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Fred Hutchinson Cancer Center
University of Washington

Consent to take part in a research study:

Implementing a plant-based whole-foods meal delivery service for patients undergoing autologous hematopoietic cell transplantation for Multiple Myeloma: A pilot study

Short title: Plant-based foods for improving the microbiome after auto-HCT

Principal Investigator: Kate Markey, MBBS, MClinRes, PhD, FRACP. Fred Hutchinson Cancer Center. Telephone: 206-667-7195

Emergency number (24 hours): 206-598-6190

Ask for Dr. Kate Markey

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to determine the feasibility of providing a plant-based, whole-food meal delivery service for people undergoing autologous hematopoietic stem cell transplantation for multiple myeloma. During the study, you will receive plant-based meals, delivered by a company called Thistle, and we will ask you to track what you eat.

Participating in the research study does not mean that you can only eat the delivered meals. We encourage a variety of oral intake as long as additional foods are still within our food safety guidelines for ASCT patients.

People who agree to join the study will be asked to meet with a research-focused dietitian weekly over about 5 weeks. The study involves enrolling in a meal delivery service, stool and blood sample collection for research, and food diaries and questionnaires about your symptoms and health. As well as understanding the feasibility of the meal deliveries, we are interested in tracking changes in the intestinal microbiome after your transplant and will do this by analysing stool samples.

We do not know if eating the food provided by Thistle will be well-tolerated during the transplant period, and we aim to find that out during this research study. We do not know if eating more plant-based foods will benefit participants directly, but we hope the information we learn will help people going through autologous stem cell

transplant in the future. A healthy microbiome has been linked with better outcomes in patients having this type of transplantation in prior research studies.

You do not have to join this study. You can choose to follow your regular diet instead of participating in this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need in order to make an informed decision about joining this study.

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.

We invite you to join this research study because you have multiple myeloma and are receiving an autologous hematopoietic stem cell transplant. Up to 20 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. If you say “no,” you would have no penalty or loss of benefits. Whatever you decide, your regular medical care would not change.

Why are we doing this study?

We want to know if eating a plant-based, whole-food diet might help prevent gut microbiome damage during the autologous transplant process. To answer this bigger question, we first need to prove that our meal delivery strategy is feasible and well-tolerated by patients receiving transplantation, and this first step is the goal of this study.

Thistle is a commercial company that delivers plant-based, high nutrient meals directly to peoples homes. There is a rotating menu of prepared meals (breakfasts, lunches, dinners and snacks) that will be delivered to participants at their homes or at local accommodation near the Fred Hutch clinics.

What research tests, procedures, and treatments are done in this study?

If you agree to be in this study:

- We will enroll you in the Thistle meal delivery service for about 5 weeks. Deliveries will be made twice per week to your home residence. The service includes breakfast, lunch, dinner, and a snack for every day. You will not be

restricted in what you can eat or how much you eat while participating in this study.

- Thistle will need your email address, delivery address and a phone number (for you or your caregiver) in order to ensure logistics of the deliveries can be completed.
- You will be able to 'log in' to the Thistle website and modify your deliveries according to your preferences.
- We will ask you to complete a daily food record (3 days per week) of what and how much you eat, including Thistle meals and any other food you eat throughout the day.
- In collaboration with Fred Hutch Nutrition Assessment Shared Resource (NASR), we will complete a 24-hr recall assessment over the phone at 3 time points (before transplant, after transplant when your blood cells start to recover and at study end).
- We will ask you to complete a series of short surveys that ask about your quality of life and symptoms you may be experiencing, once at the beginning of the study and once at the end. Some of the questions may be sensitive. Questions that make you feel uncomfortable would not have to be answered.
- We will take 2 blood samples of 30 mL each (about 6 teaspoons), once before your transplant, and once about 4 weeks after your transplant. This takes 1-2 minutes, and will be collected at scheduled clinical blood draws.
- We will ask you to self-collect stool samples at home about once a week during your participation in the study and return them when you come to clinic visits.
- We will examine your medical records.

Your blood will be tested at Fred Hutch and your stool samples will be sent to Zymo Genomics and Northwest Metabolomics Center for testing. All research samples will be coded with a unique code. The codes themselves do not contain information that could identify you.

We will also conduct genetic testing on your blood cells and stool samples. Your tissue contains DNA. DNA makes up the genes that serve as the "instruction book" for the cells in our bodies. By studying genes, researchers can learn more about diseases such as cancer. There are many different types of genetic tests, and in this study we may perform sequencing on the immune cells that we collect from your blood.

How long would you stay in this study?

If you join this study, you would stay in this study for about 5 weeks, starting about 1 week before your transplant and lasting until about 4 weeks after your transplant when you are discharged.

Your participation in the study will end if any of the following happen:

- You do not end up having an autologous hematopoietic stem cell transplant.
- Your doctors and clinical team 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 risks?

- The blood draw may briefly cause you to feel faint, lightheaded, or nauseated, and may cause bruising and/or swelling around the draw site.
- The stool collection may be embarrassing or messy.
- The surveys we ask you to complete about your quality of life and symptoms may make you feel uncomfortable.
- Your (or a caregivers) email address, physical delivery address, and contact phone number need to be shared with Thistle.
- Results of your genetic tests may be released by accident. This risk is very low, because we keep your personal information private. If your results become known, you may have problems with family members or insurance knowing about your genetic test results.
- If you experience an allergic reaction or suspected food-borne illness from the study food, please contact your doctor/medical provider at once.

What are the benefits?

Although we do not know if this study will benefit you directly, we hope the information we learn will help people with multiple myeloma 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 would not change if you decide to say “no”.

You have other choices for treatment. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about these choices.

Other choices include: following your regular diet or participation in another research study.

Enrollment in this study may exclude you from other research studies.

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 medical records and 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. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Center, University of Washington.
- Office for Human Research Protections, and other regulatory agencies as required.
- Thistle; they are supplying the meals for this study.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be disclosed if required by law. For example, we are required to report certain diseases and infections to public health authorities. We are also required to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you about lab tests. Or a court may order that study information 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.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

How is my genetic information protected?

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect genetic information about people who join research studies.

GINA restricts access to genetic information so that it cannot be used for health insurance coverage decisions. GINA prevents health insurance companies or group health plans from:

- Asking for genetic information obtained in research studies, or
- Using genetic information when making decisions regarding your eligibility or premiums

GINA *does not* help or protect against genetic discrimination by companies that sell life, disability or long-term care insurance.

Would we pay you if you join this study?

There is no payment for being in this study.

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 your study doctor 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 Principal Investigator, Dr. Kate Markey at 206-667-7195. She 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, 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.

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

Your information and tissue samples (such as blood and stool samples) will be used for the purposes of this study. For example, we will evaluate your fecal microbiome to determine if initiating and maintaining a plant-based whole-food diet leads to increased production of microbe-generated metabolites known to support gut health. We will evaluate your blood for metabolites and watch as immune cells recover from transplant. We will study these immune cells using a method called flow cytometry. We may also perform special types of sequencing of the immune cells (e.g. transcriptomics, or T cell receptor sequencing). We will also use the information you give us how you like the meal delivery service to help us prepare future studies.

Your tissue samples might help researchers develop new products. This research could be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your tissue samples.

During this study, we do not expect any test results that would affect your care, so we do not plan to return results to you.

Will my information and/or tissue samples ever be use for future research?

After we do tests on tissue in this study, some tissue may be left over. We invite you to donate this leftover tissue for future research. This may include genetic research. We also would like to use your information for future research.

If you join this study, you would not have to donate tissue or information for future research. You would be free to say "yes" or "no." Regular medical care would not change if you say "no."

If you say "no," your tissue and information (even if made anonymous) will not be used in future research.

If you donate tissue and information, it would be stored in a secure location. If we want to use your tissue for other research or share it with other scientists for research, an ethics review committee (IRB) would review the request. The IRB would decide if we need to ask you for permission to do the research.

Your donated tissue and information would be used only for research. This research could be done by for-profit companies. Researchers would not report their results to you or your doctors. The research results would not be included in medical records. The results would not affect your medical care.

Research with tissue and information might help develop new products. If these products make money, there is no plan to share the money with the participants who donate the tissue.

If you donate tissue and information for research, you could withdraw the donation at any time by calling Dr. Kate Markey at 206-667-7195. You would have no penalty for withdrawing the donation, and regular medical care would not change. We could not return donated tissue to you or your doctor, but we might be able to destroy the donated tissue. We could not destroy tissue if it is stored or shared without any label saying who donated it. In this case, it could still be used for research.

Future genetic research databases

Several genetic databases are available to help researchers understand different diseases. These databases contain DNA code and medical information from participants who have various diseases.

As part of this study, we would like to release DNA code and information about your medical condition into a genetic database in order to help future research. The genetic database would not contain names, addresses, or other information that could be used to identify you.

The DNA code in a genetic database cannot be used by itself to identify any specific person. A researcher who already has DNA code about you could use information from a genetic database to learn more about you. Once we release information to a genetic database, we no longer have any control over the use of this information.

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.

Your responsibilities

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

- Follow the schedule of study visits and sample collections to the best of your ability.
- Record your food intake at least 3 days per week.
- Help us understand the usefulness of the meals so we can design another larger study in the future.
- Tell us if you experience any side effects or reactions to the study meals.

For more information

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

If you have questions about:	Call:
This study (including complaints and requests for information)	206-667-7185 (Dr. Kate Markey)
If you get sick or hurt in this study	206-667-7185 (Dr. Kate Markey)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center) 206-543-0098 (Human Subjects Division, University of Washington)
Your bills and health insurance coverage	206-606-6226 or toll-free at 800-304-1763

Emergency number (24 hours): 206-598-6190

Ask for Dr. Kate Markey

Read each question and think about your choice. When you decide on each question, please circle **YES** or **NO**.

Do you agree to donate your tissue and information to study cancer? (circle one) **YES** **NO**

Do you agree to donate your tissue and information to study other health problems, such as diabetes, Alzheimer's disease, or heart disease? (circle one) **YES** **NO**

Is it OK if someone contacts you in the future to ask you to donate more tissue or information for research? (circle one) **YES** **NO**

Is it OK if we send your genetic information to one or more databases for future research? (circle one) **YES** **NO**

Signatures

Please sign below if you:

- have read this form (or had it read to you);
- 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

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

Protocol: RG1124594
Current consent version date: July 15th, 2024
Previous consent version date: N/A
Copies to: patient, medical record