Official Title: Using MOST to EMPOWER: Optimizing an emotion regulation intervention to enhance well-being among adolescents and young adult cancer survivors
NCT04317417
IRB Approval Date: 05/10/2024

Wake Forest School of Medicine

Division of Public Health Sciences/Section on Social Sciences and Health Policy

# MOST EMPOWER: OPTIMIZING AN EMOTION REGULATION INTERVENTION TO ENHANCE WELL-BEING AMONG ADOLESCENTS AND YOUNG ADULT CANCER SURVIVORS

Informed Consent Form to Participate in Research

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## INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are an adolescent or young adult cancer survivor between the ages of 15-39 and have completed treatment for cancer within the past five years. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent that you do not understand. You may also discuss the study with your friends and family.

## WHY IS THIS STUDY BEING DONE?

This purpose of this study is to test a digital health intervention that may promote well-being among adolescents and young adult cancer survivors. We hope to learn more about wellness and health-related quality of life among young adult cancer survivors by promoting well-being and teaching skills for healthy coping and mood management.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We expect that 352 adolescents or young adult cancer survivors will be enrolled in this study. Approximately 90 participants will be recruited from the Wake Forest Baptist Comprehensive Cancer Center, 90 participants will be recruited from the Levine Cancer Institute and Levine Children's Hospital, 90 participants will be recruited from the Robert H. Lurie Comprehensive Cancer Center of Northwestern University, 90 participants will be recruited from MD Anderson Comprehensive Cancer Center, and the remaining participants will be recruited from the community partners and through social media.

**WHAT IS INVOLVED IN THE STUDY?**

If you choose to take part in this study, you will be asked to complete an initial online questionnaire lasting about 20 minutes. Once you have completed the questionnaire, you will be given access to the EMPOWER study intervention. As part of the intervention, you will be asked to go online daily to the study website. You will receive self-paced online instruction and practice in skills that may promote well-being. This intervention will last 5 weeks, with 8 skills-based sessions. Each session includes a presentation of instructional material and brief, real-life skills practice. During the intervention, subjects will also complete a brief questionnaire at the end of each week. The brief questionnaires will take 3-5 minutes to complete. At the beginning of each week, you will read materials online about one or two new skills. Then for the remainder of the week, you will practice these skills and record your participation online. The sessions will take about 10 minutes a day and focus on promoting well-being and teaching skills for healthy coping and mood management. We realize that you might have some normal interruptions in your life or some unexpected delays, so you have 8 weeks to complete the intervention lessons. The intervention will also have a topical "discussion board" focused on individual intervention skills. You will be able to share only content that you want to share. In addition, the discussion boards are private (open to the study team and research participants only), monitored by the study team, and participants will use the EMPOWER PID with avatar only for additional privacy.

Participants who utilize the "Discussion" Feature during the EMPOWER Study will have the option to participate in a phone interview after the intervention. This phone interview will provide the study team with valuable information on how to improve the intervention for future use. The phone interview is optional. You will not receive additional compensation for participating in the phone interview.

Once you have completed the intervention, you will be asked to complete three online follow-up questionnaires. The questionnaires will be emailed to you at the following time points: immediately following completion of the EMPOWER intervention, 2 months after intervention completion and 4 months after intervention completion. Each questionnaire can be completed online and should take no more than 20 minutes.

**HOW LONG WILL I BE IN THE STUDY?**

You will be in the study for about 6 months. You can stop participating at any time. If you decide to stop participating in the study, please talk to the investigators or study staff first.

**WHAT ARE THE RISKS OF THE STUDY?**

As part of this study, you are being asked to complete questionnaires. You may feel that the questions are personal or remind you of difficult times. If any questions are upsetting to you, you may refuse to answer them. In rare cases, when participants experience elevated levels of stress, a member of our study team will reach out to you to provide support.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Use of text messaging is not a secure form of communication. If you choose to receive text messages, text messages will be sent to the phone number that you provide to the study team. Message rates differ from carrier to carrier, so please contact your wireless phone provider to inquire about the details of your plan. To discontinue receiving text messages, please contact the study team either by phone or in person.

Please note that depending on the settings used on your mobile device or computer, messages received through text messaging or apps may appear on your mobile phone or computing device as soon as they are received, even when the phone or device is locked. These messages could therefore be seen and read by others who are near your phone or device when the messages are received.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

If you agree to take part in this study, there may or may not be direct benefit to you. The EMPOWER intervention may help you learn to manage your well-being and improve your quality of life. We hope the information learned from this study will benefit others in the future.

**WHAT OTHER CHOICES ARE THERE?**

This is not a treatment study. You do not have to participate in this study.

**WHAT ARE THE COSTS?**

There are no costs to you because of participating in this study. Costs associated with accessing the internet or text messaging as a preferred method of contact are your own responsibility. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

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**WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?**

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, including the sponsor of the study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

**WILL YOU BE PAID FOR PARTICIPATING?**

You will receive up to $25 for completing the five brief questionnaires ($5 for each of the five surveys) and $25 for completing each of the four longer questionnaires for a maximum of $125. You will be paid after you complete each study assessment by an electronic gift card.

**WHO IS SPONSORING THIS STUDY?**

This study is being sponsored by the National Cancer Institute which is part of the National Institutes of Health. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

**WHAT ABOUT MY HEALTH INFORMATION?**

In this research study, any new information we collect from you about your health or behaviors

is considered Protected Health Information. The information we will collect for this research study includes: your name, telephone number, email address and information about your cancer diagnosis.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password-protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries and the National Cancer Institute.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's research record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be

deidentified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are finished.

You can tell Dr. John Salsman that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

**Dr. John Salsman**
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

## WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because you fail to follow the study procedures or because the study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

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**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. John Salsman at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

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You may print a copy of this online informed consent form for your records or contact us and we will mail you a copy.

**Please Choose One**:

☐I accept the consent and wish to participate in this study

☐If you accept, please enter Name_____

Email_____

☐I decline the consent and do not wish to participate in this study.

**Reason for refusal**

☐I do not have time to participate

☐I am concerned about privacy

☐I am ill or have health concerns that may interfere with my ability to participate

☐I do not want to be reminded of having cancer

☐I have another reason, please describe:_____