Principal Investigator: Adnin Zaman, MD
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Study Title: The Influence of Combined Oral Contraceptives on Weight, Body Composition, Eating Behaviors, and Appetite in Pre-menopausal Women with Overweight or Obesity

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about the effects of combined oral contraceptives (COCs) versus non-hormonal contraceptives (NHCs) on body weight, body composition, eating behaviors, and appetite in pre-menopausal women with overweight or obesity.

You are being asked to be in this research study because you are a pre-menopausal female planning to start a COC (Sprintec) contraceptive or using a non-hormonal form of contraception.

Some of the blood samples collected during this study will be used for genetic research (research about genes that code for traits that are passed on in families). This will help us learn more about the impact of a person's genes on weight loss while on contraception. This information could help researchers eventually tailor weight loss programs to a person's genetic profiles.

When your samples are used for this kind of genetic research, the results will not be told to you and will not be put in your health records. Your samples will only be used for research and will not be sold. The research done with your samples may help to develop new products in the future, but there is no plan for you to be paid.

Other people in this study

Up to *120* people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will undergo screening evaluations to see if you are eligible to be in the study. If you are eligible to be in the study, you will be asked to complete measurements including height, weight, vitals, a DXA scan, labs, questionnaires, and a diet diary before beginning your chosen contraceptive method.

Once you begin your contraceptive method (Sprintec) or agree to remain on your non-hormonal contraceptive, your study participation will last 6 months. You will be asked to complete measures for the study after 3 months of participation and again at the end of the study after 6 months.

During the study, you will be asked not to participate in any other weight loss, exercise, or diet programs and not to participate in any other research studies that might change your weight. During the study, you will be asked not to take any weight loss medications or supplements, including weight loss medications or weight loss supplements.

If you join the study, you will undergo the following steps:

1. Screening Procedures

You will be asked to have the following screening procedures done to see if you are eligible to be in this study. These screening procedures will take up to 1 hour in total. The procedures will be performed on the Anschutz Medical Campus of the University of Colorado at the CWHC.

Review of the eConsent Form: This consent form will be reviewed with you in detail. You will have the opportunity to ask any questions about the study. If you agree to participate in the study, you will sign the consent form. No other procedures will occur until you sign the consent form.

Vital Signs and Body Measurements: Your blood pressure and heart rate will be measured. Your height will be measured, and your weight will be measured using a digital scale.

Screening Questionnaires: You will be asked to fill out questionnaires that give us information on your demographics, weight history, medical history, social history, mood, and eating attitudes.

Health and Physical Exam: A standard medical history will be taken, and a physical exam will be performed by a medical professional.

Pregnancy Test: If you are a female of reproductive age, you will be given a urine pregnancy test. You cannot be in this study if you are pregnant.

2. Study Assessments

Body Weight and Vitals: Your weight will be measured using a digital scale at baseline and study months 3 and 6. You may be asked to wear a hospital gown when we are measuring your bodyweight. At baseline and months 3 and 6 your vitals will also be measured. We will also look in the electronic medical record for any clinic weights taken on you in the past 12 months.

Body Composition: You will be asked to come to the CTRC to measure your level of body fat mass and lean mass using a special x-ray. During this procedure, you will lie on a bed and a small amount of x-ray will be passed through your body. This test takes approximately 30 minutes. There is no pain associated with this test. A pregnancy test will be given prior to the scan in all women of childbearing age who have not had their uterus removed. All subjects will have one DXA scan performed at baseline and month 6.

Blood Draw: You will be asked to fast overnight for a blood draw at baseline and month 6. This means you will not be able to eat or drink anything except water for 12 hours prior to this test. This blood draw will be conducted to measure changes in metabolic blood markers. In addition, we may keep a small portion of your blood for future analyses. That portion of this test is optional – described below. Approximately 4 teaspoons of blood will be removed by putting a needle into your vein.

Questionnaires: You will be asked to answer a series of short questionnaires related to your eating. You will be asked to answer these questionnaires either on a paper form or on a computer. All of your answers will be confidential. You will be asked to answer these questionnaires at baseline and study months 3 and 6.

Dietary Record: You will be asked to complete a record in which you will record all of your food and beverage intake for 3 days. These records will be performed at baseline and at study months 3 and 6.

Measurements of Hunger and Satiety: You will be asked to rate your hunger level and your satiety periodically during the day for 3 consecutive days. At study months 0 and 6, these measures will coincide with the 3-days that you are also compiling 3-day diet diaries. These questions will be

sent to you via text message before and after each meal (breakfast, lunch, and dinner). If you do not answer the questions, you will be prompted again by a text message. These measures will be conducted at baseline and at study months 3 and 6.

Outline of Study Procedures

Outcome Measures by Study Month				
	Screening	Baseline	Month 3	Month 6
Consent	x			
H&P	x			
Body Weight (kg) and Vitals (BP)	x	x	x	x
Body Composition (DXA)		x		x
Lab Collection: Glucose, Insulin, Lipids		x		x
Eating Behavior Questionnaires		x	x	x
3-day Diet Diaries		x		x
Dietary Adherence with VAS		x	x	x

Generally, this will translate into the following number of visits:

- **Screening:** 1 visit (1 hour visit)
- **Baseline:** 1-2 visits (up to 2 x 30-minute visits for DXA and blood draw)
- **Month 3:** 1 visit (~30 minutes)
- **Month 6:** 1-2 visits (up to 2 x 30-minute visits for DXA and blood draw)

This does not include measures you are asked to complete at home (such as diet diaries and questionnaires).

Consent and some screening procedures (with the exception of screening labs, physical exam, and DXA) may be performed virtually or over telephone (rather than in person). In the event of a public health emergency, natural disaster, or severe inclement weather or other compelling reason determined by the study PI that could cause in person study procedures to be suspended for participant safety, participation may extend longer than 6 months, or the study duration may be shortened. Outcome measures may not follow the exact timeline outlined above, may be modified, or may not be performed if indicated for participant safety.

Optional Consent for Data and Specimen Banking for Future Research
Dr. Zaman would like to keep some of the data and blood samples that are taken during the study but are not used for other tests. If you agree, the data and samples will be kept and may be used in future research to learn more about the treatment of obesity. The research that is done with your data and samples is not designed to specifically help you. It might help people who have obesity and other diseases in the future. Reports about research done with your data and samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your data and samples will not affect your care.

The choice to let Dr. Zaman keep the data and samples for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your data and samples can be kept for research, you can change your mind at any time and contact study staff to let them know that you do not want Dr. Zaman to use your data and samples any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until Dr. Zaman decides to destroy them.

When your data and samples are given to other researchers in the future, Dr. Zaman will not give them your name, address, phone number or other information that will let the researchers know who you are.

Sometimes data and samples are used for genetic research (about diseases that are passed on in families). Even if your data and samples are used for this kind of research, the results will not be told to you and will not be put in your health records. Your data and samples will only be used for research and will not be sold. The research done with your data and samples may help to develop new products in the future, but there is no plan for you to be paid.

The possible benefits of research from your data and samples include learning more about what causes obesity and other diseases, how to prevent them and how to treat them. The greatest risk to you is the release of your private information. Dr. Zaman will protect your records so that your name, date of birth, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any data or sample collection and storage by Dr. Zaman.

Please read each sentence below and think about your choice. After reading each sentence, circle "yes" or "no." If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your data and samples, you may still take part in the study.

1. I give my permissions for my data and blood to be kept by Dr. Zaman for use in future research to learn more about how to prevent, detect, or treat obesity.

   ☐ Yes ☐ No _____Initials

2. I give my permissions for my data and blood to be used for research about other health problems (for example: causes of heart disease, osteoporosis, diabetes).

   ☐ Yes ☐ No _____Initials

3. I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

   ☐ Yes ☐ No _____Initials

You can cancel your permission to use your data and samples or to contact you for future research studies at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use your data and/or blood samples, they will be disposed of and no longer used for research. If you withdraw consent to contact you for future studies, we will delete you from our recruitment list.

Adnin Zaman, MD
University of Colorado Denver
Campus Box C263
12348 E. Montview Boulevard
Aurora, CO 80045

What are the possible discomforts or risks?
There are certain risks and discomforts that may be associated with this research. They include:

Risks of DXA Scan: As part of this study, you will have at least two DXA scans. DXA is a way of looking inside the body using X-rays. X-Rays are a type of radiation. Your natural environment

has some radiation in it. Each DXA will give you about the same amount of radiation that you would get from your environment in 2 days. All women of child-bearing potential will have a negative urine pregnancy test before the DXA. It is possible that the study team will incidentally identify potential bone disorders (i.e., possible osteoporosis) and follow up testing will be recommended by the study MD. To minimize the risk of radiation exposure from the DXA scan, trained technicians conduct will conduct all scans, thus, reducing the likelihood of repeat assessments.

Risks of Screening Procedures: The primary risk from the screening procedures in this study is diagnosis of a previously unknown disease. If a previously undiagnosed disease is found during screening or during any of the procedures, the study doctor will discuss the diagnosis with you and refer you to your primary care provider for follow up or to the emergency room if there is a serious abnormality.

Risks of Blood Draw: Each time blood is drawn about 4 teaspoons will be removed by putting a needle into the vein. A total of 8-10 teaspoons will be drawn throughout the entire study. This is the standard medical method used to obtain blood for tests. You may feel pain when the needle goes into the vein but should not feel any after it is in the vein. A bruise may form at the site after the needle is removed. There is also a slight chance you may become lightheaded or faint during this procedure. To minimize the risks associated with venipuncture, all procedures will be conducted by trained personnel.

Risks of Confidentiality and Privacy: The use of questionnaires and collection of personal medical information poses a risk to confidentiality and privacy and may cause embarrassment. There are no alternatives that would permit the acquisition of the information required. These risks will be minimized by not including personal identifying information on the forms, when possible, and by conducting interviews and collection of personal information in a private setting. We will do all we can to protect your information, but it cannot be guaranteed. In addition, you will be asked to fill out several questionnaires which will take some time and effort. Some of the questions may include sensitive information. If you wish to not answer a question, you may skip that question.

Risks if you Become Pregnant: If you become pregnant during the study, the treatment or procedures involved in the study may involve risks to the embryo or fetus which are currently unclear.

Unknown Risks: The study may include risks that are unknown at this time.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

What are the possible benefits of the study?
This study is designed for the researcher to learn more about the feasibility of recruiting pre-menopausal women with overweight or obesity who are starting a COC. This research study will also help the researchers understand more about the effects of prescribing a combined oral contraceptive versus non-hormonal forms of contraception on body weight, body composition, cardiometabolic risk factors, eating behavior, and appetite.

This study is not designed to treat any illness or to improve your health.

Who is paying for this study?
This research is being sponsored by the National Institutes of Health.

Will I be paid for being in the study?
You will not be paid for any screening measures that you complete. You will be paid $100 for completing all measures at baseline, study month 3, and study month 6. This will add up to a total of $300 if you complete all of the measures. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

Occasionally, an assessment may need to be repeated to obtain an adequate measurement. For example, if the body position on the DXA scan was not optimal. If this occurs, we will ask you to repeat the outcome measure that was not adequate. However, you will only be compensated for one outcome measure.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?
You may need to pay for medical care to follow up abnormalities that may be found during screening procedures or outcome measures. You may need to pay for parking during study visits at months 0, 3, and 6. Parking in the visitor lots near the CTRC is $1 per hour on weekdays, and a flat rate of $1 on weekends and after 4 PM on weekdays.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?
The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. You will be removed from the study if you become pregnant or develop a medical condition that makes you ineligible for the study. You will be removed from the study if you choose to participate in another weight or exercise program or research study. You will be removed from the study if you chose to take a weight loss medication or supplement.

What happens if I am injured or hurt during the study?
If you have an injury while you are in this study, you should contact Dr. Adnin Zaman immediately. Her email address is adnin.zaman@cuanschutz.edu. Or you can contact study staff at (303) 724-9096 and they will contact Dr. Zaman immediately. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?
The researcher carrying out this study is Adnin Zaman, MD. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may email Dr. Zaman at adnin.zaman@cuanschutz.edu. You will be given a copy of this form to keep. The main person to contact if you have questions about this study is Dr. Zaman. You can also talk to a Subject Advocate at the Clinical Translation Research Center (CTRC). The phone number there is (720) 848-6662.

You may have questions about your rights as someone in this study. You can call Dr. Zaman with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at (303) 724-1055.

Who will see my research information?
The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:
- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

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Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:
- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- National Institutes of Health who is the company paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* of the following health information about you collected in this study available to:

Some of the research procedures involve genetic testing or the use of your genetic information. Your genetic information will not be released to others.

Information about you that will be seen, collected, used, and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Your social security number
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Psychological and mental health tests
- Alcoholism, Alcohol or Drug abuse
- Tissue samples and the data with the samples.

What happens to Data, Tissue, Blood and Specimens that are collected in this study?
Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data, tissue, blood, and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data and blood given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data and blood, collected from you.
- If data and blood are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures
In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this form about the study, or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study and agree to provide consent electronically: I will be able to get a signed and dated copy of this consent form by downloading or emailing myself a copy of the signed eConsent, which I may choose to print as well.

To indicate that you agree to sign electronically and that you consent to participate in the study, type your name and today's date in the space below. Additionally, use your finger or mousepad to sign this consent.

Signature:_____ Date:_____

Print Name:_____

To indicate that you agree to sign electronically, that you obtained consent and the subject's questions were answered, type your name and date in the space below. Additionally, use your finger or mousepad to sign this consent.

Consent form explained by:_____ Date:_____

Print Name:_____