CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

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STUDY TITLE: EFFICACY OF PLYOMETRICS TO INCREASE BONE MASS IN MALES WITH LOW BONE MINERAL DENSITY

INTRODUCTION

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

This is a research study. Research studies include only people who choose to participate. As a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is simply an effort to make you better informed so that you may give or withhold your consent to participate in this research study.

Please take your time to make your decision and discuss it with your family and friends.

You are being asked to take part in this study because you are a healthy male who participates in leisure time physical activity.

This study is being sponsored by the Department of Nutrition and Exercise Physiology, University of Missouri-Columbia.

In order to participate in this study, it will be necessary to give your written consent.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to determine how effective long term (12 months) jump training (plyometrics) is at improving bone density and increasing hormones that promote bone formation, as compared to long-term resistance training. This research is being done because the long-term benefits of regular plyometric exercise or resistance training on bone health in males with below normal bone density are unclear.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 250 people will take part in this study at the University of Missouri-Columbia.
**WHAT IS INVOLVED IN THE STUDY?**

**Visit 1:** Begin the informed consent process and describe the study purpose and the requirements.

All participants must: 1) be males between 25 and 60 years of age who participate exclusively in leisure time physical activity at least 4 hours per week for the past 24 months; 2) be apparently healthy; 3) be physically able to perform plyometrics or resistance training; 4) be willing to keep daily records of physical activity and food intake; 5) be willing and able to provide accurate information about your medical history; 6) follow a normal sleep/wake cycle; and 7) be willing to take a calcium and vitamin D supplement daily.

All participants must not: 1) smoke, or have quit smoking within the last 6 months; 2) drink excessive amounts of alcohol (more than 3 drinks per day); 3) take medication that affects bone; 4) have a disease that affects bone; or 5) participate regularly in plyometrics or resistance training.

**Visit 2:** If you decide to participate in the study you will come back for Visit 2 and sign the consent form. Then you will undergo a dual X-ray absorptiometry (DXA) bone density test. You will be required to lie still for approximately 10 minutes during this procedure. You will be exposed to a small amount of radiation during the scan, equivalent to 1/10th the radiation of a chest X-ray and about 1/1000 of a similar Computed Tomography scan. All study participants will undergo additional bone density tests at 6 and 12 months. **It is important to note that in order to be eligible to participate in this study, the DXA scan must indicate that you have below normal bone mineral density.** You will be provided with the results of your bone mineral density test. If you have any questions about the results you will need to contact your family practitioner. Interpretation of the results of your bone mineral density test must be performed by a physician.

You will also fill out a medical and physical activity history questionnaire. You must provide information about your medical history, including history of illness, injuries, and drug treatment that may affect your ability to safely and effectively participate in the study. You also must provide accurate information about your physical activity history.

If you meet the eligibility requirements of the study (i.e., age, activity level, no diseases or medications that affect bone, below normal bone mineral density), you will be provided a 7-Day diet record form to record your dietary intake and return at the next visit. You will also be given a form to record your physical training for 7 days.

**Visit 3:** You will have your blood drawn on five occasions during the study (0, 3, 6, 9, 12 months). Following an 8-12 hour fast, your height and weight will be measured and a blood sample will be taken from a vein in your forearm using the same procedure as would be followed at a health clinic. On three of these occasions (0, 6, and 12 months) additional blood samples (3) will be collected during the 24 hours after your normally scheduled training. The amount of the blood sample is very small and will not affect your health (15 mL, 1 tablespoon). The blood will be used to measure markers of bone formation and breakdown and hormone levels. Your blood will be analyzed for factors that may affect your bone mass.

Your blood will be kept frozen for 5 years after the study is completed and the results are published in a research journal. No additional tests will be performed on your blood sample.
The study will require regular visits to the Exercise Physiology Laboratory, each visit lasting 30-90 minutes during the course of the exercise intervention. On several occasions (0, 6, and 12 months) during your normally scheduled training we will determine your feelings of pain, fatigue and exertion using surveys to help determine your experience with the training program and monitor your risk for pain and/or injury.

You will continue your normal exercise program throughout the study and you will maintain your normal life at home, work or school. You are allowed to quit at any time without penalty or loss of any benefits. You will be asked to discontinue the study if the research and medical staff determine it is in your best interest to do so.

You will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group.

**Interventions:** All exercise training sessions will be conducted at the McKee Gym Fitness Center, under the supervision of trained exercise personnel.

**Group 1: If you are participating in the plyometric intervention you will attend 3 training sessions per week until you complete the 12-month exercise intervention.**

Participants will complete 10 repetitions of 10 different exercises to accumulate 40-120 loading cycles (jumps). The plyometric exercise sets will include: squat jumps, forward hops, split squat jumps, lateral box push offs, bounding, bounding with rings (lateral), box drill with rings, lateral hurdle jumps, zigzag hops, single leg lateral hops, and progressive depth jumps (10-100cm). The intensity of plyometric training will progress, with low intensity jumps weeks 1-2, low and moderate jumps weeks 3-4, and high intensity jumps weeks 5-6, followed by a rest week. You will steadily increase the intensity and number of jumps over each training cycle.

**Group 2: If you are participating in the resistance training intervention you will attend 2 training sessions per week until you complete the 12-month exercise intervention.**

Each exercise session will be made up from the following resistance exercises: squats, bent over row, dead lift, military press, lunges, and calf raises. Prior to and every 6 weeks during the Resistance Exercise Training (RET) intervention, maximal strength testing will be performed. This will involve a warm-up set of 5-10 repetitions, equal to 40-60% of your perceived maximum for each exercise. After a brief rest period, a second set of 3-5 repetitions at an intensity between 60-80% of perceived maximum will be performed. Subsequent attempts will be conducted using incremental increases in weight until a failed attempt, typically within 3 to 5 maximal attempts. One repetition maximums (1RM) will be conducted for squat, dead lift, and military press exercises, and modified maximums (10 repetitions) will be calculated for exercises in which 1RM are not commonly performed.

To account for strength adaptations as a result of strength training improvements, a progressive exercise program will be used. Weeks 1-2 will include one warm-up set (10 repetitions at 20% 1RM) and 3 moderate intensity sets (10 repetitions at 50% 1RM) for each exercise performed. Weeks 3-4 will be comprised of one warm-up set (10 repetitions at 20% 1RM), two sets at a moderate intensity (10 repetitions at 60% 1RM), and one set at high intensity (6-8 repetitions at 70-75% 1RM). Weeks 5-6 will be comprised of one warm-up set (10 repetitions at 20% 1RM), two sets at moderate intensity (10
repetitions at 60% 1RM), and one set at high intensity (3-5 repetitions at 80-90% 1RM). Week 7 will be a rest week.

**HOW LONG WILL I BE IN THE STUDY?**

Completion of all exercise training and testing procedures will take approximately 12 months.

You can stop participating at any time. Your decision to withdraw from the study will not affect in any way your medical care and/or benefits.

**WHAT ARE THE RISKS OF THE STUDY?**

While on the study, you are at risk for the side effects described below. You should discuss these with the investigator and/or your doctor. There may also be other side effects that we cannot predict.

Risks and side effects related to the study tests and procedures include:

There is a possibility of bruising and soreness at the site of the blood draw. Sterile procedures will be used so the chance of getting an infection is very remote.

There is a possibility of muscle and joint injury as a result of participating in the weight lifting exercises of the resistance training and the jumping of the plyometric training. Participants will be instructed in the safe and proper procedures for all exercise activities by qualified exercise physiologists and supervised by exercise personnel at all times. All exercise sessions will include warm-up and cool-down procedures to further minimize the risk of injury.

**Reproductive risks: The effects of the DXA scan on the male reproductive system are unknown but could cause harm. If you have any questions about the reproductive issues, please discuss them with the investigator or your doctor.**

You will be exposed to a small amount of radiation. Radiation effects are cumulative. You should always inform future doctors of your participation in this study.

For the reasons stated above the investigator will observe you closely during the study described above and, if you have any worrisome symptoms, notify the investigator immediately. Dr. Pam Hinton’s telephone number is (573) 882-4137. For more information about risks and side effects, ask the investigator or contact Dr. Hinton at (573) 882-4137.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

If you agree to take part in this study, there may or may not be direct medical benefit to you. You may expect to benefit from taking part in this research to the extent that you are contributing to medical knowledge. We hope the information learned from this study will allow for more specific exercise prescriptions for men with low bone mineral density.

In addition, you will: 1) participate in a supervised exercise program; 2) potentially improve your bone mass, strength, and balance; 3) receive free bone mineral density screening and results; 4) receive free diet and physical activity analyses; 5) receive free calcium and vitamin D supplements; and 5) have free parking and access to the McKee Gym locker room and showers during exercise sessions.
WHAT OTHER OPTIONS ARE THERE?
You have the option to not participate in this study.

WHAT ABOUT CONFIDENTIALITY?
Information will be stored in the investigator’s file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the study personnel at the University of Missouri-Columbia in a form that could identify you without your written consent, except as required by law. If the investigator conducting this study is not your primary, or regular doctor, she must obtain your permission before contacting your regular doctor for information about your past medical history or to inform them that you are in this study.

It is possible that your medical and/or research record, including sensitive information and/or identifying information, may be inspected and/or copied by the study sponsor (and/or its agent), the Food and Drug Administration (FDA), federal or state government agencies, University of Missouri Health Sciences Institutional Review Board or hospital accrediting agencies, in the course of carrying out their duties. If your record is inspected or copied by the study sponsor (and/or its agents), or by any of these agencies, the University of Missouri-Columbia will use reasonable efforts to protect your privacy and the confidentiality of your medical information.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

WHAT ARE THE COSTS?
There is no cost to you for the study procedures. You will not be charged for blood tests that are part of this research study.

WILL I BE PAID FOR PARTICIPATING IN THE STUDY?
You will be compensated $1000 for completion of the study. You will be paid $300 for completion of the first six months of the study and an additional $700 upon completion of the entire study.

WHAT IF I AM INJURED?
It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri. In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

WHAT ARE MY RIGHTS AS A PARTICIPANT?
Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate. If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future care in the University of Missouri-Columbia. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, the investigator of this study may decide to end your participation in this study at any time after she has explained the reasons for doing so and has helped arrange for your continued care by your own doctor, if needed.

You will be informed of any significant new findings discovered during the course of this study that might influence your health, welfare, or willingness to continue participation in this study.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Health Sciences Institutional Review Board (which is a group of people who review the research studies to protect participants’ rights) at (573) 882-3181.

You may ask more questions about the study at any time. For questions about the study or a research-related injury, contact Dr. Pam Hinton at (573) 882-4137 or Dr. John Thyfault at (573) 882-9818.

A copy of this consent form will be given to you to keep.
I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. I have read this consent form and my questions have been answered. My signature below indicates my willingness to participate in this study.

Subject/Patient*  Date

Legal Guardian/Advocate/Witness (if required)**  Date

Additional Signature (if required) (identify relationship to subject)***  Date

*A minor’s signature on this line indicates his/her assent to participate in this study. A minor’s signature is not required if he/she is under 7 years old. Use the “Legal Guardian/Advocate/Witness” line for the parent’s signature, and you may use the "Additional Signature" line for the second parent’s signature, if required.

**The presence and signature of an impartial witness is required during the entire informed consent discussion if the patient or patient’s legally authorized representative is unable to read.

***The "Additional Signature" line may be used for the second parent’s signature, if required. This line may also be used for any other signature which is required as per federal, state, local, sponsor and/or any other entity requirements.

“If required” means that the signature line is signed only if it is required as per federal, state, local, sponsor and/or any other entity requirements.

SIGNATURE OF STUDY REPRESENTATIVE

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered questions regarding the study to the best of my ability.

Study Representative****  Date

****Study Representative is a person authorized to obtain consent. Per the policies of the University of Missouri Health Care, for any 'significant risk/treatment' study, the Study Representative must be a physician who is either the Principal or Co-Investigator. If the study is deemed either 'significant risk/non-treatment' or 'minimal risk,' the Study Representative may be a non-physician study investigator.