**Official Title:** Using a SMART Design to Optimize PTSD Symptom Management Strategies Among Cancer Survivors

**NCT:** NCT04058795

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DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
**ADULT**
***Using a SMART Design to Optimize PTSD Symptom Management Strategies among Cancer Survivors***

Many cancer patients who received a stem cell transplant express symptoms of trauma and stress. The purpose of this study is to investigate if mobile app therapy reduces these traumatic stress symptoms and improves quality of life. Information from this study may help develop target treatments for traumatic stress symptoms in survivors of stem cell transplant.

You may receive either a mobile app or usual care therapy to begin the study. After 4 weeks, you may receive cognitive behavior therapy or coaching during the remaining 8 weeks. During the study, you will be asked to complete questionnaires 4 times over a period of 6 months, at the time your participation is complete.

There are no physical risks to you associated with this study. One possible risk of this study is the discomfort that some people feel when answering questions about personal or emotional subjects.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have received a stem cell transplant. 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.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Smith's and her research team's salaries will be paid by this grant.

**WHO WILL BE MY DOCTOR ON THIS STUDY?**
If you decide to participate, Dr. Sophia Smith will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

**WHY IS THIS STUDY BEING DONE?**
The purpose of this study is to test new methods for managing symptoms of cancer-related posttraumatic stress disorder (PTSD). Research has shown that some patients who received a stem cell transplant 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 (CaDC)* mobile app that can be downloaded and used on mobile devices, such as smartphones or tablets.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**
Approximately 600 cancer survivors and 75 caregivers will take part in this study – from Memorial Sloan-Kettering Cancer Center in New York, NY, from Fred Hutchinson Cancer Center in Seattle, WA, Duke University Medical Center in Durham, NC, and from national recruitment.

**WHAT IS INVOLVED IN THE STUDY?**
If you agree to be in this study, you will be asked to sign and date this consent form. If you have not already done so, you will be asked to complete two questionnaires to make sure you are eligible.

If eligible and you decide to join the study, you may be asked to download a mobile app and register an account. If you need help, a study team member will provide a tutorial of the process. The registration process will explain the risks and benefits of using the app. You can cancel the registration process at any time. After registering, you will be asked to answer questionnaires at 4 weeks. We will use your answers to determine if the activities are useful for helping you manage symptoms of cancer-related PTSD.

First randomization: After you have read and electronically signed the consent form, you will be randomly assigned, like flipping a coin, to one of two groups – Mobile app or Usual care. If you are assigned to the Mobile app 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 assigned to the Usual care group, no actions are required.

Second randomization: After 4 weeks, you will complete a PTSD questionnaire / assessment. From there, you will be instructed either to continue in your assigned group OR be randomized again to one of two groups – Mobile coaching or Cognitive behavior therapy (CBT). If you are randomized to the Mobile coaching 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 with the support of a coach. If you are randomized to the CBT group, you will be asked to participate in weekly cognitive behavioral therapy sessions with a licensed therapist. Conversations will occur by phone and may be recorded.

Cancer Distress Coach: This mobile app can be used as an education and symptom management tool or to improve face-to-face care with a healthcare professional. Within the mobile app, multiple modules help facilitate your use. The Learn module provides education about how you may feel, with information from cancer-related resources. The Track Progress module provides you feedback on the assessments. The Manage Symptoms module provides you with ways to manage your stress in the moment that you are experiencing it (e.g., guided imageries, relaxation exercises). The Get Support

module provides you a way to 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, 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 mobile 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 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 push notifications at any time.

**HOW LONG WILL I BE IN THIS STUDY?**
Your participation in the study will last 6 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 at Week 12 and Month 6. 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.

**WHAT ARE THE RISKS OF THE STUDY?**
There are no physical risks to you associated with this 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

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) 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 and/or cognitive behavioral therapy 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.

**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. For patients of Fred Hutchinson Cancer Center, trained research personnel at Fred Hutchinson Cancer Center may review your medical records if necessary. For patients who reside in New York (NY), New Jersey (NJ), or Washington state (WA), due to interventionist resources at Memorial Sloan Kettering (MSK), your personal information may be shared with the MSK study team in conjunction with administering a study intervention. All necessary precautions will be taken with regard to your privacy to insure your personal information remains safe.

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 DUHS Institutional Review Board, the Duke Cancer Institute, and/or the Duke Office of Audit, Risk and Compliance.

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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.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project – the NIH.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law

designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

**WHAT ARE THE COSTS TO YOU?**
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.

**WHAT ABOUT COMPENSATION?**
You will receive $25 after completing the Week 4 survey, $25 after completing the Week 12 survey, and $25 after completing the 6 month survey.

**WHAT ABOUT RESEARCH RELATED INJURIES?**
Study-related injuries are not expected since this study only involves mobile technology usage. 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. However, 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.

For questions about the study or research-related injury, contact Dr. Smith at 919-684-9628 during regular business hours, after hours, and on weekends and holidays.

**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.

You may choose to stop participating at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Smith in writing and let her know that you are withdrawing from the study. Her mailing address is DUMC 3322, Durham, NC 27710. You will be asked to cite a reason for your withdrawal.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

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The use of your data and samples will not result in commercial profit.

A description of this clinical trial will be available on https://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. This study is NCT04058795.

**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, Duke School of Nursing 307 Trent Dr., DUMC 3322, Durham, NC 27710. Her phone number is (919) 684-9628. This phone number (with voicemail) is monitored 24 hours a day, 7 days a week, including holidays. Her email is Sophia.smith@duke.edu. Please be aware that use of email may result in a potential loss of confidentiality because email is not a secure means of communication.

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.”

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CANCEL AGREE

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