Official Title: Impact of the Mediterranean Diet on the Gut Microbiome and Symptoms of Diarrhea-Predominant Irritable Bowel Syndrome
NCT03269032
IRB-Approved Date: 9/6/2022

Wake Forest®
School of Medicine

Department of Internal Medicine-Gastroenterology

Impact of the Mediterranean Diet on the Gut Microbiome and Symptoms of Diarrhea-Predominant Irritable Bowel Syndrome

(Healthy Adults)

Informed Consent Form to Participate in Research
Richard Weinberg, MD, Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are a healthy adult. Your participation is voluntary. Please take your time in making your decision whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to see if the type of diet you eat causes changes in the types of bacteria that normally live in your gastrointestinal (GI) tract.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Ten people at Wake Forest Baptist Health will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

During this study we will provide you with daily meals and snacks for 4 weeks. During the first 2 weeks these meals and foods will be like a typical American diet. For the second 2 weeks the meals and food will be designed to be like a Mediterranean-style diet. During the study you will make several visits to the Clinical Research Unit (CRU), as described in detail below.

At your first visit to the CRU, you will have a consultation with a dietitian, which includes completing a food frequency questionnaire and obtaining a resting metabolic rate by indirect calorimetry, a device that measures the amount of oxygen and carbon dioxide in your breath.

At your second visit to the CRU, you will provide a stool sample. If you are a woman, we will obtain a urine sample to ensure that you are not pregnant. If you are pregnant you will not be able to participate further in the study. You will then receive your first set of meals and snacks, which will be like a typical American diet. You will return to the CRU three times weekly just to pick up additional meals and snacks. If you have any problems with the diet, or have been feeling hungry, you can talk to the dietician about making adjustments.

After completing the first two weeks of the study, you will return to the CRU and provide another stool sample. If you are a woman, we will obtain a urine sample to ensure that you are not pregnant. If you are pregnant you will not be able to participate further in the study.

You will then receive your next set of meals and snacks, which will be a Mediterranean-style diet. If you consume alcoholic beverages, we will ask you to substitute 5 ounces of red wine for an equivalent amount of other alcoholic drink, at the same frequency you usually drink alcohol.

You will return three times weekly just to pick up meals and snacks.

After completing the two weeks of the Mediterranean-style diet, you will return to the CRU for the last time to provide a final stool sample.

Storage of Biological Tissue

If you agree to participate in this study, we will store your stool samples in the Section of Gastroenterology to use in this study and in future research to learn more about other diseases. An Institutional Review Board (IRB) must approve any future research study that uses your stool samples, and the samples will be given only to researchers approved by Dr. Richard Weinberg. To participate in this study, you must be willing to provide these samples for future research.

Your stool samples will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only Dr. Weinberg and his staff will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers, and neither will the code that links your identifiers to the sample.

In the future, researchers may want to contact you about other research studies. Would you like to be contacted for information about future research studies?

____YES you may contact me for future research studies

____NO I do not want to be contacted regarding future research studies.

How Long Will I Be in the Study?

You will be in the study for 4 weeks. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

What Are the Risks of the Study?

There is a very small chance that changing your habitual diet by eating the meals provided by the CRU could cause GI symptoms such as heartburn, indigestion, or a changes in your bowel habits. As with any foods, if you do not properly store and refrigerate the foods the CRU kitchen gives you, there could be a small risk of you getting food poisoning. Otherwise, the risk of harm

or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine medical or psychological examinations.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including food, will be paid for by the study. Costs for any medical care you may require during the study, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always a very small risk that de-identified information might be re-identified.

Subject information may be provided to Federal, State, and other regulatory agencies as required by law. The Food and Drug Administration (FDA), for example, may inspect research records at any time, and could learn your identity if this study falls within its jurisdiction.

If you choose to participate in this study, your medical record at Wake Forest Baptist Medical Center will indicate that you are enrolled in a research study. Information about the research, lab tests, and any interventions you get as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a North Carolina Baptist Hospital (NCBH) medical record will be created for you to ensure that important information is available to doctors in case of an emergency. This part of the medical record will be kept secure, and access to this information will be limited to individuals with proper authority, but who may not be directly involved with this research study.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. In the future, findings from this research study could result in development of products that have commercial value. If this happens, there are no plans to provide you with any financial compensation or for you to share in any profits.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences. The sponsor is

providing money to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, information about your health or behavior is considered Protected Health Information. The information we will collect for this research study includes**:** stool samples. We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information on a password protected computer.

Your Protected Health Information and other information that identifies you may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your Protected Health Information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your Protected Health Information. If it is disclosed by them, your Protected Health Information may no longer be covered by federal or state privacy regulations. Your Protected Health Information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If this happens, your Protected Health Information might no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Richard Weinberg that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Richard B. Weinberg
[redacted]

However, if remove your permission to use your Protected Health Information you will not be able to continue in the study. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study. By signing this form you give us permission to use your Protected Health Information for this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because new information becomes available, you failed to follow instructions, or because the entire study has stopped.

We will tell you about any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Richard Weinberg at [redacted].

The Institutional Review Board (IRB) is a group of people who review research studies to protect your rights. If you have a question about your rights as a research participant, would like to discuss problems or concerns, have any questions, want to offer input, or want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date: _____Time:____ am pm