Mobile Apps to Reduce Distress in Breast Cancer Survivors using an Adaptive Design

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Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is being funded by the NIH.

Key Information About This Research Study

Cancer can impact all aspects of life. While the primary focus of treatment is on eliminating or containing the cancer, the psychological toll can sometimes go unnoticed for breast cancer survivors. Researchers and clinicians do not have a lot of information about how we can provide psychological support through mobile technology.

The purpose of this study is to gather information about how people use and respond to supportive smartphone apps. Our research team tested a suite of smartphone apps called IntelliCare among breast cancer survivors. In a limited sample size, IntelliCare was successful in decreasing mood symptoms among women with breast cancer. The National Cancer Institute (of the NIH) is providing funding to test the impact of IntelliCare in a larger sample of breast cancer survivors. The purpose of the study is to see if IntelliCare will bring improvements in mood to breast cancer survivors compared to a patient education smartphone app.

You are being asked to be in this study because you received news of a breast cancer diagnosis within the last 5 years. You might like to take part in this study because your mood may improve from using either the IntelliCare apps or the patient education app. Your participation in this study will benefit future breast cancer survivors by finding accessible and cost effective ways of providing supportive care.

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers

or others before you make a decision. Taking part of this study is not expected to interfere, nor should it replace, any usual care you are receiving.
Up to 313 people will be in this study.

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Sponsor:	NIH

What will happen if you are in the study?

STUDY PROCEDURES

This entire study from this moment to the final thing you do will last slightly more than one year (63 weeks).

Study Schedule

Step	Weeks	Study Phase	What will I do?	Time required?
1	0	Screening	Complete Online Interest Form Review/Sign Consent Form Phone Interview	60 minutes
2	2	Pre-Assessment	Complete Questionnaire	60 minutes
3	3-11	Intervention	Use assigned apps	
4	11	Post- Assessment 8 weeks	Complete Questionnaire Phone Interview	60 minutes 30 minutes
5	37	Post-Assessment 6 months	Complete Questionnaire	60 minutes
6	63	Post- Assessment 1 year	Complete Questionnaire	60 minutes

You will be asked to complete an Online Interest Form. You will answer questions about your mood, cancer history, and willingness to do the study requirements. You will also provide contact information. Submitting the Interest Form does not guarantee that you will be able to participate in the study. It will allow us to save this data and contact you soon to determine if you may be eligible for the study.

If you appear to be eligible for the study, the Study Coordinator will contact you to set up a phone interview. Additional details about the study will be provided during the call. This will typically occur within 48 hours of receipt of the online interest form but may take up to 7 days.

SCREENING (PHONE INTERVIEW)

- The Study Coordinator will call you at your appointment time.
- We will ask you to identify yourself. We will review the study's requirements, which include receiving a breast cancer diagnosis in the past 5 years and current mood symptoms. You can discuss any questions or concerns you may have about participating in the study.
- If you agree to participate, you will do the following:
    - We will email you a unique website address to access the online consent form.
    - We will walk through this consent form with you to make sure you are fully informed about the study.
    - If you would like additional time to review this consent form before agreeing to participate, we can set up a time to call back to continue the screening phone interview.
    - If you agree to participate in this study, you will check the box at the bottom of the electronic version of this form and digitally sign your name to consent to the study. Click submit.
    - The program will allow you to download a copy of the consent form. We will store the document in our database as well.
- Next, we may ask you some additional questions about your cancer history, general health, and health history. You will also be asked questions about whether you feel suicidal. In cases of suicide risk, a clinical psychologist on the team may follow-up with you to ask some more questions.
- If you are eligible for the study, you will be sent a Welcome email with directions for downloading your assigned smartphone app on your phone.
- If you are not eligible for the study, you will be told at that time.

PRE-ASSESSMENT

- **Questionnaire:** You will complete an online Questionnaire asking about your general health, mental health, health habits, and daily life activities.
    - If you have any concerns about the questions, please contact the Study Coordinator (email: arcstrial@virginia.edu, or call toll-free: 833-762-0853).
    - You may receive reminder emails from our study team to complete the Questionnaire.

- After you complete it, you will advance to the Intervention study phase. For the next nine (8) weeks, you will use your assigned study app(s). You can start immediately.

INTERVENTION (8 weeks):

You will be randomly assigned (like the flip of a coin) to 1 of 2 study groups. You have an equal chance of being assigned to either group. Neither you nor the researchers can choose, or change, your group.

GROUP 1 - Patient Education App Group:

You will download and use an app with information about distress management. This includes mood related distress symptoms, causes, and factors that impact distress and management strategies. Some of the material is like the other group but presented in a different way. You may launch and use the app as often as you want. There are no specific time requirements.

GROUP 2 – IntelliCare App Group:

You will use a smartphone app program designed to improve your mood through brief and interactive exercises. It is made up of a suite of 6 apps. Each app focuses on one skill related to mood or distress management. The exercises contained in each app can be completed in a matter of minutes. The exercises contain step-by-step instructions to help change behaviors and thoughts that can contribute to mood symptoms. You may receive automated prompts from the apps encouraging you to engage with them. Each week, you will download and use 1 of the IntelliCare apps until you have tried all of them. You are encouraged to continue using the apps that you find helpful and to discard the ones that are not. We expect it may take you up to one week to benefit from each app.

If you are assigned the IntelliCare apps, after 1 week you may be randomly assigned (like the flip of a coin) to 1 of 2 additional groups.

GROUP 2a – IntelliCare App with added phone coaching group. In addition to using the IntelliCare apps, you will receive support using and benefitting from the apps from a member of our study team. This person will serve as your "coach." Please note that your coach is not a trained counselor and will not be doing therapy with you. The role of your coach is to help guide and support you through the IntelliCare program. You and your coach will have an initial 30-minute phone call as well as a brief check-in phone call 3 weeks later. You and your coach may also communicate during the trial through secure text messages. If you are assigned to receive added phone coaching, your coach will contact you after 1 week through a call or text message to set up the initial coaching call.

GROUP 2b – IntelliCare App without added phone coaching group. You will continue to use the apps without additional coaching.

FOLLOW UP

Post-Assessments at the end of 8-Weeks, 6-Months and 1 Year:

- **Questionnaire:** At the end of the 8-week intervention, you will complete the Post-Assessment Questionnaire online. You will answer questions about your health, activities, and well-being. You may receive reminder emails to complete the Post-Assessment.
- **Phone Interview:** Those in the IntelliCare App Intervention Group will complete a 30-minute phone interview at the end of the 8-week intervention. You will be asked to provide feedback about the apps and coaching, to determine if tailoring the apps to breast cancer survivors is needed, and if so, how.
- Questionnaires will be completed again at the 6 month and 1 year Post-Assessments. You may receive reminder emails to complete the post-assessments.
- You can continue using your assigned app(s) between each Post-Assessment and up to the end of the study. If you received phone coaching during the Intervention period, you will no longer continue to do so after the end of the 8-weeks.

How long will this study take?

The total time to complete all phases of this study is not expected to exceed 6 hours. Your participation in this study will require the completion of a screening, 4 questionnaire batteries, and using your assigned app(s) at your convenience. Using the app(s) is not included in the time estimates, and the amount of time you spend during the study may vary depending on how much you use the app(s). All components of this study will be completed remotely, by Internet or phone.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to completing the questionnaires and using the apps include:

Breaches of privacy and/or confidentiality

- The risk of a violation of privacy and confidentiality is rare. This means someone outside of the study team may see your private health information. The study team will take precautions to treat your information as highly sensitive.

Emotional discomfort due to:

- **Internet concerns**

Some adults may not have concerns doing online activities (going to a website, giving information, etc.). Others may feel less comfortable doing this. Some may have concerns about the confidentiality of their digital data.

- **Answering questions of a personal nature**
  Questions of a sensitive and personal nature will be asked during the study during the phone screen. These include questions about medical history, depression, substance use. This may cause some likely emotional discomfort for some. If the study is concerned, you may be referred to someone for counseling.

Risks from Completing Questionnaires

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and to the next question.

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. You may benefit from using your assigned smartphone app(s). In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would be determined by your physician. The smart phone group of apps used in this study are publicly available.

Will you be paid for being in this study?

You will be paid up to $200 in gift cards for finishing this study. The gift cards will be sent about a week after you complete each Post-Assessment. If you do not finish the study, you will be paid based on your completion of the following:

- $50 gift card after the 8-week Post-Assessment
- $50 gift card after the Post-Assessment at 6 months
- $100 gift card after the Post-Assessment at 1 year

All payments will be sent via email. If you decide not to finish this study, you will be paid based on the visits that you complete as noted above. However, if the study leader decides you should not continue, but you met full criteria and completed the necessary steps in the timeline presented, you will be paid the full amount for the study.

Will being in this study cost you any money?

Being in this study will not cost you any money. The surveys and apps are being used for research purposes, and will be provided at no cost to you or your health insurance. Standard text messaging and data usage rates apply and you will not be compensated if you go over your plan's limit.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia or at your local health care provider.

Even if you do not change your mind, the study leader can take you out of the study. You will be notified if this occurs.

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research

- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside or outside of the University of Virginia. They will not be sent with information that could identify you such as name, address or phone number.

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.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVA will not use it in the following cases.

- You have agreed in writing to allow UVa to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

Would you like the study team to communicate with you by email or text message?

If you choose to communicate with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy but we want to tell you about this possible risk.

You do not have to agree to communicate with the study team by email or text message to be in this study. If you agree to texting or emailing, the study team will collect your phone and /or email address from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

Please contact the Principal Investigator listed earlier in this form to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Philip Chow, Ph.D.
Department of Psychiatry and Neurobehavioral Sciences
P.O. Box 400400, Charlottesville, VA 22904-0400
Telephone: 434-924-5401

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483, Charlottesville, Virginia 22908, Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE