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

Welcome to the EMPOWER study of positive emotion skills for young adult cancer survivors! On this page is some important information about participating in the study. Please read through it and, if you decide you would like to participate, you can start the initial questionnaires right away. If you have questions about this consent form, please contact Dr. John Salsman, the study investigator or Denisha Little-Greene, study Project Manager.

INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH

TITLE

ENHANCING MANAGEMENT OF PATIENT REPORTED OUTCOMES WITH EMOTION REGULATION (EMPOWER)

INVESTIGATOR

John Salsman, Ph.D., Principal Investigator

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 were diagnosed with cancer between the ages of 15-39, are currently between the ages of 18-39 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 document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to test the feasibility or workability of a new program designed to help young adults with cancer to manage their mood better. We hope to learn more about what effects mood may have on the health and well-being of young adults with cancer by developing an online intervention that teaches healthy coping skills in a practical and acceptable way.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We expect that 60 people will be enrolled in this study. 40 people will be recruited from the Comprehensive Cancer Center of Wake Forest University. 20 people will be recruited from the Robert H. Lurie Comprehensive Cancer Center of Northwestern University.

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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 25-30 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 to receive self-paced instruction and practice in learning new mood regulation and coping skills. There are 8 lessons that can be completed over the course of 5 weeks. 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 20-30 minutes a day and focus on teaching you skills to deal with stress and better manage your mood. 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.

After the intervention, you will be asked to complete an audio-recorded phone interview lasting about 30 minutes. This is being done so that the study researchers can learn how you felt about doing the study. You understand that you may request the recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the audiotape before it is used. You should also understand that you will not be able to inspect, review, or approve the audiotape before it is used in this study. The audiotapes will be destroyed once their use in this study is finished.

Once you have completed the intervention, you will be asked to complete two online follow-up questionnaires. The first will be 1 week after you finish. The next will be 1 month later. Each questionnaire can be completed online and should take no more than 30 minutes.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 3 months. You can stop participating at any time. If you decide to stop participating in the study we ask that you to 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 three questionnaires, an online intervention, and a phone interview. You may feel that the questions are very personal or remind you of difficult times. If any questions are upsetting to you, you may refuse to answer them. If the questions make you very upset, we will help you to find a counselor.

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.

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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. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

Costs associated with accessing the internet are your own responsibility. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

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.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $15 for each completed questionnaire for a maximum of $45. You will be paid in full upon completion of the study 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 ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

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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.

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.

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.

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

Choose one:

- ☐ I accept the consent and wish to participate in this study
- ◉ I decline the consent and do not wish to participate in this study

Your signature documents your permission to take part in this research. Please enter your full name to continue.

(box provided for participant to enter name if they accept the consent and wish to participate)

If participant declines consent: the following will appear on the screen: *Optional:*
Reason for refusal

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- ☐ 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)

WFU School of Medicine Institutional Review Board
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