Mental Health App for Cancer Survivors Study (MACS Study)

10/22/2024

NCT06472726

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

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Study Title for Participants: Mental Health App for Cancer Survivors Study (MACS Study)

Formal Study Title: Mental Health App for Cancer Survivors Study (MACS Study)

Lead Researcher: Earlise Ward*, MS, PhD, LP*

Institution: UW Carbone Cancer Center

Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

Why are researchers doing this study?

Having head and neck cancer (HNC) can be psychologically distressing and traumatic. Researchers report that up to half of HNC survivors will experience depression after cancer treatment. We propose the adaptation of a mental health digital app to treat depression among head and neck cancer patients and survivors.

We invite you to take part in this research study because you have a history of head and neck cancer, and diagnosis of mild depression.

What will I need to do in this study?

The research team will ask you to utilize the mental health digital app to treat depression for 6 weeks.

We expect that you will be in this research study for up to 6 months.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you are:	You may NOT want to be in this study if you:
Comfortable having researchers ask questions about your mental health. Willing to work on your mental health by utilizing a mental health digital app for 6 weeks. Willing to participate in the study for up to six months. Interested in contributing to scientific knowledge even though you may or not benefit directly from the study.	Are nervous about giving information about your mental health. Are nervous about using a mobile app May not have time to complete study questionnaires.

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

If you decide not to take part in the study, you have other choices. For example:

- You may choose to get regular care by contacting your primary care provider for a referral to mental health care.
- If you do not have health insurance, you can contact Access Community Health Centers or Journal Community Mental Health Center to get services. They use sliding scale fees based on income.
- You may choose to take part in a different study if one is available.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When you go to a health provider for care, the provider focuses on how to help you as an individual. When you take part in a study, you are helping to answer a research question. In this study we want to know if the IONA Mind app can reduce levels of depression among patients treated for head and neck cancer. Iona for HNC has not been cleared by the FDA and is an investigational device being

studied in the context of a clinical investigation. It does not replace the care of a medical provider or a patient's medication.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the Lead Researcher, Dr. Earlise Ward at 608-262-7917.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

If I take part in the study, what will I do?

Download the digital mental health app. The digital app contains mental health plans and personalizes activities based on the user responses. It is a mobile app designed to help people manage symptoms of depression. A person will not read what you type in the app. A chatbot will select responses from pre-programmed text, rather than generating new responses.

Respond to the initial evaluation of depression. Utilize the digital mental health app for a 6-week period. We recommend you complete all the lessons within the course at your own pace.

It's best to use the app every day for around 10 minutes. The app will tell you what is up next each time you open it.

Submit information about your mental health once a week for 6 weeks, during app utilization, with the same questionnaire to evaluate depression utilized in the initial evaluation. Respond to a survey about satisfaction with the mental health app 1-2 weeks after completing the app utilization.

Participate in an interview about satisfaction with the mental health app and acceptability of the app 1-2 weeks after completing the app utilization.

Submit information about your mental health 1-month after completion of app utilization.

Submit information about your mental health 3-months after completion of app utilization.

The information will be submitted using a survey link approved by the University of Wisconsin Institutional Review Board. Your responses about your mental health will not be collected or stored in the app. All your responses will be sent to the University of Wisconsin team.

As part of the study, we will collect audio recordings of you during the qualitative interview procedures. A written copy of the recordings will be made for use in the

research and will not be used for purposes outside of the study or in any papers or publications.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

Things you tell the researchers about your mental health
Name, email, phone number, home address for interview scheduling and compensation
Your email will be shared with the app developers team, so they can send you reminders about the app via email
Results of tests or procedures done as part of the study
Information about your cancer diagnosis and treatment. These information may be asked directly to you or collected from your medical records as well as information added to your medical records during the course of this study. This information could include your medical history; your cancer diagnosis, cancer treatment.We will get this information from your health care providers.
Number of times the app was accessed, duration of app utilization per day, and activities utilized within the app

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

If you decide to leave the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Principal Investigator: Earlise Ward, email:

earlise.ward@fammed.wisc.edu, or to the Research Manager: Lucretia Sullivan Wade, email: sullivanwade@wisc.edu.

Will being in this study help me in any way?

Being in this study may improve your mental health, helping you feel better. The study treatment might not work at all, or it might have side effects. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about mental health digital apps to support patients with head and neck cancer.

What are the study risks?

Psychological risks such as emotional reactions to being asked about depression

- There is a risk that your information could become known to someone not involved in this study, which might make you uncomfortable.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience.

IONA Mind©

The IONA Mind© will provide the following study-related items/procedures for you at no cost during participation in the study: mental health digital app account and information brochure.

What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will 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. The study is protected by a Certificate of Confidentiality from the National Institutes of Health. This means that even if the police or courts ask to look at the data we have collected, we will not share any information that would identify you as a participant in the study.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program. This also includes the Department of Health and Human Services and the Food and Drug Administration (FDA).

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once your

health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, with appropriate confidentiality protections, we might use that we collect during this study for other research or share it with other researchers without additional consent from you.

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.

We will share information collected for this study with researchers or organizations outside UW-Madison, including IONA Mind©.

We will share the following data from this study: information about digital app utilization will be received from IONA Mind© such as number of times the app was accessed, duration of app utilization per day, which modules of the app were utilized.

The study doctor and staff will send your personal information to a third-party company and their representatives for the purpose of carrying out reimbursements for this study.

Will information from this study go in my medical record?
A medical record may be created for you if you do not already have one. Your medical record might say that you participated in this study, and a copy of this consent and authorization form might go in your medical record. None of the information we collect for this study will go in your medical record.

Will I receive the results of research tests?

You can choose to receive results of the following tests or procedures: questionnaires about depression. Please indicate your choice below.

☐ Yes, please give me results from the tests/procedures listed above.
☐ No, DO NOT notify me of results from the tests/procedures listed above.

The questionnaires you will complete in this study ask about symptoms of emotional distress and depression. We are using the questionnaires only for research, and to follow-up on mental health issues. If requested, we may tell you the results. If the questionnaires show that you are experiencing suicidal ideations, the Principal Investigator, Earlise Ward, will facilitate immediate referral for appropriate care, and contact a family member or caregiver of your preference. Please inform an emergency contact we may call if needed.

What else do I need to know?

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

If it is an emergency, call 911 right away or go to the emergency room.
For non-emergency medical problems, contact the study team for instructions.
Call the Lead Researcher, Earlise Ward, at 608-265-1700 (24 hours) to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
Your health insurance company may or may not pay for this care.
No other compensation (such as lost wages or damages) is usually available.
UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

Will I receive anything for participating?

A subject stipend of $25 following the initial data collection, $25 at the end of the 6-week period of mental health app utilization and data collection, and $50 if selected for a final interview for your time and effort. This stipend will be included to help offset time/cost expenses for this study (research study visits to the UWHC) and will be provided up to and not to exceed $4,999 in 12 months. This stipend is considered taxable income. If payment to an individual exceeds more than $600 in one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) on a 1099 (Miscellaneous Income) form. You will be sent a 1099 MISC tax form from the University of Wisconsin-Madison and a copy will be sent to the IRS. Study staff will discuss this with you before your participation in the trial will begin, including the amount available during your time in this study. .

The University of Wisconsin uses a third-party vendor to provide these stipends. You will be provided instructional handouts regarding the use of this system.

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Permission to communicate about the study by email

We are requesting your email address so we can provide compensation and schedule a final interview. The app developers would like to have your email to send reminders about app utilization. Email is generally not a secure way to communicate about your

health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the Principal Investigator, Dr. Earlise Ward, email: earlise.ward@fammed.wisc.edu, phone number: 608-622-1530 , or the Research Manager Lucretia Sullivan Wade, email: sullivanwade@wisc.edu, phone number: (608)217-5172.

How many people will be in this study?
We expect about 30 people will be in this research study.

Who is funding this study?
This research is being funded by the UW Carbone Cancer Center Head and Neck SPORE Grant, which is a National Cancer Institute (NCI) grant.

Will my data be used for future research?
This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your data indefinitely. To get your data, future researchers must seek approval from this institution and review by an IRB may be required.

We will protect the confidentiality of your information to the extent possible. Your data will be coded to protect your identity before it is shared with other researchers. Only the study team will have a code key that can be used to link to your identifying information. The code key will be securely stored.

We will do our best to protect your data during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your data. In either case, we cannot reduce the risk to zero.

Because data from this research study can be useful for many different kinds of research, organizations like the National Institutes of Health (NIH) have created large databases that collect data from research studies. We will put data from this study in a federal database or in other public scientific resources to make the information broadly available. We cannot predict how this information will be used in the future. Because it can be used for many kinds of research, your information may be used for research that you disagree with or would not choose to be involved in.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Signature of Participant Date

Printed Name of Participant

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent