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St. Jude Children's Research Hospital
Fred Hutchinson Cancer Center

Consent to take part in a research study:

LTFU
Long-Term Follow-Up Study

salsa
Study of Active
LifeStyle Activation

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Important things to know about this study:

As a participant in the Long-Term Follow-Up (LTFU) study being conducted by St. Jude Children's Research Hospital, you are invited to participate in a related research study, called *SALSA (Study of Active LifeStyle Activation).*

SALSA is research that has been designed for adult survivors of childhood cancer who may be at higher risk of heart problems due to their prior cancer treatment. The goal of this research is to see if there are better ways to help people at high risk of heart problems increase their physical activity and improve their diet.

SALSA will enroll around 400 people who are not very physically active, or who do not meet heart healthy diet recommendations, or are overweight. Study participation will last about one year. All study activities can be done from home and will require tracking of your physical activity levels and diet. During this time, participants will receive feedback via phone or web video on how to increase their physical activity levels and improve their diet. The study will provide materials for participants to self-collect their blood pressure, weight, and a small amount of blood at home. We do not know if being in this study will help participants, but we do not believe there are any significant side effects from the study procedures.

Before you learn more about SALSA, it is important to know your rights:

- Whether or not you take part in this study is entirely up to you. You are free to say yes or no.
- You may stop being part of this study at any time. If you decide not to be in SALSA, or to withdraw from SALSA at any time, there is no penalty and your regular medical care will not be affected. Your relationships with St. Jude, the LTFU Study, or the institution where you received treatment also will not be affected.

What will happen to me if I join this study?

The following is a more complete description of the study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you are interested in joining this study, we will first ask you to complete the following activities to see if you are eligible:

- **Physical activity and current health, height, and weight.** We will ask you a few questions about your usual amount of physical activity in a typical week and your current health. This should take less than 5 minutes.

- **Diet questionnaire.** This should take no more than 30 minutes to complete. We will ask you questions about your usual diet during the past month. You can choose to skip any question you feel uncomfortable answering.

If your activity levels are low, your diet does not meet recommended heart health guidelines, or you are overweight, you may be eligible to participate in the rest of SALSA. The rest of the study involves completing the following activities:

- **Study questionnaire.** This more detailed questionnaire should take no more than 20 minutes to complete. We will ask questions about your attitudes about healthcare, exercise and eating behaviors, and quality of life. The questionnaire can be done online, on paper, or by phone, whichever is easier for you. If a question makes you uncomfortable, you may choose not to answer.

- **Physical activity monitor (ActiGraph).** We will mail you an activity monitor to track your physical activity. We will ask you to wear the monitor at all times for 7 days, including while you sleep if possible. You do not need to wear the monitor when you shower or swim. The monitor is a small electronic device about the size of a pager, typically worn on the waist. The monitor gives minute-by-minute estimates of how much your whole body is moving. The monitor does not track your location.

- **Self-measured weight and blood pressure.** The study will mail you a Bluetooth-enabled scale and blood pressure monitor. You will be asked to download a free app (software program) called “Healthmate” to your smartphone which can then automatically transmit any weight and blood pressure measurements. The scale and blood pressure monitor are yours to keep forever. If you do not have a smartphone, the study will lend you a device to use as long as you have Wi-Fi access.

- **Dried blood spot (DBS).** Study participants can do this at home. It takes less than 10 minutes. DBS requires the use of a lancet (a small sharp point) to prick the chosen finger so that drops of blood can form. This is similar to the blood sugar testing used by diabetics, or blood spots collected from newborn babies. About 6 blood drops are required to fill a specimen card. Once complete, you should clean your pricked finger with an alcohol wipe and cover it with a bandage. We will analyze the blood spots for markers of heart health. These results cannot be returned to you because the blood spot tests being used are not designed for clinical care.

- **Heart health educational session.** You will have the opportunity to review your cancer history and its impact on heart health with a study healthcare provider (nurse practitioner or physician assistant experienced in cancer survivorship). This should take no more than 20-minutes and can be scheduled at a time convenient for you. This can be by phone or web video, similar to a telemedicine appointment done with your regular healthcare provider.

Some of these activities will also be requested 3, 6, or 12 months after starting the study. The following Table summarizes when each activity is requested:

Study Activity	Start of study	At 3 months	At 6 months	At 12 months (end of study)
Study questionnaire	X			X
Diet questionnaire	X	X	X	X
Physical activity monitor (1 week)	X	X		X
Weight and blood pressure	X		X	X
Dried blood spot	X			X
Educational session	X	*	*	*

* You may be eligible for additional sessions with a study healthcare provider depending on which study group you are assigned to.

After completing these activities at the start of the study, you will be randomly assigned to either Group #1, #2, or #3.

*If you are assigned to **Group #1** the following will also happen:*

- **Diet and physical activity apps.** The free "Cronometer" app can be used to provide feedback on your diet and how well your diet matches up with heart healthy food choices. The "Withings" activity watch (worn on the wrist) can be used to track physical activity over time, and can be connected to the Healthmate app. The watch is yours to keep forever. We would ask that you to give the study team access to your Healthmate and Cronometer accounts so that they can monitor your physical activity and diet remotely. Study staff will be available to help you with any problems.

- OPTIONAL: After 12 months, participants in Group #1 can choose to receive the information that one of the other groups below receive for up to 6 additional months.

*If you are assigned to **Group #2** the following will also happen:*

- **Action Plan.** In addition to the standard educational session, the study nurse practitioner or physician assistant will spend extra time (about 10-15 minutes) with you to provide more personalized recommendations (your "Action Plan") to improve your diet and physical activity levels. You will have the opportunity to review this "Action Plan" with a study healthcare provider every 2 months and update it as necessary. Each follow-up appointment (phone or web video) can be scheduled at a time convenient to you and should take no more than 15 minutes.

*If you are assigned to **Group #3** you will not receive an Action Plan, but will receive the following instead:*

- **More personalized physical activity and diet feedback.** While all participants will receive the Withings activity watch and access to the Cronometer diet tracking app, Group #3 participants will be reminded to use them on a regular basis. If you are part of Group #3, we will remind you to wear the watch during awake hours and to record your diet for 5 days each month. Study staff will then use information from your Withings watch and Cronometer app to send you personalized weekly physical activity goals and monthly dietary goals via text message, email, or phone call (your choice). After 6 months, goals will be updated less frequently, just once every 1-2 months.

- **Peer support through Facebook.** We have created a private study Facebook group for Group #3, where Group #3 study participants can share their experiences trying to

become more active and improve their diet. Study staff will also provide additional information on physical activity and diet on this private Facebook page. If you do not have a Facebook account, the study can help you make one. Although we encourage participants to try it, you can still participate in the study even if you choose not to use Facebook.

As shown in the Table above, 3 months after starting the study, we will re-measure all study participants' physical activity levels (using the "Actigraph" monitor for 7 days) and diet (using the diet questionnaire to measure diet over the past month). Depending on what your activity levels and diet are like, you may be assigned to a new group. For example, some Group #2 participants may switch to Group #3 and vice versa. Some participants may switch to a brand-new Group #4.

*If you are assigned to **Group #4** after 3 months, this will involve:*

- **Health Coach.** Our study health coaches have graduate degrees in nutrition science and experience in nutrition and exercise coaching. They can work with you to help improve your diet and increase your physical activity levels. The health coach can meet with you by phone or web video every 1 to 2 weeks for 3 months, and then once a month for the remaining 6 months of the study. These free appointments can last 10-30 minutes and be scheduled at a time convenient to you.

How long will I be in the study?

If you meet all study eligibility criteria, the study will last about one year.

Can I stop taking part in this study?

If you are thinking about dropping out of this study, please tell us. You can stop taking part in SALSA at any time. Your relationship with the LTFU Study will not be affected. If you leave the study, your information cannot be removed from the study records.

What are the risks of being in this study?

The finger prick for the dried blood spot may briefly cause pain at the site, and rarely, bruising or an infection can occur at the puncture site. It is unlikely but there may be loss of confidentiality or privacy where someone other than the research team may find out that you were in this study or see your information. How we will protect your privacy is reviewed further below.

What are the benefits of being in this study?

Study participants will have the opportunity to review their childhood cancer history and its effect on heart health with a study healthcare provider. Participants will get free access to devices and software that can provide feedback on their activity levels, diet, weight, and blood pressure. Participants may receive additional personalized information to further improve diet and increase physical activity levels. We also hope the information from this study will provide future benefits for other people who were treated for cancer as children.

Will my information or blood samples ever be used for future research?

In addition to the planned uses described above, we might remove all identifiers and codes from your information or blood samples. We could then use or share them with other researchers for future research. If you do not want your anonymous information or tissue samples used for other projects, you should not participate in this study.

If we do share your information or tissue with others, we would not be able to stop the future research, even if you asked later. There will be no way to link the information or blood samples back to you. We will not contact you or otherwise inform you before we share your information or tissue for future research.

How will my privacy and the confidentiality of my personal information be protected?

Some people or organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB and the St. Jude Children's Research Hospital IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Fred Hutchinson Cancer Center.
- St. Jude Children's Research Hospital.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other federal agencies as required.

We will do our best to keep the personal information in your medical record confidential, but we cannot guarantee total confidentiality. Your personal information may be given out if required by law. For example, a court may order study information to be disclosed. Such cases are rare. We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

A description of this clinical trial will be available on *http://www.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.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that generally we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information. We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

How will I find out the results of this study?

Results from the study will be communicated with you through the LTFU newsletter as they become available once the study is completed.

Will I be paid to be in this study?

Everyone invited to join the study will receive $20 upfront, regardless of whether you decide to participate or not, or if you are eligible or not. If you want to participate and are eligible for the study, you will receive a free scale, blood pressure monitor, and the Withings watch to keep. You will also receive $25 to complete measurements at 3 months and 6 months, and $50 to complete the final measurement at 12 months (total of $100). We will also send you a $10 gift card when you return the ActiGraph device at baseline, 3 months, and 12 months.

How much will this study cost me?

There are no extra costs for being in this study. You will need to have access to either a telephone and/or the internet in order to participate in the study. The study will not be able to pay for these services. However, you will not need to purchase any special equipment or software for your phone or computer. The study can lend you a device to connect to the internet if you do not have a smartphone or computer.

What if I get sick or hurt after I join this study?

For a life-threatening problem, call 911 right away or seek help immediately. Contact your health care provider when the medical emergency is over or as soon as you can. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent. You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

For more information

If you have questions or concerns about this study, you may talk to your doctor anytime. Other people you can talk to are listed below.

If you have questions about:	Call:
This study (including complaints and requests for information)	206-667-4630 (Dr. Eric Chow, Principal Investigator) 206-667-4630 (Kari Jenssen, Research Coordinator)
If you get sick or hurt in this study	206-667-4630 (Dr. Chow)
Your rights as a research participant	206-667-4867 (Meghan Scott, Director of Institutional Review Office, Fred Hutchinson Cancer Center)

Signature of Participant

If you have read this form (or had it read to you), asked any questions, and agree to participate, please sign:

Printed Name Signature Date