Consent Form: Bioscience

Title of research study: Effects of Vitamin D3 Supplementation on Dynamic Stability in community Dwelling Older Adults

Investigator: Thurmon E. Lockhart, Ph.D., Professor, School of Biological and Health Systems Engineering

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you may be eligible for the research concerning the fall risk and low serum 25-hydroxyvitamin D level (i.e., Vitamin D level).

Why is this research being done?

Low serum 25(OH)D levels, a marker of vitamin D deficiency, are associated with accelerated loss of muscle mass, reduced muscular strength and power, impaired balance, and increased postural sway. Vitamin D_3 supplementation may provide an effective solution for reducing falls. Although the contribution of vitamin D in improving health and functional capacity are well supported in the literature, Vitamin D_3 supplementation to reduce falls in the community-dwelling elderly population has produced mixed results. As such, the main goal of this study is to evaluate the effect of vitamin D_3 supplementation on dynamic stability in an older population. Secondary objectives include postural stability, gait parameters, handgrip strength, timed up and go test, and serum 25-hydroxyvitamin D analysis. We hypothesize that 6 months of vitamin D_3 supplementation will improve dynamic stability and will lead to improved postural stability and walking characteristics and decrease the fall risk.

How long will the research last?

We expect that individuals will spend a total of 2 hours per data collection period which will occur five times during the 6 month period. Thus, you will spend total of about 10-12 hours in testing and participating in the proposed activities.

How many people will be studied?

We expect about 70 people will participate in this research study.

What happens if I say yes, I want to be in this research?

It is up to you to decide whether or not to participate.

For the testing, please report to the Glencroft Retirement Community's Rehabilitation Gym and Physical Therapy area in Glendale, AZ and, the Locomotion Research Laboratory, Physical Education Building East, Rm. 163, Arizona State University, Tempe, AZ.

You will be assigned to one of two groups: Group 1 will receive 1000 IU/day of a vitamin D_3 supplement; Group 2 will be given a placebo control capsule. Supplement packages will be administered in blindly coded boxes containing a one-month supply of the treatment. Your

compliance will be validated by collection of empty (used) supplement packages upon subsequent clinic visits.

Prior to any testing, assessment of pre-intervention mobility-related outcomes and serum 25(OH) D_3 testing, a questionnaire will be distributed and an interview/survey will be conducted to adequately determine eligibility for the study, according to mentioned exclusion/inclusion criteria. This survey will ask questions to determine if you qualify for this study. It will take about 15 minutes to complete the survey. You may quit the survey at any time if you do not want to continue answering questions. If you complete the survey, you will be told whether you qualify for the study. If you wish to continue to participate in the recruitment process, you will be asked to sign a formal consent form. If you have any questions, please contact Dr. Thurmon Lockhart. Information collected from this survey may be used in research reports in aggregate form only.

Following enrollment in the study, you will perform two pre-intervention baseline tests. The first will occur within 3 weeks of the screening visit, with the second taking place within the following four weeks. Treatment will be administered for the subsequent 6 months and 3 more tests will take place at 2 month intervals. The testing days (treatment visits) will comprise of the following: (1) blood draw in the morning; (2) 45-60 minute break for snack and recovery; (3) Dynamic Stability Analysis – walking for about 2 minutes while wearing an accelerometer at your chest level and on your ankles; (4) Gait Analysis & Timed Up and Go –10 minutes; (5) Postural Stability & Hand Grip Strength test – 5 minutes. The postural stability measures will be performed in quiet standing, with foot placement standardized on the forceplate, and the looking in the forward direction with arms by your sides. Two visual conditions will be given: eyes-open (EO) and eyes-closed (EC). Each measurement will last for 60 seconds and will be repeated twice for each condition. A 3 minute rest will be provided between measurements. For the handgrip strength measure - when instructed, you will squeeze the dynamometer as hard as possible for 3 seconds. Three trials will be required for each hand, with the mean constituting the final outcome measurement. For the timed get-up and go test, you will be asked to stand from a seated position, walk 3 m at your usual pace, turn around, walk back to the chair, and sit down. Walking aids are permitted and no instructions will be given about the use of the chair arms.

You will be compensated for your travels needs and time commitments at a rate of $40 per visit.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me?

Vitamin D toxicity can cause non-specific symptoms such as anorexia, weight loss, polyuria, and heart arrhythmias. More seriously, it can also raise blood levels of calcium which leads to vascular and tissue calcification, with subsequent damage to the heart, blood vessels, and kidneys. The use of supplements of both calcium (1,000 mg/day) and vitamin D (400 IU) by postmenopausal women was associated with a 17% increase in the risk of kidney stones over 7 years in the Women's Health Initiative. As such, during the treatment, caregivers will report on a questionnaire whether any problems or adverse events were encountered. At clinic visits, the research assistant will inquire about problems or adverse events. If an adverse event does occur, the issue will be discussed with the PI (Dr. Lockhart) who will, with the consultation of Glencroft group, determine whether the your supplementation should be halted or discontinued.

To minimize the risk during blood drawing, a licensed nurse/phlebotomist will perform the procedure. Accordingly, if at any point the participant feels uncomfortable with the aforesaid measurement procedures/blood drawing, they can cancel the trial.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

What else do I need to know?

If you agree to participate in the study, then consent does not waive any of your legal rights. However, no funds have been set aside to compensate you in the event of injury.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Arizona State University – Dr. Thurmon E. Lockhart, thurmon.lockhart@asu.edu, or 480-965-1499.

This research has been reviewed and approved by the Bioscience IRB ("IRB"). You may talk to them at (480) 965-6788 or research.integrity@asu.edu if:

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	