Official Title: Implementation of a Mediterranean Diet Program for Overweight or Obese Pregnant Women in a Low-resource Clinical Setting

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Wake Forest University
School of Medicine

Department of OB/GYN

IMPLEMENTATION OF A MEDITERRANEAN DIET PROGRAM FOR OVERWEIGHT OR OBESE PREGNANT WOMEN IN A LOW-RESOURCE CLINICAL SETTING

Informed Consent Form to Participate in Research
Julio Mateus Nino, MD, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to compare two healthy diet styles during pregnancy. You are invited to be in this study because you are currently pregnant. Your participation in this research will involve being randomly assigned (like flipping a coin) to either receive routine healthy diet advice and counseling, or to receive advice and counseling for the Mediterranean style diet. You will be asked to complete a questionnaire during enrollment and contacted every 4-5 weeks to discuss your progress and receive additional advice and counseling which will take about 15 minutes. In addition, you will be encouraged to perform regular physical activity and blood will be collected at 2 time points during your pregnancy. You will receive 6 free meals every 3 weeks as well as oil and snacks. We also plan to collect data regarding your medical history, current pregnancy, and the baby outcome.

All research studies involve some risks but the risks of participating in this study are minimal. A breach of confidentiality is a risk with any research study, however, your data will be de-identified and stored on a secure, password-protected drive, database, and/or in a locked cabinet. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate. Your alternative is to not participate in this study.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies help scientists learn new information that may help other people in the future. You are being asked to be in this study because you are currently pregnant. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. 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 find out if a Mediterranean diet program can be provided to pregnant women in our practice, how well the diet is followed, and if weight gain as well as pregnancy/baby outcomes are better with the Mediterranean diet compared with a routine healthy diet style.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

60 people at Myers Park and North Park OB/GYN Clinic will take part in this study. In order to identify the 60 subjects needed, we may need to screen as many as 180 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to do the following things:

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin.

1. Mediterranean diet (MedDiet) program

   The Mediterranean diet (MedDiet) is a well-known healthy diet that consists of a large amount of plant-based foods such as fruits, vegetables, beans, and nuts with olive oil as the principal source of fat. Dairy, fish, and poultry are consumed in moderation and red meat only eaten occasionally.

2. Current routine healthy diet program
   The current routine healthy diet program follows the recommendations provided by the American College of Obstetricians and Gynecologists. It recommends the consumption of grains, fruits, vegetables, protein foods, and dairy foods during pregnancy.

At enrollment, you will be asked to complete 2 questionnaires.

1. The Federation of Gynecology and Obstetrics (FIGO) Nutrition Checklist, which allows us to access your baseline nutritional intake and determine if it is adequate for you and your baby.
2. The Food Insecurity questionnaire, which allows us to determine if you will need help with your nutritional needs during pregnancy.

At enrollment (between 6-16 weeks of pregnancy) and between 26-30 weeks of pregnancy, you will have approximately 1.5 teaspoons of blood withdrawn from a vein. The total amount of blood withdrawn during the study will be approximately 3 teaspoons.

At enrollment and every 4-5 weeks, you will receive dietary counseling for the diet program you are randomized to. A member of the research team will provide you with educational materials such as recipes, shopping lists, and meal plans. This counseling will include guidance to control weight gain during your pregnancy. You will be encouraged to participate in regular physical activity throughout your pregnancy.

You will receive 6 free meals every 3 weeks which will be delivered to your home. You will also receive free oil and snacks during your routine prenatal visit at the clinic.

How Long Will I Be in the Study?

You will be in the study throughout your pregnancy. We will collect additional information about your health at the time of your delivery. If you deliver a baby, we will collect information about the baby's health until the baby is 6 weeks old.

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.

Below is a summary of study activities:

	Screening/ Enrollment/ Randomization 6-16 Weeks		**Between 20-24 weeks of pregnancy**		**Between 26-30 weeks of pregnancy**		**Between 34-38 weeks of pregnancy**	
	Routine Diet	**MedDiet**	**Routine Diet**	**MedDiet**	**Routine Diet**	**MedDiet**	**Routine Diet**	**MedDiet**
Informed consent	X	X						
Inclusion/ Exclusion criteria	X	X						

Medical record release	X	X						
Medical, reproductive, & obstetric history*	X	X						
Nutrition (FIGO) checklist	X	X						
Food insecurity screening	X	X						
Diet information & handouts provided	X	X						
Diet and physical activity counseling	X	X	X	X	X	X	X	X
Blood draw for: 1. CRP 2. metabolic panel 3. Lipid panel 4. A1C	X	X			X	X		
Routine Diet adherence screening			X		X		X	
MedDiet adherence screening				X		X		X
6 meals delivered every 3 weeks	X	X	X	X	X	X	X	X
Oil and snacks provided	X	X			X	X		
Exercise/food recall and general assessment questionnaire			X	X	X	X	X	X
Pregnancy data collected*	X	X	X	X	X	X	X	X
Delivery data collected**								
Neonatal data collected**								

*Data will be collected through medical records
**Data will be collected at 6 weeks post-delivery through medical records.

What Are the Risks of the Study?

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 physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

As part of this study, you will be asked questions about your diet and physical activities. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins, and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks to your health.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be a direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may include:

- less weight gain during your pregnancy
- better nutrition for you and your baby
- improved baby outcomes

Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

What Other Choices Are There?

You do not have to be in this study. You should talk to the researchers about all the choices you have. Instead of being in this study, you have the option to receive the routine diet advice during your pregnancy.

What Are the Costs?

All study costs, including any study products or procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. Food other than the meals delivered to your house, the oil and snacks provided during your prenatal visits 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 or permitted by law, or necessary to protect the safety of yourself or others.

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

I give permission to Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to contact me by text message at the number I provided to send information, reminders, and to communicate with me about the research study. I understand that I am responsible for the standard text message rate of my carrier. I also understand that text messaging is not a secure form of communication and I accept the risk that individuals not involved in the research study may be able to access the text messages. I also understand that texting is not to be used for emergency situations.

By providing my email address, I give permission for Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

Will You Be Paid for Participating?

You will receive no payment for taking part in this study.

You will receive 6 free meals every 3 weeks delivered to your home. You will also receive oil and snacks during your prenatal visit at Myers Park or North Park Clinic.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University School of Medicine, Clinical & Translational Science Institute. The sponsor is providing money or other support to the researchers 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, any information we collect from you and any information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

- Medical, reproductive, and obstetric history
- Physical and dietary habits
- Current food insecurities
- Your demographics (age, gender, race, ethnicity, level of education, type of insurance, zip code)
- Current pregnancy, delivery, and neonatal data and outcomes

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") 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 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 Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), 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 health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your 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,

videotapes, audiotapes or other recorded media which identify you unless we have your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may 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. At that time any research information not already in your medical record will either be destroyed, or it will be de-identified.

You can tell Dr. Julio Mateus Nino 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:

Julio Mateus Nino, MD, PDH
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. 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.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of 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 it is in your best medical interest, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given 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. Julio Mateus Nino at [redacted] (after hours [redacted]).

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

NEONATAL RECORDS ACKNOWLEDGMENT
I understand and agree that the study team will collect my pregnancy outcomes data and neonatal data for my newborn at the end of a potential pregnancy as part of the study and that all of my statements and consents which I had given in the original Informed Consent remain valid.

Subject Name (Printed): _____

Subject Signature: _____Date: _____Time: _____ am/pm

Subject cell phone number: _____

Subject email address: _____

Person Obtaining Consent (Printed): _____

Person Obtaining Consent: _____ Date: _____ Time: _____ am / pm