Official Title:	Diet and the Colonic Exfoliome: A Novel, Non-Invasive Approach to Testing Interventions in Humans
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Fred Hutchinson Cancer Research Center (Fred Hutch)
Consent to take part in a research study:

Fish and Fiber

Principal Investigator: Johanna Lampe, PhD. RD, Fred Hutch, (206) 667-6580

EMERGENCY CONTACT
Please call Project Manager, Lisa Levy
Weekday daytime: (206) 667-6340
Evenings, weekends and after-hours: (206) 979-3745

Important things to know about this study.

The purpose of this research is to understand the combined effect of fish oil and fiber. There have been many studies looking at them separately, but not together. Studies in animals have shown that the combination reduces colon tumor formation. We are interested in understanding how the combination works in the human body and what potential it may have to prevent colon cancer. We will look at changes in health markers in blood and stool as well as changes in the intestinal microbial communities (as seen in the stool).

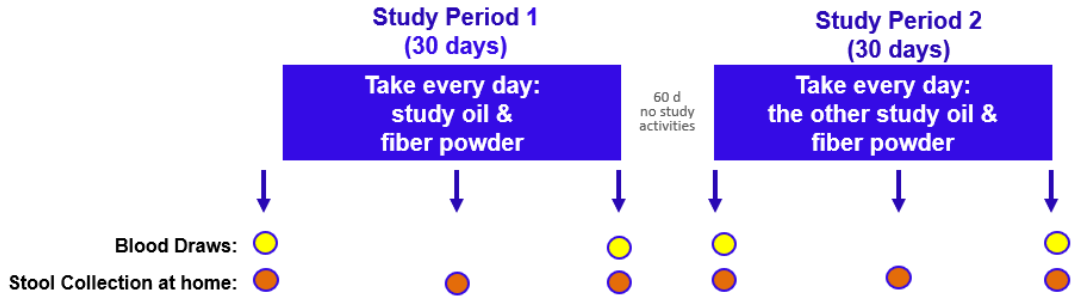
Participants go through two study periods. During one study period they incorporate fish oil and a fiber powder (all provided by the study) to their usual diet. During the other period they take the "placebo" (supplements that look exactly like the fish oil ones but contain corn oil instead, and a powder that is a similar corn product but is not considered a fiber). Half the participants start with the fish oil plus fiber supplements, and the other half will start with the placebo supplements. All participants go through both periods.

If you decide to participate, this is what we ask you to do:

1) Take the study supplements every day for 30 days each period.
2) Come to our center (in South Lake Union) for blood draws at the beginning and end of each period.
3) Collect stool samples (at home) at the beginning, middle and end of each period and bring them to our center.
4) Fill out forms and questionnaires At the beginning and during the study.

You do not have to join this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will also give you any other information that you may need in order to make an informed decision about joining this study.

Here is a summary of the main activities:



Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We invite you to join this research study.

Up to 40 people will join this study.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions. You do not have to be in the study. You are free to say "yes" or "no", or to drop out after joining.

Why are we doing this study?

Studies in animals have shown that both fish and dietary fiber may reduce colon tumor formation, and that the two in combination are even more effective. The bacteria in the gut may play an important role. In humans, some epidemiologic studies suggest that people who consume high-fiber diets or use fish oil supplements may have a lower risk of colorectal cancer, but there are no controlled dietary studies looking at the combined effects.

What research activities are done in this study?

1) **Take the study supplements** every day for 30 days each period.

   The supplemental oils (fish oil during one study period, and corn oil during the other period) come in small glass bottles. We ask you to consume 2 bottles of oil each day. Each little bottle contains about 1 tablespoon of oil. It has a very mild taste. You can add it to your food, mix it into a liquid or take it straight. We ask you not to cook with it because some of the oil's properties that may be beneficial are lost when heated.

   The supplemental fibers (soluble corn fiber during one study period, and maltodextrin -also made from corn- during the other period) come in packets. We ask you to consume one packet a day. These powders do not have any flavor and can be easily added to other foods or liquids.

   During the study visits at the beginning and mid-point of each study period, we will give you a box with all the supplements needed.

2) **Blood draws** at the beginning and end of each of period. A certified health care assistant will draw blood from a vein in your arm (approximately 45 ml or about 2.25 tablespoons). These draws are usually in the early morning. We ask that you not eat anything during the night or for breakfast. This means you will be fasting for 10 hours. You may drink as much water as you want.

   After the first draw we will send a sample to QUEST Diagnostics to make sure your liver and kidney functions are within the normal range. If they are not within normal range, we will provide you with a copy of the results for you to consult with your doctor, but you would not be able to continue with the study. During these clinic visits we will also measure your height and weight.

3) **Collect stool samples** at the beginning, middle and end of each period and bring them to our center. We will provide you with collection kits to take home. There will be four small plastic vials that have a little spoon on the lid to aid you in putting some of your stool into the vials.

4) **Forms and questionnaires** at the beginning of the study ask you about your health, habits and usual diet. During the study periods there will be questions about how you are feeling.

How long would you stay in this study?

If you join this study, you would stay in it for at least 4 months.

Study staff could take you out of this study at any time. This would happen if:

- They think it is in your best interest not to continue in the study.
- You are not able or willing to follow study procedures.
- The whole study is stopped.

If you withdraw from the study for any reason, previously collected information would remain in the study records and would be included in the analysis of results. This information could not be removed from the study records.

What are the side effects (risks)?

Possible risks of participating	
DIETARY SUPPLEMENTS When: Period 1: Every day for 30 days Period 2: Every day for 30 days	**Risks:** Oil supplements: Fish oil may cause belching, bad breath, heartburn, nausea, loose stools. There are people who may not know that they are allergic to fish. Fiber supplements may cause mild bloating and abdominal distension. Most people adapt to these supplements within 3-5 days. **Safety measures:** Taking the supplements with meals can often decrease gastrointestinal side effects. Participants will be instructed to report all symptoms. Study staff will be available via text and email for any concerns and to suggest ways to minimize side effects. A daily form will include space for commenting about symptoms or issues. If there are any indications that a participant has a food allergy that was not previously known, we immediately have them stop the intervention. The study coordinator has an emergency cell phone and can be reached 24/7 by study participants.
BLOOD DRAWS Total: Four fasting blood draws When: Period 1: A week before starting & Day 30 Period 2: Day 1 & 30	**Risks:** We do not expect you to have any side effects from the amount of blood taken for this sample. You may experience a little discomfort or have a temporary bruise from having blood drawn. Some people feel lightheaded or feel faint. **Safety measures:** Our staff has many years of experience and will make every effort to minimize any risks. Our staff will be attentive. If you feel lightheaded we will have you lie down until the feeling goes away. Everyone gets something to eat and drink after each blood draw.
STOOL COLLECTIONS Total: Six When: Period 1: Days 1, 15 & 30. Period 2: Days 1, 15 & 30	**Risks:** Collecting may feel inconvenient or uncomfortable.

What are the benefits?

Although the study will not benefit you directly, we hope the information we learn will help people prevent colon cancer in the future.

You have other choices besides this study.

You do not have to join this study. You are free to say "yes" or "no". Your regular medical care will not change if you decide to say "no" since the study is not related in any way to your health care.

Protecting Privacy as an Individual and the Confidentiality of Personal Information

If you join this study, some people or organizations might 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 Hutch IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Research Center
- US Food and Drug Administration (FDA)
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other regulatory agencies as required.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- 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.

Would we pay you if you join this study?

If you join this study and do what is necessary, you will receive a check for $250. If you do not complete the study, you would receive a partial payment based on the following schedule: If you complete all the activities of only one study period then we will pay you $75.

Would you have extra costs if you join this study? There are no extra costs for being in this study.

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

For a life-threatening problem, call 911 right away or seek help immediately. Contact the study manager when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact the study manager. If treatment is necessary, 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, loss of a job, 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 form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

Your rights

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

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.

Your responsibilities

If you join this study, you would have some responsibilities.

- Follow the schedule of study visits and procedures.
- Take study supplements as directed.
- Tell us about any side effects.

For more information

If you have questions or concerns about this study, you could talk to are listed below.

EMERGENCY CONTACT
Please call Project Manager, Lisa Levy
Weekdays 9am-5pm: (206) 667-6340
Evenings, weekends and after-hours: (206) 979-3745

If you have questions about:	**Call:**
This study (including complaints and requests for information)	(206) 667-6580 (Dr. Johanna Lampe, Principal Investigator) (206) 667-6340 (Lisa Levy, Project Manager)
If you get sick or hurt in this study	(206) 667-6580 (Dr. Johanna Lampe, Principal Investigator)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center)

What will my information and/or samples be used for?

Your information and stool and blood samples will be used for the purposes of this study.

In addition, be aware that by agreeing to participate in this study, your information, blood and stool samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board if required by law. The information that identifies you will first be removed from your information or samples. If you do not want your deidentified information or samples to be used for future research studies without your consent, you should not participate in this study.

Signature

Please sign below if you:

- have read this form;
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant:

Printed Name	Signature	Date

Protocol: RG1006100
Current consent version date: 07/15/20
Previous consent version date: 10/24/19
Copies to: Participant

FHCRC IRB Approval
OCT 29 2020
Document Released Date