ICF: Survivor

Title of Study: Promoting Self-Management of Long-Term Follow-Up Care for Adolescent and Young Adult (AYA) Survivors of Pediatric Cancer

NCT04075734
Document Version: 4 Date: 2.10.2020

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ONLINE CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Promoting Self-Management of Long-Term Follow-Up Care for Adolescent and Young Adult (AYA) Survivors of Pediatric Cancer

Phase 3b AYA Survivor

Principal Investigator: Katie Devine, PhD
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STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. The purpose of the research is to develop and pilot test a self-management and peer mentoring program to assist adolescent and young adult (AYA) survivors in improving self-management skills for long-term follow-up care. If you take part in the research, you will first be asked to complete an online questionnaire (~35 min). You will then be randomly assigned (like flipping a coin) to one of two groups.
If you are assigned to group A, you will be asked to complete the online questionnaire 3 more times, at about 8 weeks, 5 months, and 12 months after you start the study. If you are assigned to group B, you will be asked to complete an online educational self-management program for cancer survivors, matched with a peer mentor (also a cancer survivor), and complete 6 video or phone calls with your peer mentor as you complete the online program. You will schedule these calls at a time convenient for both of you. After that, you will be asked to complete the online questionnaire again 3 more times - at about 8 weeks, 5 months, and 12 months from the start of the study. If you are assigned to group B, reviewing the 5 online educational modules should take you less than 20 minutes per week (for 5 weeks) and about 30 minutes per week (for 6 weeks) for video or phone call with your peer mentor. Regardless of your group, you will be paid $50 for each completed online survey, for a total of $200. You should not experience any harm or burden by participating in this research study. You can choose not to answer any question in the questionnaire or not to discuss any topic you do not wish with your peer-mentor (if assigned). We will make every effort to keep your information in the research record confidential, but total confidentiality cannot be guaranteed. A possible benefit of taking part is learning tips for managing your healthcare. Your alternative to taking part in the research study is not to take part in it.

This informed consent form provides information about a research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part in it, you should feel free to ask them and should expect to be given answers you completely understand. It is your choice whether to take part in the research. Your alternative to taking part is not to take part in the research.

After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this informed consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?
Dr. Katie Devine is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Katie Devine may be reached at (732) 235-7549 or Katie.devine@rutgers.edu.

Dr. Katie Devine or another member of the study team will review this informed consent with you. You will be given a copy of the consent form to keep.

Sponsor of the Study:
This study is funded by the National Institutes of Health, National Cancer Institute.

Why is this study being done?
This study is being done to develop and pilot test a self-management and peer mentoring program to assist adolescent and young adult (AYA) survivors in improving self-management skills for long-term follow-up care. Self-management skills include things such as maintaining your health records, navigating the health care system, and communicating with healthcare providers and caregivers.

Who may take part in this study? And who may not?
You may be included in this study if you are a childhood cancer survivor who is currently 18 to 25 years old and completed treatment at least 2 years ago and you currently do not independently manage your follow-up care.

Why have I been asked to take part in this study?
You have been asked to take part in the study because you are a childhood cancer survivor.

How long will the study take and how many subjects will participate?
Your participation in this study will last about a year. The study itself will last about two years. A total of 50 survivors and about 20 peer mentors will complete the study.

What will I be asked to do if I take part in this research study?

All participants will be asked to complete an online questionnaire (about 35 minutes long) that asks about disease knowledge, self-management skills, follow-up care, and health motivation.

You will then be randomly assigned (like flipping a coin) to one of two groups: Group A or Group B. You have an equal chance of getting one group or the other but there is no way to know ahead of time which group you will get.

If you are assigned to Group A:

You will be asked to complete three more questionnaires at about 8 weeks, 5 months, and 12 months after you start the study. Once you complete the study, if you are interested, you may request access to the online educational modules on self-management skills for young adult survivors.

If you are assigned to Group B:

You will be matched with a peer mentor who is another young adult cancer survivor that will share his or her experience with you and offer support as you go through the program. You will be asked to complete six weekly video or phone calls with your mentor and complete 5 online educational modules that correspond with calls 2-6 with your mentor. These will be scheduled at time convenient for you both. You will also be able to receive and send secure text messages with your peer mentor. We will ask for your permission to audio-record your conversations with your peer mentor. After you complete the program, we may ask you to complete a brief (~20 minute) phone interview to gather your feedback on how we can improve the program. You will also be asked to complete three more questionnaires after you complete your calls with your mentor (about 8 weeks after you start the study), about 3 months later (about 5 months after you start the study), and 5 months later (about 12 months after you start the study).

For both groups, we are asking for your permission to obtain the following information from the doctors you have visited in the year of your participation in this study: your Cancer Treatment Summary (also called a Survivorship Care Plan), History and Physical dates, and dates and types of diagnostic tests/visits completed. If you agree, you will sign a Release of Medical Records form for each doctor you have visited. A postage-paid envelope will be enclosed for your convenience to return signed copies back to us. You do not have to agree to release information from medical records to be part of the study.

What are the risks and/or discomforts I might experience if I take part in this study?
We do not expect you to experience any risks or discomfort while completing questionnaires as our questions will focus on barriers to managing health care and strategies to help childhood cancer survivors better manage their care. You can choose not to answer any question if you want. All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. You may be asked to work with a cancer survivor peer mentor during the program; although this person will be trained to keep all information about you confidential, total confidentiality cannot be guaranteed. It is possible that discussing your history with another cancer survivor could cause emotional discomfort. You can choose how much information you want to share about yourself.

Are there any benefits for me if I choose to take part in this study?
There are no direct benefits to you from being in the study. Tips for managing your health care may be beneficial. Your feedback on the program will help us design a better program for

childhood cancer survivors in the future.

What are your alternatives if you don't want to take part in this study?
Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you during or after the study is completed, you will be contacted.

Will there be any cost to me to take part in this study?
You will be asked to use your personal phone for communication via phone and text, which may incur costs depending on your phone plan.

Will you be paid to take part in this study?
You will receive $50 per questionnaire completed (for a total of $200).

How will information about you be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Your research data, including audio-recorded conversations, the context of text messages, and your engagement with the online modules/website, will be identified using a number rather than your name. If you agree, your peer mentor will audio-record your call. Your mentor will send audio recordings to the study team using an online secure file transfer service. Your peer mentor will be responsible for destroying the original recording from their device. The study team will store audio recordings on a password-protected computer. A member of the study team will write out the interview as soon as possible and remove any identifying information from the written document. The recording will be destroyed upon completion of the study procedures. Data regarding your website usage (e.g., log-ins, screens viewed, responses given) will be downloaded securely by researchers and identified using a Study ID, not your name. Radiant Creative Group LLC, the company that hosts this website, may have access to certain personally identifiable information used to create your account on the site (i.e., your first name, last initial, and email address). This information is used solely for the purposes of supporting your user log-in and personalizing some site messages. Radiant uses industry standard methods to protect your information and will not, under any circumstances, share your information with any third parties.
We will keep an electronic file that links your name and ID number separately in a password-protected file that will only be accessible by authorized study personnel. This link will be destroyed at the end of the study. DatStat (a company whose software is being used in the study to administer online surveys and store research data) and TigerConnect (a company providing secure message, call, and video call services for this study) use a number of physical, technical, and administrative safeguards to protect data, including industry standard encryption of communication between the web browser and data center. These data will be accessed by authorized members of the study

team using secure web portal.

A description of this clinical trial will be available on 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 website at any time.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institute of Health. The researchers will use this Certificate to legally refuse to disclose any information or documents that may identify you, including from a court order. This means that research material collected about you for this study will not be released to anyone who is not connected with this study unless:

- You request or consent to its release;
- A law requires its release (such as reporting communicable diseases or child abuse to State agencies);
- It is used for other scientific research, as allowed by federal regulations protecting subjects; or
- It is requested by the U.S. federal or state agency sponsoring the research that is needed for auditing or program evaluation or to meet the requirements of the Food and Drug Administration (FDA).

What will happen to my information collected for this research after the study is over?
After information that could identify you has been removed, de-identified information collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time. If you do not want to start the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing to Dr. Devine (address provided on page 1). Any data that you have already provided will be kept in a confidential manner.

Who can I call if I have any questions?
If you have any questions about taking part in this study, you can call the study principal investigator, Katie Devine, PhD, Rutgers Cancer Institute of New Jersey at (732) 235-7549.

If you have any questions about your rights as a research subject, you can call the IRB Director at (732) 235-9806 or the Rutgers Human Subjects Protection Program at (732) 235-8578.

Audiotaping
We are asking for your permission to audiotape your video conference/phone calls with your mentor and your exit interview with the research team for analysis by the research team and for mentor supervision purposes. You do not have to agree to be recorded in order to participate in the study. The recordings will be identified using a number rather than your name. If you agree, your peer mentor will audio-record your call. Your mentor will send the audio recordings to the study team using an online secure file transfer service. Your peer mentor will be responsible for destroying the original recording from their device. For your exit interview, the study team member will record your interview, transfer the audio file to a password-protected computer, and delete from the recording device. The study team will store audio recordings on a password-protected computer. A member of the study team will write out the call/interview as soon as possible and remove any identifying information from the written document. The recording will be destroyed upon completion of the study. The investigator will not use the recording(s) for any other reason than that stated in this consent form without your written permission.

Do you give permission to audio-record as described during participation in this study?

_____ Yes, I give permission to record me as described during participation in this study.
_____ No, I do not give permission for recording.

Future contact consent
We are asking for your consent to be contacted about participation in future research studies. For example, if we were to do another mentoring study in the future, we may contact you to consider serving as a mentor. If you agree, we will securely store your contact information (i.e., first and last names, phone number, email address, and mailing address) as well as cancer history (i.e., diagnosis, date of diagnosis, and end of treatment date) in a separate file from any research data, with access granted only to limited authorized research staff. We will store this information for up to 10 years from date of consent, after which it will be destroyed by the PI.

Do you consent to be contacted by Dr. Devine and her research team about future research study opportunities?

___Yes, I consent for Dr. Devine and her research team to contact me in the future with more survivorship research opportunities. I understand I am at no obligation to participate in future studies.
___No, I do not want to be contacted in the future about research opportunities.

By submitting this form, you acknowledge that you have read this information and agree to participate in this research, with the knowledge that you are free to withdraw your participation at any time without penalty.

Submit