Research Subject's Consent Form Cover Sheet
Randomized Crossover Pilot Study: Exercise and Peanut Consumption
PI IRB#: 7466

Overview

Below is a summary of the study in which you are asked to participate. This outline is meant to be a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form, which you will have to sign if you decide to participate in the study. The consent form contains detailed information about the study and about the risks which you will need to consider before making your decision. Read the consent form carefully and discuss it with others before deciding to take part. And remember that, even if you agree to participate, you can change your mind at any time.

Purpose of Study

The purpose of this study is to compare the effects of exercise and eating peanuts on inflammation and heart rate variability.

Participation is Voluntary

As with all research, this is a voluntary study, and you do not have to participate if you do not want to. You may stop participating at any time.

Procedures

- **Screening and Eligibility:** You will be asked questions about your health and eating habits over the phone or in person to see if you will be able to take part in the study.

- **Consent Appointment:** You will be asked to read and sign the informed consent form as well as complete some forms and evaluations. If you would like to participate in the study, you will be asked to agree to keep a constant body weight (<±3%), not change your eating habits except for what is asked of you, and keep current levels of physical activity, except for the study interventions, throughout the study. You will also need to present a note from a physician indicating medical clearance for exercise training.

- **Exercise and Diet Trial Period/Run-in**: You will meet with research staff who will guide you in completing a two week trial period. You will be asked to eat pita chip snacks twice per day for a week, and then for the second week, you will be asked to stretch four times a week for 30 minutes at the gym while wearing a heart rate monitor.

- **Baseline Exercise Test**: If you follow the instructions during the trial period, you will be scheduled to take a baseline exercise test to determine your fitness level.

- **Laboratory Testing Sessions:** Four times throughout the study, you will be scheduled to have your blood drawn and body metrics measured such as height, weight, body composition, and waist circumference. Resting heart rate and other data will also be collected.

- **Dietary Assessment**: You will meet with research staff to complete a dietary assessment in which you will be asked questions about the foods you typically eat.

- **Peanut Intake/Exercise:** You will be randomly assigned to one of two groups. In the peanut group, you will be asked to eat about a handful of roasted, unsalted peanuts twice a day for 4 weeks. In the exercise group, you will be trained and asked to do high intensity interval training four times a week for four weeks. After the four weeks of either eating peanuts or exercising, you will be asked to stop eating peanuts or exercising for 4 weeks. Then you will switch groups to the peanut group if you were in the exercise group or to the exercise group if you were in the peanut group.

Risks

This study includes some risks and discomforts (please refer to the consent form for further details and explanations of these risks). The risks associated with exercise training are those typical of any physical activity. Other risks and discomfort include: discomfort during blood drawing and during the baseline exercise test. Every effort will be made to minimize these risks by evaluation of background information relating to the participant's health and fitness and by careful observations during testing. Emergency equipment and trained personnel are available to deal with unusual situations that may arise.

Benefits

This study is not designed for your direct benefit.

The benefits of moderate exercise are well known. Any information that is important to the participant's health will, with the participant's permission, be transmitted to their physician. Additionally, eating peanuts regularly may reduce the risk of heart disease.

You may contact the Principal Investigator, Richard Sloan at 646-774-8940 with any questions.

Please read and sign the attached consent form for a full description of the study.

Research Subject's Consent Form
Informed Consent for Participation in Research
The Anti-Inflammatory Effects Exercise and Peanut Consumption
PI IRB #7466

Purpose of Study
The purpose of this study is to examine and compare the effects of peanut consumption and aerobic exercise on heart health. You are being asked to participate because you are an overweight and sedentary, but otherwise healthy individual between the age of 21 and 45 years old.

Voluntary
Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate or withdraw your participation will not affect your current or future treatment at the New York State Psychiatric Institute or Columbia University.

Alternatives to Participation
This is not a treatment study. Information being collected is for research purposes only and is to learn more about the effects of dietary intervention and exercise on cardiovascular health, not about you. The alternative to participating is this study is not to participate.

Procedures
Eligibility During the Study
Your eligibility is checked at multiple times during the early stages of the study through a series of evaluations, questionnaires, and tests done during study meetings. These include a Baecke Physical Activity Questionnaire, Dietary Questionnaire, questions about medical history, and submaximal cardiopulmonary tests. These help to determine whether or not you are able to continue. Also, in the event that you are unable to follow the procedures required, you may be withdrawn from the study.

Consent Session
If you agree to participate you will be asked to meet for less than an hour at the Division of Behavioral Medicine, Department of Psychiatry, on the 15th floor of the Columbia University Medical Center to read and sign the informed consent form and complete additional forms that will be needed for study protocol. You are required to present a note from a physician indicating medical clearance for high intensity aerobic exercise training. Your BMI will be estimated at this time. At this time, you must agree to maintain constant body weight (<±3%) and current levels of physical activity, except for the study interventions, throughout the protocol. If you meet the required eligibility criteria, study staff will schedule you for the next appointment.

Two Week Run-in

You will then begin a two week trial period, or run-in. You will meet at the Division of Behavioral Medicine to receive labeled pita chip snacks and will be asked to eat the snacks twice a day for one week. After one week, you will meet with the research assistant who will collect your labeled packets, determine if you did well enough to continue and provide instructions on how to proceed with the second phase of the run-in. You will be asked to come to the PlusOne Fitness Center four times for a week for 30 min of stretching while wearing the Polar Heart Rate (HR) monitor. Coaches will provide you detailed instructions on how to perform the stretching and how to utilize the heart rate monitor. After each stretching session, you will upload the data from the heart rate monitor to a secure cloud-based server provided by Polar using an account that is anonymous and does not have any identifiable information contained within. Stretches will consist of arm circles, neck rotations, toe reach, gluteal stretches, lateral leg swings, Achilles stretch and ankle rolls. Your participation will be checked by gym attendance records and HR monitor data. If you sufficiently follow the instructions, you will be able to continue to the next part of the study.

Baseline Exercise Test (CPET)

At the Division of Behavioral Medicine, you will be guided to complete a cardiopulmonary exercise test which takes about 10 minutes. You will be asked to listen to an audiotape test instructions and commence stepping to the metronome beat at 15 steps per minute for a 2 minute period. The step rate then will be increased to 20 steps per minute for an additional 2 minutes. The test will continue to increase in speed until your heart rate reaches 80% of your maximal heart. The maximum test duration will be 10 minutes.

Laboratory Session 1

During the first lab session, your blood will be drawn and your height, weight, and body composition will be measured. Your heart rate will also be measured. You will be asked to wear ECG leads and respiration monitoring bands and rest quietly for 5 minutes, after which 20 minutes of resting ECG and respiration data will be collected. After the blood draw, you will receive a light breakfast. Lab sessions will take about 1 hour and will be conducted at the facilities belonging to the Division of Behavioral Medicine on the 15th and 16th floors of the Columbia University Medical Center.

Dietary Assessment

For about 30 minutes, you will meet with the research assistant at the Division of Behavioral Medicine to assess your eating patterns. You will be guided in how to eat the peanuts without changing your diet too much. You must agree to avoid omega 3 supplements and nuts, and not eat excessive amounts of high fat fish like salmon (>8oz), flax seeds and chia seeds, soy (including soybean oil and canola oil) and food products that contain these (limit to <1 serving a day). You can otherwise maintain your regular diet. You will be asked questions about alcohol, caffeine, and cocoa consumption.

4 Week Period: Peanut Diet

You will be provided with labelled packets of peanuts weekly for four weeks and asked to eat two packets each day and record when and where you consume the peanuts. After each week you will return the empty packets and receive new ones for the next week from the research assistant.

At any point in time during the 4 weeks, a research assistant may ask for details about when and where you ate the peanuts in the last 24 hours.

4 Week Period: Exercise

For four weeks, you will be asked to participate in 4 training sessions per week that last about 20-30 minutes, with 24 hours of rest after each training day. Exercise sessions will take place at the PlusOne Fitness Center at CUMC/NYPH. Each session begins with a 3 minute low intensity warm-up, and then you will exercise aerobically as rapidly as you can for 20 seconds, aiming to reach 85% of your maximum heart rate. This 20 second period is followed by 40 seconds of low intensity exercise. You will be asked to complete 8 such intervals for sessions 1 and 2, 10 intervals for sessions 3 and 4, and 12 intervals for the remaining sessions. Research assistants will provide thorough training for you on how to perform the exercise and how to utilize the heart rate monitor. After each exercise session, you will upload the data from the heart rate monitor to a secure cloud-based server provided by Polar using an account that is anonymous and does not have any identifiable information contained within. Research assistants will be available throughout the week to answer questions about the protocol.

4-week Washout Period:

At the conclusion of the first 4 week period, you will be asked to resume your diet and activity as it was before the intervention. This means that you will be asked to discontinue eating peanuts or discontinue exercising for 4 weeks before continuing on to the second intervention, which will be peanut consumption if you were originally assigned to the exercise group, or exercise if you were originally assigned to the peanut group.

Further Lab Sessions and CPETs

After each 4 week period, including the washout period, you will be asked to complete a set of laboratory sessions in which your fasting blood will be drawn and a cardiopulmonary test like the first one will be given. Lab sessions will take about 1 hour and the cardiopulmonary tests will last at most 10 minutes. Both will be conducted at the same locations as were used previously.

For women only: You will be asked to track and report your menstrual cycle once you enroll in the study. It is very important that we know when you ovulate during the month that you do your first exercise and laboratory. Therefore, we will give you a 7-day ovulation kit at the start of the study, and we will ask you to use this kit so that we can estimate your ovulation date. The ovulation test is a very quick and simple urine test that you will do at home. If for some reason you do not ovulate during this time, we may reschedule your lab and exercise test to the following month, and ask you to monitor your ovulation during that month as well. We will try to schedule each of the lab and exercise tests to be done following your ovulation date in that month.

Risks and Inconveniences

During the blood draw, you may feel slight pain from the needle or experience some dizziness. You may also develop a temporary bruise where the needle was inserted. If there is any difficulty in obtaining the blood or if there is some medical reason why we cannot perform the blood test, you will discontinue the study.

There exists the possibility of certain changes occurring during the cardiopulmonary test. These include abnormal blood pressure; fainting; irregular, fast, or slow heart rhythm; and, in rare instances, heart attack, stroke, or death. Every effort will be made to minimize these risks by evaluation of preliminary information relating to the participant's health and fitness and by careful observations during testing. Emergency equipment and trained personnel are available to deal with unusual situations that may arise. Since this is a submaximal exercise test, the risks associated are those typical of any physical activity, and are low.

The risks associated with exercise training are those typical of any physical activity. All participants will have been carefully screened prior to the initiation of the exercise protocol to minimize the risk of adverse events. Participants will be required to present a note from a physician indicating medical clearance for exercise training.

Although we are currently unaware of any risks, there may be possible risks to the dietary intervention, such as previously unknown allergies.

Benefits

This study is not designed for your direct benefit. The primary benefit of this study will be to increase understanding of how dietary interventions and exercise influence cardiovascular health. The cardiorespiratory benefits of moderate exercise are well known. Any information that is important to the participant's health will, with the participant's permission, be transmitted to their physician.

Results

While blood tests are sometimes done for clinical purposes, the kind of blood test you will have as part of this study is for research purposes only. This means that they are not designed to provide clinical information that might be helpful to you or your doctor and they may not show problems that would normally be found in a blood test ordered to evaluate a specific medical problem. If significant abnormalities are detected, you, or a physician whom you may designate, will be informed by a phone call.

Confidentiality

Your participation in this study will be confidential and if the results are published, your name will not be identified. Your records will be kept in locked files in locked offices and access will be allowed only to members of the research team or institutional personnel as part of a routine audit. Your name and other personal identifying information will be stored in an electronically secure database at Columbia University. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). The study could not be completed without this information. We will do everything we can to avoid disclosure about your participation in this study.

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

Study Compensation
You will receive $25 for each blood draw, $25 for each submaximal exercise test, and $50 if you achieve 85% adherence to both the exercise and dietary arms of the study. In total, you could receive compensation of $250.

In Case of Injury
If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator, Dr. Richard Sloan, at (646) 774 - 8940 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Please be aware that:

1. The New York State Psychiatric Institute, Columbia University and New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary by the medical staff of this hospital.

2. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.

3. No monetary compensation for wages lost as a result of injury will be paid to you by the New York State Psychiatric Institute, Columbia University or by New York Presbyterian Hospital.

4. By signing this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

Questions
Research personnel will answer all current or future questions about the procedures and/or responses to the best of their ability. If you have any questions about this study in the future, you may reach Dr. Richard Sloan at 646-774-8940.

You will be notified of significant new findings that may relate to your willingness to continue to participate.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a

committee that protects the rights of human subjects in research studies). You may call the IRB Main Office at (646)774-7155 during regular office hours.

Documentation of Consent

I voluntarily agree to participate in the research study described above. I have received a copy of this consent form. I have been informed that if I believe I have sustained injury as a result of participating in a research study, I may contact the Principal Investigator, Dr. Richard Sloan at (646) 774-8940 so that I can review the matter.

Print name: _____

Signed: _____ Date: _____

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

Print name: _____
Person Designated to Obtain Consent

Signed: _____ Date: _____