Pilot Study to Develop a Group-Based E-Health Intervention for Young Adult Cancer Survivors

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CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

AIM 2

Study Title:	**Pilot Study to Develop a Group-Based eHealth Intervention for Young Adult Cancer Survivors**
Sponsor:	**Moffitt Cancer Center**
Principal Investigator:	**Laura Oswald, PhD**
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WHY AM I BEING ASKED TO PARTICIPATE IN THIS RESEARCH STUDY?

We are asking you to participate in this study because you are currently between the ages of 18-39 years old, you were diagnosed with a non-metastatic cancer when you were between the ages of 18-39 years old, and you completed cancer treatment within the past 5 years.

WHAT IS THIS STUDY ABOUT?

The purpose of this study is to develop and test an online group therapy program that was designed for young adult cancer survivors.

WHAT WILL HAPPEN DURING THIS STUDY?

A member of the study staff will explain this study to you and answer any questions you might have. If you are eligible and choose to participate, you will be asked to participate in a group therapy program that was designed for young adult cancer survivors. The program includes 10 weekly sessions that are each 2 hours long. The sessions will be held over videoconference (Zoom), so you do not have to come to the cancer center to participate. The sessions will take place on the same day and time each week, and we will work with you to schedule them. In each session, you will meet with the same group of young adult cancer survivors and a group facilitator to work through the program content together. Some of the topics covered in the program are stress management skills, relaxation strategies, and health topics that were identified by other young adult cancer survivors as important to them (for example: how cancer can impact physical and social changes, school/work, self-esteem, and dating/family relations).

You will also be asked to complete short homework assignments after each group therapy session that were designed to help you practice the skills discussed each week. Finally, you will be asked to complete some surveys online. There is a set of surveys before the first group session (about 30 minutes to complete), a brief weekly survey after each of the 10 group

sessions (about 5 minutes to complete), and another set of surveys after the last group session (about 30 minutes to complete). We will email you links to access each of these surveys.

In total, we expect that you will spend about 2.5 hours per week on this study (2 hours in the group session, 30 minutes completing the weekly homework assignment and survey).

We will record the weekly group sessions to make sure the group is being offered with the highest quality and all regulations are being followed. Recording is a required part of this study. We will also review your medical record to collect clinical information (for example: date of cancer diagnosis, stage of disease, previous treatments).

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?
In total, we expect up to 24 people will participate in all parts of this research study. In this part of the study, we expect up to 10 people will be in the 10-week group therapy program.

WHAT HAPPENS IF I DO NOT WANT TO BE IN THIS RESEARCH STUDY?
Your participation in this study is completely voluntary. If you decide not to participate in this study, there will be no penalty or loss of benefits to you.

ALTERNATIVES TO PARTICIPATION
This study is for research purposes only. The only alternative is to not participate in this study.

WHAT HAPPENS IF I SAY "YES" BUT I CHANGE BY MIND LATER?
You can change your mind about being in the study at any time, and there will be no penalty or loss of benefits to you. However, please note that any information collected up to the point of your withdrawal may not be able to be removed from the study.

The Investigator or the sponsor can stop your participation at any time without your consent.

WILL BEING IN THIS STUDY HELP ME?
You are not guaranteed to benefit from being in this study. However, it is possible that you could feel better understood, validated, or supported after talking with other young adults about your experiences with cancer. In addition, this research could benefit other young adult cancer survivors in the future. This study will help researchers and clinicians understand how to help young adult cancer survivors manage stress and have better quality of life.

ARE THERE RISKS TO ME IF I AM IN THIS STUDY?
It is possible that the privacy of your information could be compromised. However, there are procedures in place to minimize this risk. In addition, you might feel some stress or discomfort when talking about your cancer experience in the group sessions, when completing the homework assignments, or when answering the survey questions. You can choose to discuss as much as you feel comfortable doing so, and you can skip any survey questions that you do not want to answer. The topics that will be discussed in the group sessions and asked about in the surveys are topics that are often discussed with medical providers and others, and they are unlikely to cause significant distress. Another potential risk is that people may choose to join the group sessions while engaging in other activities (for example: walking or driving). This could be distracting and has the potential to result in harm. We encourage you to participate in the group sessions while seated and in a place where you do not have to do other things at the same time. Video and audio of the group sessions will be recorded. It is possible that your face may be recognizable, and your identity may be known. There may be other risks which are currently unknown.

WILL I GET PAID?
If you agree to participate in this study, you could receive up to $150 for your participation. We are offering $50 each for completing the series of surveys before the program begins and after it ends. We are also offering $5 for completing each of the 10 weekly surveys after the group sessions. Altogether, this adds to a maximum of $150 over the course of the study.

WILL IT COST ANYTHING TO BE IN THIS STUDY?
There is no cost to participate.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?
We understand that information about you and your health is personal, and we are committed to protecting the privacy of your information. Because of this commitment and because of federal law, we must obtain your authorization before we use or disclose your information for this study.

By participating in this study, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

We will store all information that we collect that could be used to identify who you are in a location that is separate from the rest of the research data. All study information will be stored on secure, encrypted, and password-protected servers, and only authorized study staff will have access to it.

We ask everyone in the program to respect the privacy and confidentiality of the other participants, but we cannot guarantee this. Please keep this in mind when choosing what to share in the group sessions.

WHO WILL HAVE ACCESS TO THE INFORMATION COLLECTED DURING THIS STUDY?
We will limit who has access to your personal information, so that only people who need to review it have access. We cannot promise complete secrecy. There are reasons why information about you may be used or seen by other people beyond the study staff during or after this study. Examples include:

- University officials, government officials, study funders, auditors, and the Institutional Review Board to make sure the study is done in a safe and appropriate manner.
- Appropriate authorities for reasons of health and safety – for example, if you indicate that you plan to harm yourself or others, or for public health reasons.

We will not ask you about child abuse. However, if you tell us about child abuse or neglect, we may be required or permitted by law or policy to report it to authorities.

HOW MIGHT THE INFORMATION COLLECTED IN THIS STUDY BE SHARED IN THE FUTURE?
We will keep the information we collect about you during this research study for study recordkeeping. Your name and other information that can directly identify you will be stored securely and separately from the rest of the information we collect from you.

De-identified information from this study may be shared with the research community. For example, we may publish the study results in scientific journals, present the study results in scientific presentations, and/or submit study information to databases and data repositories used for research. Before we share any of this study's information, we will remove or code personal information that could directly identify who you are before the study data are shared. However, we cannot guarantee total anonymity of your personal data.

HIPAA AUTHORIZATION – PERMISSION TO USE PERSONAL HEALTH INFORMATION FOR RESEARCH

WHO WILL DISCLOSE, RECEIVE, AND/OR USE YOUR INFORMATION?
Your records are confidential, and they will be kept in a secure environment and protected to the full extent of the law.

To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including Moffitt Cancer Center, and each site's study team, research staff, and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any sponsor of the study, including the following sponsors: Moffitt Cancer Center.
- Any federal, state, or local governmental agency that regulates the study (such as the U.S. Food and Drug Administration (FDA) and Florida Department of Health (FDH). The U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP).
- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze, and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered.

Moffitt Cancer Center cannot guarantee the privacy of your information or block further use or distribution, after the information has left Moffitt Cancer Center. Others listed above may further disclose your information, and it may no longer be covered by federal privacy regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research.

You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

WHAT INFORMATION WILL BE USED OR DISCLOSED?
By participating in this study, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you in this informed consent form and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the study doctor listed on this information sheet. Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You do not need to provide this authorization, but if you do not, you cannot participate in this study.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By **mail**: Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044
- Or call **toll free**: 877-992-4724
- Or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00048401.

WHERE CAN I GET MORE INFORMATION?
You may call the National Cancer Institute (NCI)'s Information Service at: 1-800-4-CANCER (1-800-422-6237).

Visit the NCI's Websites at:
- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov