NCT03868631
1/27/2017

Muscle growth and strength development following a 12-week strength training program

INTRODUCTON

The purposes of this form are (1) to provide you with information that may affect your decision as to whether or not to participate in this research study, and (2) to record your consent if you choose to be involved in this study.

RESEARCHERS

Drs. Carol Johnston and Chris Wharton, Nutrition and Exercise & Wellness professors, and Heidi Lynch, a doctoral student, at Arizona State University Downtown, Phoenix, have requested your participation in a research study.

STUDY PURPOSE

The purpose of the research is to evaluate different protein sources for adequately supporting strength and lean body mass (LBM) development during a 12-week weight training program.

DESCRIPTION OF RESEARCH STUDY

You have indicated to us that you are healthy and have not participated in a weight training program for at least one year. If female, you do not have a history of pregnancy or lactation within the past 3 months. Also, you are not currently injured or in rehab for a recent injury. This study will involve the completion of brief demographic and health history questionnaire to demonstrate the absence of conditions that may contraindicate participation.

This research entails that you visit our test facilities on three occasions on ASU's Downtown Phoenix campus. At your first visit, you will be asked to complete a survey about your general health. Your height and bodyweight will be measured. In addition, body composition (relative amounts of fat and muscle tissue) will be determined by using a FDA-approved bone density measurement machine. The procedure is called Dual-energy X-ray Absorptiometry (DXA). You will be asked to lie face up on an open, padded table for about 7 minutes while the scanner arm of the DXA machine passes over the entire body. You can wear regular clothing but any metal must be removed. You will be exposed to a small amount of radiation (1-4 microSieverts) that is within an acceptable range per the FDA. For comparison, you would be exposed to approximately 80 microSieverts on a transatlantic airline flight of 8 hours, 50 microSieverts living in Denver, Colorado, at an elevation of 5,000 feet for approximately 4 weeks, or 30 to 40 microSieverts during a typical chest x-ray. (For test accuracy, you will be asked about test procedures using barium/isotopes in the recent past and be scheduled for your visit with an adequate lapse of time.) Next, thigh muscle size will be evaluated by ultrasound and circumference measurement. Finally, you will have your lower body strength assessed using a dynamometer machine. For this test you will be seated on a machine and extend and bend your lower leg at constant speeds. The power and torque (force) you generate will be measured.

You will be randomly assigned to one of two protein supplement groups and be instructed to consume ~20 grams of a protein powder daily (representing 80-100 calories) for 12 weeks. During the 12-weeks you will engage in a weight training program which will take place 3x per week for about 60 minutes per session. The training will take place at the Sun Devil Fitness Complex at the ASU Downtown Campus. You will receive individual attention by a trained investigator at each visit. You will be trained to slowly build strength over 12 weeks. Typical weight training protocols will be followed using typical exercises (including bench press, incline chest press, leg press, leg curl, leg extension, seated pull-downs, seated rows, calf raises, and abdominal exercises).

You will return to the research lab for a second visit at the middle of training (week 6) and at the end of the training (week 12), and the same procedures as described for the first visit will be repeated. You will be asked to complete a 3-day diet record at the start and end of the 12-week study. You will be provided with a calendar to track protein supplement ingestion and weight training.

RISKS

Anytime you are exposed to radiation there is potential risk. If there is ANY chance of being pregnant then you should not undergo the DXA scanning. Females will take a urine pregnancy test prior to the DXA scan. A certified X-ray technician will complete all DXA scans. Any time someone participates in weight lifting there is risk of injury including a pulled muscle or broken bone. Close supervision by trained investigators will be provided at all times during the lifting exercises.

BENEFITS

It is expected that you will get stronger by participating in this study and learn strength training techniques. You will be provided with all your health marker test results if desired including bone mineral density, body fat composition, and maximal power generated on the dynamometer.

NEW INFORMATION

If the researchers find new information during the study that would reasonably change your decision about participating, then they will provide this information to you.

CONFIDENTIALITY
All information obtained in this study is strictly confidential unless disclosure is required by law. The results of this research study may be used in reports, presentations, and publications, but your name or identity will not be revealed. In order to maintain confidentiality of your records, Dr. Johnston will use subject codes on all data collected, maintain a master list separate and secure from all data collected, and limit access to all confidential information to the study investigators.

WITHDRAWAL PRIVILEGE
You may withdraw from the study at any time for any reason without penalty or prejudice toward you. Your decision will not affect you any manner.

COSTS AND PAYMENTS
You will receive a $25 REI or Athleta gift card at the second testing appointment (week 6) and another $25 REI or Athleta gift card at the final testing appointment, (after week 12) for a total for $50 in the form of two gift cards to REI or Athleta.

COMPENSATION FOR ILLNESS AND INJURY
If you agree to participate in the study, then your consent does not waive any of your legal rights. However, in the event of harm, injury, or illness arising from this study, neither Arizona State University nor the researchers are able to give you any money, insurance coverage, free medical care, or any compensation for such injury. Major injury is not likely but if necessary, a call to 911 will be placed.

VOLUNTARY CONSENT
Any questions you have concerning the research study or your participation in the study, before or after your consent, will be answered by Dr. Carol Johnston, 500 N. 3rd St., Phoenix, AZ 85004. [602-827-2265]

If you have questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Research Compliance Office, at 480-965 6788.

This form explains the nature, demands, benefits and any risk of the project. By signing this form, you agree knowingly to assume any risks involved. Remember, your participation is voluntary. You may choose not to participate or to withdraw your consent and discontinue participation at any time without penalty or loss of benefit. In signing this consent form, you are not waiving any legal claims, rights, or remedies. A copy of this consent form will be given to you.

Your signature below indicates that you consent to participate in the above study.

_____ ___ _____ _____
Subject's Signature Printed Name Date

_____ ___ _____
Contact phone number Email

INVESTIGATOR'S STATEMENT
"I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature. These elements of Informed Consent conform to the Assurance given by Arizona State University to the Office for Human Research Protections to protect the rights of human subjects. I have provided the subject/participant a copy of this signed consent document."

Signature of Investigator_____ Date_____