Informed Consent Form Cover Page for ClinicalTrials.gov Record

Official Study Title:

Improving Symptom Management for Survivors of Young Adult Cancer

Brief Title:

Symptom Management for YA Cancer Survivors

NCT #: NCT04035447

Duke University Health System (DUHS) Protocol #: Pro00103249

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
(Improving Symptom Management for Survivors of Young Adult Cancer)

The purpose of this research study is to gain a better understanding of the experiences of young adults (aged 18-39) who have been diagnosed with hematologic, breast, endocrine or gastrointestinal cancers, melanoma, or germ cell tumors. Participants will compete a baseline assessment and four follow-up assessments over 12 months. Each of these assessments will include the completion of surveys. At the end of the baseline assessment, participants will be randomized (like the flip of a coin) into either a Symptom Management Program or the waitlist group that will receive the Symptom Management Program in approximately six months. The Symptom Management Program includes eight, 90 minute group sessions with other young adult cancer survivors held over Zoom over a 10 week period. Participants will be given access to a mobile application and wireless activity tracker to use during the program.

There are minimal risks associated with this study. The greatest risks of this study include loss of confidentiality. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential.

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 been diagnosed with cancer. 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 a member of the 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 the PI's (Dr. Caroline Dorfman) salary 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, you will not have a different medical doctor. Your regular doctor will continue to be your doctor throughout the time that you are in the study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to aid in the development of an intervention aimed to improve symptom management for young adult cancer survivors and to examine the impact of the intervention.

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HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 120 people will take part in this study at Duke University Medical Center.

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. Your medical record will be reviewed to obtain information about your cancer, treatments related to cancer, and other health conditions. Your medical provider will be asked to provide medical clearance for participation in the home-based exercise program included as a part of the intervention. You will be asked to sign a medical release form so the study team may contact your medical provider to request medical clearance and communicate information about your health to your doctor during the study.

In this study, you will be randomly assigned (like the flip of a coin) to a Symptom Management Program or the waitlist group who will receive the Symptom Management Program in approximately six months. During the Symptom Management Program, you will participate in eight 90 minute group sessions with four other young adult cancer survivors held over Zoom over a 10 week period.

You will be given access to a study-specific mobile application during your time in the Symptom Management Program. You can access the application on a study iPad or on your own personal devices. The mobile application will allow you to access symptom management strategies, track symptoms and physical activity in real time, complete assignments, and chat with other group members. You will receive push notifications based on your input and session materials. Based on your medical provider's approval, you may participate in a home-based exercise program.

You will be asked to wear and be provided with a wireless activity tracker (Garmin vívofit 4) over the course of the study. The activity tracker will monitor the number of steps taken per day as well as distance. You can monitor your activity in the mobile application.

All participants will complete an initial assessment and follow-up assessments 3, 6, 9, and 12 months later. You will be given the option to complete assessments on a study iPad or on your own personal devices. During each assessment, you will answer questions about topics including your physical health (i.e., medical comorbidities, disease characteristics), pain, fatigue, psychological distress, symptom severity and interference, self-efficacy for managing symptoms, social support, and physical activity. Assessments will take 30 minutes to complete.

We will send you automated text messages throughout this study. To do this we use a web-based system, called Twilio, which uses your phone number to send you messages. We plan to use this feature to send you text message reminders to complete study assessments. If you agree to receive text message reminders about study assessments, we will contact you this way approximately 15 times during the study. If you change your mind about the messages or if your contact phone number changes, please contact the study team. These messages are one-way only, so you cannot reply. If you have questions or concerns about information in a message contact your study team.

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The Symptom Management Program Zoom sessions will be audio/video recorded. The audio/video recording will be reviewed by members of the study team. Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study for approximately 12 months.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
There are minimal risks associated with this study. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. Some of the topics discussed during Symptom Management Program sessions may make you feel uncomfortable. Discussing your health or stressors associated with your health may be upsetting. You may choose to not discuss concerns that you find upsetting. Also, you may stop your participation 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.

While we do not anticipate many adverse events and the program is consistent with physical activity recommendations, you may be at risk for adverse events related to exercise such as injuries/falls, lymphedema flares, hypotension or hypoglycemia, and cardiovascular events.

Many companies and applications on your smartphone commonly use text platforms and cloud-based companies to send and receive information. We use Twilio to send you text messages. Twilio does encrypt your information on their servers, but no system is completely safe. If they decide to share these data, it may no longer be covered under the privacy protections. Information that identifies you, such as your phone number, may be sent to and permanently kept by Twilio and their business associates. Information disclosed to these companies or their business partners may no longer be covered under the privacy protections. Because text messaging does not provide a completely secure and confidential means of communication, if you wish to keep your communication completely private please let us know and we will communicate with you only through regular channels like the telephone and email.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
Participation in this study will provide you with an opportunity to learn skills that can help you better manage symptoms or improve your overall health. We expect that the information learned from this study will benefit other young adult cancer patients in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people

including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

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 or for your care, 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. The key to the code will be kept securely at DUHS.

You will be identified in the audio/video session recordings by your study ID number. Any link to your name will be kept in a password protected computer database kept separate from other study data. All recordings will be stored in a password protected computer file on an encrypted laptop and a DUHS secure server. Audio/video recordings will be available only to authorized study personnel as necessary for the purposes of this study and will be identified by your study ID number. After the study has been completed, all audio/video recordings will be destroyed.

Pattern Health will maintain the mobile application. The mobile application syncs with the Garmin activity tracker and allows participants to monitor their physical activity. Application data is stored in a MySQL database, which allows the database to be kept separate from the web browser to protect access to the database. In addition the hard drive of the database machine is encrypted. Only study staff will have access to the data collected through the application.

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 or for information that is required by the Food and Drug Administration (FDA).

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.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the National Institutes of Health, the Duke University Health System Institutional Review Board, Duke Cancer Institute & Office of Audit, Risk and Compliance. If your research record is reviewed by this group, they may also need to review your entire medical record. 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 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 will 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.

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.

WHAT ARE THE COSTS TO YOU?
There will not be any cost to you as a result of participating in this study.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to a total of $150 for your expenses related to participation (e.g., time). This reimbursement will consist of $30 for completing each of the study assessments. If you choose to withdraw from the study, you will only receive compensation for the parts of the study that you completed.

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WHAT ABOUT RESEARCH RELATED INJURIES?
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. Caroline Dorfman, PhD at 919-416-3473 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. All data that have already been collected for study purposes will be sent to the study sponsor.

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. Caroline Dorfman in writing and let her know that you are withdrawing from the study. Her mailing address is 2400 Pratt Street, 7th Floor, Room 7058, Durham, NC 27705.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at anytime without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

If you choose to withdraw from the 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 samples or data, we will no longer be able to identify and destroy them.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Caroline Dorfman at 919-416-3473 during regular business hours, after hours, and on weekends and holidays.

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.

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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."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

Do you want to receive text message reminders for study assessments?

_____yes _____no