Title: Effects of functional food diets on cardiometabolic and metabolomics profiles in minority young adults

NCT number: NCT04635917

ICF date: May 08, 2024

CONSENT FORM AND HIPAA AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

INVESTIGATOR'S NAME: JAAPNA DHILLON
PROJECT IRB #: 2022561

STUDY TITLE: Effects of functional food diets on cardiometabolic and metabolomics profiles in minority young adults

We invite you to take part in this research study. This consent form tells you why we are doing the study, what will happen if you join the study, and other important information about the study.

Please take as much time as you need to read this consent form. You can discuss it with your family, friends, or personal doctor. If there is anything you do not understand, please ask us to explain. Then you can decide if you want to take part in the study or not.

The Principal Investigator is Dr. Jaapna Dhillon. The people working with Dr. Dhillon on this study are called the study team.

The National Institute of Minority Health and Health Disparities (called the sponsor in this form) is paying for this study.

WHAT SHOULD I KNOW BEFORE I DECIDE WHETHER TO TAKE PART IN THIS STUDY?

- Research studies help us to learn new things and test new ideas about healthy lifestyles.
- Taking part in a research study is voluntary. You decide if you want to take part, and you can stop taking part at any time.
- *We are doing this study* to examine the effects of a personalized functional food diet on health outcomes and the gut microbiome compared to a conventional dietary advice. We are also hoping to learn if the outcomes are influenced by ethnicity/race.
- About 120 people will take part in this study at the University of Missouri.

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- If you take part in this study, you will come to *Gwynn Hall Room 018 six* times (including the screening visit). You will have *blood tests, questionnaires, and physical and clinical exams.* We will explain these procedures in this form.
- In the event we are unable to obtain the samples needed for this study, you may be asked to reschedule study visits at the MU Hospital's clinical research center (CRC) located on the fifth floor of the hospital.
- The total amount of time you could be in this study is about **10** *weeks*.
- Taking part in this study may or may not make your health better. We hope that the information we learn from this study will help in the improvement of health with functional foods.
- As with any research study, there are risks that we know about and there may be some we don't know about. We will explain these risks in this form.
- We will only include you in this study if you give us your permission first by signing this consent form.

Why Are The Researchers Doing This Study?

In this study, we want to find out if a personalized functional food diet for 8 weeks improves health outcomes more than conventional dietary advice and if these outcomes are influenced by ethnicity or race.

What will happen if I take part in this study?

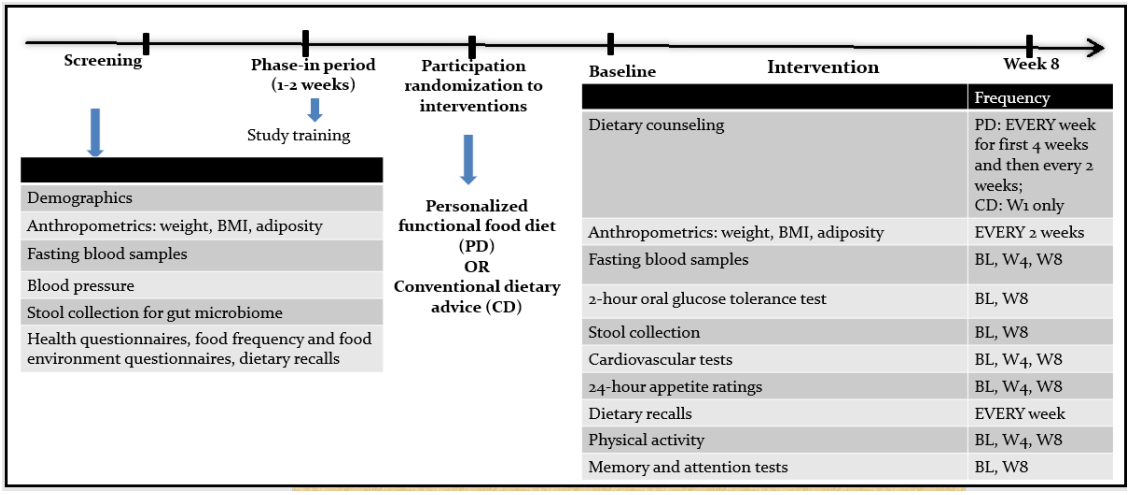

Figure 1: Study design and outcome measures. BL: Baseline, W4: Week 4, W8: Week 8

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Screening Tests

If you decide to join this study, you will sign this form and then you will have some screening tests to see if you qualify to be in the study. These are the screening tests:

- Physical Exam: You will have a physical exam to assess your height, weight, body fat%, waist and thigh circumference, and blood pressure like what happens during regular doctor visits.
- Questionnaires: The study investigators will also ask you complete questionnaires related to your health, stress perceptions, and dietary habits and environment.
- Stool Sample: We will ask you to provide a sample of your stool (3 ounces) for testing microbiome.
- Blood Tests: We will take about 3.2 teaspoons of blood from a vein in your arm for some tests. We will also take finger-stick blood drops.
- Urine test: If you are female, you will be asked to urinate on pregnancy test strips to confirm non-pregnant status.

If the results of these tests show that you can be in the study, you can start the study ***within one month***. If you do not qualify to be in the study, then you will not be able to participate in the study.

Research Study Groups

To find out if Personalized Functional Food Diet (PD) works better than Conventional dietary advice (CD) for metabolic and heart health, this study has *2* groups. 1) Personalized Functional Food Diet (PD): Participants in the PD group will receive personalized nutrition advice. Participants will be provided with functional foods such as nuts, fruits and vegetables. Diets will be individualized and formulated in partnership with a registered dietitian hired for the study. 2) Conventional dietary advice (CD): Participants in the CD group will receive non-personalized, conventional dietary advice by a dietitian based on the MyPlate guidelines at the onset of the study.

Because we don't know which of the *interventions* is best, we will "randomize" you into one of the *2* study groups for 8 weeks. "Randomize" means putting you into a group by chance. It is

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like flipping a coin or pulling a number from a hat. You will have a 50% chance of being placed in *either* group. A computer program chooses which group you go in. You *and the study investigators* cannot choose which group you go into.

Study Tests and Procedures

The intervention will be conducted over 8 weeks. One to two weeks prior to the 8-week intervention, you will begin the phase-in period, where you will be asked to maintain consistent diet and physical activity and will be provided with study training so that you are well-informed and completely understand all the procedures. The 8-week intervention requires 5 measurement visits to the MUPAW facility in Gwynn Hall, Room 018 or clinical research center (CRC) at the University hospital on Mizzou campus and 6-8 dietary counseling/data collection visits.

Study visits 1, 3 and 5 (baseline, week 4 and week 8)

a) If you are female, you will also be asked to urinate on pregnancy test strips to confirm non-pregnant status.
b) Your height and weight will be measured using standard scales, and your body fat percent will be measured using a bio-electrical impedance scale.
c) Your waist, hip and thigh circumference will be measured using a tape. Your waist height will be measured using a caliper. This measurement requires you to lie on your back, and the caliper will measure the height of your abdominal region, which gives an indication of your abdominal fat.
d) Your blood pressure will be measured using an automated blood pressure device. Your endothelial health will be assessed non-invasively using an EndoPat device which requires the placement of two fingertip probes, one on each hand. After a 5-minute recording at rest, a blood pressure cuff will be inflated on one arm for an additional 5 minutes.
e) You will be asked to provide stool (approx. 3 ounces) samples to assess gut microbiota. You will be provided the sterilized sealed specimen containers and will be asked to deposit the samples in the containers and return to Gwynn Hall.
f) A fasting blood sample (5.3 teaspoons) will be taken from a vein by a trained professional to determine serum glucose, insulin, lipids, triglycerides, adiponectin, desaturases etc. concentrations. In addition, a finger-stick blood drop will be taken to

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assess blood glucose using a glucometer. You will be required to fast for 8-12 hours prior to the visit. After the fasting blood sample is taken, you'll be asked to drink a sweet liquid that contains 75 g of glucose. And, another blood draw (5.3 teaspoons) will be taken 15 min, 30 min, 60 mins and 120 mins after. You will either be stuck each time for the blood draws during this visit or a catheter will be placed in your arm for the multiple blood draws during the visit (with saline infusions to flush the catheter). The catheter will be removed at the end of the visit. Catheter placement and management will only be done by a registered nurse or EMT-P. The total amount of blood drawn during the whole study will be 37 teaspoons. It will be up to the nurse or EMT-P's discretion to choose the most appropriate and safe body site for the blood draws.

g) You will also be asked to take some tests for attention and memory and complete health, stress perception, diet and environment questionnaires.

h) At the end of this visit:

1. You will be given a physical activity monitor that measures your free-living physical activity levels for two days (1 weekday and 1 weekend day). This is a device about the size of a small pager that is worn on your waist level to monitor your daily physical activity levels and to predict your daily energy expenditure. You will wear this device for 48 hours, except when you go to bed and when you are taking a shower or swimming (as the device is not water resistant)
2. You will be asked to record your hourly appetite ratings for 24 hours during waking hours using appetite questionnaires.
3. You will be asked to record your diet palatability and liking ratings using scales.
4. You will be asked to report your dietary intake using a 24-hour dietary recall method.

All these measurements will be repeated at the mid-point of the study i.e. at Week 4 (except OGTT, and endothelial/arterial function) and at the end of the study i.e. at Week 8 as well.

Study visits 2 and 4 (Weeks 2 and 6)

a) Your weight, body fat percent, waist, hip and thigh circumference, waist height and blood pressure will be measured like before.

b) At the end of this visit:

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1) You will be asked to wear a physical activity monitor for two days (1 weekday and 1 weekend day).

2) You will also be asked to record your hourly appetite ratings for 24 hours during waking hours.

3) You will be asked to report your dietary intake using a 24-hour dietary recall method.

4) You will be asked to record your diet palatability and liking ratings using scales.

Dietary counseling, dietary data collection and food collection

You will be seen by a dietitian on a weekly basis (in Gwynn hall or online) to establish your dietary prescription and monitor dietary adherence. Participants in the PD group will be counseled every week for the first 4 weeks and thereafter every 2 weeks. Participants in the CD group will be counseled at the onset of the study only and but will meet with the dietitian every week for the first 4 weeks and thereafter every 2 weeks for dietary data collection. Participants in the PD group will also meet with study researchers every week during the 8-week study to collect their study foods. Participants in the CD group will get their foods upon completion of the 8-week study.

Every day during the study

If you're in the PD group, you will be asked to connect with the study researchers virtually, online, or in-person at pre-decided sites on campus so that researchers can personally witness and confirm your consumption of study foods and note your sleep habits. This will be done every day during the study unless it's a weekend or you are not available in which case you will be asked to send time-stamped videos documenting consumption of study foods. If you're in the CD group, you will be asked to connect with the study researchers virtually or online in order to monitor sleep habits.

Duration of Participation

Your participation in this study requires 5 measurement visits and 8 dietary counseling or dietary data collection visits.

The length of each measurement visit is:

i. Visits 1,5: 3.5 hours at Gwynn Hall or CRC

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ii. Visits 2, 3, 4: 60 minutes at Gwynn Hall

The length of each dietary counseling visit is 60 minutes at Gwynn Hall or online.

We will keep the information *and* samples we collect from you for this study *to use in future research/to share with other investigators to use in future studies* without asking for your consent again. Information that could identify you will be removed from your research *data/samples* so no one will know that *it/they* belong to you.

The results of research testing may be shared with the dietitian so he/she/they can provide you with appropriate dietary counseling.

We will tell you if we learn information from these procedures that may be important for you to know. It is possible that this will mean you need more testing or treatment for a new or existing medical condition. You and/or your health plan/insurance will be responsible for the costs of this extra testing and/or treatment.

How Long Will I Be in the Study?

You will be in this study for about 10 weeks.

CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time without giving a reason. If you stop being in the study, your regular medical care will not change. Leaving the study will not affect your future medical care at the University of Missouri.

There is no penalty to you if you do not join the study or if you leave it early. You will not lose any benefits you are entitled to if you leave the study.

What health risks or problems can I expect from the Study?

There are minimal risks to taking part in any research study.

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We will closely watch everyone in the study for side effects. You need to tell the study investigator immediately if you have any problems, side effects, or changes in your health. *Investigator's* telephone number is 765-409-8756.

The possible risks are as follows:

- Fasting: May result in shakiness, nervousness, sweating, dizziness or light-headedness, sleepiness, confusion, difficulty speaking, anxiety, or weakness.
- Venipuncture: This is the standard medical procedure for obtaining a sample for blood tests. The blood collections may result in fainting, dizziness, pain, bruising and/or infection at the site of collection. Some bleeding may also occur during individual sticks and insertion of the catheters as well after the catheters have been removed. These risks will be greatly minimized by using sterile procedures and having a person experienced in phlebotomy procedures do the individual sticks. Catheter placement and management will only be done by a registered nurse or EMT-P. You will need to fast and participate in blood draws 3 times over the study duration each visit spaced by 4 weeks, and once during the screening visit. Hence, there is minimal risk involved to you. We expect adverse reactions to fasting and blood draws to be rare, not severe, and completely reversible.
- Ultrasound: Ultrasound is a low risk, pain-free way to locate a vein for venipuncture. A water-based gel is applied to the skin to create good contact with the transducer to the skin. While the gel may feel cold to some during the ultrasound, it wipes off easily once the imaging is complete
- Nut consumption: Repeated exposure to nuts can lead to a sensitivity or allergic response to nuts. If this occurs, you will be withdrawn from the study immediately. If you develop a rash or have difficulty breathing, you will be asked to stop taking nuts and contact your physician immediately.
- Fruits and vegetables consumption: Potential risks may include allergies, and gastrointestinal discomfort if consuming too many fruits and vegetables in one sitting. However, we screen for allergies to food items prior to enrollment, and participants are counseled by the study dietitian on how to include these foods in their diets, so risk is minimal.
- Endopat measurements: EndoPat device requires the placement of two fingertip probes, one on each hand. After a 5-minute recording at rest, a blood pressure cuff is inflated on one arm for an additional 5 minutes. Prolonged constriction of the arm may result in numbing of the

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extremities. However, the numbing is easily reversible within a few seconds and researchers will ensure that occlusion is not carried out longer than expected.

- Questionnaires: Some of the screening questions or study surveys may be sensitive in nature and may make you feel uncomfortable, but these questions would not be any more invasive than a general health checkup by a doctor. You can skip any questions that you do not want to answer.
- Economic risks: Possibility of finding a previously undiagnosed medical condition during screening and not having insurance coverage for further evaluation and treatment, as well as time lost from work or studies. If you are pregnant or become pregnant while in this study, there may be risks to you, the embryo or fetus that we do not know yet. However, if you are female, then we will be conducting a pregnancy test during the screening, baseline, week 4, and week 8 visits to make sure that you are not pregnant.
- Psychological risks: Risks may involve the stress of identifying a previous unknown medical condition during the screening selection. Psychological risks will be minimized by explaining this as being part of the informed consent and making sure that if a significant medical condition is diagnosed as part of the screening, every effort will be made to explain the condition to the subject, with recommendations for follow-up.

Are There Benefits to Taking Part in the Study?

You may benefit by receiving dietary counseling for a healthy diet. However, you may not benefit from participation and that there are no guarantees that your health or wellness will improve. In general, the study may lead to more effective dietary strategies for optimal health.

What about Privacy And Confidentiality?

The study team needs to *collect/use* some of your health/personal information. This information comes from questions we ask you, and forms you fill out. One risk of taking part in a research study is that more people will handle your personal health information. We are committed to keeping your personal information confidential. The study team will make every effort to protect your information and keep it confidential to the extent allowed by law. However, it is possible that an unauthorized person will see it. We are committed to respecting your privacy during the study visits. Privacy cannot be guaranteed for some time-sensitive blood collections and memory and attention tests since they'll be conducted in group settings. However, efforts will be made to

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segregate participants appropriately and put up curtains during blood draws to minimize discomfort.

Your information will be stored in the investigator's electronic/computer or paper files. Computer files are protected with a password and the computer is in a locked office that only study team members can open. Paper files are kept in a locked drawer in a locked office that only study team members can open.

Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location. Information that may identify you may not be given to anyone who is not working on this study without your written consent, or if required by law.

The people who may use and/or release your research information include:

- Those working on the study team at the University of Missouri
- The study sponsor, National Institute of Minority Health and Health Disparities
- The members of the University of Missouri Institutional Review Board (IRB)
- Those who check on research activities to make sure it is being done correctly and safely
- Other government or inspection agencies

We may present the results of this study in public talks or written articles, but we will not use information that can identify you.

By signing this consent form, you give us permission to utilize video conferencing in order to assess compliance to study food consumption.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not

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connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

CAN I SEE MY RESEARCH RECORDS?

You will be able to see your research records during the study.

Are There Any Costs To Being In The Study?

The study will pay for all research tests and procedures. You and/or your health plan/insurance will not be billed for tests and procedures that are done in this research study.

Will I be Paid for Taking Part in this Study?

If you do not qualify for the study, we will give you a $10 check after the screening visit.

If you qualify for the study but withdraw prior to starting the study, we will give you a $10 check when you withdraw.

If you qualify and participate in the study, your compensation will be pro-rated. You will be compensated $20/2-week testing period. If you complete all visits in the study and are compliant with the study protocol as assessed by dietary and data records, and study visits completed, you will be compensated an additional $120 at the end of the study. The total amount that you could receive is $200. Payment will be in the form of checks ***by mail 2 weeks after the last visit you complete.***

We will need your social security number in order to pay you. Any payment may need to be reported as income on your tax return. If you are not a resident/citizen (non-resident alien) of the United States, you will need to work with the MU Nonresident Tax Specialist at 573-882-5509.

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What Happens If I am Injured During The Study?

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff.
The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri.

In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information.
This statement is not to be construed as an admission of liability.

What Are My Rights as a Study Participant?

Taking part in this study is voluntary. You do not have to take part. Your present or future medical care will not be affected if you decide not to take part.

If you do decide to take part, you can change your mind and drop out of the study at any time. This will not affect your current or future care at the University of Missouri Hospitals and Clinics. There is no penalty for leaving the study and you will not lose any benefits that you are entitled to receive.

If the study investigator decides to take you off the study, *he/she* will explain the reasons and help arrange for your continued care by your own doctor, if needed.

We will tell you about any new information discovered during this study that might affect your health, welfare, or change your mind about taking part.

Where Can I Get More Information About This Study?

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A description of this clinical trial will be available on 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.

Who Can Answer My Questions About The Study?

If you have more questions about this study at any time, you can call Dr. Dhillon at 765-409-8756.

You may also contact the University of Missouri Institutional Review Board (IRB) if you:

- Have any questions about your rights as a study participant;
- Want to report any problems or complaints; or
- Feel under any pressure to take part or stay in this study.

The IRB is a group of people who review research studies to make sure the rights of participants are protected. Their phone number is 573- 882-3181 and their email muresearchirb@missouri.edu.

If you want to talk privately about your rights or any issues related to your participation in this study, you can contact University of Missouri Research Participant Advocacy by calling 888-280-5002 (a free call), or emailing MUResearchRPA@missouri.edu.

We will give you a copy of this consent form. Please keep it where you can find it easily. It will help you to remember what we discussed today.

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SIGNATURE OF STUDY PARTICIPANT

My initials below indicate my choice about using my *data/samples* for future research:

My *data/samples* may be stored and used for future research.

Yes _____ No _____

Consent to Participate in Research

By signing my name below, I confirm the following:

- I have read/had read to me this entire consent form.
- All of my questions were answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits were explained to me.
- I voluntarily agree to take part in this research study. I have been told that I can stop at any time.

Subject's Signature	**Date**

Signature of Witness (if applicable)	**Date**

SIGNATURE OF PERSON AUTHORIZED TO OBTAIN CONSENT*

I have explained the purpose of the research, the study procedures (identifying those that are investigational), the possible risks and discomforts and potential benefits of the study, and have answered questions regarding the study to the best of my ability.

Signature of Person Authorized to Obtain Consent	**Date**

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