



Consent to Participate in a Research Study
Cancer Distress Coach RCT

INTRODUCTION

You are being asked to take part in this research study because you have received a cancer diagnosis or care for someone with cancer. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to take part in this research study, you will be emailed a copy of this signed and dated consent form to the address associated with the mobile device account used to enroll in the study. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time.

You should not participate in the research study until all of your questions are answered. We encourage you to read the Privacy Policy as well as the informed consent.

Dr. Sophia Smith will conduct the study and it is funded by the Duke Institute for Health Innovation.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test new methods for managing symptoms of posttraumatic stress disorder (PTSD). Research has shown that some cancer patients and their caregivers experience symptoms of PTSD for many months and even years after the diagnosis and treatment. The study team has worked with the National Center for PTSD to develop the Cancer Distress Coach (CDC) app that can be downloaded and used on mobile devices such as smartphones or tablets.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We anticipate enrolling 1000 subjects in this study.

WHAT IS INVOLVED IN THE STUDY?

If you decide to join the study you will need to register an account and confirm your agreement to participate in this study. Then, periodically we will ask you to answer questions and/or perform activities on your mobile device. Your study data will include your responses to surveys and activities. Anonymous usage statistics will be collected.

There will be an electronic consent process explaining the risks and benefits of using the app. You can cancel the registration process at any time. After registering, you will be asked to provide information every 4 weeks for 8 weeks that we will use to determine if the app is useful for helping manage symptoms of cancer-related PTSD. A signed copy of your consent document will be sent to the email address you used to register for the study. This is not an encrypted email.

Randomization: After you have read and electronically signed the consent form and registration, you will be randomized, like flipping a coin, to one of two groups. If you are randomized to the first group, you will be asked to perform activities such as learning about PTSD, recording your daily stress level, and using tools such as guided imageries, meditations, and relaxation exercises. If you are randomized to the second group, you will be asked to perform all of these activities after 4 weeks when the full app becomes available.

Cancer Distress Coach: This app can be used as an education and symptom management tool or to improve face-to-face care with a healthcare professional. The learn activities provide education about



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how you may feel, with information from cancer-related resources. The insights activities will provide feedback on the assessments and present inspirational quotes. The main intervention activities will provide you with ways to manage your stress in the moment that you are experiencing it (e.g., guided imageries, relaxation exercises). In the find support activities, you can set up a support network and find informal support or (immediate) professional care.

Questionnaire assessments: You will be asked to provide some basic demographic information about yourself. This will include your age, gender, race and ethnicity, and email address. You will also be asked to answer some questions about your overall distress and symptoms using the PTSD Checklist instrument, skills, and experience in using the app. When you complete the PTSD Checklist you will receive feedback with your risk level (low, moderate, or high). This information is not a diagnosis, and should be conveyed to your healthcare provider if you have any concerns. We cannot diagnose PTSD using this app.

Feedback assessments: You will be asked to provide feedback about the app and the study.

We may send notices (called “push notifications”) to your device asking you to complete these activities. You may choose to act at your convenience, (either then or later) and you may choose to participate in all or only in some parts of the study. These surveys and activities should take you about 5-10 minutes to complete. You can adjust the app settings to turn on and off sending notifications at any time.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will last two months. You will be asked to complete all the activities initially after you download the app and provide consent. You will be asked to repeat the questions on symptoms 4 weeks from when you enroll and again 4 weeks later. We hope that you will complete all of the questionnaires from when you first enroll. You will be notified when you have a task to complete. You are free to continue to use the app for as long as it remains on your device; and, we will not be storing your data after the two month study period.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks to you associated with this proposed study.

One possible risk of this study is the discomfort that some people feel when answering questions about personal or emotional subjects. Some of the questions we will ask you as a part of this study may make you feel uncomfortable. You may refuse to answer almost any of the questions, and you may take a break at any time during the study. You may stop being in this study at any time.

There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed. There is a risk that study data might be subpoenaed for legal purposes

All Duke ResearchKit and ResearchStack mobile applications or ‘apps’ have a Privacy Policy which you should read carefully. Neither Apple nor Google has access to any data collected by ResearchKit and ResearchStack apps. Any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. As you use the app, it will ask you for specific permissions, which you choose whether to allow. These permissions can be revoked by you at any time. You are encouraged to limit personal identifiers you enter into mobile applications (particularly date of birth, address, place of employment, and other details that could allow someone to identify you)



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only to those that you wish to voluntarily share with others. Data from the study will be stored at Duke but may also be stored, at least temporarily, on your device.

Email is not a secure mode of communication. If you are uncomfortable receiving emails for this study then you should discuss this concern with the study team, as it may not be the right study for you.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (such as battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, you may remove the mobile app from your device.

We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

In this study, we are studying what effects this mobile app has on its users. As such, while we cannot state that using Cancer Distress Coach will or will not benefit you, we hope that the information you contribute will benefit others in the future.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

Since no medical treatments are provided during this study there are no alternative therapies. The only alternative is to not participate.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. This information will be stored in a password-protected network computer location on a server at Duke, and access to the information will be restricted to the research personnel.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Office for Human Research Protections, the Duke University Health System Institutional Review Board, the Duke Cancer Institute, and/or the Duke Office of Audit, Risk and Compliance.

The study results will be retained in your research record for six years after the study is completed. At that time, the information identifying you will be removed from such study results at DUHS.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

WHAT ARE THE COSTS?

There will be no cost to you or your insurance for taking part in the study. If you do not have an unlimited data/text plan, you may incur additional charges if you exceed your plan.



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WHAT ABOUT COMPENSATION?

You will not be compensated for being in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?

Study-related injuries are not expected since this study only involves mobile technology usage. However, if needed, immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. There is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

If you decide to withdraw, we ask that you click on the "leave study" option within the app.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You may contact the principal investigator, Dr. Sophia Smith. Following is her contact information.

Dr. Sophia Smith

Associate Professor, Duke School of Nursing
307 Trent Dr., DUMC 3322
Durham, NC 27710

(919) 684-9628 *This phone number (with voicemail) is monitored 24 hours a day, 7 days a week, including holidays.

sophia.smith@duke.edu

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

"By agreeing you confirm that you read the information and that you wish to take part in this research study."

CANCEL

AGREE