Developing a Digital Intervention forAdolescent Nonsuicidal Self-injury

Trial ConsentDocument

NCT07224165

04/27/2026

Permission to Take Part in a Human Research Study

Title of Research Study: *Digital Intervention for Adolescent Nonsuicidal Self-injury: A Trial*

Investigator: Kaylee Kruzan PhD, Center for Behavioral Intervention Technologies, Feinberg School of Medicine,DepartmentofPreventive Medicine, Northwestern University

Supported By: This research is supported by funding made available through the National Institutes of Health.

Before you get started with the study, we would like to share some important information about this research study and obtain your consent to participate. Please take the time to read this information carefully. If you have any questions we will provide you with contact information later in the document.

Key Information about this research study:
The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is explained later on in this form.

- The purpose of this study is to evaluate how a digital mental health app can support adolescents who engage in nonsuicidal self-injury (NSSI). If you join the study, you will be asked to do 3 main things:
  - Participate in a brief 10-15 minute "start up" call
  - Interact with a **smartphone app designed to provide mental health support for 8 weeks.**
  - Complete **research surveys online.**

We expect that you will be in this research study for 16 weeks. The primary risk of participation is the possibility that you will experience distress or fatigue while completing the research interviews or questionnaires. You have the option to stop a research survey at any time without penalty. The main benefit is helping researchers improve services for adolescents who engage in NSSI in the future.

Why am I being asked to take part in this research study?
We areasking you to take part in this research study because we are interviewing English-speaking adolescents (14-18 years old) who report current (2 or more times in past month) nonsuicidal self-injury (e.g., cutting, burning without suicidal intent) and own a smartphone.

Why is this research being done?
ResearchersfromNorthwesternUniversity's Center for Behavioral Intervention Technologies (CBITs) aim to evaluate how a mental health smartphone app can support adolescents who engage in NSSI.

This study will give researchers the opportunity to explore how the app works for adolescents who are not currently engaged in mental health treatment.

The purpose of this study is to evaluate how the app helps adolescents manage NSSI and mental health symptoms.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.

- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Question:

My participation in this research study is voluntary.

Is this statement true or false? (True or False)

(A) True
(B) False

Howlongwilltheresearchlastandwhatwill I needtodo?
We expect that you will be in this research study for 16 weeks. You will be asked to use a smartphone app for 8 weeks, and fill out mental health questionnaires at three timepoints (study start, week, 4, and week 8). You will no longer be asked to use the app after 8 weeks, but if you would like to continue use you can do so.We will ask you tofill out two additional questionnaires at weeks 12 and 16.There isa total of 5 online surveys over the course of the study. You'll additionally be asked to complete a 10-15 minute "start up" call with research staff to help you get the app set up on your phone and to answer any questions. You may also be invited to participate in an optional 30-minute interview at week 4 or week 8 to discuss your experience in the study.
The primary risk of participation is the possibility that you will experience distress or fatigue while completing the research interviews or questionnaires. You have the option to stop a research survey at any time without penalty. The main benefit is helping researchers improve services for adolescents who engage in NSSI in the future.

More detailed information about the study procedures can be found under the section **What happens if I say"Yes, I wanttobeinthisresearch"?**

Whathappensif I donotwanttobeinthisresearch?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Whomcan I talkto?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator on this study, Kaylee Kruzan, Ph.D. at 312.503.3114 , Monday-Friday, 9am-5pm CST.

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This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 80 people will be in this research study.

Whathappensif I say"Yes, I wanttobeinthisresearch"?
After you read this consent form and agree to participate by digitally signing the form, you will continue on to complete an online questionnaire as part of our screening assessment (~30 minutes to complete.) This assessment will include questions about your recent mood and mental health history.

As a participant in the study, you may be randomly assigned to one of two app experiences, designed to support adolescents who engage in NSSI. You will receive your random assignment, along with information about completing additional surveys and downloading the app onto your personal smartphone, through email. You will be asked to set up a brief 10-15 minute phone call with research staff at the beginning of the study so they can answer any questions you may have about the study and help you to get the app set up.

You will be asked to use your version of the app over the course of 8 weeks. While the app features differ slightly based on what your random assignment, all are designed to help support you in learning strategies to improve well-being. In all, you will be asked to use the app for 8 weeks.

1. If you are randomly assigned to experience A: Your experience will include engaging with psychoeducational content and different in-app exercises weekly. You will be able to contact the study team if you run into technical issues when using the app.

2. If you are randomly assigned to experience B: Your experience will include engaging with psychoeducational content through an app weekly. You will be able to contact the study team if you run into technical issues when using the app.

Research Assessments

Once enrolled in the study you will be asked to complete research assessments online. You will be asked to complete 5 online surveys. The first survey will be sent to you soon after you consent to participate in the study. **You will receive additional surveys 4, 8,12, and 16 weeks after you join the study**. The surveys will take approximately 30 minutes to complete and will include questions about your mental health and your opinions on the app.

What does it mean to be "randomly assigned"?
Randomly assigned means that every participant has an equal chance of receiving one of two versions of the app. A computer program will be used to randomly assign you to the the app features that you will use during the 8 week trial.

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The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have a one in two chance of being given either treatment.

Question:

How is my study group assignment determined? (Multiple choice)

(A) I get to choose which group I'd like to be in
(B) I am randomly assigned by a computer
(C) Study staff choose my group assignment
(D) None of the above choices

Whataremyresponsibilitiesif I takepartinthisresearch?
If you take part in this research, you will be responsible to: use the app regularly over the course of 8 weeks and answer surveys at 5 timepoints.

Whathappensif I say"Yes",but I changemymindlater?
You can leave the research at any time; it will not be held against you. If you decide to leave the research, contact the investigator so that the investigator can remove you from the study.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment. All data collected up to that point will be secured appropriately and access to the data limited to study team members and carefully managed. Any published data will be aggregated and completely de-identified. You may be asked why you chose to withdraw.

Is there any way being in this study could be bad for me?
It is unlikely, but possible, for you to experience some psychological discomfort in answering questions during the study. Secondly, a possible risk for any research is that confidentiality could be compromised - that is, that people outside the study might get hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail later in this form. There are additional risks due to the nature of this intervention being delivered via smartphone. Depending on the nature of your smartphone service plan, there is the potential for text message and/or data plan overages. We encourage you to discuss your plan with research staff before enrolling in the study. There is also the potential for loss of confidentiality if someone else were to use your phone and read information you have entered into the apps and/or messages you have sent to your coach. We recommend password protecting your phone to reduce confidentiality risks.

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include an improved understanding of your mental health as a result of answering surveys.

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What happens to the information collected for the research?
Efforts will bemade to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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

Data Sharing
De-identifieddata from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

Ifyouagree to take part in this research study, we will pay you up to $12 0.00 in a Virtual Amazon Gift Card for your time and effort. The amount of compensation is pro-rated for the number of surveys you complete. You will receive a Virtual Amazon Gift Card through email upon completion of each assessment.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Kaylee Kruzan, PhD

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Institution: Northwestern University
Department: Center for Behavioral Intervention Technologies
Address: 750 N Lake Shore Drive, Chicago, IL 60611

Your safety is important to us. We asked you for the name and number of a trusted adult in an earlier survey. As a reminder, this person should be someone who is 18 years of age or older that could help you if you, or the study team, become(s) concerned about your safety. This could be a parent or guardian but does not have to be. Other examples of a trusted adult may include: an older sibling, aunt or uncle, neighbor, or a family friend.

We will reach out to the trusted adult if you report intent and plan to end your life on survey questions, in communication with the study team, or in the interview itself. In all these cases, we will call you first and ask you questions to understand more about your safety. The call could go 3 different ways:

1) We learn that you do not intend to end your life and we will help you to come up with a safety plan that you can use if your distress increases and you ever feel concerned about your safety. In this case, we will not call the trusted adult.

2) We learn that you intend to end your life and you have a plan to do so. We will let you know that we are concerned about your immediate safety and that we will call the trusted adult.

3) If we are unable to reach you when we call, we will try 3 times within 1 business day and leave a voicemail each time. If we are unable to reach you after 3 calls, we will call the trusted adult to let them know that we are concerned about your safety.

Before providing your consent, please verify that the name and contact information of a trusted adult who we can call in the event that we are concerned about your immediate safety is correct below. As a reminder, we will need this contact information to fully enroll you into the study. If you have any questions about this, you can scroll up and re-read section "Your safety is important to us" for details on why we need this information or you can ask a study team member at the time of your interview.

- The name of trusted adult you listed in the screening is: **[name pipedinfromscreening]**
- Is this correct? Yes, No
- [If **yes**, display:] The phone Number of the trusted adult you listed in the screening is: **[phone number pipedinfromscreening]**
- Is this correct? YesNo
- If no, please provide the phone number of your trusted adult: _____

- [If **no**, display] Please provide an updated name of a trusted adult: _____
- Please provide the phone number of your updated trusted adult: _____
- Is this correct? Yes No
- If no, please provide the phone number of your updated trusted adult.

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Optional Elements:
The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by selecting "I agree" or "I disagree".

I agree	I disagree	
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.
_____	_____	I would like the researcher to let me know when results are published via email.

Your signature documents your permission to take part in this research.

Consent Summary:
I have read this form and I understand the research study. I have been told whom to contact if I have questions. I agree to participate in the research study described above; this is signified by checking the box below and typing my name in the space provided. I will print a copy of this consent form for my records after I complete this authorization.

Your typed name will serve as your digital signature. Typing your name will indicate your consent to take part in this research. You can print a copy of this signed document or ask the research team to provide you a copy.

_____ _____
Signature of Participant Date

_____
Typed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Typed Name of Person Obtaining Consent