Official Title: Cancer within a Pandemic: A Telehealth Intervention Designed to Augment Psychological Resilience amidst Dual Health Threats

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Wake Forest®
School of Medicine

Comprehensive Cancer Center-Department of
Hematology/Oncology

INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH
WFBCCC #01520

TITLE : CANCER SURVIVORS EXPERIENCE WITHIN A PANDEMIC

INVESTIGATOR
Katie Duckworth, Ph.D., Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to test an online support group designed to help young adults who have had cancer treatment to manage their mood during a pandemic. You are being asked to take part in this study because you are a young adult cancer survivor between the ages of 18-39 and have undergone treatment for cancer. Your participation in this research will be for about 2 months

Participation in this study will involve answering questionnaires. All research studies involve some risks. A risk to this study that you should be aware of is that you may feel uncomfortable answering the questionnaires. You may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include not participating in this study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Katie Duckworth, Ph.D. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

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 a young adult cancer survivor between the ages of 18-39 and have undergone treatment for cancer. 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 an online support group designed to help young adults who have had cancer treatment to manage their mood during a pandemic. We hope to learn more about what effects a support group may have upon the health and well-being of young adults who have undergone cancer treatment by offering an online support group that teaches healthy coping skills in a practical and acceptable way. We would also like to know if certain parts of the online material is more effective in helping subjects manage their mood.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We expect that 15 people will be enrolled in this study at Wake Forest University Baptist.

WHAT IS INVOLVED IN THE STUDY?

If you choose to take part in this study, you will be asked to complete some initial online questionnaires lasting about 25-30 minutes. After that you will attend weekly support group meetings online. The meetings will happen at the same time each week.

Participants will attend one weekly intervention session of one hour in length over eight consecutive weeks. Sessions will be held via WFBMC's HIPPA-compliant WebEx platform. Participants must have access to the Internet. Participants must provide their own device such as a computer, laptop, or smartphone that allows for video and microphone use. Participants must use headphones with a microphone during the weekly sessions. If they do not have headphones, the research team will send them some in advance of the start of the group.

After 4 weeks, you will be asked to complete seven online follow-up questionnaires, these questionnaires should take no more than 30 minutes. You will be asked to complete these questionnaires again at the end of the study. If you do not have headphones for your computer, the study team will provide these for you. Additionally, the study team will request the best phone contact number and address for you and a family member or friend who can serve as an emergency contact.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 2 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 questionnaires, 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.

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.

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 educational material may help you learn to manage your mood. 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. 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 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?

Study participants will receive a $50 gift card via mail within the first week of the study.

Who is Sponsoring this Study?

This study is being sponsored by Wake Forest Health Sciences. 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, address, dates related to you (like your birthdate, admission dates, and discharge dates), telephone numbers, email address, medical record number (MRN), 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.

You can tell Dr. Duckworth 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. Katie Duckworth
[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.

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.

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. Katie Duckworth 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].

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

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00070150
Meeting Date Approved 1/20/2021
Version Valid Until: 1/19/2022

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

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