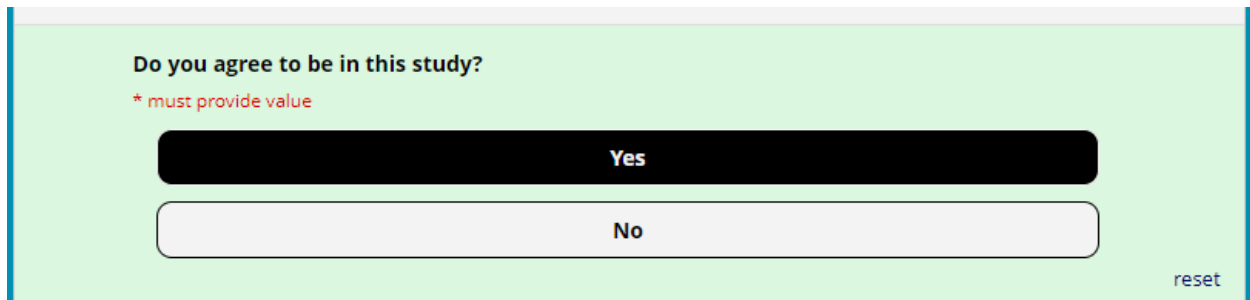
Assent for Minor Participants (Age 12-17)

Please complete if the study participant is 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 close the survey, talk to my parents, or email study staff at mhapps@slhs.org to quit the study. I understand that no one will be angry with me if I decide not to be in this research study. 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.

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Do you agree to be in this study?

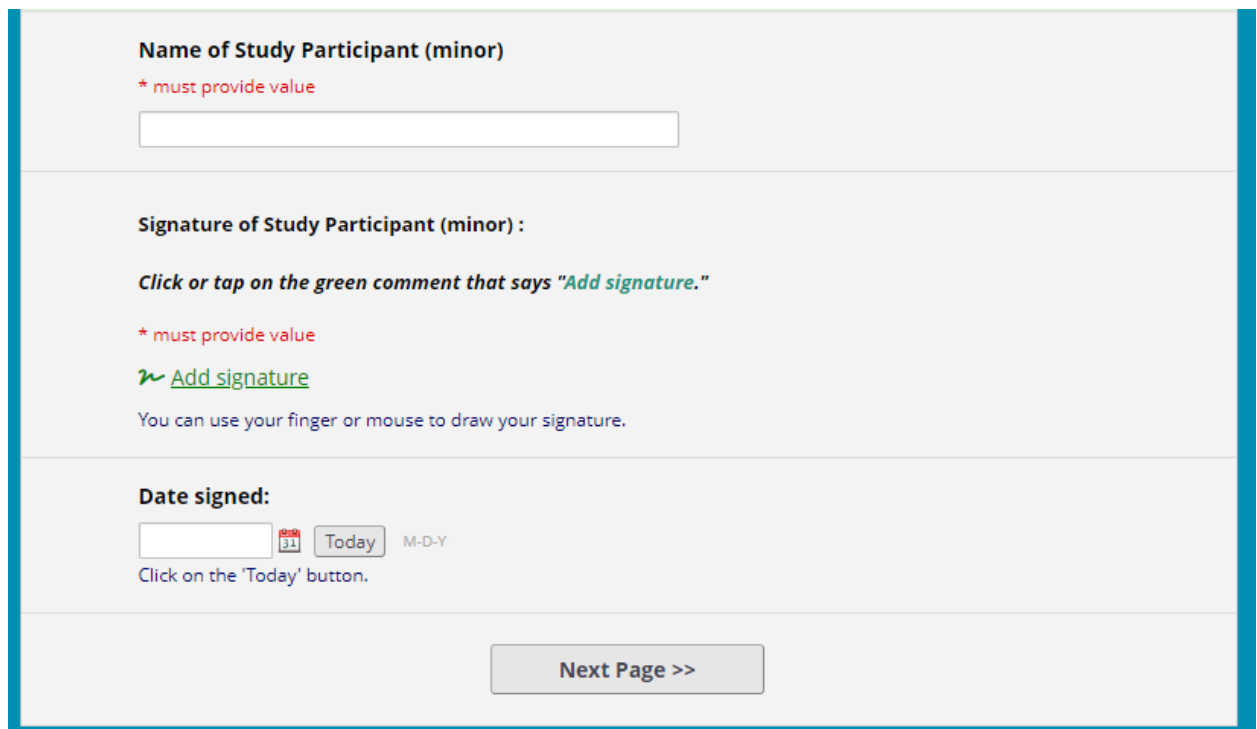
* must provide value

Yes

No

reset

If the participant selects "no" then "We appreciate your time and consideration for the MHAPPS Study, thank you!" will appear. If the participant selects "yes" in REDCap then the following will appear:




Name of Study Participant (minor)

* must provide value

Signature of Study Participant (minor) :


Click or tap on the green comment that says "Add signature."

* must provide value

 [Add signature](#)

You can use your finger or mouse to draw your signature.

Date signed:

 Today M-D-Y

Click on the 'Today' button.

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In REDCap, the study staff attestation below will be in a study staff facing form stored separate from the participants signed copy.

Study staff: your signature here attests that you have reviewed the consent form with the potential participant and all questions they may have had about study participation have been answered.

Name of study staff

Signature of study staff

Date Signed