Technology Enabled Services to Enhance Depression Care

NCT05406791

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ONLINE CONSENT FORM INTRODUCTION

Hi there! Before you get started with the study, we'd like to share some important information about the study and obtain your permission to participate. This form contains information about:

- The purpose of the study
- What you'll be asked to do
- Potential risks & benefits of study participation
- Information that will be gathered and how it will be handled
- Your rights as a research participant and who you can contact with questions

The key sections of this document have been broken up for your convenience. At the end of certain sections, there will be corresponding comprehension questions. These will help to reinforce key points we'd like you to be aware of before agreeing to participate in this research study.

If you still have questions about the study after you've gone through this consent form, you'll have an opportunity to ask a study staff member questions.

SECTION 1: ABOUT THIS RESEARCH STUDY

Title of Research Study: Technology Enabled Services to Enhance Depression Care
Short Title: iCan4Wellness Study

Principal Investigator(s):
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Supported By: This research is supported by funding made available through the National Institutes of Health.

Conflict of Interest Disclosure:
If your doctor is also the person responsible for this research study, please note that they are interested in both your clinical care and how this research study is carried out. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

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 in this form.

- The purpose of this study is to evaluate how mental health smartphone apps can support people experiencing symptoms of depression and anxiety.

- If you join the study, you will be asked to do two main things:
  - Interact with a smartphone app designed to help people self-manage stress, depression, and anxiety.
  - Complete research surveys online. You may also be invited to complete optional telephone interviews.
- We expect that you will be in this research study for 12 weeks.
- The primary risk of participation is the possibility that you will experience distress, psychological discomfort, or fatigue while completing the research surveys. You have the option to stop a research survey at any time without penalty.
- The main possible benefit is learning helpful strategies to manage stress and mood.

Why am I being asked to take part in this research study?
You are being invited to take part in this research study because you are an adult who is currently receiving care, or may in the future receive care at Rush University Medical Center. You have a smartphone and have expressed interest in using a smartphone app to learn ways to manage stress, depression, and anxiety.

How many people will be in this study?
We expect to recruit 130 people to participate in this research study.

What should I know about participating in a research study?
- 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.
- You do not have to answer any question you do not want to answer.

SECTION 2: HOW TO JOIN AND WHAT YOU'LL BE ASKED TO DO

What happens if I say, "Yes, I want to be in this research?"
After you read this consent form, and you agree to participate (by digitally signing this form), you will receive information about completing an additional paid survey. Once you complete the paid survey, a study team member will review your responses and contact you to confirm whether you are eligible to continue in the study. If you are eligible to continue in the study, a phone call will be scheduled to help you download the study app onto your personal smartphone.

How does the study experience differ for each participant?

As a participant, you will be assigned to one of two groups:

If you are assigned to group 1, you will use a mental health app called Vira and receive support from a study "coach." You will be asked to complete the following tasks during the first 8 weeks of the study:

- Download the Vira app, keep it running in the background on your personal smartphone, and answer two daily questions. While on your smartphone, the Vira app will ask you to answer two daily questions about your mood and will combine your mood responses with information gathered by your smartphone sensors to help you understand how your daily

activities, habits, and surroundings may be related to your mood. Using the app for a few minutes a day will help you to get the most out of the program.

- Stay in touch with your coach: At the beginning of the study, your coach will help you download the Vira application during a phone call and develop a plan for how you can use the Vira app to manage stress, depression, and/or anxiety. As part of the program, you may communicate with your coach to get support through text messaging and brief phone calls.
- Complete longer in-app surveys about your mental health: Once a week, spend about five minutes answering questions in the app that will help your coach understand how you are doing so they can best support you.

If you are assigned to group 2, you will use a mood education app on your own. You will be asked to complete the following tasks during the first 8 weeks of the study:

- Download the mood education app on your personal smartphone and use it as needed. Study staff will help you download the mood education app and then you will use the app on your own, as needed. The mood education app will contain information about understanding and managing stress, depression, and anxiety.

You will not be able to pick which group you end up in, nor will the study staff get to choose. Your group assignment is made by the computer, and it is entirely up to chance (random). This method helps ensure the research study is fair.

Question:
Who chooses which study group I end up in? (Multiple choice)

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

Research Surveys (All Participants)

Once enrolled in the study, in addition to using one of the mental health apps, you will be asked to complete research surveys online. You will be asked to complete a total of 4 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, and 12 weeks after you join the study. The surveys will take approximately 30 minutes to complete, and will include questions about your mood, your health, and your opinions about the technology you are using for the study. Payment for completing the online surveys is outlined in section 5 under the heading titled **"Payment."**

Optional Telephone Interviews (Group 1 Only)

If you are assigned to group 1, you may be invited to complete additional optional telephone interviews to share feedback about using the Vira app and working with the study coach. If you let us know that you are interested in completing these additional interviews, a member of the study team

will reach out to schedule a time to speak with you. Payment for completing the additional interviews is outlined in section 5 under the heading titled **"Payment."**

SECTION 3: RISKS, BENEFITS, RIGHTS, AND ALTERNATIVES TO PARTICIPATING IN THIS STUDY

Will being in this study help me in any way?
We cannot promise any benefits to you or others from taking part in this research. However, possible benefits include: Learning helpful ways to manage stress and mood.

Is there any way being in this study could be bad for me?
The risks of harm from being in this study are minimal. One possible risk is that using the mental health apps might not work well at decreasing symptoms of depression or anxiety. So, there is a risk that the treatment we're testing might not fully meet the need of every participant. We consider this risk to be minimal however, because all treatments come with the risk that they will not work for some.

Participants might also experience distress, psychological discomfort or fatigue while completing the research assessments. You can stop a research assessment at any time if you are experiencing distress (for example, if it feels like it is too much mentally or emotionally). Symptom worsening and distress is not expected to be any more frequent or severe than is typically experienced in the normal course of treatment for psychiatric illness. In the case of worsening symptoms, you will be referred to your health care provider at Rush University Medical Center.

There are additional risks because this program is delivered via smartphone. There is a risk that you may be injured if you interact with the study apps while driving, so we ask that you do not use the study apps while driving. Depending on the nature of your smartphone service plan, there is the possibility for data and text plan overages. We encourage you to discuss your plan with research staff before enrolling in the study. There is also the possibility 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.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have steps in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?"**

Can I be removed from the research without my OK?
The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include if the study team decides that you would benefit from receiving a higher level of care.

What happens if I do not want to be in this research, or I change my mind later?
Participation in research is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or leave the study at any point, your decision will not affect your relationship with any healthcare provider you may receive services from. Instead of being in this research study, you can choose to receive care from your provider at Rush.

You can leave the research at any time and it will not be held against you.

Question:
My participation in this research study is voluntary.

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

SECTION 4: INFORMATION THAT WILL BE GATHERED AND HOW IT WILL BE HANDLED

What information will be collected for the research?

Study data will include information that you give through study assessments (surveys and interviews), interactions with study staff (via phone, email, and text message), and your app usage. If you are assigned to group 1, and you install the Vira app, our software development partners at Ksana Health (who manage the Vira app) will gather information from your smartphone sensors about your location (deidentified data only, meaning it does not contain anything identifying who you are), physical activity, and motion. This data, if available from your device, will be transferred securely to Ksana's servers daily in order to give insights into your behavior (which will be shared with you). Please note that study interviews and other interactions with study staff may be audio recorded and transcribed, and these will be included as study data.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information 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 Institutional Review Board ("IRB") and other representatives of this institution. An IRB is a committee that protects the rights of people who participate in research studies. 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.

Part 1: Privacy & Confidentiality

We take your privacy very seriously. As part of our commitment to your privacy, you have been assigned a unique study ID that will follow you throughout the course of the study. Any study data with your name or other information that could directly identify you will be stored in a secure protected format. Once you download the assigned study app, your mobile phone will collect and send data about your app usage to a secure server (computer). Our software development partners at Ksana Health and Audacious Software will store only the minimum amount of identifying information needed to create and maintain your user account, and all of your information is stored on secure servers for your protection.

Part 2: Data Sharing

De-identified data 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 promise anonymity of your personal data. The research team may share data from this study with the following individuals.

- Authorized members of the Northwestern University and Rush University Medical Center workforce who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study).

- Your Rush primary care team, psychiatrists, and other individuals involved in your treatment program. Information shared with your care team may be entered into your medical record. Any study information in your medical record will be kept indefinitely.

- Other researchers and contractors working on this study (and other studies) who are collaborating to further research and agree to protect the data.

- Study monitors and auditors, for example from funding agencies, who make sure that the study is conducted properly.

- Readers and reviewers of scientific journals that may publish the results of this and other studies that involve your data.

- The information that we share about you with the people mentioned above will not include direct identifiers like your name, address, or telephone number.

Question:
Once I sign the consent form, the researchers may share information collected about me with study staff, collaborators, and others who agree to protect the information.

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

Certificate of Confidentiality:
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. Identifiable information that could still be disclosed beyond the research team. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.
Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not

connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Limits to Confidentiality

If we believe you are at imminent risk of harming yourself or someone else, we will contact emergency services to locate you and ensure your safety and the safety of others. We may share information with your care team at Rush.

Question:
When would the research study staff have to break confidentiality? (Multiple choice)
*Breaking confidentiality means that study staff may contact your provider, or emergency services if we learn that you or someone else may be at risk of being harmed.

(A) If I mention information about the abuse or neglect of a minor, elderly person, or disabled individual
(B) If I share information about being in danger of harming myself or others
(C) If my records were to be subpoenaed by the court
(D) Choices A and B above

SECTION 5: COSTS, PAYMENTS, AND STUDY CONTACT INFORMATION

Will it cost me anything to participate in this research study?

Taking part in this research study is not likely to lead to any costs to you.

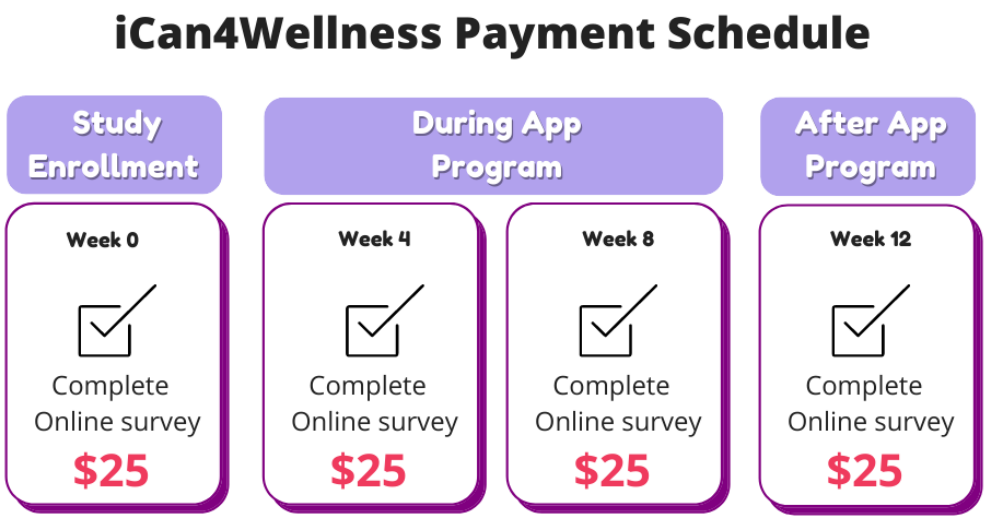
You and your insurance company will be charged for the health care services that you would usually be responsible to pay.

You will not be charged for use of the mental health app or coaching service provided through this study. All costs required for this study (including use of the apps and coaching) will be paid for by a grant from the sponsor, the National Institute of Mental Health. However, participants will be asked to download the apps onto their personal smartphones and may interact with a study coach via text message; therefore, study participation will require use of personal text and data plans. While the study apps use a small amount of data, participants who have a limited monthly data and/or text messaging package will be responsible for keeping track of their usage per their smartphone plans and will be responsible for paying any overage fees incurred as a result of exceeding their monthly plans. The research study is not responsible for any overages and in no way endorses or expects participants to surpass their monthly plan limits.

Payment

Research Surveys (All Participants)

If you agree to take part in this research study, we will pay you $25 for your time and effort for each survey that you complete, for a total of up to $100.



Optional Telephone Interviews (Group 1 Only)

If you are assigned to group 1, and you agree to complete one or more of the optional telephone interviews, you are eligible to earn an additional $25 for each 30-60 minute interview you complete. All participants assigned to group 1 will be invited to complete a coaching user feedback interview at week 4. Approximately 10 participants will be invited to complete app usability interviews at weeks 4, 6, and 8. The table below shows the payment schedule for the interviews:

Interview Schedule	Week 4	Week 6	Week 8
App Usability Interview	$25	$25	$25
Coaching Feedback Interview	$25		

Payment Methods

Depending on Northwestern University payment guidelines, and availability at the time of your participation, payments to participants will be paid in one of the following ways:

- Gift card: The following gift card payment methods are only available to participants earning no more than $225 per calendar year.
    - Amazon.com gift card: You would be sent a code to your email address that will allow you to redeem an Amazon.com gift card. Gift Cards may only be redeemed toward the purchase of eligible goods and services provided by Amazon.com. You must create an account with Amazon to use the card. No fees apply to Amazon Gift Cards and the balance will not expire.
    - PNC Stored Value (Visa) Card: If you do not have an Amazon account or do not wish to be paid through Amazon, you may request a Stored Value (Visa) Card instead. The cards may be virtual or physical as per your preference.
- Check: Participants earning more than $225 per calendar year must be paid by check. Checks require a signed W9 form and will be mailed to your mailing address.
- Through Northwestern University (NU) Payroll if you are an NU employee

To process your payment, the study team may gather your name, email address, mailing address, date of birth, and social security number. Please allow approximately 2-4 weeks for your payments to

be processed. A Form 1099 will be sent to you if your total payments (from this study and other Northwestern University studies) are $600 or more in a calendar year.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, treatment will be offered. However, the cost of treatment provided will be billed to you or your insurance company. Your insurance company may not pay the costs related to research participation.

If you are a patient at Rush University Medical Center, Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to any member of the study team or you can contact the Northwestern University coordinator for this research study, Olga Barnas, at 312-503-4610, Monday -Friday, 9-5pm CT with any questions about this research study.

This research has been reviewed and approved by an Institutional Review Board ("IRB") – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB by phone at (312) 503-9338 or by email at 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.

SIGNATURE SECTION

By indicating "yes" below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You may print a copy of this document or request a signed copy of this document by contacting the research team at ican4wellness@northwestern.edu.

Do you wish to participate? Yes No

[Display the components below this line only if respondent indicates "yes" to "do you wish to participate"]

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 clicking on I agree or I disagree.

The researcher may keep my contact information in order to contact me in the future to see whether I am interested in participating in other research studies.

- I agree
- I disagree

The researcher may email me in the future to share findings from this study.

- I agree
- I disagree

Please provide your name, signature, and date below.

ONLINE CONSENT

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

_____ _____
Signature Date

_____
Typed Name

_____ _____
Signature of Person Obtaining Consent Date

_____
Typed Name of Person Obtaining Consent

You have agreed to participate in this research study by providing the above information. Please submit this form by clicking here.
[submit button]