Strategic Hormonal Evaluation in Keto-AdaptatioN (SHEKAN)

The Ohio State University

IRB Approval Novemeber 25, 2025

IRB# 20250337

The Ohio State University Combined Consent to Participate in Research

Study Title:	**Strategic Hormonal Evaluation in Keto-AdaptatioN**
Principal Investigator:	**Madison Kackley**
Sponsor:	Davis Heart and Lung institute: Ketogenic Research in Women's Health Fund

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The SHEKAN study aims to understand how a ketogenic diet (KD) affects women's health and hormones over three menstrual cycles. The ketogenic diet is a low-carbohydrate, high-fat diet that shifts the body's metabolism from using glucose (sugar) to using ketones (produced from fat) for energy. While this diet has been studied for various health benefits, little is known about how it interacts with women's natural hormonal cycles. You will follow a ketogenic diet while researchers track changes in their hormones, metabolism, and body composition (muscle and fat balance). Advanced, non-invasive FemTech devices (such as Femometer and Mira) will be used to monitor hormonal fluctuations. Each week, you will undergo a series of non-invasive tests, including metabolic rate assessments, body composition scans, and surveys about your experiences. Blood samples will be collected to measure key reproductive hormones, such as estrogen, progesterone, luteinizing hormone

(LH), and follicle-stimulating hormone (FSH). The goal is to identify patterns between the menstrual cycle, ketone levels, and hormonal balance, providing insights into how ketogenic diets might impact women differently than men. By exploring these connections, the SHEKAN study aims to advance women's health research and offer personalized nutritional guidance to individuals interested in ketogenic diets.

1. Why is this study being done?

To investigate the physiological, hormonal, metabolic, and behavioral adaptations that occur in healthy, premenopausal women undergoing keto-adaptation over the course of 16 weeks. The study aims to characterize changes in reproductive hormones and evaluate the broader health effects—including insulin sensitivity, lipid markers, body composition, mood, sleep, and energy—associated with a well-formulated ketogenic diet.

2. How many people will take part in this study?

This study plans to enroll up to 24 participants to account for a 20% attrition rate. The target sample size for analysis is 20. If 20 participants complete the study recruitment will be discontinued.

3. What will happen if I take part in this study?

First, you will visit the test center to discuss the study and to give your consent to participate. If you do consent to participate, you will be screened for your eligibility to participate, this will be based on:

1. Your confirmation of regular cycles
2. Ability to wear/use all devices for the duration of the study. Devices will be returned at the end of the study.
3. Your responses to specific Inclusion/Exclusion criteria as follows:

<u>Inclusion:</u>

- You are free of major health concerns
- You are between 18-45 years old
- You have monthly menstrual cycles that last 27-32 days
- You are willing to self-report menstrual cycles
- You have access to a smart phone, computer, or tablet to track diet

<u>Exclusion:</u>

- You have a history of reproductive disorders
- You are currently pregnant or lactating
- You have recurring disordered eating behaviors or other food insecurity concerns
- You have suffered a lower body injury in the last 6 months

- You are currently suffering from another major health concern that may impair your ability to participate

If you meet all inclusion and none of the exclusion criteria, then you are eligible for the study. If you are interested in participating in the study, then you will be scheduled to return to the study center for the testing visit at a time that is convenient for you.

Study Overview

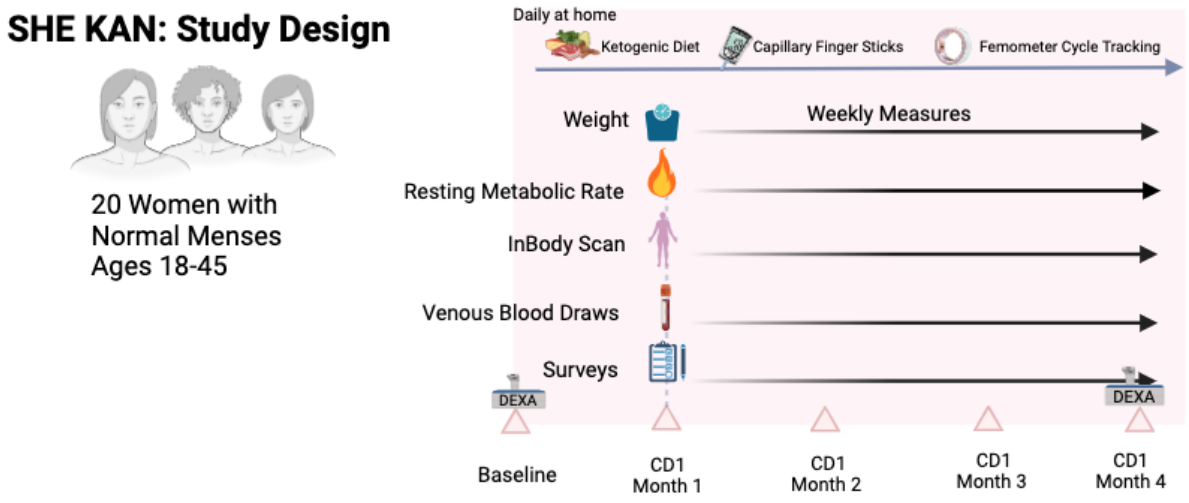


Figure 1 | Study schematic, showing timeline for a study day.

Study Procedures

Study Day	Screening	Weekly	Daily
Visit to Study Center	X	X	
Informed consent	X		
Medical history questionnaire, menstrual history form, reproductive history questionnaire, health symptoms questionnaire, general behavioral inventory, ASA24 and anthropometrics[1]	X		
Body Composition Scan*[2]	X		
Hydration Status[3]	X	X	
Resting Metabolic Rate Test[4]		X	
InBody Scan[5]	X	X	
Whole blood collection[6]		X	
Surveys[7]	X	X	
These are at home testing			

Fem Tech Use[8]			X
Fasted Capillary Ketone and Glucose Measures[9]			X

1. At screening you will complete a Medical History Questionnaire, Menstrual History Form, Reproductive History Questionnaire, Health Symptoms Questionnaire, General Behavioral Inventory, and ASA24 diet assessment. We will then get anthropometric data from you, which includes measuring your hip circumference, waist circumference, BMI, height, and weight. The participant will be familiarized with the use of the InBody.
2. You will complete a DEXA scan which will determine your fat mass and lean mass.
3. Participants will be asked to void the bladder and collect a sample for hydration status. We will also test for Hcg in the urine to ensure participants are not pregnant.
4. Resting Metabolic Rate (RMR) will be recorded weekly, which will require you to arrive fasted. Your resting energy metabolism will be measured so we know how many calories you burn at rest. This test requires that you lie still and relax for 30 minutes. The room will be dark, quiet and at a comfortable temperature to allow you to rest. After the 30-minute rest period you will be instructed to remain awake but still. A plastic see-through hood will be placed over your head. This hood will allow you to breathe normally while we collect samples of the air you are breathing in and out. A measuring device, known as a metabolic cart, is attached to this hood via a plastic hose and measures the gases in the air collected by the hood to determine how many calories you burn at rest. This test will last about 45 minutes.
5. After RMR testing you will be asked to complete the InBody assessment, which is a device that will measure body fat percentage and body composition. You will be asked to stand on the InBody and hold the two poles attached. This test will require you to stand still for about 2 minutes.
6. Venous blood will be collected which will be used to measure reproductive hormones after RMR and InBody scan.
7. A conglomeration of health, behavior, and dietary surveys will be completed once on screening day. In addition to these, surveys on menstrual symptoms, dietary habits, emotional well-being, and sleep will be completed weekly. The surveys will include - PROMIS Cognitive Function Survey, PROMIS Depression Scale, PROMIS Sleep Disturbance Scale, PROMIS Anxiety Scale, Multidimensional Assessment of Fatigue, Menstrual Symptom Questionnaire, and IPAQ.
8. Participants will be provided with FemTech devices, educated on proper use and expected to use FemTech daily. Devices will be returned at the end of the study:

    - **Mira Fertility Urine Based Fertility Kit-** This kit includes a meter and testing strips to use during the study to measure urine levels of Progesterone, Estradiol, Follicle Stimulating Hormone and Luteinizing Hormone. You will use the testing strips from the device user guide.
    - **Femometer-** The world's first wearable smart ring designed for ovulation and period tracking. Just slip it onto your finger before sleep, and let it read your body's data. The ring continuously monitors your basal body temperature (BBT), eliminating the need

for any manual input. By monitoring your body temperature in real time, the Femometer ring claims to calculate when you will ovulate.

9. Participants will be familiarized with how to use and conduct fasted daily capillary ketone and glucose measures using the KetoMojo device. This device will be returned at the end of the study.

4. How long will I be in the study?

Participation in this study will last approximately **16 weeks**, depending on scheduling and individual availability. Study activities include:

- **Baseline Visit (Week 0)** – Screening, consent, initial measurements, and device distribution.
- **Weekly In-Person Visits (Weeks 1–16)** – Urine pregnancy testing and protocol-specific assessments.
- **Final Assessment (Week 12–16)** – Body composition analysis, metabolic testing.

All visits will occur in person. There will be **no re-contact or follow-up after the final study visit** unless required for safety notification or regulatory purposes.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Femometer Ring

Femometer rings come in multiple sizes, but your ring should not fit in a fashion that compresses the skin or restricts blood flow. This could cause swelling, oxygen restriction, and if not treated tissue death.

InBody

There are no known risks or side effects to completing an InBody assessment.

Blood Draws

Blood draws may cause discomfort at the skin puncture site and a small bruise may develop that may persist for several weeks. There is also a small possibility of an infection. In total we will take 96mL of blood throughout the entire study, which is roughly ~ 6.5 tablespoons which is about 2/5 of a cup of blood. Blood draws will be done via butterfly needle. Risks are minimized by using sterile disposable needles and gauze and the practice of aseptic (sterile) techniques during the blood draw.

Body Composition-DEXA

This research study involves exposure to radiation from a DEXA EXPERT spine, femur or whole body scan, . This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you will receive in this study is about 0.78 mSv or 78 mrem, and is approximately equivalent to a uniform whole body exposure of 95 days of exposure to natural background radiation. This use involves minimal risk and is necessary to obtain the research information desired.

Cycle Tracking

Using electronic cycle tracking apps such as being implemented in this study do run the risk of data breaches. Precautions have been taken to secure HIPAA protected health information as well as deidentifying participant information. However, in the event of a data breach compromising participant privacy all parties will be notified.

Surveys

Surveys may cause emotional distress due to the sensitive nature of female health to many women. These risks will be mitigated by informing you of the survey's nature before you complete each and referring you to any clinicians needed if you feel it is necessary. Participation is always completely voluntary and if the nature of a survey becomes too distressing for you, you are free to stop at any time.

Urine

Pregnancy Tests: Weekly urine pregnancy tests will be performed before blood collection and DEXA scans to ensure participant safety. These tests are not diagnostic. Results will be shared immediately. If a test is positive, the participant will be withdrawn from the study and referred to a healthcare provider.

Finger-stick Testing

The finger stick may cause a slight immediate discomfort at the specific stick site. Under normal conditions, there are minimal risks to you when performing finger-sticks that include: bruising; light-headedness or dizziness due to fear of needles; itching and infection.

7. What benefits can I expect from being in the study?

You may experience potential health-related benefits, such as gaining a better understanding of your menstrual cycle patterns, resting metabolic rate, and body composition trends. These benefits are not guaranteed.

The primary benefit of this research is to help scientists better understand how ketogenic diets affect hormonal and metabolic health in women.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

All research data will be coded with a unique study ID and stored on secure, encrypted servers. The only document linking your name to your study ID will be the signed consent form, stored separately in a locked cabinet or password-protected file accessible only to the PI and designated staff. Deidentified data may be shared with qualified collaborators under a data use agreement. Once data are deidentified, it cannot be withdrawn.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If we find information that significantly impacts your health, we **will** share it with you.

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 the website at any time.

10. Will my de-identified information (and bio-specimens) be used or shared for future research?

No.

11. What are the costs of taking part in this study?

There are no costs for you to participate in this study

12. Will I be paid for taking part in this study?

By law, payments to participants are considered taxable income. Participants will be paid $50 for each full cycle they complete in the form of a check in person. The first month may not be a full cycle, thus participants will be paid $50 upon completion of their FIRST full cycle in the study (from onset of period to onset of period). They will be paid another $50 dollars after the second complete cycle and the remaining $50 after the last. In total, participants could receive $150 in compensation.

13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

15. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact Madison Kackley, PhD., (740) 817-1622, and Kackley.19@osu.edu

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Madison Kackley, PhD., (740) 817-1622, and Kackley.19@osu.edu

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time