

# Associations Between Hormone replacement therapy, Testosterone replacement therapy, Body Composition, Cardiorespiratory Fitness, and Immune Aging in Older Adults

IRB #: 26-130

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Laboratory: Exercise and Performance Nutrition Laboratory, Lindenwood University

## Study Overview

The purpose of this study is to learn more about how hormone replacement therapy (HRT) and testosterone replacement therapy (TRT) may be associated with healthy aging in older adults. As we age, changes in hormone levels can affect muscle mass, body composition, metabolism, physical function, cardiovascular fitness, and immune health. While hormone therapy is used by some older adults, more research is needed to understand how it may be associated with these different aspects of health and the biological processes involved in healthy aging.

This study includes assessments of body composition, resting metabolism, muscular strength, cardiovascular fitness ( $VO_2\text{max}$ ), immune function, and blood-based biomarkers. Researchers will compare these measures among older adults who use HRT or TRT and those who do not use hormone therapy. The results may help researchers better understand the relationships between hormone therapy, physical function, immune health, and other biological features of healthy aging.

## Participation at a Glance

- Total Study Duration: 1 Day
- Number of Visits: 1
- Time per Visit: 2-3 hours
- Participant Pre-Visit Requirements:
  - 8-hour food fast
  - Avoid exercise prior to visit
  - Wear athletic clothing (without hard metal/plastic components or reflective logos) and shoes
- Compensation: \$25 gift card

## How to Get Started

1. Complete the [screening form](#).
2. Our team will review your info and contact you with eligibility.
3. If eligible, we will schedule your visit (see next section for details).
4. The visit includes: informed consent, intake paperwork (health history, confirmation study criteria is met), body composition and resting metabolic rate measurements, blood draw, strength testing, and a cardiovascular fitness assessment ( $VO_2\text{Max}$ ).

## Study Visit Outline

|                                                         |           |
|---------------------------------------------------------|-----------|
| Visit Length                                            | 2-3 hours |
| Consent                                                 | X         |
| Medical and Health History Review                       | X         |
| Review of the Inclusion and Exclusion Criteria          | X         |
| Height & Body Mass                                      | X         |
| Resting Heart Rate & Blood Pressure                     | X         |
| Body Composition (DEXA)                                 | X         |
| Resting Metabolic Rate                                  | X         |
| Blood Sample Collection                                 | X         |
| Forearm Strength Assessment                             | X         |
| Knee Extensor Strength Assessment                       | X         |
| Cardiovascular Fitness Assessment (VO <sub>2</sub> Max) | X         |
| Provide Compensation and Results                        | X         |

## Procedure Details

- **DEXA Scan** – A DEXA scan is a low-dose X-ray that measures bone, muscle, and body fat. Participants lie still on a padded table while a scanner passes over the body. The scanner does not touch the body, and the participant will not feel anything. The test takes about 7 minutes.
- **Resting Metabolic Rate** – Resting metabolic rate (RMR) measures how much energy your body uses at rest to support basic functions such as breathing, circulation, and maintaining body temperature. To measure RMR, you will arrive at the laboratory after an overnight fast and avoid exercise before testing. After resting quietly, you will lie comfortably while breathing into a device that measures the oxygen you use and carbon dioxide you produce. These measurements are used to estimate how much energy your body uses while at rest.
- **Blood Sample Collection** – A trained research team member will collect blood from a vein in the arm using standard procedures. Approximately 94 mL of blood will be collected during the study visit. Blood samples will be used to help researchers better understand immune function and biological markers associated with healthy aging and hormone therapy use. These samples will be analyzed to evaluate immune cell populations, blood characteristics, and biochemical, hormonal, inflammatory, and other molecular markers that may provide insight into how hormone therapy is associated with the aging process. All samples will be appropriately labeled, transported, processed, and stored using approved safety and handling procedures until analysis.
- **Forearm Strength Assessment** – Forearm strength will be assessed using a handgrip strength test. You will squeeze a handheld device as hard as you can for several short trials with each hand. The strongest measurement from each hand will be recorded. Handgrip strength is a simple measure of muscle strength that can provide information about physical function and healthy aging.

- **Knee Extensor Strength Assessment** – Knee extensor strength will be assessed using a specialized strength-testing device. While seated, you will be asked to straighten your knee and push against resistance as hard as you can for several short trials. The device measures the amount of force produced by the muscles used to straighten the knee. These measurements will help researchers evaluate lower-body muscle strength and physical function as they relate to healthy aging and hormone therapy use.
- **VO<sub>2</sub>Max Aerobic Capacity:** This test measures aerobic fitness and how efficiently the body uses oxygen during exercise. You will exercise on a stationary bicycle while breathing through a device that measures the oxygen you use and carbon dioxide you produce. The test will begin at a light workload and gradually increase until you reach your maximum effort. Heart rate will be monitored continuously throughout the test. The test will be supervised by trained research staff, and you may stop at any time if you feel uncomfortable.

### Compensation & Benefits

- Total Compensation Amount: \$25 gift card
- Compensation Distribution: The gift card will be provided at the end of the research visit.
- Non-monetary Benefits:
  - Body Composition Results
  - Resting Metabolic Rate Results
  - Strength Results
  - VO<sub>2</sub>Max (aerobic/endurance capacity) testing results

### Risks & Safety

- *Privacy and Confidentiality:* We are collecting data that could identify you, such as name, phone number, and email address. Every effort will be made to keep your information secure. Only research team members can see any data that may identify you.
- *Risk from Blood Collection:* You will have blood sampled from your arm one time during the study. The blood sample will be collected by research staff members who are trained in phlebotomy. It is possible that blood collection may cause your arm to get sore and/or bruise at the collection site. Blood collection also increases the risk of getting an infection, feeling dizziness, or fainting. To minimize any pain, swelling and bruising due to multiple blood collections, an elastic bandage will be placed on your arm after the collection. You will also be instructed to avoid activity with that arm for the remainder of the day and to keep all bandages over the collection site, as needed, until the following day. Research team members will also give you instructions on how to prepare a cold pack later in the day when testing is completed.
- *Radiation Exposure:* You will have one DEXA scan completed to assess your body composition. This scan will expose you to a dose of radiation considered by medical

experts to be small or trivial. The dose you will receive is similar to the same amount of radiation you will be exposed to by living in a populated community.

- *Risk of Injury:* Because you will be performing maximal aerobic exercise testing and completing strength testing, there is a risk of fatigue, shortness of breath, dizziness, nausea, muscle soreness, musculoskeletal injury, abnormal cardiovascular responses, or other exercise-related complications. The risk of injury will be minimized by having trained study team members supervise and conduct the testing. These team members are trained in CPR/AED and/or certified as strength and conditioning specialists. Additionally, physical risks associated with intense exercise will be minimized by conducting a health appraisal during screening.
- *Risk of Discomfort or Skin Irritation:* Due to performing maximal exercise testing that require you to wear a heart rate monitor or seatbelt like straps, there is a risk for irritation or discomfort where the monitor and straps are placed. While it is possible that you may experience this discomfort, it is not likely as the monitor and straps will be properly fitted and can be adjusted at any point to ease or eliminate discomfort.

## Frequently Asked Questions (FAQs)

### **Q: Will I receive my test results?**

A: Yes. You will be provided with a summary of your results for body composition, resting metabolic rate, strength assessments, and maximal aerobic capacity (VO<sub>2</sub>Max) at the end of your participation.

### **Q: Can I withdraw from the study at any time?**

A: It is always your choice to participate in this study. You may withdraw at any time. You may choose not to answer any questions or perform tasks that make you uncomfortable. If you decide to withdraw, you will not receive any penalty or loss of benefits. If you would like to withdraw from a study, you can contact the research team at [epnl@lindenwood.edu](mailto:epnl@lindenwood.edu) or (636) 949-4676; the Principal Investigator, Chad Kerksick, PhD directly at (636) 627-4629 or [ckerkicksick@lindenwood.edu](mailto:ckerkicksick@lindenwood.edu). You may also contact the laboratory coordinator, Anthony Hagele at (636) 949-4785 or [ahagele@lindenwood.edu](mailto:ahagele@lindenwood.edu).

### **Q: Will my information be kept private?**

A: We will do everything we can to protect your privacy. We do not intend to include information that could identify you in any publication or presentation. Any information we collect will be stored by the researcher in a secure location. The only people who will be able to see your data are members of the research team, qualified staff of Lindenwood University, representatives of state or federal agencies.

### **Q: What if I miss a visit?**

A: Contact the research team as soon as possible. We will attempt to reschedule within the study timeframe when possible.

**Q: Do I need to be undergoing hormone replacement therapy?**

A: You do not need to undergo hormone replacement therapy (HRT) or testosterone replacement therapy (TRT) to take part. We are recruiting participants that are both undergoing HRT/TRT and those that are not receiving any therapy.

**Q: Will I be asked to start hormone therapy as part of the study?**

A: No. This is an observational study, meaning the research team will not provide or prescribe hormone therapy. We are studying participants who are already using HRT or TRT as well as participants who are not using hormone therapy.

**Q: Will I need to stop taking my hormone therapy or other medications before the study?**

A: No. You should not stop or change any medications or hormone therapy because of this study. Please let the research team know about any medications, supplements, or hormone therapies you are currently taking so we can accurately document your health information.

**Q: How much blood will be collected?**

A: Approximately 94 mL of blood will be collected during the study visit. This is about 6 tablespoons, or just under ½ cup. Blood will be collected by trained research personnel using standard procedures.

**Q: Do I need to fast before my visit?**

A: Yes. You will be asked to fast overnight before your study visit. The research team will provide specific instructions about when to stop eating and drinking before your appointment. You should also avoid exercise before testing as instructed by the research team.

**Q: What should I wear to the study visit?**

A: Comfortable clothing and athletic shoes are recommended, as you will complete strength and aerobic fitness assessments. You may also want to dress in layers for comfort during the visit.

**Q: Do I need to be physically active to participate?**

A: No. You do not need to be an athlete or regularly exercise to participate. The study is designed to evaluate a range of physiological and health characteristics in older adults.

**Q: Will I need to exercise to my maximum effort?**

A: Yes. The VO<sub>2</sub>Max assessment is designed to measure your maximal aerobic capacity and will gradually increase in intensity until you reach your maximum effort. Trained

research staff will supervise the test throughout, and you may stop at any time if you feel uncomfortable or no longer wish to continue.

**Q: Can I bring a friend or family member to the visit?**

A: Yes, you are welcome to bring a friend or family member to your visit. They will not take part in the study procedures, but they are welcome to wait in the designated areas during your appointment.

## Location

Lindenwood University  
Exercise and Performance Nutrition Laboratory (EPNL)  
Fieldhouse, Rm 126  
209 S Kingshighway St., Saint Charles, MO 63301

