Informed Consent Statement/HIPAA Authorization

Changes to Muscle Quality and Sarcopenia Status After Short-Term Resistance Training in Older Adults

KEY INFORMATION

- This project is studying the amount and quality of muscle
- Your participation in this research project is completely voluntary
- Your participation will take 6 weeks.
- You will be asked to do the following procedures:
    - Sign and date this form, the informed consent.
    - Complete a health history questionnaire and submit it with a physician clearance form to your personal physician. Clearance must be granted for participation in the study.
    - Your body composition will be measured with different methods, including a full body scan that uses low levels of radiation, mild electrical currents you will not feel. These measurements will tell us how much fat and muscle mass your body has.
    - Handgrip, upper body and lower body strength will be measured.
    - Balance and walking tests will be used to assess leg power, strength, and balance.
    - We will have you record food intake for three days at multiple time points.
    - You will be randomly assigned to one of two exercise groups or a control group. If selected to an exercise group, you will schedule to work out with a study team trainer 2 days per week for 6 weeks. If you are selected to the control group, you will receive educational information about the benefits of exercise and will receive a weekly phone call.
    - All of the above-mentioned procedures will take place again after the 6-week intervention period.

  More detailed information on the procedures can be found below.
- Risks with participating include exposure to low-dose radiation and physical exertion.
- Benefits to participating include feedback and insight to the outcomes of exercise on muscle strength and function.
- Your alternative to participating in this research study is to not participate.

DETAILED INFORMATION

INTRODUCTION

The Department of Health, Sport, and Exercise Sciences at the University of Kansas supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish to participate in the present study. You may refuse to sign this form and not participate in this study. You should be aware that even if you agree to participate, you are free to withdraw at any time. If you do withdraw from this study, it will not affect your relationship with this unit, the services it may provide to you, or the University of Kansas.

PURPOSE OF THE STUDY

The purpose of this study will be to evaluate the physical function and characteristics of body composition and muscle quality (muscle and fat) in older adults.

PROCEDURES
The following procedures will take place over several visits to KU research laboratories:

Visit 1 – Screening (day 0)-Contact via email
Inclusion criteria: •Subject has provided written and dated informed consent to participate in the study. •Subject is a male or female between 55 and 85 years of age, inclusive. •Subject is in good health as determined by a health history questionnaire and has been provided clearance from their personal physician. •Subject is untrained in resistance and aerobic exercise (does not participate in structured physical activity, including walking, more than 3 times per week). Exclusion Criteria: •Subject has a history of alcohol or other drug abuse in the past year. •Subject has a history or current presence of congestive heart failure, or any other form of cardiovascular disease that might put the subject at risk. •Subject has a significant history or current presence of untreated bleeding disorder, diabetes mellitus, high blood pressure (BP) [systolic BP> 140 and/or diastolic BP> 90], thyroid disease, tachyarrhythmia, heart disease, kidney disease, or liver disease. •Subject currently suffers from a sleep disorder and/or has a known history of (or is currently being treated for) clinical depression, eating disorder(s) or any other psychiatric condition(s) that might put the subject at risk and/or confound the results of the study. •Subject has a history of orthopedic injury or surgery within the last year that may prevent them from completing the study procedures. •Subject has arthritis of the hand which could impair his/ her ability to grip a handgrip measurement device. •Subject has severe arthritis defined as grade 3 or higher as diagnosed by a physician. •No history of CT scans (computed tomography), PET and nuclear medicine studies, or procedures that involve traceable dyes within the past year. Nuclear medicine imaging studies use agents that will interfere with the DXA whole body scan. •No implants, hardware, devices, or other foreign material in the measurement area. These devices will make whole body measurements difficult to interpret when the devices or implants are located within the scan field.

After signing an informed consent (this form) and completing a health history questionnaire, you will schedule to meet with the study team on multiple separate visits as outlined below. We will also provide your physician a form of medical clearance to participate in an exercise program along with your self-reported health history questionnaire. Clearance must be granted prior to proceeding with the testing procedures. For your first visit, we will request you arrive in a rested (>5 hours of sleep and no vigorous exercise within previous 24 hours) and fasted (>8 hours no food) state. Consumption of water and decaffeinated tea or coffee with no additives is permitted.

Visit 2 – Baseline (PRE) (day 1) at KU Edwards Campus (Regents Center Rm. 004 and BEST Rm. 160) in Overland Park
Upon arrival, your vital signs (heart rate and blood pressure), weight, height, current medications, ongoing illnesses and demographics (age, sex, race, and ethnicity) will be assessed and recorded.
You will have your body composition tested with several different devices. You will be asked to remove any metal objects from your person. You will also be asked to provide a urine sample. The urine sample will be used to determine your hydration status prior to assessments. The assessments will take about 90 minutes to complete in total.
Dual-Energy X-ray Absorptiometry (DXA) Body composition will be assessed using DXA. This device is a whole-body scanner that can tell us how much muscle and how much fat are contained within your body. Prior to each scan your height, weight, sex, birthdate, and race will be entered in to the device software by a certified technician. You will be instructed to lay supine on the padded scan table with your hands lying flat on the scanner bed and positioned near your body but not touching the hip. Your legs will be kept together by a Velcro strap wrapped around your lower leg, just above the ankles. A

total body scan with the appropriate body thickness (thin, standard, or thick, based on chest depth) will be selected with each scan lasting approximately 6 minutes.

Bioelectrical Impedance Analysis (BIA) You will be asked to remove any metal jewelry from your body, socks, and shoes then lie on your back on a padded examination table for 5-10 minutes while the investigator cleans your skin from hair, dirt, or lotion with alcohol for electrode placement. Body tissue impedance is measured when an extremely low, harmless electrical current is passed through your body, carried by water and fluids in and around the cells. Electrodes are to be placed on the wrist and on the ankle. Additional electrodes will be placed on the hand and foot, 5 cm from the first location's placement. To run the assessment, your height, weight and sex will be entered into the BIA device and the current will run for less than 1 second, undetected.

Isometric handgrip strength (HG) Handgrip strength of the dominant hand will be assessed using an adjustable handle hydraulic handgrip dynamometer. The HG width will be modified such that the 2nd phalanx of the middle finger is perpendicular to the device and the setting used will be recorded as will the preferred hand dominance for subsequent testing sessions. You will perform the HG tests in a standing position with your arm near your body, the elbow bent at 90°, and turned similar to using a hammer. The scores from three trials will recorded. This assessment takes less than 5 minutes.

Mobility and **physical function** Balance and walking tests will be conducted from the heel-to-toe walk, short physical performance battery, 4-meter walk, and get up and go test will be measured to assess your mobility before and after the training or control period.

Heel-to-Toe Walk (HTW) The HTW requires you to walk on a measured and marked 3-meter line with feet directly in line with each one another, where you will place the back of your heel in line with the big toe of your opposite foot, in tandem on a marked line on the floor. Starting behind a marked line, the timer will record from the onset of movement at one end of the 3-meter course and stops once the trailing foot crosses the end mark of the course.

Short Physical Performance Battery (SPPB) The SPPB includes three standing tests (feet side by side, semi tandem, and tandem), a 4-meter walk (4MW) used to measure gait speed, and a chair-rise test. For the standing/balance tests, feet will be placed side by side with your inner heels and big toes touching, the semi-tandem will require the big toe of the back foot to touch the heel of the lead foot, and the tandem stand will require you to stand with the tip of your big toe touching the back of your lead heel. Each position will be held for 10 seconds and your time (if less than 10 seconds) will be recorded and scored. For the 4MW, you will start with your toes behind a marked line, similar to the HTW. On your initial movement the timer will start. The time it takes you to walk 4 meters will stop once your trailing foot crosses a second marked line on the course. You will be instructed to walk at your usual speed, as if strolling down the driveway to check the mail or walking down the street to go to the store. The time will be recorded and scored. The chair rise test will require you to fold your arms across your chest and stand up using only leg strength. If you can complete one practice repetition, then you will be asked to perform 5 in a row and the time from first movement until final seated position will be recorded and scored.

Timed Get-Up-and-Go (TGUG) The TGUG will be performed on a measured and marked 3-meter course on rubber tile flooring using an armless chair and a digital stopwatch. You will begin the test in a seated position, hand palms flat on your thighs, with your feet behind a line marked on the floor. You will be instructed to stand up without use of your arms, walk along the 3-meter line, turn around past the end of the line, and return to the start position as quickly and as safely as possible. The stopwatch will begin at the first sign of movement and will stop once you return to the seated position.

Maximal muscle strength for the upper and lower body will be determined. To do this, the study team will demonstrate how to complete the bench press and leg press movements. After demonstration from a study team member, you will be asked to complete the movement at a low weight. You will be given

sufficient rest in between attempts. Each attempt will get progressively more difficult and once you cannot complete 5 repetitions at a given weight, the test will be complete.

You will also be given a 3-day dietary record and instructed to document every morsel of food or drink you consume. You will be asked to return the completed record within one week.

If you meet the study criteria will return to the site and be familiarized with the remaining experimental procedures and you will be randomized into one of three groups:

- Group 1: Resistance Training (free-weight/dumbbell) and supervised instruction (DBRT)
- Group 2: Resistance Band Training (variable elastic bands) and supervised instruction (EBRT)
- Group 3: Non-Exercise Control (no training) current activity level + education material (NEC)

Your 6-week training schedule will be established if you are selected to participate in the DBRT or EBRT groups. If you are randomized to the NEC group, we will set up a weekly check in phone call schedule.

6-Week Resistance Training or Control- (day 2-day 44)
If you are randomized to the DBRT or EBRT groups, you will participate in a 6-week program of resistance training 2 days per week at the Exercise and Human Performance Laboratory (BEST 160) at the KU Edwards Campus in Overland Park or Robinson Center weight room (ROB 102W) on the KU Lawrence Campus with certified trainers. Training intensity will be determined on your first training day Exercises will include upper- and lower-body movements, including: lunge, squat, deadlift, chest press, rows, overhead press, and pull-downs. If adherence to training drops below 80%, then you will be dismissed from the study. If an illness occurs where you might miss more than 2 consecutive training sessions, you will be dismissed from the study.
If you are randomized to the NEC group, a study team member will call you weekly based on your pre-arranged schedule and check in. They will ask if your health status has changes and if you are doing well. During the final week of training, another 3-day dietary record will be provided (either electronically or in person) with instruction to return during the next assessment visit. Upon completion of the POST1 assessment, participants in NEC will receive recommendations for exercise and physical activity established by the National Institute of Health called Go4Life.

Visit 3- Post Supervised Intervention Testing (POST1) (day 45)
You will visit the laboratory for POST1 assessment and will return completed 3-day dietary record that was provided during the final week of training (week 6 for NEC group). Training compliance, adverse events, illnesses, weight, vital signs, and use of medications will be assessed. You will undergo testing for body composition (BIA and DXA). Maximal muscle strength for the upper body bench press and lower body leg press using the 5-RM model and handgrip strength will be determined. Mobility and physical function from the short physical performance battery heel-to-toe walk, 4-meter walk, and get up and go test will be assessed.

RISKS
You will be asked to provide maximal effort during the functional assessments. These maximal efforts may result in rapid heart rate and breathing rate as well as delayed onset muscle soreness (DOMS) but only for short durations. You will be instructed to warm up and cool down prior to and after any assessment to minimize chance of muscle strain or soreness. In addition, you may have skin abrasions due to shaving and cleansing the skin with alcohol prior to electrode placement.
Exposure to X-Ray Radiation
This research study involves a procedure that uses x-rays. You are volunteering to participate in a study in which your body composition will be assessed using Dual-Energy X-Ray Absorptiometry, commonly

referred to as DXA. The evaluation is being done not because you are sick and the procedure will help you feel better or because it will help your doctor diagnose the problem. The information that will be gained from the x-ray procedure may, however, provide important research data. The scanner will not enclose or touch you, and you can wear your regular clothing (no metal or jewelry allowed). The DXA scan information is being used solely for descriptive and comparison purposes.

The University of Kansas fosters a positive safety culture and has adopted the philosophy of safety that all exposures to radiation, other hazardous materials, and risks from physical hazards shall be kept 'as low as reasonable achievable.' There are certain limitations placed upon this procedure to achieve that aim:

> If you have received nuclear medicine imagining studies (radionuclide and radiopaque agents) within the past two months, you may not participate in the study. These agents will interfere with the DXA whole body scan. If you have metal devices or implants, you may not participate in the study. These devices will make whole body measurements difficult to interpret when the devices or implants are located within the scan field. If you have recently undergone CT (Computed Tomography), PET, or fluoroscopic, studies, you cannot participate in this study.

The parts of your body that will receive the most radiation are the skin, although your whole body will be exposed to the radiation. During a measurement, the shutter opens to let the x-ray beam of radiation pass up through the scanner table and your body. The radiation field at the table top is 0.75 inches by 0.12 inches. You will see the detector arm of the DXA pass systematically back and forth over you. Lead oxide shielding surrounds the x-ray tube insert inside the tube housing assembly and reduces radiation levels around the scanner table. The system is also equipped with a Class II Laser device. A Class II rating indicates a low power visible laser that is not normally hazardous to eyesight but has the potential to be hazardous if viewed directly for an extended period of time. Because of the potential hazard, DO NOT stare directly into the beam while the laser is in operation.

The amount of radiation that you will receive from a DXA whole body scan is fifty times less than a chest x-ray. Mr. Michael Lemon, the Radiation Safety Officer at the University of Kansas, can provide you with more information about radiation exposure if you are interested.

The DXA measurements are being made by trained personnel who have received formal GE training for DXA total body scans. A physician, Dr. Jeffrey Burns, M.D., Board Certified advisor and medical consultant to the program, will provide medical assistance and supervision for those who voluntarily participate in the Herda research program, will be reviewing at least monthly, records of individuals who participate in the study.

BENEFITS

The benefits to participation in this study include: (1) Feedback given to you regarding your muscular strength, muscle mass, and muscle quality can be provided immediately after completion of the study, (2) feedback to the you regarding the efficacy of a training program (and how to participate in one in your home or community, and (3) become aware of how changes in strength, muscle mass, and muscle quality can effect daily activity performance reported as a result of this study. Upon completion of the study, we will be happy to share the overall results of the study to you. The study results, at large, will impact recommendations made to clinicians of how to prevent and treat the progression of sarcopenia in older adults.

PAYMENT TO PARTICIPANTS

As a participant you will receive no payment for your participation in this study.

INFORMATION TO BE COLLECTED

To perform this study, researchers will collect information about you. This information will be obtained from: Pre-Participation Exercise & Health History Questionnaire and medical clearance from your physician. Also, information will be collected from the study activities that are listed in the Procedures section of this consent form.

Your name will not be associated in any publication or presentation with the information collected about you or with the research findings from this study. Instead, the researcher(s) will use a study number or a pseudonym rather than your name. Your identifiable information will not be shared unless (a) it is required by law or university policy, or (b) you give written permission.

Your identifiable information will be removed from the data and biospecimens collected during this project, and the de-identified data and biospecimens will be used for future research without additional consent from you. The de-identified information collected about you will be used by: Dr. Ashley Herda, members of the Exercise and Human Performance Laboratory research team, KU's Center for Research and officials at KU that oversee research, including and the University of Kansas Human Research Protection Program committees and offices that review and monitor research studies.

Permission granted on this date to use and disclose your de-identified information remains in effect indefinitely. By signing this form you give permission for the use and disclosure of your information for purposes of this study at any time in the future.

INSTITUTIONAL DISCLAIMER STATEMENT

In the event of injury, the Kansas Tort Claims Act provides for compensation if it can be demonstrated that the injury was caused by the negligent or wrongful act or omission of a state employee acting within the scope of his/her employment.

REFUSAL TO SIGN CONSENT AND AUTHORIZATION

You are not required to sign this Consent and Authorization form and you may refuse to do so without affecting your right to any services you are receiving or may receive from the University of Kansas or to participate in any programs or events of the University of Kansas. However, if you refuse to sign, you cannot participate in this study.

CANCELLING THIS CONSENT AND AUTHORIZATION

You may withdraw your consent to participate in this study at any time. You also have the right to cancel your permission to use and disclose information collected about you, in writing, at any time, by sending your written request to: Dr. Ashley Herda, Dept. of Health, Sport, and Exercise Sciences, 12600 Quivira Road, RC 120 Overland Park, Kansas 66213. If you cancel permission to use your information, the researchers will stop collecting additional information about you. However, the research team may use and disclose information that was gathered before they received your cancellation, as described above.

QUESTIONS ABOUT PARTICIPATION

Questions about procedures should be directed to the researcher listed at the end of this consent form.

PARTICIPANT CERTIFICATION:

I have read this Consent and Authorization form. I have had the opportunity to ask, and I have received answers to, any questions I had regarding the study and the use and disclosure of information about me for the study. I understand that if I have any additional questions about my rights as a research participant, I may call (785) 864-7429 or write the Human Research Protection Program (HRPP), University of Kansas, 2385 Irving Hill Road, Lawrence, Kansas 66045-7563, email irb@ku.edu.

I agree to take part in this study as a research participant. I further agree to the uses and disclosures of my information as described above. By my signature I affirm that I am at least 18 years old and that I have received a copy of this Consent and Authorization form.

_____ _____

Type/Print Participant's Name Date

_____

Participant's Signature

[If signed by a personal representative, a description of such representative's authority to act for the individual must also be provided, e.g. parent/guardian.]

Researcher Contact Information

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