California State University
SAN MARCOS

CONSENT TO PARTICIPATE IN RESEARCH

INVITATION TO PARTICIPATE

Kara Witzke, a researcher at California State University San Marcos is conducting a study on the effects of jumping exercise on bone health in premenopausal women. You are invited to participate in this study because you are a premenopausal woman between the ages of 18-42 years, have a history of regular menstrual cycles (10-12 per year), do not smoke, are not obese or underweight, do not use medications known to affect bone metabolism (such as thyroid hormone, aromatase inhibitors for cancer, hormone replacement therapy, selective estrogen receptor modulators (SERMS) and bisphosphonates for low bone mass within the previous 6 months.) If you take hormone birth control pills or Depo Provera, you will be asked to continue on your current medication throughout the study period. You also do not have a chronic disorder that affects bone metabolism and/or the ability to participate in exercise training such as diabetes, hyperparathyroidism, uncontrolled hypothyroidism, balance difficulties, or use narcotic medication. Lastly, you have not participated in exercise associated with a large volume of jumping (i.e., volleyball, basketball, high-impact aerobics, plyometrics, gymnastics, etc) within the past year.

PURPOSE OF THE STUDY

This study will compare the effects of a 9-month home-based exercise program using three jumping heights (off of 4”, 8”, 12” box heights) and three numbers of repetitions (10, 50, 100 jumps per session), on three dimensions of bone health (bone density, bone remodeling and bone strength).

Low-cost osteoporosis prevention strategies including jumping exercises, could lower the incidence of osteoporotic fractures without an increase in medical costs, and provide an alternative to drug therapy. This project will allow us to determine the minimum amount of jumping exercise required to improve bone health in premenopausal women and will lead to future research on how exercise improves bone quality and reduces fracture risk.

DESCRIPTION OF THE PROCEDURES

You will be randomly assigned to one of 10 different groups. The groups consist of nine different jumping groups (3 different jump heights, 3 different jump numbers), and a control group. If you are assigned to a jumping group, you will participate in jumping exercises off of a box according to your assigned group, that should only take 1-5 minutes to complete. You will be given a step to take home, in order to complete the jumping activity, 3 days per week (for 9 months). If you are assigned to the control group, you will not complete any jumping exercises but will participate in all testing procedures.

You will be evaluated on several different measurements before and after the 9-month exercise program. All testing will be completed at the Human Performance Laboratory at Cal State San Marcos. Testing will consist of:

- filling out health, nutrition, and exercise questionnaires

- a bone density scan of your whole body, hips, and spine that will require you to lay on a padded table for about 10 minutes
- impact forces on your feet during jumping that will require you to jump off of your assigned box height onto a metal plate, (In addition, you will be asked to come to the lab for 5 minutes at months 3 and 6 for "jumping practice" and to measure impact forces on your feet.)
- drawing a small amount of blood from a forearm vein to measure factors in your blood associated with bone metabolism.

The time commitment for each of the two testing sessions (one session before and one session after the 9 month exercise program) will be no more than 1 hour (2 hours total for both), and the two jumping practice sessions will last no more than 5 minutes each. You should wear a t-shirt and shorts without metal (zippers/buttons) for the pre- and post-testing sessions.

RISKS AND INCONVENIENCES

There are minimal risks associated with this study. Although unlikely, there is a risk of injury from the jumping exercises in this study. Any medical care required as a result of injury will be your responsibility. Bone density testing does expose you to very minimal levels of radiation, similar to what your body absorbs during an airplane flight across the country. However, to minimize risk of potential radiation exposure to a developing fetus, you will be asked to take a simple urine-based pregnancy test prior to the bone scan.

Blood draws may cause slight, but tolerable discomfort during the procedure and slight bruising and/or soreness in the contact area.

Although unlikely, a breach of confidentiality could occur. To safeguard against this, your health, nutrition, and exercise survey responses will be kept confidential; available only to the research team for analysis purposes. (See Confidentiality below for additional safeguards). As a participant in this study, you may withdraw your participation at any time without any consequence to you.

BENEFITS

You can expect to receive some fitness benefits from your participation in this study. You will also receive the results of your bone density assessments and will therefore gain knowledge of the effects of exercise on your general fitness and risk of osteoporosis. This knowledge is central to your ability to make important decisions regarding your future health. You are encouraged to discuss the results of your assessments with your primary care physician. Your participation will also help researchers find simple, low-cost osteoporosis prevention strategies that may benefit many women in the future.

ECONOMIC CONSIDERATIONS

You will not need to pay for anything associated with this study. If you are a student, you have the option of registering for KINE 499 Independent Study during the second semester of your participation, to receive 3 units of upper division academic credit. In this case, your regular student fees will also apply to the class.

CONFIDENTIALITY

Your identity will be protected by using secret code numbers on all data sheets and passwords on computer files. The master list of subjects' names and code numbers will be kept in a locked cabinet in a secured laboratory. All data will be presented in summary form in study reports, with no reference to you personally, or your individual data. Accountability will be maintained by periodic review of work by the research team, consultants and safety officer. You should know that the Cal State San Marcos Institutional Review Board (IRB) may inspect study records as part of its auditing program, but these reviews only focus on the researchers and the study, not on your responses or involvement. The IRB is a committee that reviews research studies to make sure that they are safe and that the rights of the participants are protected.

VOLUNTARY PARTICIPATION

Participation is voluntary. You do not have to participate in this study if you do not want to. If you agree to be in this study, but later change your mind, you may withdraw at any time. There are no consequences of any kind if you decide you do not want to participate.

QUESTIONS

If you have any questions about this study I will be happy to answer them now. If you have any questions in the future, please contact the principal investigator:

Dr. Kara Witzke
333 S. Twin Oaks Valley Rd.
San Marcos, CA 92096
Office phone: 760-750-7355
email: kwitzke@csusm.edu.

If you have any questions about your rights as a research participant, you may contact our Institutional Review Board at 760-750-4029.

☐ I agree to participate in this research study.

_____ _____
Participant's Name (print) Date

_____
Participant's Signature

_____
Researcher's Signature

This document has been approved by
Institutional Review Board at
California State University San Marcos
Expiration Date: April 13, 2012