S1820 Research Study Informed Consent Document

Study Title for Participants: Testing diet intervention versus non-diet intervention for management of bowel symptoms in rectal cancer survivors.

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

S1820, "A Randomized Trial of the **A**ltering **I**ntake, **M**anaging **S**ymptoms Intervention for Bowel Dysfunction in **R**ectal **C**ancer Survivors Compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (**AIMS-RC**)."

(NCT04205955)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try answering questions about how to keep diseases like cancer from happening, to find out if someone has a disease like cancer, and to treat diseases like cancer.

We are asking you to take part in this research study because you have bowel symptoms from your rectal cancer treatments.

Taking part in this study is your choice.

You can choose to or not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose your medical care or give up any rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It is important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for information on other clinical trials and cancer information.

Why is this study being done?

This study is being done to answer the following question:

Can your bowel symptoms from rectal cancer treatments improve by having health coaches help you manage your diet or change what you eat (or "diet intervention")?

We are doing this study because we want to find out if diet intervention is better or worse than getting healthy living information from health coaches.

What is the usual way to treat bowel symptoms from rectal cancer treatments?

The usual way for patients to treat bowel symptoms from rectal cancer treatments is over-the-counter medicines. Examples of bowel symptoms are diarrhea, constipation, loss of bowel control, gas, stomach pain, nausea, vomiting, and loss of water in the body. Other ways to improve bowel symptoms are pelvic floor (area just below your stomach) exercises, over-the counter-supplements, and fiber supplements or teas. Sometimes, these different ways are combined to treat bowel symptoms. Patients have been known to change their diet on their own to help ease their symptoms. Your doctor will explain and tell you which treatment(s) may be best for you. These treatments may or may not control bowel symptoms from rectal cancer treatments.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual treatment as explained above.
- You may choose to take part in a different research study, if one is available.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will complete a "run-in" period. The run-in period is a time for you to finish the first set of study activities and make sure you are ready to take part in the study phone calls. This period will last 2-3 weeks. You will be asked to fill out a 3-day food and symptom diary, a 24-hour diet recall, and a bowel symptom survey by telephone. If you finish these activities, you will be randomly picked by a computer to get diet intervention phone calls or the healthy living information phone calls for 17 weeks. You will also get email/text messages (3 messages every week) during the 17-week period based on the group you are picked to be in. If you finish the run-in period and are randomized, you will be in the study for another 26 weeks.

Your study doctor/nurse will ask you about your bowel symptoms and quality of life by asking you to fill out surveys at 18 weeks and 26 weeks after you are told which group you are in.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important that you think carefully about these as you make your choice.

Risks

We want to make sure you know about some key risks. There is more information in the "What risks can I expect from taking part in this study?" section of this document.

If you choose to take part in this study, there is a risk that the study (a diet intervention through phone calls) may not be as good as the healthy living information in treating your bowel symptoms.

There may be some risks that the study doctors do not know about yet.

Benefits

There is data that the diet intervention (health coaches helping you manage your diet or change what you eat) may help treat bowel symptoms and improve quality of life in rectal cancer survivors. This study may help the study doctors learn things that may help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can stop taking part in the study at any time.

If you choose to stop, let your study doctor/nurse or health coach know as soon as you can. It is important that you stop safely. If you choose to stop, you can decide if you want to let your study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may change your health or your choice to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer best for you.
- New information becomes known and the study is no longer best for you.
- You do not follow the study rules.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), or study sponsor (SWOG Cancer Research Network). The study sponsor is the organization that is in charge of the study.

It is important that you understand the information in the informed consent before making your choice. Please read or have someone read this document to you. If there is anything you don't understand, be sure to ask your study doctor/nurse.

What is the purpose of this study?

The purpose of this study is to find out if a diet intervention, or changing what you eat, is better or worse than healthy living information to treat bowel symptoms from rectal cancer treatments.

Studies have shown that bowel symptoms (such as diarrhea, constipation, lack of bowel control, and more bowel movements) are common after rectal cancer treatments (like surgery, chemotherapy, and/or radiation). Research also shows that bowel symptoms can lead to poor quality of life in patients with rectal cancer.

Some patients with rectal cancer treat their bowel symptoms by changing their diet and the type of foods they eat. However, they may have very little support in changing their diet in the right way. Diet interventions that teach patients how to find foods that cause bowel symptoms and change their diets based on the problem foods may help with bowel symptoms and improve quality of life. There are few treatments for bowel symptoms after rectal cancer treatments that have been tested in research.

This study will help study doctors find out if the diet intervention is more helpful than the healthy living information in treating bowel symptoms after rectal cancer treatment. To decide if it is more helpful, study doctors will be looking to see if the diet intervention leads to less bowel symptoms compared to healthy living information.

There will be about 94 people taking part in this study.

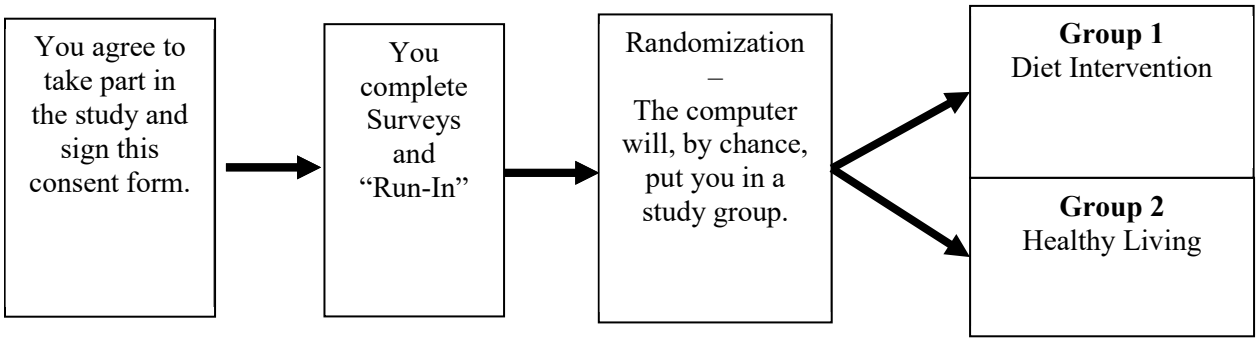
What are the study groups?

This study has two study groups (Group 1 and Group 2). A computer will select you to be in one of these groups. This is called "randomization." It means that your study doctor will not choose, and you cannot choose, which study group you will be in. You will be put into a group by chance. The study staff will tell you which group you will be in.

The study activities will be given to you by trained health coaches from the University of Arizona in Tucson, Arizona. The health coaches have taken 12 week training classes in health and nutrition. The health coaches have 2 or more years of experience in cancer. The health coaches have worked with hundreds of cancer patients in research studies testing diet interventions. You will be asked to give your telephone number, home address, and email address to your study staff. This information is needed so the University of Arizona health coaches can get in touch with you. Your information and name will only be given to the University of Arizona team. The University of Arizona team will not have your medical information. If you are in Group 1 or Group 2, you

will get a welcome phone call from your health coach, followed by weekly calls for 6 weeks, calls every other week for 2 months, and then calls monthly for 2 months. After your welcome phone call, you will also get one short text message or email.

Another way to understand what will happen to you during this study is to read the chart below. Start reading from the left side and read across to the right, following the lines and arrows.



- **Group 1—Diet Intervention**

  If you are in this group, you will get a diet intervention, or a change in what you eat, through 10 phone calls for 17 weeks (about 4 months). A trained health coach from the University of Arizona will be calling you to give you the diet intervention. Each phone call will last 15-60 minutes. Some phone calls will be shorter, and some may be closer to 60 minutes. You and your health coach will decide how long each phone call should be.

  The diet intervention is called Altering Intake, Managing Symptoms for Rectal Cancer, or AIMS-RC.

  The AIMS-RC phone calls will be given as follows:

  Session 1 introduces the group activities. A trained health coach will talk to you about your bowel symptoms. The coach will work with you to find your goals for changing your diet to control bowel symptoms. The coach will talk about any diet changes that you are already using to treat your bowel symptoms. The coach will teach you how to use a 3-day food and symptom diary to find foods that help your symptoms and foods that make your bowel symptoms worse.

  Sessions 2-6 will be weekly calls. In these calls, the health coach will teach you how to use your food and symptom diary to change the way you prepare foods to help with bowel symptoms. Your health coach will go over your food diary, bowel symptoms, and goals with you.

  Sessions 7-8 will be every other week phone calls. In these calls, the health coach will go over the information that you learned about diet change in Sessions 1-6. Your health coach will also talk about how to follow a healthy diet after cancer treatments.

Sessions 9-10 will be monthly phone calls. Here, your health coach will go over what you've learned and how far you've come in the last 8 phone calls, and go over the diet change skills that you learned.

A notebook with information on the diet intervention will be given to you.

In addition to the 10 phone calls, you will also get short text and/or email messages during the 17-week diet intervention. You can choose to get the messages through texts or emails. At Session #1, you will receive one welcome message. In Sessions #7-10, you will receive 3 text messages or emails every week from the trained health coach in between your phone calls. The messages are used to support your use of the diet intervention.

There will be about 47 people in this group.

- **Group 2—Healthy Living Information**

If you are in this group, you will get healthy living information after rectal cancer treatment through 10 phone calls for 17 weeks (about 4 months). You will not get the diet intervention through phone calls. A trained health coach from the University of Arizona will call you to give you the healthy living information. Each phone call will last about 15-60 minutes. Some phone calls will be shorter, and some may be closer to 60 minutes. You and your health coach will decide how long each phone call should be.

The healthy living information is given in 10 topics, and the health coach will talk about each topic with you during each phone call. The 10 topics are:

1. ACS Diet and Activity Recommendations
2. Sleep
3. Skin Care
4. Sun Safety
5. Active Wear
6. Bone Health
7. Food Safety
8. Survivorship and Surveillance
9. Evaluating Online Resources
10. Clinical Trials

Session #1, you will get one welcome text or email message. The health coach will talk to you about the group and topic #1 listed above.

Sessions #2-6, you will get weekly calls from the health coach to talk about topic #2 to #6 listed above.

Sessions #7-8, you will get 3 text messages or emails every week from the trained health coach on the 10 topics from the phone calls. The phone calls will happen every other week, and the health coach will talk about topic #7 and #8 listed above. You can choose whether to get text messages or emails.

Sessions #9-10, you will get 3 text messages or emails every week from the trained health coach on the 10 topics from the phone calls. The phone calls will happen monthly, and the health coach will talk about topic #9 and #10 listed above. You can choose to get text messages or emails.

A notebook with healthy living information will be given to you.

There will be about 47 people in this group.

What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review your treatments. This helps your doctor decide if it is safe for you to take part in the study. Your study doctor or study staff will also ask you some questions about your bowel symptoms. This is done using 5 questions on how bad your bowel symptoms are. Based on your answers, you can take part in the study if your study doctor finds out that you have bowel symptoms.

If you can and decide to join the study, you will be asked to answer a set of surveys. They will take about 15-60 minutes to complete. The surveys include questions about your:

- Quality of Life (physical, emotional, social, and spiritual)
- How prepared you feel in managing bowel symptoms
- Your reasons for managing bowel symptoms
- Emotions or feelings that you might show about managing bowel symptoms.
- Your highest education, if you are married, or have a partner, if you changed your diet after your operation, and how long it took for you to feel good about eating after your operation.

After you answer the baseline surveys, study staff will give you a packet to take home. This packet includes a 3-day food and symptom diary, with steps on how to fill out the diary. You will get a phone call from a trained staff member at the University of Arizona in 48 hours of getting the packet. During this phone call, the staff member will:

- Teach you how to use the food and symptom diary and send it to the University of Arizona team (by mail or email).
- Ask you about the kind of foods you ate, and how much you ate, in the last 24 hours.
- Ask you questions about your bowel symptoms.

This call will last about 60 minutes.

When the University of Arizona team gets your food and symptom diary, they will go over the diary. If you filled out the diary and sent it back to the University of Arizona team, you will be put, by chance, into Group 1 or Group 2. If you did not fill out and send back the diary, you will not continue with the study. If you do not continue with the study, the University of Arizona team will mail a packet to you with information on healthy living after cancer treatment.

At week 18 & week 26 after you find out which group you're in, you will:

- Get a phone call from a trained staff member at the University of Arizona to answer questions about your bowel symptoms. This call will take 10 minutes.
- Fill out a packet of surveys at your clinic or hospital. The surveys have some of the same questions that you answered when you first started the study. The surveys will take about 30-60 minutes to answer. The questions in these surveys ask you about your:
    - Quality of Life (physical, emotional, social, and spiritual)
    - How prepared you feel in managing bowel symptoms
    - Your reasons for managing bowel symptoms
    - Emotions or feelings that you might show about managing bowel symptoms
    - How satisfied you are with the phone calls from the health coaches

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that the diet intervention may not be more helpful than the healthy living information.

You may also have the following:

- Be asked questions about things you don't talk about all the time; this may make you feel unhappy.
- You may become tired or unhappy from the time taken to be on the phone and filling out surveys.
- Your bowel symptoms may get worse.

There may be some risks that doctors do not yet know about.

Possible Side Effects of Participation

If you become tired or unhappy, your health coach and study doctor/nurse will find out how to best take care of this. Your health coach will let your study doctor/nurse know about any emotional problems or worries for your safety. If you tell the coach that you want to hurt yourself, the coach must report this to your study doctor/nurse. Your study doctor/nurse may tell you about support and counseling that you can use. These may include social work, psychology, and others. You or your insurance may have to pay for these services. Your study doctor/nurse will work with you to find the best information, as needed.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your study doctor/nurse about:
    - all medicines you are taking
    - if you have been or are taking part right now in another study.
- Take part in all scheduled phone calls.
- Fill out all surveys.

What are the costs of taking part in this study?

You should not have to pay to be a part of this study. However, you may have to pay for text messaging. If you have to pay more money to get study text messages, you may get the messages through email. You may also need to pay more money to buy foods for a healthy diet.

Ask your study doctor or nurse for help to find the right person to talk to if you are unsure what will be billed to you or your insurance.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What happens if I get hurt taking part in this study?

If you get hurt while taking part in this study and need treatment, please talk with your study doctor/nurse right away about your choices. The study sponsors will not pay for treatments if you get hurt on the study. Your insurance may not pay for treatments if you get hurt on the study. Ask them if they will pay. If you do not have insurance, you would need to pay for the treatments.

If you feel that you got hurt because of a mistake made by the study doctors or others in charge of the study, you have the right to ask for payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

It is very important to us to protect your information. The study doctors will do their best to protect it. The study doctors must help protect your information if there is a court case. However, some of your information may be given out by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not tell others who you are.

Some of your health information, such as your treatments and medicines you took, will be stored by the study sponsor in a research database. However, your name and information will not be put in the database. If information from this study is given in journals or at scientific meetings, your name and other personal information will not be used.

There are groups that may look at your study records. Your health information in the research database also may be shared with these groups. They must also protect your information, unless the law tells them to give it to another group.

Some of the groups that may look at your study records are:

- The study sponsor (SWOG Cancer Research Network) and University of Arizona.
- The NCI Central Institutional Review Board (IRB), which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The NCI and the groups it works with to go over research.
- The NCI's National Clinical Trials Network and the groups it works with to do research.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research, with protections for your privacy. The goal of this data sharing is to make more research data available that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at this stored information and information from other patients to see who had side effects across many studies, or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor/nurse will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor, _____(*insert name of local study doctor*) at _____(*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the _____ (*insert name of organization or center*) Institutional Review Board at _____ (*insert telephone number*).

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

My signature agreeing to take part in the study

I have read this consent form, or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature _____

Date of signature _____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature _____

Remote consent:

Consent obtained by: Phone_____Videoconference_____

Date of phone or videoconference:_____

Date the signed consent was received:_____

Include a brief reason for performing the informed consent discussion over the telephone/videoconference: