**University of North Carolina at Chapel Hill**
**Consent to Participate in a Research Study**
**Adult Participants**

**Consent Form Version Date:** 09/15/2023
**IRB Study #** 22-2340
**Title of Study**: A pilot randomized factorial trial to promote physical activity and healthy eating among young adult cancer survivors
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**Funding Source and/or Sponsor:** UNC-CH Lineberger Comprehensive Cancer Center

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CONCISE SUMARY

This is a research study to test a behavioral physical activity and nutrition program designed specifically for adolescent and young adult cancer survivors. Study participants will use technology including a Fitbit activity tracker, and study mobile app, along with behavioral lessons, goal setting, and feedback for 3 months.

All participants will be sent a Fitbit activity tracker to measure their physical activity levels. They will complete online questionnaires about their health, diet, and lifestyle at the beginning of the study, midway at 6 weeks, and again at the end of the study after 3 months. All participants will learn about their group assignment during a video chat or phone call kick-off session with a health coach that will last 30-45 minutes.

The greatest risk of this study includes the possibility of injury when increasing physical activity as part of the program. Participants may benefit from participating in this study by improving diet and activity behaviors, which is associated with health benefits such as reduced risk for diabetes, some types of cancer and heart disease.

## What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the

study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this study?**

The purpose of this study is to provide adolescent and young adult cancer survivors with tools and strategies to increase healthy lifestyle activities. This study uses a study app for diet monitoring and a physical activity tracker. This study will evaluate the effectiveness of this type of intervention in this population of cancer survivors. You are being asked to be in the study because you meet the following criteria: 1) current age 18-39; 2) diagnosed with first invasive cancer between the ages of 15-39 years; 3) within 10 years of diagnosis with no evidence of progressive disease or second primary cancers; 4) completed active cancer directed therapy (cytotoxic chemotherapy, radiation therapy and/or definitive surgical intervention) at least six months prior to enrollment, except may be receiving "maintenance" therapy to prevent recurrences.

**Are there any reasons you should not be in this study?**

You should not be in this study if you have any of the following criteria:

1. Report a history of heart attack or stroke within previous 6 months
2. Untreated hypertension, hyperlipidemia, or diabetes, unless permission is provided by your health care provider.
3. Health problems which preclude ability to walk for physical activity (e.g., lower limb amputation)
3. Past diagnosis of or receiving treatment for a clinically diagnosed eating disorder (anorexia nervosa or bulimia nervosa) or any compensatory behaviors within the previous 3 months
4. Currently pregnant, pregnant within the past 6 months, or planning to become pregnant within the next 6 months
5. Hospitalization for depression or other psychiatric disorder within the past 12 months
6. History of psychotic disorder or bipolar disorder
7. Currently participating in a weight loss, nutrition, or physical activity study or program or other study that would interfere with this study
8. Currently using prescription medications with known effects on appetite or weight (e.g., oral steroids, weight loss medications), with the exception of individuals on a stable dose of SSRIs for 3 months)
9. Previous surgical procedure for weight loss or planned weight loss surgery in the next 6 months.
10. Inability to speak and read English

11. Do not have iPhone with active data and text messaging plan
12. No internet access.
13. Not willing to be randomized to any experimental condition.
14. Are already adherent to the American Cancer Society's recommendation of exercising ≥ 150 minutes/week of moderate-to-vigorous intensity physical activity.
15. Are already adherent to the American Cancer Society's recommendation of consuming > 5 servings of fruits and vegetables/day.

**How many people will take part in this study?**
Approximately 80 people will take part in this study.

**How long will your part in this study last?**
Your part in this study will last approximately 4 months. You will be sent a Fitbit activity tracker to measure your physical activity. You will complete online questionnaires about your health, diet, and lifestyle at the beginning of the study and again 6 weeks and at the end of the study after 3 months. At these time points, you will wear your Fitbit for 7 days to track your physical activity, and we will ask you to step on a scale at home for a weight measurement.

**What will happen if you take part in the study?**
After you consent to participate, you will be sent a link to a set of online questionnaires and a physician consent form if required. The online questionnaires that you complete at home will take you approximately 30-45 minutes. These questionnaires will include questions related your background, diet, and physical activity. You will also complete an online questionnaire about your food intake on one weekday and one weekend day. Each food questionnaire will take approximately 30 minutes.

To start off the program, you will have an individual video chat session (Kickoff Session) with a health coach to provide information on how to use the intervention app, and review guidelines on dietary monitoring, and resources on exercise safety. Then you will be randomized to receive 4 other components of the program. Being randomized is like flipping a coin, so you will not get to choose these components. These components will be: 1) simplified dietary tracking based on the Traffic Light Approach (daily tracking of green (low-calorie, high nutrients) vs. red (high-calorie, high-fat, low nutrients) foods), 2) dietary goals using Traffic Light Approach (daily green or red food goals vs. no goals), 3) supportive text messages (yes (≤ 5 per week) vs. no), and 4) lesson delivery (all provided once vs. weekly). We are testing how these different components help people stick to the program.

After your Kickoff Session and for the entire 3-month program, you will be asked to wear your Fitbit, and track your foods using the study app. The data from your app and Fitbit will be transmitted to the study. It is anticipated that you will spend no more than 10-15 minutes per day tracking your foods.

**Follow-up Assessments**: After 6 weeks you will be asked to complete online questionnaires that will take approximately 30 minutes. After 3 months, you will be asked to complete online questionnaires that will take approximately 30-45 minutes. You will also complete an online

questionnaire about your food intake on one weekday and one weekend day during the week that you do your online questionnaires. Each food questionnaire will take approximately 30 minutes. We will ask you to step on your for a final weight measurement. You will receive a $25 incentive for completing the 3-month assessment. The activity tracker will be provided to you at the end of the study as an incentive for completing all measurements (baseline, 6 weeks, 3 months).

**What are the possible benefits from being in this study?**

Research is designed to benefit society by gaining new knowledge. You may also expect to benefit by learning more about exercise, nutrition, and cancer survivorship. You will receive health information that may help you become more physically active, improve your health, and prevent disease. You will also be helping us learn more about the best ways to communicate health information to young adult cancer survivors.

**What are the possible risks or discomforts involved from being in this study?**

There are no major risks associated with the assessment visits or participating in the study.

Risks of Increasing Physical Activity.

There may risks associated with increasing physical activity, including, but not limited to, injuries to the muscles or joints of the body. Other risks include abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, exacerbation of exercise-induced asthma symptoms, and very rare instances of heart attack, stroke, or even death. To help ensure your safety, the study will follow guidelines and safety recommendations for physical activity set forth by the American College of Sports Medicine. The study will provide you with information and recommendations for safely starting an exercise program and increasing your physical activity and will make modifications to your program if you experience any of the above problems. The safest way to start becoming more physically active is to begin slowly and build up gradually. During this study, you will receive information on exercise safety. These are not intended to be a substitute for consultation with your personal physician and/or health care provider. You may want to talk with your doctor by phone or in person before you start becoming much more physically active. You should report any problems to the researchers.

Risks associated with Questionnaires

As part of the study, you will be asked about personal factors related to your eating, physical activity, and weight. You may feel uncomfortable while completing the surveys, because of the personal nature some of the questions. You can elect not to share this private information. You should contact researchers if you feel that you have experienced any emotional distress as a result of study participation.

Risk of Breach in Confidentiality

This would mean that a person or persons outside the study team will find out that you are participating in this study and/or access the information you share with the study. This is a very rare possibility. Though the likelihood is very rare, it is possible that your data could be accessed by others should you lose your mobile device or lend the device to other people. In addition, there is a possibility that others may see your smartphone communications, including notifications or messages when the application is open, or see an open webpage while you are

completing online questionnaires. If you would like, you may set up a passcode on your mobile phone to help prevent unauthorized access to your device, text messages, and research data. Additional information on how your study records will be kept private is written below.

*Fitbit*: You will also receive a Fitbit activity tracker. These devices require use of the companion Fitbit website and smartphone app. This is protected by a unique user login and password. Though you will need to enter your Fitbit username and password as part of the setup process for the study, we will not store your Fitbit usernames or passwords on our servers. All website information on your activity and weight data that are accessed by study staff will be kept confidential. The risk of breach of confidentiality over the Fitbit website will be partly subject to your comfort with sharing information on your individual profile. Fitbit will have access to the data that you choose to track within the Fitbit app/website and the information you choose to include on your individual Fitbit profile, but they will not have access to any other information about you that is collected as part of the research study.

*MyDataHelps App:* As part of this study, you will also be asked to use a third-party study app – the Young Adult Cancer Survivors Healthy Eating and Active Lifestyle Study (YACS-HEAL) (also called MyDataHelps). While participating in the study, you must set permission to share information from your Fitbit with the study app. Data shared with the YACS-HEAL app may be shared with the company that provides the software platform, so you should be sure to review the App's privacy policy and terms to make sure you are comfortable with its data use and sharing practices before signing this consent and authorization. https://rkstudio-customer-assets.s3.amazonaws.com/CareEvolution/PrivacyPolicy.html

Risk of Wearing Fitbit Activity Tracker
There is also the possibility of minor skin irritation associated with wearable devices. We recommend taking it off occasionally, not wearing it too tightly, and keeping it clean and dry. You should regularly clean your wearable device—especially after working out or sweating. Rinse the wearable device with water or wipe it with a small amount of rubbing alcohol. Do NOT use hand soap, body soap, dish soap, or household cleaners which could get trapped beneath the band and irritate skin. Always dry the wearable device well before putting it back on. If you start to experience skin irritation on your wrist, we suggest you remove the device and contact a member of the study team to discuss the issue and determine whether you would like to continue participating in the study.

Pregnancy
If you become pregnant during the study, there is very little risk to you or your baby; however, we ask that you notify the study staff and your participation will be stopped. We recommend that any weight intervention during pregnancy be managed through your primary care provider. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

**What if we learn about new findings or information during the study?**

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

**How will information about you be protected?**

The study team will store any personal information you provide, and your tracker data, in secure databases that comply with the University of North Carolina's policies on sensitive information storing and transmission. This means that there are very strong protections in place to keep your information from being accessed by individuals not authorized to access it. Information you share through online questionnaires uses a secure server that complies with the University security policies. You will be asked to voluntarily allow the study team to access your Fitbit data through the Fitbit website by entering your Fitbit username and password. Your usernames and passwords will not be stored by the study in any manner.

Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

As the purpose of this research is to study timing of lessons and supportive text messages, by signing this consent on the last page of this form you are giving permission for the study team to contact by the mechanism identified below that you provide. This communication may contain personal information about you and may be sent or received by the study team member's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team.

This information may include information such as reminders and notification requests to contact the study team. If you do not want to receive un-protected communication that may contain personal information, then you should not consent to participate in this study.

If you have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities concluded, or you withdraw from the study, you will no longer receive un-encrypted (un-protected) communication specific to this study.

The study team may use the following email and phone to send communication: 919-966-5852 or email uncweightresearch@unc.edu.

**What will happen if you are injured by this research?**

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside

funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.
If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

**What if you want to stop before your part in the study is complete?**
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

**Will you receive anything for being in this study?**
If you complete all of the assessments (baseline, 6 weeks, and 3 months), you will be able to keep the Fitbit activity tracker (valued at $100) that you will use during the study. If you decide to withdraw from the study or do not complete all of the study assessments, we will ask you to return the Fitbit activity tracker to the UNC Weight Research Program. There are no costs associated with being in the study.

You will be receiving $25 for taking part in this study. Any payment provided for participation in this study may be subject to applicable tax withholding obligations

**Will it cost you anything to be in this study?**
It will not cost you anything to be in this study.

**Who is sponsoring this study?**
This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.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.

**What if you have questions about your rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

**Participants will be shown a link that says "I consent."**
Thank you for reviewing the Informed Consent document. Please choose one of the following:
-I have read the information and voluntarily agree to participate in this research study. NOTE: If you consent to participate in this study, you will be provided with a web link where you can download a PDF copy of the consent form. Please print a copy of this consent form for your records. If you do not have a printer available, you may save the PDF copy (use the File, Save As function in your browser) for future reference.
-I do not wish to participate in this research study.

SUBMIT

*If the person picks yes, provide a message that says* "You have indicated that you **will** participate in this research study. Please confirm by entering your initials here" *(provide box and submit button). After submit, get text that says* "Congratulations on enrolling in this research study. You may download a PDF copy of the consent form at www.xxx/xxxxxxxx
If you have questions or concerns about the study, please contact the UNC Weight Research Program by phone at 919-966-5852 or email uncweightresearch@unc.edu."

*If the person picks no, provide a message that says,* "Thank you for your time. You have chosen **not** to participate in this research study. If you have any questions, please contact the UNC Weight Research Program by phone at 919-966-5852 or email uncweightresearch@unc.edu."