Food is Medicine vs Lifestyle Medicine For Cardiovascular Kidney Metabolic (CKM) Syndrome

Clinical Trial # NCT06461273

Document Date – 2024/11/15

This document contains all four consent forms used in this study.

All participants signed the document titled "Consent for Screening" to allow access to the medical record for eligibility determination.

Eligible participants were then randomized to one of three intervention arms and asked to consent to the treatment to which they were randomized.

RUTGERS HEALTH

CONSENT FOR SCREENING

Title of Research: Food is Medicine vs Lifestyle Medicine: A Community Based Pragmatic Randomized Control Trial for Patients with Cardiovascular Kidney Metabolic (CKM) syndrome

Principal Investigator: Novneet Sahu MD, MPA

RESEARCH SUMMARY: The purpose of this screening is to collect eligibility information and determine whether or not you can participate in the main study and to store this information for future use. It is your choice whether to take part or not.

PURPOSE: We are looking to screen up to 200 people to determine eligibility to participate in a lifestyle medicine program. We will select 60 participants from those screened who are qualified for enrollment and invite them to participate. You will grant us access to your medical record so that we can assess your eligibility for enrollment.

RISKS/BENEFITS: The risks for screening are minimal with the possibility of a loss of confidentiality. The benefit is that it may qualify you for participation in our program and study.

ALTERNATIVES: Your alternative to taking part in the research study is not to take part in it and to continue your existing treatment plan with your primary care physician.

Who is conducting this research?
Novneet Sahu, MD is the Principal Investigator of this research. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Sahu is joined by Dr. Saul Bautista, MD; Dr. Emily Merchant, PhD; and Dr. Andrew Lynch, PT, PhD.

Dr. Sahu may be reached at:

185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Research: This research is being sponsored by the Rutgers Equity Alliance for Community Health (REACH; https://www.reach.rutgers.edu).

Why is this research being done?
Most Americans sick with chronic disease have been diagnosed with disease of the heart, kidneys, or metabolic system (cardiovascular kidney metabolic syndrome, CKM) such as hypertension, diabetes, or obesity. Many more are at risk for developing CKM. Those with diagnosed CKM and those at risk have a greater risk of other conditions like cancer and early death compared to those without CKM. While there are medications and surgeries to help deal with the consequences of CKM, the literature clearly shows that

changing diet and lifestyle are effective at reversing many aspects of CKM and preventing additional conditions and early death. However, lifestyle change is challenging for many.

We are not studying whether changes in diet and lifestyle are effective in reversing CKM. We are seeking to determine if group education classes focused on food choices, cooking, stress reduction, and physical activity are better than the current medical care model or simply providing healthy produce.

Who may take part in this research and who may not?
Individuals between the ages of 18 and 75 who are patients of the Family Practice Center at Rutgers Health – University Hospital who have been diagnosed with CKM without other substantial health challenges are eligible to participate in this research.

Inclusion Criteria
Participants will be included if they meet the criteria to be diagnosed with CKM which may include metabolic syndrome, overweight/obesity, poor control of blood sugar to include diabetes and pre-diabetes, high cholesterol and other blood fats, high blood pressure, chronic kidney disease, and cardiovascular disease with other metabolic risk factors. Additionally, they must have access to the MyDataHelps platform either through an internet connected device like a personal computer, Ipad, or their personal phone and consent to its use.

Exclusion Criteria
Some people may be excluded from the study if they have conditions that do not allow them to exercise in a group setting or require more extensive medical monitoring and intervention. This includes people with uncontrolled issues with their hearts and lungs (chest pain with exercise, dizziness/fainting, heart rhythm issues, recent surgery, uncontrolled hypertension, advanced heart failure, severe lung disease, etc.), significant mental health concerns (suicidality, substance abuse issues, major depressive symptoms, etc.), or other major organ system conditions (advanced chronic kidney disease, liver disease, neuromuscular diseases like Parkinson's Disease or advanced multiple sclerosis, active cancer).

1. Women who are pregnant or may become pregnant in the next 6 months are ineligible.
2. Individuals who have received a major organ transplant or who are on the transplant list are ineligible.
3. Individuals with a life expectancy of less than three years due to a medical condition are ineligible.
4. Lastly, people who have participated in diabetes, nutrition, or weight research intervention in last 12 months; those without access to the internet, and those who do not speak English will not be eligible.
5. Only one member of each household may take part in this study.
6. Individuals currently facing acute unresolved health-related social needs, including but not limited to, unstable housing, lack of reliable transportation, and unemployment are ineligible.
7. Individuals who have started treatment with a class of medications known as GLP-1 within 120 days of the program start or those not on a stable dose are ineligible.
8. Individuals who have undergone bariatric surgery.

Why have I been asked to take part in this research?
You have been asked to take part in this research because you may have factors associated with CKM syndrome and because you may benefit from changes to your diet and physical activity in addition to the changes that your physician recommends.

How long will the research take and how many participants will take part?

No more than 200 participants will be screened, and a total of 60 people will be selected for enrollment. The remaining eligible participants not initially selected for enrollment will be placed on a waitlist if a participant eligible for enrollment declines participating in the program and study.

The screening process will take 15 minutes to complete.

What will I be asked to do if I take part in this research?
If you take part in this research, you will be asked to interact with a smartphone application called MyDataHelps. The research team will use this application for two purposes – to access your medical information that is relevant to the study and to have you complete questionnaires about your health and lifestyle.

If you are eligible to be in the study and you are still interested in participating, you will be notified electronically via email. You will be invited to attend an orientation session which describes the study procedures and given another consent form to read and sign. That consent form will further explain the procedures, risks, and potential benefits of the main study prior to enrollment.

Data Privacy/Security Risks of Mobile Apps:
The data collected via the MyDataHelps app will be stored on your personal device and uploaded to the respective servers of each app.

Information collected by mobile applications or 'apps' is subject to their terms of use, and end user license agreements. You are encouraged to review the MyDataHelps and Terms of Use and End User License Agreement prior to using the mobile applications. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Rutgers Health cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Rutgers Health. During the study, you are encouraged to limit personal identifiers you enter into these mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to that information that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Strava). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully. For the purposes of this study, the data managed in the MyDataHelps secure platform for use and analysis by the Rutgers Health study team.

Access to Medical Records
To understand your health, we need to gather information from your medical records. We are looking for the results of blood tests, measures of your vital signs, and the types of medications you are using.

We will gather information about how your body is controlling the amount of sugar in your blood (hemoglobin A1c), and the cholesterol and fat in your blood (lipoprotein measurements and triglycerides).

We will also get measurements of your weight, body mass index, and waist size.

We will import a list of medications that you are taking, focusing on the medications being used to manage your CKM syndrome if you are taking any.

You will need to grant us access to your medical record through the MyDataHelps application. You will be asked to grant access to your record for **beginning the day you sign this form and up to 2 months after the date you sign this form if determined to be eligible for the study and if you choose to**

remain in the pool of screened eligible participants. We need access for this long to make sure that we can get the most accurate information about your eligibility until the program start. Once you grant access, you (and your medical team) will not have to do anything different – the application will handle everything.

Your medical records will also be accessible through an institutional clinical trial platform known as OnCore.

What are the risks of harm or discomforts I might experience if I take part in this research?
The risks for screening are minimal with the possibility of a loss of confidentiality.

Are there any benefits to me if I choose to take part in this research?
There are no benefits to you directly if you choose to participate in screening other than qualification to participate in our program and study.

What are my alternatives if I do not want to take part in this research?
If you choose not to take part in this research, you may continue to work with your primary care physician/family medicine physician to manage your CKM Syndrome.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research. If new information is learned that may affect you after the research or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
You will be notified of whether you meet eligibility to participate in the program and continue with the study.

Will there be any cost to me to take part in this study?
There is no cost to you to participate in the screening process

Will I be paid to take part in this study?
There is no compensation for you to participate in the screening process

How will information about me be kept private or confidential?
All documents and information pertaining to this research study will be kept confidential in accordance with all applicable federal, state, and local laws and regulations. You understand that data generated by the study may be reviewed by RUTGERS's Institutional Review Board and the Office for Human Subjects Protections (OHRP) to assure proper conduct of the study and compliance with federal regulations.

Electronic data will be stored on a password protected storage platform. Data files will be coded numerically to remove all personal identifiers. If paper data is collected it will be stored in a locked file cabinet and will be numerically coded to remove personal identifiers. Only study team members will have access to this data. The results of this study may be published. The MyDataHelps application complies with HIPAA regulations and is secured. If any data is published, you will not be identified by name.

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

The research team may use or share your information collected or created for this research with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards

- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

A description of this clinical trial will be available on 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 website at any time.

What will happen to my information—data, recordings and/or images collected for this research after the research is over?
Study subject information is subject to HIPAA requirements which requires that research records including signed consent forms that contain the HIPAA authorization must be retained for 6 years after the date on which the subject signed the consent form or the date when it last was in effect, whichever is later.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for participation, but you must do this in writing to:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

Any data that has already been collected cannot be withdrawn

Even if you withdraw from taking part in the study, outcome data will continue to be collected about you, such as medical course or lab results obtained through medical chart review. Public records may also be consulted, such as those establishing survival status.

At any time, the Principal Investigator can take you out of this research because it would not be in your best interest to stay in it. The Principal Investigator can stop treatment even if you are willing to stay in the research.

Who can I contact if I have questions?
If you have questions, concerns, or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR RESEARCH

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is the purpose of the research and how will my information be used?
The purpose of collecting and using your health information for this screening is to help investigators determine your eligibility for the program and study

What information about me will be used?

- Medical history or treatment
- Medications
- Laboratory/diagnostic tests or imaging

Who may use, share or receive my information?
The research team may use or share your information collected or created for this research with the following people and institutions:

- Rutgers University Investigators Involved in the Research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Data Privacy:
Breach of confidentiality: As with all research, there is a chance that confidentiality could be compromised; however, we are taking precautions to minimize this risk.

Will I be able to review my research record while the research Is ongoing?
No. We are not able to share information in the research records with you until the research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say Yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and stop taking part in the research) at any time. If you take away permission, your information will no longer be used or shared in the research, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision:

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185 South Orange Avenue
Newark, NJ 07103

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How long will my permission last?
Your permission for the use and sharing of your health information will last until the end of the research.

AGREEMENT TO PARTICIPATE

Participant Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this research have been answered. I agree to take part in this research.

Participant Name (Print):

Participant Signature: Date:

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the research including all of the information contained in this consent form.

Investigator/Person Obtaining Consent Name (Print):

Signature: Date:

RUTGERS HEALTH

CONSENT TO TAKE PART IN RESEARCH
Medically Tailored Groceries

Title of Research: Food is Medicine vs Lifestyle Medicine: A Community Based Pragmatic Randomized Control Trial for Patients with Cardiovascular Kidney Metabolic (CKM) syndrome
Principal Investigator: Novneet Sahu MD, MPA

RESEARCH SUMMARY: This consent form is part of an informed consent process for research study, and it will provide information that will help you decide whether you want to take part in this research. It is your choice whether to take part or not.

PURPOSE: We are seeking to determine if education classes focused on food choices, cooking, stress reduction, and physical activity are better than the current medical care model or simply providing healthy produce to reduce the effects of cardiovascular kidney metabolic (CKM) syndrome. If you take part in the research, you will be asked to participate in a 12-week medically tailored grocery program which may include classes and educational materials with simple preparation methods, recipes, nutrition information and grocery shopping tips provided that will be tailored to the specific foods contained in the weekly food box. You also will complete physical performance testing and a series of dietary and behavioral assessments three times (about 2 hours each time; before the education sessions, after the last session, and 6 months after the last session). You will also grant us access to your medical record so that we can access the results of blood work. Your time in the research will take a total of 9 months.

RISKS/BENEFITS: Possible harms or burdens of taking part in the study may be muscle soreness (possible) and muscle strains and ligament/joint sprains (rare) due to engaging in greater physical activity associated with physical testing, an adverse medical reaction associated with your existing diagnosis, or a loss of confidentiality. The benefits of taking part in this research include an opportunity to improve your health-related knowledge in terms of growing produce, cooking, and physical activity, all of which may lead to disease reversal, health restoration, medication reduction or improved health with a reduction of the risks associated with CKM syndrome. However, it is possible that you may not receive any direct benefit from taking part in this research.

ALTERNATIVES: Your alternative to taking part in the research study is not to take part in it and to continue your existing treatment plan with your primary care physician.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research?
Novneet Sahu, MD is the Principal Investigator of this research. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Sahu is joined by Dr. Saul Bautista, MD; Dr. Emily Merchant, PhD; and Dr. Andrew Lynch, PT, PhD.

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The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Research: This research is being sponsored by the Rutgers Equity Alliance for Community Health (REACH; https://www.reach.rutgers.edu).

Why is this research being done?
Most Americans sick with chronic disease have been diagnosed with disease of the heart, kidneys, or metabolic system (cardiovascular kidney metabolic syndrome, CKM) such as hypertension, diabetes, or obesity. Many more are at risk for developing CKM. Those with diagnosed CKM and those at risk have a greater risk of other conditions like cancer and early death compared to those without CKM. While there are medications and surgeries to help deal with the consequences of CKM, the literature clearly shows that changing diet and lifestyle are effective at reversing many aspects of CKM and preventing additional conditions and early death. However, lifestyle change is challenging for many.

We are not studying whether changes in diet and lifestyle are effective in reversing CKM. We are seeking to determine if group education classes focused on food choices, cooking, stress reduction, and physical activity are better than the current medical care model or simply providing healthy produce.

Who may take part in this research and who may not?
Individuals between the ages of 18 and 75 who are patients of the Family Practice Center at Rutgers Health – University Hospital who have been diagnosed with CKM without other substantial health challenges are eligible to participate in this research.

Inclusion Criteria
Participants will be included if they meet the criteria to be diagnosed with CKM which may include metabolic syndrome, overweight/obesity, poor control of blood sugar to include diabetes and pre-diabetes, high cholesterol and other blood fats, high blood pressure, chronic kidney disease, and cardiovascular disease with other metabolic risk factors. Additionally, they must have access to the MyDataHelps platform either through an internet connected device like a personal computer, Ipad, or their personal phone and consent to its use.

Exclusion Criteria
Some people may be excluded from the study if they have conditions that do not allow them to exercise in a group setting or require more extensive medical monitoring and intervention. This includes people with uncontrolled issues with their hearts and lungs (chest pain with exercise, dizziness/fainting, heart rhythm issues, recent surgery, uncontrolled hypertension, advanced heart failure, severe lung disease etc.), significant mental health concerns (suicidality, substance abuse issues, major depressive symptoms, etc.), or other major organ system conditions (advanced chronic kidney disease, liver disease, neuromuscular diseases like Parkinson's Disease or advanced multiple sclerosis, active cancer).

1. Women who are pregnant or may become pregnant in the next 6 months are ineligible.
2. Individuals who have received a major organ transplant or who are on the transplant list are ineligible.
3. Individuals with a life expectancy of less than three years due to a medical condition are ineligible.

4. Lastly, people who have participated in diabetes, nutrition, or weight research intervention in last 12 months; those without access to the internet, and those who do not speak English will not be eligible.
5. Only one member of each household may take part in this study.
6. Individuals currently facing acute unresolved health-related social needs, including but not limited to, unstable housing, lack of reliable transportation, and unemployment are ineligible.
7. Individuals who have started treatment with a class of medications known as GLP-1 within 120 days of the program start or those not on a stable dose are ineligible.
8. Individuals who have undergone bariatric surgery.

Why have I been asked to take part in this research?
You have been asked to take part in this research because you have been diagnosed with CKM syndrome and because you may benefit from changes to your diet and physical activity in addition to the changes that your physician recommends.

How long will the research take and how many participants will take part?
A total of 60 people will participate in the program and research.

All participants will complete three (3) testing sessions over the course of 6 months – before the study, half-way through the study and 6 months after the start of the study. We anticipate these testing sessions taking about two hours each on a single day.

The active phase of the research and program will be 12 weeks long and will begin after the first in-person testing session.

Medically Tailored Grocery Arm – You will receive one produce box per week over the course of 12 weeks. The box will include fresh, locally grown produce and nutrition and cooking information to help you best use the produce in the box.

What will I be asked to do if I take part in this research?

If you take part in this research, you will be asked to interact with a smartphone application called MyDataHelps. The research team will use this application for two purposes – to access your medical information that is relevant to the study and to have you complete questionnaires about your health and lifestyle.

Data Privacy/Security Risks of Mobile Apps:
The data collected via the MyDataHelps app will be stored on your personal device and uploaded to the respective servers of each app. Data will also be stored on the Garmin activity monitor itself. The study team will also provide directions on how you may set up your own personal Garmin Connect account and connect your activity monitor.

Information collected by mobile applications or 'apps' is subject to their terms of use, and end user license agreements. You are encouraged to review the MyDataHelps and Garmin Connect Terms of Use and End User License Agreement prior to using the mobile applications. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Rutgers Health cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Rutgers Health. During the study, you are encouraged to limit personal identifiers you enter into these mobile applications (particularly your name,

date of birth, address, place of employment, and other details that could allow someone to identify you) only to that information that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Strava). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully. For the purposes of this study, the data managed in the Garmin Connect platform is transmitted to the MyDataHelps secure platform for use and analysis by the Rutgers Health study team.

Access to Medical Records

To understand your health, we need to gather information from your medical records. We are looking for the results of blood tests, measures of your vital signs, and the types of medications you are using.

We will gather information about how your body is controlling the amount of sugar in your blood (hemoglobin A1c), and the cholesterol and fat in your blood (lipoprotein measurements and triglycerides).

We will also get measurements of your weight, body mass index, and waist size.

We will import a list of medications that you are taking, focusing on the medications being used to manage your CKM syndrome if you are taking any.

You will need to grant us access to your medical record through the MyDataHelps application. You will be asked to grant access to your record for **90 days prior to the day you sign this form and up to 9 months after the date you sign this form.** We need access for this long to make sure that we can get the most relevant data about these measures. Once you grant access, you (and your medical team) will not have to do anything different – the application will handle everything.

Your medical records will also be accessible through an institutional clinical trial platform known as OnCore.

Comprehensive Assessment

You will complete the following procedures (Questionnaires and Physical Performance Testing) three times over the course of the study:

1. Before the Intervention Period (first assessment)
2. After the Intervention Period (12 weeks after the first assessment)
3. 6 months after the Intervention Period (24 weeks after the second assessment).

Questionnaires

Diet ID: The Diet ID™ questionnaire asks about how you eat most of the time. You will be shown two pictures of foods. You will choose the picture that most closely resembles the foods that you eat regularly. Each time you choose, the program will update the pictures to find the combination that best fits you.

Estimated completion time – 6 minutes.

Household Food Security Questionnaire: You will be asked a series of questions about how you and the other members of your family have access to food.

Estimated completion time – 8 minutes.

***Attitudes and Behaviors*:** The "**Cooking with a Chef"** survey uses 8 scales to measure your attitudes and values towards getting and cooking food.

Estimated completion time – 30 minutes.

The International Physical Activity Questionnaire - Short Form (IPAQ) asks you to report how often you walk and perform moderate and vigorous physical activity (exercise).

Estimated completion time – 5 minutes.

Most Significant Change- Is a form of participatory monitoring and evaluation. It involves the collection and selection of stories of change

*Estimated completion time – 60 minutes**

** This will only occur once after the intervention period (2nd assessment)*

Physical Performance Testing

You will be asked to complete a series of assessments with the Rutgers Physical Therapy team three times in the Stanley S. Bergen Building (across from University Hospital).

Duration: 2 **hours**

Vital Sign and Body Measurement: Prior to beginning any testing, you will have your heart rate and blood pressure taken while you are at rest, seated comfortably in a chair. Additionally, we will take measurements of your waist and hips.

Estimated completion time – 5 minutes.

VO2 Maximum (VO2Max): Is a measure of your cardiorespiratory fitness. This will be measured using YMCA Step Test. You will be asked to step up and down on a 12-inch (30 cm) step in a box formation (step up-up- down-down) 72 times over the course of 3 minutes at a rate of 24 steps per minute. This will be done while keeping pace with a metronome set to 96 beats per minute (4 beats = 1 step). At the end of 3 minutes, you will be asked to sit and your pulse will be taken for 60 seconds.

Estimated completion time – 10 minutes.

6-minute walk test (6MWT): The 6MWT is a self-paced walking test around a set track that allows you to take standing and seated rest breaks as needed. Distance walked is an indicator of physical function and can predict VO2 max from 6MWT distance. We will use both the step test and the 6MWT to predict VO2 max and assess your cardiorespiratory fitness.

Estimated completion time – 10 minutes.

Grip strength testing: You will use a strength measuring device (dynamometer) to see how hard you can squeeze. You'll be seated in a chair with your arm at your side and elbow bent.You will be asked to maximally squeeze 3 times in each hand. You will have one minute of rest between each trial.

Estimated completion time – 8 minutes.

Sit-to-Stand Tests: You will stand up and sit down as many times as possible from a standard height chair with arm rests in 30-seconds. You will be encouraged to use your hands and momentum as little as possible. The number of repetitions completed during the test will be recorded. The time to complete the first 5 repetitions of sit to stand will also be recorded. You will do this twice.

Estimated completion time – 5 minutes.

Maximal Strength Testing: You will complete the Isometric Mid-Thigh Pull (IMTP). You will stand on a wooden platform with your knees and hips slightly bent. You will grasp a handle that is connected to a force sensor anchored to the platform. You will simultaneously push as hard and fast as you can into the platform by extending your legs and pull up on the handle for five seconds. You will repeat this three times with at least a minute between trials.

Prior to completing maximum effort trials, you will be instructed in the proper posture and form for the test. You will have at least three practice trials prior to the maximum effort. The testers will

monitor your effort to prevent excessive use of your lower back muscles to create force and the trial will be stopped if this is observed.

Estimated completion time – 10 minutes.

Intervention

Food Box Program: You will participate in a food box program. The box will include fresh, locally grown produce. Food boxes will be tailored by a Rutgers Registered Dietician and dietetics students. Each food box will contain seasonally available fruit and vegetables and other items including protein, dairy/cheese, and legumes that may be available at the time of the food box delivery. Food boxes will be either delivered to your home address or available for pick up at the Greater Newark Conservancy based on your preference. Classes and educational materials provided will be tailored to the specific foods contained in the weekly food box and will include simple preparation methods, recipes, nutrition information and grocery shopping tips.

Shares will be curated by the Greater Newark Conservancy and the Urban Agriculture Cooperative. The Urban Agriculture Cooperative will curate shares for 6 weeks of the program. The Greater Newark Conservancy will curate shares for 6 weeks of the program for a total of 12 weeks.

What are the risks of harm or discomforts I might experience if I take part in this research?

Physical Performance Testing

You may experience fatigue because of your participation in this study. You will be provided rest breaks after each of the physical performance tasks as needed. A physical therapist with extensive experience will be present to minimize the risk of excessive fatigue or injury. You will be given instructions and the opportunity to practice the movement at sub-maximal intensity prior to the recorded testing trials. If the tester notes any movements that could potentially cause injury, the test will be stopped.

If you become pregnant while taking part in this study, you should notify the Principal Investigator and/or study team of this fact as soon as possible to reduce any risk to the fetus or to yourself as your nutritional and physical needs will differ.

Vital signs will be measured prior to physical performance testing. Individuals with known hypertension (high blood pressure) will not complete aerobic testing if systolic blood pressure exceeds 160 or diastolic blood pressure exceeds 100. Individuals without diagnosed hypertension will not complete testing if systolic blood pressure exceeds 150 or diastolic blood pressure exceeds 100. Individuals with newly diagnosed hypertension (<3 months) will have blood pressure taken prior to physical activity.

Patients affected with Diabetes

Exercise-induced hypoglycemia (low blood sugar) is common in people with type 1 diabetes and to a lesser extent, people with type 2 diabetes using insulin. We will advise you to discuss with their primary care provider changes to your insulin regimen and carbohydrate intake prior to engaging in exercise.

Diabetic patients will be counseled and advised to monitor for symptoms of hypoglycemia (low blood sugar such as lightheadedness, excessive sweating, heart racing, and dizziness. We will keep glucose tablets on hand in the event if you experience those symptoms.

Are there any benefits to me if I choose to take part in this research?

The benefits of taking part in this research include an opportunity to improve your health-related knowledge in terms of growing produce, cooking, and physical activity, all of which may lead to disease reversal, health restoration, medication reduction or improved health with a reduction of the risks associated with CKM

syndrome. However, it is possible that you may not receive any direct benefit from taking part in this research.

What are my alternatives if I do not want to take part in this research?
If you choose not to take part in this research, you may continue to work with your primary care physician/family medicine physician to manage your CKM Syndrome.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research. If new information is learned that may affect you after the research or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
You will receive a summary of your physical performance results (VO2 max, grip strength, sit-to-stand tests, maximum strength tests) after each of the assessment sessions. We will also provide you with information to help you understand how we would expect someone like you to perform compared to other people of your same age and sex. You may then use this to discuss your situation with a physical therapist or other health coach.

You will also receive the results of your dietary assessment from DIETID. You may then use this to discuss your situation with a physician, dietician, or health coach.

Your physician will discuss any changes in your blood measures that are taken as a part of routine clinical practice.

Will there be any cost to me to take part in this study?
There is no cost for you to participate in the study or the program interventions.

There will be no cost associated with your physical performance testing.

You will have three scheduled visits with your primary care provider throughout the study period of 9 months. These visits will coincide with the regular care schedule for your medical condition. Any cost associated with regular care (Co-pays, lab tests, diagnostic imaging, etc) will be charged to your insurance company or to you.

Will I be paid to take part in this study?

You will receive a Garmin Forerunner 55 watch for the duration of the study. Upon completion of the study the device will be yours to own as a complimentary gift for completing the study. The device is valued at a retail price of $199.99

You will receive a $20 Visa gift card after completing the assessment at the 6-month post intervention follow-up. No compensation will be provided for completing the comprehensive assessments during the pre-intervention period or at the end of the intervention period.

How will information about me be kept private or confidential?
All documents and information pertaining to this research study will be kept confidential in accordance with all applicable federal, state, and local laws and regulations. You understand that data generated by the study may be reviewed by RUTGERS's Institutional Review Board and the Office for Human Subjects Protections (OHRP) to assure proper conduct of the study and compliance with federal regulations.

Electronic data will be stored on a password protected storage. Data files will be coded numerically to remove all personal identifiers. Paper data will be stored in a locked file cabinet and will be numerically coded to remove personal identifiers. Only study team members will have access to this data. The results of this study may be published. The MyDataHelps application complies with HIPAA regulations and is secured. All video/audio recordings will be kept on protected servers and will be transcribed for analysis with removal of identifying information. If any data is published, you will not be identified by name.

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

The research team may use or share your information collected or created for this research with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

A description of this clinical trial will be available on 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 website at any time.

What will happen to my information—data, recordings and/or images collected for this research after the research is over?

Study subject information is subject to HIPAA requirements which requires that research records including signed consent forms that contain the HIPAA authorization must be retained for 6 years after the date on which the subject signed the consent form or the date when it last was in effect, whichever is later.

What will happen if I am injured during this research?

Participants in this research will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include sprains, strains, and soreness due to physical testing and activity (see Risks section above). The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for participation, but you must do this in writing to:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077

novneet.sahu@njms.rutgers.edu

Any data that has already been collected cannot be withdrawn

Even if you withdraw from taking part in the study, outcome data will continue to be collected about you, such as medical course or lab results obtained through medical chart review. Public records may also be consulted, such as those establishing survival status.

At any time, the Principal Investigator can take you out of this research because it would not be in your best interest to stay in it. The Principal Investigator can stop treatment even if you are willing to stay in the research.

Who can I contact if I have questions?
If you have questions, concerns, or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR RESEARCH

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is the purpose of the research and how will my information be used?
You are invited to take part in this research which is described at the beginning of this form. The purpose of collecting and using your health information for this research is to help investigators answer the questions that are being asked in the research.

What information about me will be used?
- Medical history or treatment
- Medications
- Laboratory/diagnostic tests or imaging

Who may use, share or receive my information?
The research team may use or share your information collected or created for this research with the following people and institutions:

- Rutgers University Investigators Involved in the Research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Data Privacy/Security Risks of Group Sessions:
Your participation in group sessions is required in order to participate in the study. If you choose to participate, you volunteer to share certain protected health information (PHI), but you determine how much information to share in the group session.

Because group sessions often involve participants disclosing private medical and social information, we ask all participants in the group visit to agree to respect the privacy of all participants and keep their information confidential. However, Rutgers Health cannot make any guarantees about the confidentiality of the information you share in the group session and there is a risk that other participants may share your information with others.

By signing this informed consent confidentiality agreement, you acknowledge that you are voluntarily participating in the group session and assume the responsibility for keeping all information confidential.

Will I be able to review my research record while the research Is ongoing?
No. We are not able to share information in the research records with you until the research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say Yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and stop taking part in the research) at any time. If you take away permission, your information will no longer be used or shared in the research, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

How long will my permission last?
Your permission for the use and sharing of your health information will last until the end of the research.

AGREEMENT TO TAKE PART IN RESEARCH

Participant Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the research including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

ADDENDUM: CONSENT/AUTHORIZATION FOR PARTICIPATION IN THE CLINCARD PROGRAM

In order to compensate you for your time and effort in participating in this study outside of the pre-intervention and interventional period you will be paid $20 for the post-study visit that you complete, according to the schedule below for a total of $20

Study Period	Amount Paid
Pre-intervention (July 2024)	N/A
Intervention (August 2024-November 2024)	N/A
6 months post-intervention (May 2025)	$20

Payment for participating in this study will be made using ClinCard, a pre-paid Visa card that works like a debit card. We will give you one card that will be used to pay you at each visit/in accordance with the schedule above for the duration of the study. Your ClinCard will come with an information sheet about how to use the card and who to call if you have any questions. You may use this card online or at stores that accept Visa. Please see the ClinCard Cardholder FAQ sheet or the Rutgers ClinCard Information Page: https://sites.rutgers.edu/clincard-users/ for important details about how to use the card, about fees that may apply and what to do if your card is lost or stolen.

ClinCard is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study that you are participating in.

It is important for you to know that payments for participating in research are considered taxable income. In accordance with Rutgers Tax Policy, study teams are requested to collect your social security number (SSN) or tax identification number (TIN) if any single payment exceeds $100.00 or if there is a possibility that you will earn more than $300 on any given study in a calendar year, which is the case with this study. Your SSN or TIN will be entered into the ClinCard system, where it will be securely maintained and accessible only to the individuals at Rutgers who have an absolute need to see it.

If you earn $600 or more in payments through ClinCard at Rutgers during any calendar year, and if you have provided your SSN or TIN, the Rutgers Tax Office will issue you an IRS-1099 form (or 1042-S form if you are a non-resident alien), and you will be required to report this as income on your taxes.

If you do not provide an SSN or TIN, Rutgers' Tax Policy requires, once you have earned more than $300 in payments on a study in a calendar year, that 24% of your next payment (or portion of any payment that takes you over $300) and the remainder of payments you receive for the year, be withheld from the payment. For example, if you have already earned $300 in payments on this study in one year, and your next study visit payment would be $100, you will receive $76 on your ClinCard instead of the full $100. The Rutgers Tax Office will send that $24 to the United States Internal Revenue Service (IRS) in order to comply with US tax law. Note that the payment from Rutgers to the IRS will not identify you in any way, therefore, you will not be able to receive a refund or credit against that withholding for any other taxes.

Please also note that if, during your study participation, your situation changes and you are able to provide an SSN or TIN, you are asked to let the study team know at your next study visit. If you provide a valid SSN or TIN, funds will not be automatically withheld from that point forward. If you then go on to earn $600 or more in the calendar year, an IRS Form 1099 will be issued to you. You will report this as income on your tax return.

Transportation using the Lyft Ridesharing service for research activities:
The study team may arrange rides for you for transportation to specific programmatic study activities through the ridesharing service known as Lyft. You will not need to use cash or a credit card – the fare for the ride will be paid directly through the study. The study team will let you know if and when this service is available for your study. It is important for you to know, however, should you use this ridesharing service, that Rutgers, the State University of New Jersey, is not responsible in the event of an accident or other event that results in damage to your property, injury to you or in your death.

If you would like to participate in the ClinCard reimbursement card program, please sign this consent form in the spaces provided below. Please take as much time as you like to decide. Please ask your study coordinator any questions you may have.

CONSENT TO PARTICIPATE IN THE CLINCARD REIMBURSEMENT CARD SERVICE

If you would like to participate in the ClinCard reimbursement card program please sign this consent form in the spaces provided below.

By signing below, I agree that:

- I give permission to use and share my information about me as described in this form.
- I would like to participate in the ClinCard program and have read the disclosures and descriptions above.

- During the study I may change my mind and I may choose not to use the ClinCard program for the study by telling the study coordinator. I will not be penalized or lose any benefits to which I am otherwise entitled.

Subject Name (Print):

Subject Signature: Date:

CONSENT TO PARTICIPATE IN THE TEXT MESSAGING SERVICE FOR CLINCARD

You have the option to receive updates related to payment reminders through text message (standard text messaging rates will apply). These messages will remind you of your regularly scheduled study visits and let you know when payments made to you are loaded on your ClinCard. If you decide to opt-in for the text messaging reminders, you may receive: one payment notification after each visit; and one balance reminder after 5 ½ months of no activity.

- I understand that using the text message service for the study is optional.
- I give permission to use and share my information about me as described in this form.
- I would like to receive the optional text message service and have read the disclosures and descriptions above.
- During the study I may change my mind and I may choose not to use the text message service for the study by telling the study coordinator. I will not be penalized or lose any benefits to which I am otherwise entitled.

Subject Initials: Date:

CONSENT TO PARTICIPATE IN THE EMAIL SERVICE FOR CLINCARD

You have the option to receive updates related to payment reminders through email message. These messages will remind you of your regularly scheduled study visits and let you know when payments made to you are loaded on your ClinCard. If you decide to opt-in for the email reminders, you may receive: one payment notification after each visit; and one balance reminder after 5 ½ months of no activity.

- I understand that using the email service for the study is optional.
- I give permission to use and share my information about me as described in this form.
- I would like to receive the email reminder service and have read the disclosures and descriptions above.
- During the study I may change my mind and I may choose not to use the email service for the study by telling the study coordinator. I will not be penalized or lose any benefits to which I am otherwise entitled.

Subject Initials:

RUTGERS HEALTH

CONSENT TO TAKE PART IN RESEARCH

Title of Research: Food is Medicine vs Lifestyle Medicine: A Community Based Pragmatic Randomized Control Trial for Patients with Cardiovascular Kidney Metabolic (CKM) syndrome

Principal Investigator: Novneet Sahu MD, MPA

RESEARCH SUMMARY: This consent form is part of an informed consent process for research study, and it will provide information that will help you decide whether you want to take part in this research. It is your choice whether to take part or not.

PURPOSE: We are seeking to determine if education classes focused on food choices, cooking, stress reduction, and physical activity are better than the current medical care model or simply providing healthy produce to reduce the effects of cardiovascular kidney metabolic (CKM) syndrome. If you take part in the research, you will be asked to complete physical performance testing and a series of dietary and behavioral assessments three times (about 2 hours each time; before the education sessions, after the last session, and 6 months after the last session). You will also grant us access to your medical record so that we can access the results of blood work. Your time in the research will take a total of 9 months.

RISKS/BENEFITS: Possible harms or burdens of taking part in the study may be muscle soreness (possible) and muscle strains and ligament/joint sprains (rare) due to engaging in greater physical activity associated with physical testing, an adverse medical reaction associated with your existing diagnosis, or a loss of confidentiality. The benefits of taking part in this research include an opportunity to improve your health-related knowledge in terms of growing produce, cooking, and physical activity, all of which may lead to disease reversal, health restoration, medication reduction or improved health with a reduction of the risks associated with CKM syndrome. However, it is possible that you may not receive any direct benefit from taking part in this research.

ALTERNATIVES: Your alternative to taking part in the research study is not to take part in it and to continue your existing treatment plan with your primary care physician.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research?
Novneet Sahu, MD is the Principal Investigator of this research. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Sahu is joined by Dr. Saul Bautista, MD; Dr. Emily Merchant, PhD; and Dr. Andrew Lynch, PT, PhD.

Dr. Sahu may be reached at:

185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Research: This research is being sponsored by the Rutgers Equity Alliance for Community Health (REACH; https://www.reach.rutgers.edu).

Why is this research being done?
Most Americans sick with chronic disease have been diagnosed with disease of the heart, kidneys, or metabolic system (cardiovascular kidney metabolic syndrome, CKM) such as hypertension, diabetes, or obesity. Many more are at risk for developing CKM. Those with diagnosed CKM and those at risk have a greater risk of other conditions like cancer and early death compared to those without CKM. While there are medications and surgeries to help deal with the consequences of CKM, the literature clearly shows that changing diet and lifestyle are effective at reversing many aspects of CKM and preventing additional conditions and early death. However, lifestyle change is challenging for many.

We are not studying whether changes in diet and lifestyle are effective in reversing CKM. We are seeking to determine if group education classes focused on food choices, cooking, stress reduction, and physical activity are better than the current medical care model or simply providing healthy produce.

Who may take part in this research and who may not?
Individuals between the ages of 18 and 75 who are patients of the Family Practice Center at Rutgers Health – University Hospital who have been diagnosed with CKM without other substantial health challenges are eligible to participate in this research.

Inclusion Criteria
Participants will be included if they meet the criteria to be diagnosed with CKM which may include metabolic syndrome, overweight/obesity, poor control of blood sugar to include diabetes and pre-diabetes, high cholesterol and other blood fats, high blood pressure, chronic kidney disease, and cardiovascular disease with other metabolic risk factors. Additionally, they must have access to the MyDataHelps platform either through an internet connected device like a personal computer, Ipad, or their personal phone and consent to its use.

Exclusion Criteria
Some people may be excluded from the study if they have conditions that do not allow them to exercise in a group setting or require more extensive medical monitoring and intervention. This includes people with uncontrolled issues with their hearts and lungs (chest pain with exercise, dizziness/fainting, heart rhythm issues, recent surgery, uncontrolled hypertension, advanced heart failure, severe lung disease, etc.), significant mental health concerns (suicidality, substance abuse issues, major depressive symptoms, etc.), or other major organ system conditions (advanced chronic kidney disease, liver disease, neuromuscular diseases like Parkinson's Disease or advanced multiple sclerosis, active cancer).

1. Women who are pregnant or may become pregnant in the next 6 months are ineligible.
2. Individuals who have received a major organ transplant or who are on the transplant list are ineligible.
3. Individuals with a life expectancy of less than three years due to a medical condition are ineligible.

4. Lastly, people who have participated in diabetes, nutrition, or weight research intervention in last 12 months; those without access to the internet, and those who do not speak English will not be eligible.
5. Only one member of each household may take part in this study.
6. Individuals currently facing acute unresolved health-related social needs, including but not limited to, unstable housing, lack of reliable transportation, and unemployment are ineligible.
7. Individuals who have started treatment with a class of medications known as GLP-1 within 120 days of the program start or those not on a stable dose are ineligible.
8. Individuals who have undergone bariatric surgery.

Why have I been asked to take part in this research?
You have been asked to take part in this research because you have been diagnosed with CKM syndrome and because you may benefit from changes to your diet and physical activity in addition to the changes that your physician recommends.

How long will the research take and how many participants will take part?
A total of 60 people will participate in the program and research.

All participants will complete three (3) testing sessions over the course of 6 months – before the study, half-way through the study and 6 months after the start of the study. We anticipate these testing sessions taking about two hours each on a single day.

The active phase of the research and program will be 12 weeks long and will begin after the first in-person testing session.

You will continue your current treatment plan as coordinated with your physician for the next 6 months.

What will I be asked to do if I take part in this research?

If you take part in this research, you will be asked to interact with a smartphone application called MyDataHelps. The research team will use this application for two purposes – to access your medical information that is relevant to the study and to have you complete questionnaires about your health and lifestyle.

Data Privacy/Security Risks of Mobile Apps:
The data collected via the MyDataHelps app will be stored on your personal device and uploaded to the respective servers of each app. Data will also be stored on the Garmin activity monitor itself. The study team will also provide directions on how you may set up your own personal Garmin Connect account and connect your activity monitor.

Information collected by mobile applications or 'apps' is subject to their terms of use, and end user license agreements. You are encouraged to review the MyDataHelps and Garmin Connect Terms of Use and End User License Agreement prior to using the mobile applications. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Rutgers Health cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Rutgers Health. During the study, you are encouraged to limit personal identifiers you enter into these mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to that information that you wish to voluntarily share with others. These apps may send/receive

information with other mobile apps, including social networking apps or websites (for example, Strava). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully. For the purposes of this study, the data managed in the Garmin Connect platform is transmitted to the MyDataHelps secure platform for use and analysis by the Rutgers Health study team.

Access to Medical Records

To understand your health, we need to gather information from your medical records. We are looking for the results of blood tests, measures of your vital signs, and the types of medications you are using.

We will gather information about how your body is controlling the amount of sugar in your blood (hemoglobin A1c), and the cholesterol and fat in your blood (lipoprotein measurements and triglycerides).

We will also get measurements of your weight, body mass index, and waist size.

We will import a list of medications that you are taking, focusing on the medications being used to manage your CKM syndrome if you are taking any.

You will need to grant us access to your medical record through the MyDataHelps application. You will be asked to grant access to your record for **90 days prior to the day you sign this form and up to 9 months after the date you sign this form.** We need access for this long to make sure that we can get the most relevant data about these measures. Once you grant access, you (and your medical team) will not have to do anything different – the application will handle everything.

Your medical records will also be accessible through an institutional clinical trial platform known as OnCore.

Comprehensive Assessment

You will complete the following procedures (Questionnaires and Physical Performance Testing) three times over the course of the study:

1. Before the Intervention Period (first assessment)
2. After the Intervention Period (12 weeks after the first assessment)
3. 6 months after the Intervention Period (24 weeks after the second assessment).

Questionnaires

Diet ID: The Diet ID™ questionnaire asks about how you eat most of the time. You will be shown two pictures of foods. You will choose the picture that most closely resembles the foods that you eat regularly. Each time you choose, the program will update the pictures to find the combination that best fits you.

Estimated completion time – 6 minutes.

Household Food Security Questionnaire: You will be asked a series of questions about how you and the other members of your family have access to food.

Estimated completion time – 8 minutes.

***Attitudes and Behaviors*:** The "**Cooking with a Chef"** survey uses 8 scales to measure your attitudes and values towards getting and cooking food.

Estimated completion time – 30 minutes.

The International Physical Activity Questionnaire - Short Form (IPAQ) asks you to report how often you walk and perform moderate and vigorous physical activity (exercise).

Estimated completion time – 5 minutes.

Most Significant Change- Is a form of participatory monitoring and evaluation. It involves the collection and selection of stories of change

*Estimated completion time – 60 minutes**

** This will only occur once after the intervention period (2nd assessment)*

Physical Performance Testing

You will be asked to complete a series of assessments with the Rutgers Physical Therapy team three times in the Stanley S. Bergen Building (across from University Hospital).

Duration: 2 **hours**

Vital Sign and Body Measurement: Prior to beginning any testing, you will have your heart rate and blood pressure taken while you are at rest, seated comfortably in a chair. Additionally, we will take measurements of your waist and hips.

Estimated completion time – 5 minutes.

VO2 Maximum (VO2Max): Is a measure of your cardiorespiratory fitness. This will be measured using YMCA Step Test. You will be asked to step up and down on a 12-inch (30 cm) step in a box formation (step up-up- down-down) 72 times over the course of 3 minutes at a rate of 24 steps per minute. This will be done while keeping pace with a metronome set to 96 beats per minute (4 beats = 1 step). At the end of 3 minutes, you will be asked to sit and your pulse will be taken for 60 seconds.

Estimated completion time – 10 minutes.

6-minute walk test (6MWT): The 6MWT is a self-paced walking test around a set track that allows you to take standing and seated rest breaks as needed. Distance walked is an indicator of physical function and can predict VO2 max from 6MWT distance. We will use both the step test and the 6MWT to predict VO2 max and assess your cardiorespiratory fitness.

Estimated completion time – 10 minutes.

Grip strength testing: You will use a strength measuring device (dynamometer) to see how hard you can squeeze. You'll be seated in a chair with your arm at your side and elbow bent.You will be asked to maximally squeeze 3 times in each hand. You will have one minute of rest between each trial.

Estimated completion time – 8 minutes.

Sit-to-Stand Tests: You will stand up and sit down as many times as possible from a standard height chair with arm rests in 30-seconds. You will be encouraged to use your hands and momentum as little as possible. The number of repetitions completed during the test will be recorded. The time to complete the first 5 repetitions of sit to stand will also be recorded. You will do this twice.

Estimated completion time – 5 minutes.

Maximal Strength Testing: You will complete the Isometric Mid-Thigh Pull (IMTP). You will stand on a wooden platform with your knees and hips slightly bent. You will grasp a handle that is connected to a force sensor anchored to the platform. You will simultaneously push as hard and fast as you can into the platform by extending your legs and pull up on the handle for five seconds. You will repeat this three times with at least a minute between trials.

Prior to completing maximum effort trials, you will be instructed in the proper posture and form for the test. You will have at least three practice trials prior to the maximum effort. The testers will monitor your effort to prevent excessive use of your lower back muscles to create force and the trial will be stopped if this is observed.

Estimated completion time – 10 minutes.

Intervention
You will continue your current treatment plan as coordinated with your physician for the next 6 months and engage in lifestyle counseling with them as you desire.

What are the risks of harm or discomforts I might experience if I take part in this research?

Physical Performance Testing
You may experience fatigue because of your participation in this study. You will be provided rest breaks after each of the physical performance tasks as needed. A physical therapist with extensive experience will be present to minimize the risk of excessive fatigue or injury. You will be given instructions and the opportunity to practice the movement at sub-maximal intensity prior to the recorded testing trials. If the tester notes any movements that could potentially cause injury, the test will be stopped.

If you become pregnant while taking part in this study, you should notify the Principal Investigator and/or study team of this fact as soon as possible to reduce any risk to the fetus or to yourself as your nutritional and physical needs will differ.

Vital signs will be measured prior to physical performance testing. Individuals with known hypertension (high blood pressure) will not complete aerobic testing if systolic blood pressure exceeds 160 or diastolic blood pressure exceeds 100. Individuals without diagnosed hypertension will not complete testing if systolic blood pressure exceeds 150 or diastolic blood pressure exceeds 100. Individuals with newly diagnosed hypertension (<3 months) will have blood pressure taken prior to physical activity.

Patients affected with Diabetes

Exercise-induced hypoglycemia (low blood sugar) is common in people with type 1 diabetes and to a lesser extent, people with type 2 diabetes using insulin. We will advise you to discuss with their primary care provider changes to your insulin regimen and carbohydrate intake prior to engaging in exercise.

Diabetic patients will be counseled and advised to monitor for symptoms of hypoglycemia (low blood sugar such as lightheadedness, excessive sweating, heart racing, and dizziness. We will keep glucose tablets on hand in the event if you experience those symptoms.

Are there any benefits to me if I choose to take part in this research?
The benefits of taking part in this research include an opportunity to improve your health-related knowledge in terms of growing produce, cooking, and physical activity, all of which may lead to disease reversal, health restoration, medication reduction or improved health with a reduction of the risks associated with CKM syndrome. However, it is possible that you may not receive any direct benefit from taking part in this research.

What are my alternatives if I do not want to take part in this research?
If you choose not to take part in this research, you may continue to work with your primary care physician/family medicine physician to manage your CKM Syndrome.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research. If new information is learned that may affect you after the research or your follow-up is completed, you will be contacted.

Will I receive the results of the research?

You will receive a summary of your physical performance results (VO2 max, grip strength, sit-to-stand tests, maximum strength tests) after each of the assessment sessions. We will also provide you with information to help you understand how we would expect someone like you to perform compared to other people of your same age and sex. You may then use this to discuss your situation with a physical therapist or other health coach.

You will also receive the results of your dietary assessment from DIETID. You may then use this to discuss your situation with a physician, dietician, or health coach.

Your physician will discuss any changes in your blood measures that are taken as a part of routine clinical practice.

Will there be any cost to me to take part in this study?
There is no cost for you to participate in the study or the program interventions.

There will be no cost associated with your physical performance testing.

You will have three scheduled visits with your primary care provider throughout the study period of 9 months. These visits will coincide with the regular care schedule for your medical condition. Any cost associated with regular care (Co-pays, lab tests, diagnostic imaging, etc) will be charged to your insurance company or to you.

Will I be paid to take part in this study?

You will receive a Garmin Forerunner 55 watch for the duration of the study. Upon completion of the study the device will be yours to own as a complimentary gift for completing the study. The device is valued at a retail price of $199.99

You will receive a $20 Visa gift card after completing the assessment at the 6-month post intervention follow-up. No compensation will be provided for completing the comprehensive assessments during the pre-intervention period or at the end of the intervention period.

How will information about me be kept private or confidential?
All documents and information pertaining to this research study will be kept confidential in accordance with all applicable federal, state, and local laws and regulations. You understand that data generated by the study may be reviewed by RUTGERS's Institutional Review Board and the Office for Human Subjects Protections (OHRP) to assure proper conduct of the study and compliance with federal regulations.

Electronic data will be stored on a password protected storage. Data files will be coded numerically to remove all personal identifiers. Paper data will be stored in a locked file cabinet and will be numerically coded to remove personal identifiers. Only study team members will have access to this data. The results of this study may be published. The MyDataHelps application complies with HIPAA regulations and is secured. All video/audio recordings will be kept on protected servers and will be transcribed for analysis with removal of identifying information. If any data is published, you will not be identified by name.

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

The research team may use or share your information collected or created for this research with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

A description of this clinical trial will be available on 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 website at any time.

What will happen to my information—data, recordings and/or images collected for this research after the research is over?

Study subject information is subject to HIPAA requirements which requires that research records including signed consent forms that contain the HIPAA authorization must be retained for 6 years after the date on which the subject signed the consent form or the date when it last was in effect, whichever is later.

What will happen if I am injured during this research?

Participants in this research will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include sprains, strains, and soreness due to physical testing and activity (see Risks section above). The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for participation, but you must do this in writing to:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

Any data that has already been collected cannot be withdrawn

Even if you withdraw from taking part in the study, outcome data will continue to be collected about you, such as medical course or lab results obtained through medical chart review. Public records may also be consulted, such as those establishing survival status.

At any time, the Principal Investigator can take you out of this research because it would not be in your best interest to stay in it. The Principal Investigator can stop treatment even if you are willing to stay in the research.

Who can I contact if I have questions?
If you have questions, concerns, or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR RESEARCH

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is the purpose of the research and how will my information be used?
You are invited to take part in this research which is described at the beginning of this form. The purpose of collecting and using your health information for this research is to help investigators answer the questions that are being asked in the research.

What information about me will be used?
- Medical history or treatment
- Medications
- Laboratory/diagnostic tests or imaging

Who may use, share or receive my information?
The research team may use or share your information collected or created for this research with the following people and institutions:
- Rutgers University Investigators Involved in the Research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Data Privacy/Security Risks of Group Sessions:
Your participation in group sessions is required in order to participate in the study. If you choose to participate, you volunteer to share certain protected health information (PHI), but you determine how much information to share in the group session.

Because group sessions often involve participants disclosing private medical and social information, we

ask all participants in the group visit to agree to respect the privacy of all participants and keep their information confidential. However, Rutgers Health cannot make any guarantees about the confidentiality of the information you share in the group session and there is a risk that other participants may share your information with others.

By signing this informed consent confidentiality agreement, you acknowledge that you are voluntarily participating in the group session and assume the responsibility for keeping all information confidential.

Will I be able to review my research record while the research Is ongoing?
No. We are not able to share information in the research records with you until the research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say Yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and stop taking part in the research) at any time. If you take away permission, your information will no longer be used or shared in the research, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

How long will my permission last?
Your permission for the use and sharing of your health information will last until the end of the research.

AGREEMENT TO TAKE PART IN RESEARCH

Participant Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the research including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

ADDENDUM: CONSENT/AUTHORIZATION FOR PARTICIPATION IN THE CLINCARD PROGRAM

In order to compensate you for your time and effort in participating in this study outside of the pre-intervention and interventional period you will be paid $20 for the post-study visit that you complete, according to the schedule below for a total of $20

Study Period	Amount Paid
Pre-intervention (July 2024)	N/A
Intervention (August 2024-November 2024)	N/A
6 months post-intervention (May 2025)	$20

Payment for participating in this study will be made using ClinCard, a pre-paid Visa card that works like a debit card. We will give you one card that will be used to pay you at each visit/in accordance with the schedule above for the duration of the study. Your ClinCard will come with an information sheet about how to use the card and who to call if you have any questions. You may use this card online or at stores that accept Visa. Please see the ClinCard Cardholder FAQ sheet or the Rutgers ClinCard Information Page: https://sites.rutgers.edu/clincard-users/ for important details about how to use the card, about fees that may apply and what to do if your card is lost or stolen.

ClinCard is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study that you are participating in.

It is important for you to know that payments for participating in research are considered taxable income. In accordance with Rutgers Tax Policy, study teams are requested to collect your social security number (SSN) or tax identification number (TIN) if any single payment exceeds $100.00 or if there is a possibility that you will earn more than $300 on any given study in a calendar year, which is the case with this study. Your SSN or TIN will be entered into the ClinCard system, where it will be securely maintained and accessible only to the individuals at Rutgers who have an absolute need to see it.

If you earn $600 or more in payments through ClinCard at Rutgers during any calendar year, and if you have provided your SSN or TIN, the Rutgers Tax Office will issue you an IRS-1099 form (or 1042-S form if you are a non-resident alien), and you will be required to report this as income on your taxes.

If you do not provide an SSN or TIN, Rutgers' Tax Policy requires, once you have earned more than $300 in payments on a study in a calendar year, that 24% of your next payment (or portion of any payment that takes you over $300) and the remainder of payments you receive for the year, be withheld from the payment. For example, if you have already earned $300 in payments on this study in one year, and your next study visit payment would be $100, you will receive $76 on your ClinCard instead of the full $100. The Rutgers Tax Office will send that $24 to the United States Internal Revenue Service (IRS) in order to comply with US tax law. Note that the payment from Rutgers to the IRS will not identify you in any way, therefore, you will not be able to receive a refund or credit against that withholding for any other taxes.

Please also note that if, during your study participation, your situation changes and you are able to provide an SSN or TIN, you are asked to let the study team know at your next study visit. If you provide a valid SSN or TIN, funds will not be automatically withheld from that point forward. If you then go on to earn $600 or more in the calendar year, an IRS Form 1099 will be issued to you. You will report this as income on your tax return.

Transportation using the Lyft Ridesharing service for research activities:
The study team may arrange rides for you for transportation to specific programmatic study activities through the ridesharing service known as Lyft. You will not need to use cash or a credit card – the fare for the ride will be paid directly through the study. The study team will let you know if and when this service is available for your study. It is important for you to know, however, should you use this ridesharing service, that Rutgers, the State University of New Jersey, is not responsible in the event of an accident or other event that results in damage to your property, injury to you or in your death.

If you would like to participate in the ClinCard reimbursement card program, please sign this consent form in the spaces provided below. Please take as much time as you like to decide. Please ask your study coordinator any questions you may have.

CONSENT TO PARTICIPATE IN THE CLINCARD REIMBURSEMENT CARD SERVICE

If you would like to participate in the ClinCard reimbursement card program please sign this consent form in the spaces provided below.

By signing below, I agree that:

- I give permission to use and share my information about me as described in this form.
- I would like to participate in the ClinCard program and have read the disclosures and descriptions above.
- During the study I may change my mind and I may choose not to use the ClinCard program for the study by telling the study coordinator. I will not be penalized or lose any benefits to which I am otherwise entitled.

Subject Name (Print):

Subject Signature: Date:

CONSENT TO PARTICIPATE IN THE TEXT MESSAGING SERVICE FOR CLINCARD

You have the option to receive updates related to payment reminders through text message (standard text messaging rates will apply). These messages will remind you of your regularly scheduled study visits and let you know when payments made to you are loaded on your ClinCard. If you decide to opt-in for the text messaging reminders, you may receive: one payment notification after each visit; and one balance reminder after 5 ½ months of no activity.

- I understand that using the text message service for the study is optional.
- I give permission to use and share my information about me as described in this form.
- I would like to receive the optional text message service and have read the disclosures and descriptions above.
- During the study I may change my mind and I may choose not to use the text message service for the study by telling the study coordinator. I will not be penalized or lose any benefits to which I am otherwise entitled.

Subject Initials: Date:

CONSENT TO PARTICIPATE IN THE EMAIL SERVICE FOR CLINCARD

You have the option to receive updates related to payment reminders through email message. These messages will remind you of your regularly scheduled study visits and let you know when payments made to you are loaded on your ClinCard. If you decide to opt-in for the email reminders, you may receive: one payment notification after each visit; and one balance reminder after 5 ½ months of no activity.

- I understand that using the email service for the study is optional.
- I give permission to use and share my information about me as described in this form.
- I would like to receive the email reminder service and have read the disclosures and descriptions above.
- During the study I may change my mind and I may choose not to use the email service for the study by telling the study coordinator. I will not be penalized or lose any benefits to which I am otherwise entitled.

Subject Initials:

CONSENT TO TAKE PART IN RESEARCH
Lifestyle Medicine Program

Title of Research: Food is Medicine vs Lifestyle Medicine: A Community Based Pragmatic Randomized Control Trial for Patients with Cardiovascular Kidney Metabolic (CKM) syndrome
Principal Investigator: Novneet Sahu MD, MPA

RESEARCH SUMMARY: This consent form is part of an informed consent process for research study, and it will provide information that will help you decide whether you want to take part in this research. It is your choice whether to take part or not.

PURPOSE: We are seeking to determine if group education classes focused on food choices, cooking, stress reduction, and physical activity are better than the current medical care model or simply providing healthy produce to reduce the effects of cardiovascular kidney metabolic (CKM) syndrome. If you take part in the research, you will be asked to participate in 12 weekly group education/instruction sessions (3 hours each session), complete physical performance testing with a series of dietary and behavioral assessments three times (about 2 hours each time; before the education sessions, after the last session, and 6 months after the last session). You will also grant us access to your medical record so that we can access the results of blood work. Your time in the research will take a total of 9 months.

RISKS/BENEFITS: Possible harms or burdens of taking part in the study may be muscle soreness (possible) and muscle strains and ligament/joint sprains (rare) due to engaging in greater physical activity, an adverse medical reaction associated with your existing diagnosis, or a loss of confidentiality. The benefits of taking part in this research include an opportunity to improve your health-related knowledge in terms of growing produce, cooking, and physical activity, all of which may lead to disease reversal, health restoration, medication reduction or improved health with a reduction of the risks associated with CKM syndrome. However, it is possible that you may not receive any direct benefit from taking part in this research.

ALTERNATIVES: Your alternative to taking part in the research study is not to take part in it and to continue your existing treatment plan with your primary care physician.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research?
Novneet Sahu, MD is the Principal Investigator of this research. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Dr. Sahu is joined by Dr. Saul Bautista, MD; Dr. Emily Merchant, PhD; and Dr. Andrew Lynch, PT, PhD.

Dr. Sahu may be reached at:

185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Sponsor of the Research: This research is being sponsored by the Rutgers Equity Alliance for Community Health (REACH; https://www.reach.rutgers.edu).

Why is this research being done?
Most Americans sick with chronic disease have been diagnosed with disease of the heart, kidneys, or metabolic system (cardiovascular kidney metabolic syndrome, CKM) such as hypertension, diabetes, or obesity. Many more are at risk for developing CKM. Those with diagnosed CKM and those at risk have a greater risk of other conditions like cancer and early death compared to those without CKM. While there are medications and surgeries to help deal with the consequences of CKM, the literature clearly shows that changing diet and lifestyle are effective at reversing many aspects of CKM and preventing additional conditions and early death. However, lifestyle change is challenging for many.

We are not studying whether changes in diet and lifestyle are effective in reversing CKM. We are seeking to determine if group education classes focused on food choices, cooking, stress reduction, and physical activity are better than the current medical care model or simply providing healthy produce.

Who may take part in this research and who may not?
Individuals between the ages of 18 and 75 who are patients of the Family Practice Center at Rutgers Health – University Hospital who have been diagnosed with CKM without other substantial health challenges are eligible to participate in this research.

Inclusion Criteria
Participants will be included if they meet the criteria to be diagnosed with CKM which may include metabolic syndrome, overweight/obesity, poor control of blood sugar to include diabetes and pre-diabetes, high cholesterol and other blood fats, high blood pressure, chronic kidney disease, and cardiovascular disease with other metabolic risk factors. Additionally, they must have access to the MyDataHelps platform either through an internet connected device like a personal computer, Ipad, or their personal phone and consent to its use.

Exclusion Criteria
Some people may be excluded from the study if they have conditions that do not allow them to exercise in a group setting or require more extensive medical monitoring and intervention. This includes people with uncontrolled issues with their hearts and lungs (chest pain with exercise, dizziness/fainting, heart rhythm issues, recent surgery, uncontrolled hypertension, advanced heart failure, severe lung disease, etc.), significant mental health concerns (suicidality, substance abuse issues, major depressive symptoms, etc.), or other major organ system conditions (advanced chronic kidney disease, liver disease, neuromuscular diseases like Parkinson's Disease or advanced multiple sclerosis, active cancer).

1. Women who are pregnant or may become pregnant in the next 6 months are ineligible.
2. Individuals who have received a major organ transplant or who are on the transplant list are ineligible.
3. Individuals with a life expectancy of less than three years due to a medical condition are ineligible.

4. Lastly, people who have participated in diabetes, nutrition, or weight research intervention in last 12 months; those without access to the internet, and those who do not speak English will not be eligible.
5. Only one member of each household may take part in this study.
6. Individuals currently facing acute unresolved health-related social needs, including but not limited to, unstable housing, lack of reliable transportation, and unemployment are ineligible.
7. Individuals who have started treatment with a class of medications known as GLP-1 within 120 days of the program start or those not on a stable dose are ineligible.
8. Individuals who have undergone bariatric surgery.

Why have I been asked to take part in this research?
You have been asked to take part in this research because you have been diagnosed with CKM syndrome and because you may benefit from changes to your diet and physical activity in addition to the changes that your physician recommends.

How long will the research take and how many participants will take part?
A total of 60 people will participate in the program and research.

All participants will complete three (3) testing sessions over the course of 6 months – before the study, half-way through the study and 6 months after the start of the study. We anticipate these testing sessions taking about two hours each on a single day.

The active phase of the research and program will be 12 weeks long and will begin after the first in-person testing session.

You will participate in 12 group sessions over the course of 12 weeks that emphasize nutrition and cooking education and skills and physical activity.

What will I be asked to do if I take part in this research?

If you take part in this research, you will be asked to interact with a smartphone application called MyDataHelps. The research team will use this application for two purposes – to access your medical information that is relevant to the study and to have you complete questionnaires about your health and lifestyle.

Data Privacy/Security Risks of Mobile Apps:
The data collected via the MyDataHelps app will be stored on your personal device and uploaded to the respective servers of each app. Data will also be stored on the Garmin activity monitor itself. The study team will also provide directions on how you may set up your own personal Garmin Connect account and connect your activity monitor.

Information collected by mobile applications or 'apps' is subject to their terms of use, and end user license agreements. You are encouraged to review the MyDataHelps and Garmin Connect Terms of Use and End User License Agreement prior to using the mobile applications. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Rutgers Health cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Rutgers Health. During the study, you are encouraged to limit personal identifiers you enter into these mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you)

only to that information that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Strava). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully. For the purposes of this study, the data managed in the Garmin Connect platform is transmitted to the MyDataHelps secure platform for use and analysis by the Rutgers Health study team.

Access to Medical Records

To understand your health, we need to gather information from your medical records. We are looking for the results of blood tests, measures of your vital signs, and the types of medications you are using.

We will gather information about how your body is controlling the amount of sugar in your blood (hemoglobin A1c), and the cholesterol and fat in your blood (lipoprotein measurements and triglycerides).

We will also get measurements of your weight, body mass index, and waist size.

We will import a list of medications that you are taking, focusing on the medications being used to manage your CKM syndrome if you are taking any.

You will need to grant us access to your medical record through the MyDataHelps application. You will be asked to grant access to your record for **90 days prior to the day you sign this form and up to 9 months after the date you sign this form.** We need access for this long to make sure that we can get the most relevant data about these measures. Once you grant access, you (and your medical team) will not have to do anything different – the application will handle everything.

Your medical records will also be accessible through an institutional clinical trial platform known as OnCore.

Comprehensive Assessment

You will complete the following procedures (Questionnaires and Physical Performance Testing) three times over the course of the study:

1. Before the Intervention Period (first assessment)
2. After the Intervention Period (12 weeks after the first assessment)
3. 6 months after the Intervention Period (24 weeks after the second assessment).

Questionnaires

Diet ID: The Diet ID™ questionnaire asks about how you eat most of the time. You will be shown two pictures of foods. You will choose the picture that most closely resembles the foods that you eat regularly. Each time you choose, the program will update the pictures to find the combination that best fits you.

Estimated completion time – 6 minutes.

Household Food Security Questionnaire: You will be asked a series of questions about how you and the other members of your family have access to food.

Estimated completion time – 8 minutes.

Attitudes and Behaviors: The **"Cooking with a Chef"** survey uses 8 scales to measure your attitudes and values towards getting and cooking food.

Estimated completion time – 30 minutes.

The International Physical Activity Questionnaire - Short Form (IPAQ) asks you to report how often you walk and perform moderate and vigorous physical activity (exercise).

Estimated completion time – 5 minutes.

Most Significant Change- Is a form of participatory monitoring and evaluation. It involves the collection and selection of stories of change

*Estimated completion time – 60 minutes**

** This will only occur once after the intervention period (2nd assessment)*

Physical Performance Testing

You will be asked to complete a series of assessments with the Rutgers Physical Therapy team three times in the Stanley S. Bergen Building (across from University Hospital).

Duration: 2 **hours**

Vital Sign and Body Measurement: Prior to beginning any testing, you will have your heart rate and blood pressure taken while you are at rest, seated comfortably in a chair. Additionally, we will take measurements of your waist and hips.

Estimated completion time – 5 minutes.

VO2 Maximum (VO2Max): Is a measure of your cardiorespiratory fitness. This will be measured using YMCA Step Test. You will be asked to step up and down on a 12-inch (30 cm) step in a box formation (step up-up- down-down) 72 times over the course of 3 minutes at a rate of 24 steps per minute. This will be done while keeping pace with a metronome set to 96 beats per minute (4 beats = 1 step). At the end of 3 minutes, you will be asked to sit and your pulse will be taken for 60 seconds.

Estimated completion time – 10 minutes.

6-minute walk test (6MWT): The 6MWT is a self-paced walking test around a set track that allows you to take standing and seated rest breaks as needed. Distance walked is an indicator of physical function and can predict VO2 max from 6MWT distance. We will use both the step test and the 6MWT to predict VO2 max and assess your cardiorespiratory fitness.

Estimated completion time – 10 minutes.

Grip strength testing: You will use a strength measuring device (dynamometer) to see how hard you can squeeze. You'll be seated in a chair with your arm at your side and elbow bent.You will be asked to maximally squeeze 3 times in each hand. You will have one minute of rest between each trial.

Estimated completion time – 8 minutes.

Sit-to-Stand Tests: You will stand up and sit down as many times as possible from a standard height chair with arm rests in 30-seconds. You will be encouraged to use your hands and momentum as little as possible. The number of repetitions completed during the test will be recorded. The time to complete the first 5 repetitions of sit to stand will also be recorded. You will do this twice.

Estimated completion time – 5 minutes.

Maximal Strength Testing: You will complete the Isometric Mid-Thigh Pull (IMTP). You will stand on a wooden platform with your knees and hips slightly bent. You will grasp a handle that is connected to a force sensor anchored to the platform. You will simultaneously push as hard and fast as you can into the platform by extending your legs and pull up on the handle for five seconds. You will repeat this three times with at least a minute between trials.

Prior to completing maximum effort trials, you will be instructed in the proper posture and form for the test. You will have at least three practice trials prior to the maximum effort. The testers will

monitor your effort to prevent excessive use of your lower back muscles to create force and the trial will be stopped if this is observed.

Estimated completion time – 10 minutes.

Intervention

You will participate in a lifestyle change program that includes activities and lessons in urban agriculture, nutrition education, culinary education, and exercise which a team that includes a chef, physician, farmer, and physical therapist. The primary site of the activity sessions will be at the Greater Newark Conservancy.

Duration: 3 months
Frequency: meets 1x time per week for 3 hours

Urban Agriculture lessons will be curated and delivered by the Greater Newark Conservancy in partnership with Ethos Farm to Health. Participants will learn to cultivate a variety of crops in limited spaces, emphasizing sustainable practices and the importance of local food systems in urban communities.

Culinary and nutrition education will be curated by a professional chef working in conjunction with the project team from community partner Ethos Farm To Health. Lessons will be adapted from a variety of sources to include Culinary Medicine Curriculum.

Food Boxes will be provided during each week of the program. The box will include fresh, locally grown produce. During the culinary lessons, you will be instructed in ways to prepare some of the produce included in your weekly food box.

Physical activity sessions will be designed and delivered by Rutgers Physical Therapy team under the guidance of Dr. Lynch. This will include a variety of activities to include calisthenics, weight training, walking, running, dance, and games. The Rutgers Physical Therapy team will provide instruction for all activities and will help you modify any activities for safety.

Audio/Visual Recording

In this study, you will be given the option to journal in a notebook that we will provide to you or to perform video journaling. We are offering this as some people feel more comfortable expressing themselves verbally rather than through writing. We will provide you with a private area where you can express yourself without any discomfort or distractions. This is a reflective exercise that can help you in the health behavior change process.

In this study, we want to take pictures and videos of you and other participants while you're engaged in different activities like cooking, gardening, and exercising. We are doing this to capture your experience as it can be helpful for future participants to learn from visual recorded content. You will be asked to sign a model release form for your permission to allow us to feature you in photos and videos.

What are the risks of harm or discomforts I might experience if I take part in this research?

Lifestyle Medicine Intervention

There is a risk of injury and soreness with increasing physical activity. Injuries can include things like muscle strains and joint/ligament sprains; however, these are rare. With any new activity, you are likely to experience muscle soreness. During the program's physical activity components, you will be monitored by the Rutgers Physical Therapy team, that includes licensed clinicians and clinicians in training. You will be able to ask for help and guidance if you are uncomfortable with any of the activities. If the team notices any movement patterns that may put you at risk, they will help you with modifying that aspect of the activity.

Physical Performance Testing
You may experience fatigue because of your participation in this study. You will be provided rest breaks after each of the physical performance tasks as needed. A physical therapist with extensive experience will be present to minimize the risk of excessive fatigue or injury. You will be given instructions and the opportunity to practice the movement at sub-maximal intensity prior to the recorded testing trials. If the tester notes any movements that could potentially cause injury, the test will be stopped.

If you become pregnant while taking part in this study, you should notify the Principal Investigator and/or study team of this fact as soon as possible to reduce any risk to the fetus or to yourself as your nutritional and physical needs will differ.

Vital signs will be measured prior to physical performance testing. Individuals with known hypertension (high blood pressure) will not complete aerobic testing if systolic blood pressure exceeds 160 or diastolic blood pressure exceeds 100. Individuals without diagnosed hypertension will not complete testing if systolic blood pressure exceeds 150 or diastolic blood pressure exceeds 100. Individuals with newly diagnosed hypertension (<3 months) will have blood pressure taken prior to physical activity interventions.

Patients affected with Diabetes

Exercise-induced hypoglycemia (low blood sugar) is common in people with type 1 diabetes and to a lesser extent, people with type 2 diabetes using insulin. We will advise you to discuss with their primary care provider changes to your insulin regimen and carbohydrate intake prior to engaging in exercise.

Diabetic patients will be counseled and advised to monitor for symptoms of hypoglycemia (low blood sugar such as lightheadedness, excessive sweating, heart racing, and dizziness. We will keep glucose tablets on hand in the event if you experience those symptoms.

Are there any benefits to me if I choose to take part in this research?
The benefits of taking part in this research include an opportunity to improve your health-related knowledge in terms of growing produce, cooking, and physical activity, all of which may lead to disease reversal, health restoration, medication reduction or improved health with a reduction of the risks associated with CKM syndrome. However, it is possible that you may not receive any direct benefit from taking part in this research.

What are my alternatives if I do not want to take part in this research?
If you choose not to take part in this research, you may continue to work with your primary care physician/family medicine physician to manage your CKM syndrome.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the research, you will be updated about any new information that may affect whether you are willing to continue taking part in the research. If new information is learned that may affect you after the research or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
You will receive a summary of your physical performance results (VO2 max, grip strength, sit-to-stand tests, maximum strength tests) after each of the assessment sessions. We will also provide you with information to help you understand how we would expect someone like you to perform compared to other people of your same age and sex. You may then use this to discuss your situation with a physical therapist or other health coach.

You will also receive the results of your dietary assessment from DIETID. You may then use this to discuss your situation with a physician, dietician, or health coach.

Your physician will discuss any changes in your blood measures that are taken as a part of routine clinical practice.

Will there be any cost to me to take part in this study?
There is no cost for you to participate in the study or the program interventions.

There will be no cost associated with your physical performance testing.

You will have three scheduled visits with your primary care provider throughout the study period of 9 months. These visits will coincide with the regular care schedule for your medical condition. Any cost associated with regular care (Co-pays, lab tests, diagnostic imaging, etc) will be charged to your insurance company or to you.

Will I be paid to take part in this study?

You will receive a Garmin Forerunner 55 watch for the duration of the study. Upon completion of the study the device will be yours to own as a complimentary gift for completing the study. The device is valued at a retail price of $199.99

You will receive a $20 Visa gift card after completing the assessment at the 6-month post intervention follow-up. No compensation will be provided for completing the comprehensive assessments during the pre-intervention period or at the end of the intervention period.

How will information about me be kept private or confidential?
All documents and information pertaining to this research study will be kept confidential in accordance with all applicable federal, state, and local laws and regulations. You understand that data generated by the study may be reviewed by RUTGERS's Institutional Review Board and the Office for Human Subjects Protections (OHRP) to assure proper conduct of the study and compliance with federal regulations.

Electronic data will be stored on a password protected storage. Data files will be coded numerically to remove all personal identifiers. Paper data will be stored in a locked file cabinet and will be numerically coded to remove personal identifiers. Only study team members will have access to this data. The results of this study may be published. The MyDataHelps application complies with HIPAA regulations and is secured. All video/audio recordings will be kept on protected servers and will be transcribed for analysis with removal of identifying information. If any data is published, you will not be identified by name.

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

The research team may use or share your information collected or created for this research with the following people and institutions:
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

A description of this clinical trial will be available on 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 website at any time.

What will happen to my information—data, recordings and/or images collected for this research after the research is over?

Study subject information is subject to HIPAA requirements which requires that research records including signed consent forms that contain the HIPAA authorization must be retained for 6 years after the date on which the subject signed the consent form or the date when it last was in effect, whichever is later.

What will happen if I am injured during this research?

Participants in this research will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include sprains, strains, and soreness due to physical testing and activity (see Risks section above). The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for participation, but you must do this in writing to:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

Any data that has already been collected cannot be withdrawn

Even if you withdraw from taking part in the study, outcome data will continue to be collected about you, such as medical course or lab results obtained through medical chart review. Public records may also be consulted, such as those establishing survival status.

At any time, the Principal Investigator can take you out of this research because it would not be in your best interest to stay in it. The Principal Investigator can stop treatment even if you are willing to stay in the research.

Who can I contact if I have questions?
If you have questions, concerns, or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR RESEARCH

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is the purpose of the research and how will my information be used?
You are invited to take part in this research which is described at the beginning of this form. The purpose of collecting and using your health information for this research is to help investigators answer the questions that are being asked in the research.

What information about me will be used?
- Medical history or treatment
- Medications
- Laboratory/diagnostic tests or imaging

Who may use, share or receive my information?
The research team may use or share your information collected or created for this research with the following people and institutions:
- Rutgers University Investigators Involved in the Research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Data Privacy/Security Risks of Group Sessions:
Your participation in group sessions is required in order to participate in the study. If you choose to participate, you volunteer to share certain protected health information (PHI), but you determine how much information to share in the group session.

Because group sessions often involve participants disclosing private medical and social information, we ask all participants in the group visit to agree to respect the privacy of all participants and keep their information confidential. However, Rutgers Health cannot make any guarantees about the confidentiality of the information you share in the group session and there is a risk that other participants may share your nformation with others.

By signing this informed consent confidentiality agreement, you acknowledge that you are voluntarily participating in the group session and assume the responsibility for keeping all information confidential.

Will I be able to review my research record while the research Is ongoing?
No. We are not able to share information in the research records with you until the research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say Yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and stop taking part in the research) at any time. If you take away permission, your information will no longer be used or shared in the research, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision:

Dr. Novneet Sahu, MD
185 South Orange Avenue
Newark, NJ 07103
Office: 973-972-0077
novneet.sahu@njms.rutgers.edu

How long will my permission last?

AGREEMENT TO TAKE PART IN RESEARCH

Participant Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the research including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

Your permission for the use and sharing of your health information will last until the end of the research.

ADDENDUM: CONSENT/AUTHORIZATION FOR PARTICIPATION IN THE CLINCARD PROGRAM

In order to compensate you for your time and effort in participating in this study outside of the pre-intervention and interventional period you will be paid $20 for the post-study visit that you complete, according to the schedule below for a total of $20

Study Period	Amount Paid
Pre-intervention (July 2024)	N/A
Intervention (August 2024-November 2024)	N/A
6 months post-intervention (May 2025)	$20

Payment for participating in this study will be made using ClinCard, a pre-paid Visa card that works like a debit card. We will give you one card that will be used to pay you at each visit/in accordance with the schedule above for the duration of the study. Your ClinCard will come with an information sheet about how to use the card and who to call if you have any questions. You may use this card online or at stores that accept Visa. Please see the ClinCard Cardholder FAQ sheet or the Rutgers ClinCard Information Page: https://sites.rutgers.edu/clincard-users/ for important details about how to use the card, about fees that may apply and what to do if your card is lost or stolen.

ClinCard is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study that you are participating in.

It is important for you to know that payments for participating in research are considered taxable income. In accordance with Rutgers Tax Policy, study teams are requested to collect your social security number (SSN) or tax identification number (TIN) if any single payment exceeds $100.00 or if there is a possibility that you will earn more than $300 on any given study in a calendar year, which is the case with this study. Your SSN or TIN will be entered into the ClinCard system, where it will be securely maintained and accessible only to the individuals at Rutgers who have an absolute need to see it.

If you earn $600 or more in payments through ClinCard at Rutgers during any calendar year, and if you have provided your SSN or TIN, the Rutgers Tax Office will issue you an IRS-1099 form (or 1042-S form if you are a non-resident alien), and you will be required to report this as income on your taxes.

If you do not provide an SSN or TIN, Rutgers' Tax Policy requires, once you have earned more than $300 in payments on a study in a calendar year, that 24% of your next payment (or portion of any payment that takes you over $300) and the remainder of payments you receive for the year, be withheld from the payment. For example, if you have already earned $300 in payments on this study in one year, and your next study visit payment would be $100, you will receive $76 on your ClinCard instead of the full $100. The Rutgers Tax Office will send that $24 to the United States Internal Revenue Service (IRS) in order to comply with US tax law. Note that the payment from Rutgers to the IRS will not identify you in any way, therefore, you will not be able to receive a refund or credit against that withholding for any other taxes.

Please also note that if, during your study participation, your situation changes and you are able to provide an SSN or TIN, you are asked to let the study team know at your next study visit. If you provide a valid SSN or TIN, funds will not be automatically withheld from that point forward. If you then go on to

earn $600 or more in the calendar year, an IRS Form 1099 will be issued to you. You will report this as income on your tax return.

Transportation using the Lyft Ridesharing service for research activities:
The study team may arrange rides for you for transportation to specific programmatic study activities through the ridesharing service known as Lyft. You will not need to use cash or a credit card – the fare for the ride will be paid directly through the study. The study team will let you know if and when this service is available for your study. It is important for you to know, however, should you use this ridesharing service, that Rutgers, the State University of New Jersey, is not responsible in the event of an accident or other event that results in damage to your property, injury to you or in your death.

If you would like to participate in the ClinCard reimbursement card program, please sign this consent form in the spaces provided below. Please take as much time as you like to decide. Please ask your study coordinator any questions you may have.

CONSENT TO PARTICIPATE IN THE CLINCARD REIMBURSEMENT CARD SERVICE

If you would like to participate in the ClinCard reimbursement card program please sign this consent form in the spaces provided below.

By signing below, I agree that:

- I give permission to use and share my information about me as described in this form.
- I would like to participate in the ClinCard program and have read the disclosures and descriptions above.
- During the study I may change my mind and I may choose not to use the ClinCard program for the study by telling the study coordinator. I will not be penalized or lose any benefits to which I am otherwise entitled.

Subject Name (Print):

Subject Signature: Date:

CONSENT TO PARTICIPATE IN THE TEXT MESSAGING SERVICE FOR CLINCARD

You have the option to receive updates related to payment reminders through text message (standard text messaging rates will apply). These messages will remind you of your regularly scheduled study visits and let you know when payments made to you are loaded on your ClinCard. If you decide to opt-in for the text messaging reminders, you may receive: one payment notification after each visit; and one balance reminder after 5 ½ months of no activity.

- I understand that using the text message service for the study is optional.
- I give permission to use and share my information about me as described in this form.
- I would like to receive the optional text message service and have read the disclosures and descriptions above.

- During the study I may change my mind and I may choose not to use the text message service for the study by telling the study coordinator. I will not be penalized or lose any benefits to which I am otherwise entitled.

Subject Initials: Date:

CONSENT TO PARTICIPATE IN THE EMAIL SERVICE FOR CLINCARD

You have the option to receive updates related to payment reminders through email message. These messages will remind you of your regularly scheduled study visits and let you know when payments made to you are loaded on your ClinCard. If you decide to opt-in for the email reminders, you may receive: one payment notification after each visit; and one balance reminder after 5 ½ months of no activity.

- I understand that using the email service for the study is optional.
- I give permission to use and share my information about me as described in this form.
- I would like to receive the email reminder service and have read the disclosures and descriptions above.
- During the study I may change my mind and I may choose not to use the email service for the study by telling the study coordinator. I will not be penalized or lose any benefits to which I am otherwise entitled.

Subject Initials:

ADDENDUM: CONSENT TO AUDIO-/VISUALLY RECORD OR PHOTOGRAPH SUBJECTS

You have already agreed to take part in a research study entitled "Food is Medicine - Newark" conducted by Novneet Sahu, MD. We are asking your consent to allow us to videotape you as part of the research. You do not have to consent to be recorded in order to take part in the main research.

The video recordings will be used for analysis by the research team to understand how your attitudes have changed over the course of this study. For example, use of the video will allow researchers to review your reflections about your experiences and help guide you in the health behavior change process. The videos and images of your reflections will not be shared outside of the study team or used for any other purpose. You will not be compensated for use of the video or images.

There will be video recordings and photographs of the program activities taken to include gardening, cooking, exercise, and other social programmatic activities. These videos and images can be used for educational or marketing purposes in future iterations of the program as well as impact reporting.

The videos or still frames may include information that can identify you, such as your face, clothing, or other distinguishable characteristics.

The videos will be stored on a Rutgers-based cloud storage site and will be stored retained indefinitely.

The videos will not be used by us or distributed to investigators for other research for reasons other than those stated in this consent.

Your signature on this form permits the investigator named above to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written consent.

AGREEMENT TO BE RECORDED

Subject Name (Print):_____

Subject Signature _____ Date _____

Investigator/Person Obtaining Consent Name (Printed):_____

Signature _____ Date _____