

UNIVERSITY OF CALIFORNIA, IRVINE CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

The NUTRIENT Trial (NUTRitional Intervention among myEloproliferative Neoplasms Trial: Feasibility Phase)

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

RESEARCH TEAM

Lead Researcher

Angela G. Fleischman M.D. Ph.D.
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949-824-2559

24-Hour Telephone Number/Pager 503-481-3075

Other Researchers

Laura F. Mendez Luque M.D.

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STUDY LOCATION(S):

Sprague Hall B100

STUDY SPONSOR(S):

UCI Health Chao Family Comprehensive Cancer Center
Myeloproliferative Neoplasm Research Foundation (MPN-RF)

WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this research study is to see if people with MPN diagnosis can successfully change their diet to one of two healthy diets. We know that healthy diets can improve outcomes in other diseases and so we would like to test how a healthy diet affects MPN. But first, we must determine if MPN patients can actually follow a healthy diet.

This is a research study because we will be having you implement a diet change. We will also collection information on your ability to adhere to the diet (through both by your ability to follow the diet and your feedback), you blood samples to see how the diet changes your blood counts and inflammation markers, your stool samples to see how the diet changes the bacteria in your gut, and urine samples to measure the intake of certain foods. This sort of research looking a dietary intervention has never been done before in patients with MPNs.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 30 participants will take part in the research at UCI. This study is only available at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?

Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study

team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements

You can participate in this study if you are at least 18 years of age or older, have been diagnosed with MPN (polycythemia vera, essential thrombocythemia, or myelofibrosis), are willing to complete online surveys about your food intake and symptoms approximately every 2 weeks for 15 weeks, are willing to wear a fitbit activity tracker for 15 weeks, and are willing to provide blood, stool, and urine samples.

Exclusion Requirements

You cannot participate in this study if you do not speak, read and understand English language, are pregnant, have lost more than 10% of your total weight in the past 6 months, or have allergies to nuts or olive oil.

HOW LONG WILL THE STUDY GO ON?

This study includes 8 online questionnaires, 1 in person counseling session with a dietitian and 2 brief follow up phone calls with the dietitian, and 4 blood draws. We estimate this will take about 10 hours total of your time over a period of 15 weeks.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?

Before you can participate in the main part of the study...

You will have a “screening” questionnaire to determine if you are eligible for the study. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include asking you questions about your MPN and your general health. At the time of screening we will also ask you to have blood drawn, to collect a urine sample in the nearest bathroom, and to bring home a tube to collect a stool sample to return to us. If you are not found to be eligible for the diet intervention part of the study, we will ask to still use your blood, stool, and urine samples to determine how biological parameters correlate with food choices and symptoms on the screening questionnaire. We value your time and effort in participating in this study, so even if you are not eligible to participate in the intervention portion of the study we would like to thank you with a small gift of healthy food and also healthy diet educational materials.

During the main part of the study...

If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include...

Blood tests: we will collect blood from your arm in the same way as a usual blood draw. Blood draw will occur either in ICTS in Hewitt Hall or the lab on the 2nd floor of the Chao Family Comprehensive Cancer Center. This blood will be used to measure your blood counts, cholesterol, and levels of inflammatory proteins. We will make all efforts to draw these study labs at the same time as you get labs for your doctor’s appointments to minimize pain.

Urine: we will collect urine as a way to measure the amount of certain foods you are eating. You will be provided a cup and asked to fill it with a small amount of urine in the restroom closest to where you are. This will either be in Hewitt Hall or on the 2nd floor of the Cancer Center.

Stool Sample: Everyone has bacteria in their gut which helps them digest food. The food you eat can change the balance of bacteria in the gut, also the balance of bacteria in the gut has also been linked to inflammation. We will use your stool samples to measure the types of bacteria in your gut to see how this changes with your diet.

Online Survey: You will be sent an email with a link to a survey 6 times during the study, we will not tell you when to expect these surveys. Each survey will take approximately 10 minutes and will have

questions about what you have eaten lately, how you are feeling, and how easy the diet is to follow. If you do not complete the survey within 2 days of the email we will send you a reminder email. If you do not complete the survey within 4 days of the email we will call you. If you do not want to fill out the survey online we can also ask you the questions over the phone.

Fitness Tracker: We also are very interested in how diet affects your activity level and sleep. If you own a fitbit or other wearable fitness tracking device we will ask you to wear this and allow us access to your steps, stairs climbed, and sleep. If you do not have a wearable fitness tracker but have a smartphone with activity tracking capabilities we will gather your activity and sleep information from your phone. If you do not have a wearable fitness tracker or smartphone then we will loan you a Fitbit to wear during the entire course of the study. This is so we can see how your activity level and sleep changes with the diet.

This is the schedule of the study:

Weeks 1-2 – “lead in” period. You will be followed without intervention for two-weeks. This will allow us to obtain information on your normal eating patterns, intake, symptom burden, and level of inflammation in your blood. During this time you will complete one online survey, and donate one blood, one urine, and one stool sample. The blood and urine samples will be collected at the same time as your initial screening questionnaire. You will be given a kit to collect stool at the screening visit to bring home with you and return by mail.

Week 3-12 (10 weeks) – “intervention” period. You will be placed in one of two healthy diet groups. During week 3 you will have a 1 on 1 visit with the study registered dietician and will also have two brief follow up phone calls with the registered dietician. We will also provide you with weekly educational materials on the diet delivered via email in a colorful pdf format. You will be given provisions of healthy food or grocery gift cards twice during this intervention period. During this time period you will complete four online surveys and will donate two sets of blood, stool, and urine samples.

Week 13-15 (3 weeks) – “post intervention” follow up period. You will no longer receive educational materials but will continue with online surveys to see how you are eating and feeling. You will also donate one set of blood, urine, and stool sample. At the end of the study you will be offered the diet education materials for the other healthy diet you were not on.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

Because the intervention is a healthy diet consisting of food you likely are already eating it is unlikely that you will have any side effects. If the diet introduces foods you are not familiar with and you find you have intolerances or allergies to please let us know immediately.

Risks and side effects related to the procedures involved in this study include:

Likely

- Mild pain in arm with blood draw, bruising at site of blood draw
- Embarrassment and unpleasant odor involved in collecting stool

Less Likely

- Development of an allergy or intolerance to a food that is part of the diet but you are not familiar with
- Breach of confidentiality. We keep all of your data in a secure environment and but we cannot guarantee its security in the event that something happens beyond our control.

ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY?

Participant Benefits

Taking part in this study may or may not make your health better. While researchers hope that having a healthy diet will make MPN patients feel better and reduce inflammation, there is no proof of this yet.

Benefits to Others or Society

This study will help researchers learn more about the effect of diet on myeloproliferative neoplasm and other blood conditions, and it is hoped that this information will help in the treatment of future patients with myeloproliferative neoplasms and other blood conditions.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:

There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

You will receive either provisions of healthy foods such as olive oil or \$10 grocery cards as part of the study intervention to facilitate your adherence to a healthy diet. You will receive these twice during the intervention period of the study.

Reimbursement

You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you for participation in this study. However there may be out-of-pocket expenses such as parking and transportation fees.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately.** The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to follow up with a phone call to ask you about your experience with the study.

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.

Data Storage

Research data will be stored electronically on a secure network in an encrypted file with password protection.

Data Retention

The researchers intend to keep the research data until the research is published and/or presented.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be released or disclosed by these entities without your separate written consent, except as specifically required by law. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. Publications and/or presentations resulting from this study will not include identifiable information about you.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

ClinicalTrials.gov is a Web site that provides information about clinical trials. 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.

UCI's NCI-Designated Cancer Center or the Sponsor registers National Cancer Institute (NCI)-supported clinical trials with NCI through their Clinical Trials Reporting Program (CTRP) to provide study related information. The data provided will include the following identifiable information that may identify you: birth month/year and five-digit zip code. NCI uses the data to manage and enhance the nation's investment in cancer research.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?

Use of Specimens

Any specimens (e.g., tissue, blood, urine) obtained for routine labs will be discarded or destroyed once they have been used for the purposes described in this consent.

Investigator Financial Conflict of Interest

No one on the study team has a disclosable financial interest related to this research project.

UCI researchers may contact me in the future to ask me to take part in other research studies.

YES	NO
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WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep.

Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

Subject Signature

Date

Printed Name of Subject

Signature of Person Obtaining Informed Consent

(Individual must be listed on Page 1 of this consent)

Date

Printed Name of Person Obtaining Informed Consent

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.
 2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
 3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
 4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.
 5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
 6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.
 7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
 8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.
 9. To receive a copy of the signed and dated written consent form and a copy of this form.
 10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.
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If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.