UF Institutional Review Board
UNIVERSITY of FLORIDA

RESEARCH SUBJECT CONSENT FORM

TITLE: Villency–Proof of Action: Foot Device, Balance and Sway, Kinematics of Walking

Version 6/7/2018

PROTOCOL NO.: None
WIRB® Protocol #20182379
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SPONSOR: Villency Design Group, LLC.

INVESTIGATOR: Heather Vincent, Ph.D.
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United States

SITE: UF Orthopaedics and Sports Medicine Institute
Department of Orthopaedics & Rehabilitation
3450 Hull Road
Gainesville, Florida 32607

STUDY-RELATED PHONE NUMBERS: Heather Vincent, Ph.D.
352-273-7459
352-273-7001 (24-hour number)

Sharareh Sharififar, Ph.D.
352-273-7410

Name of person seeking your consent: _____

Place of employment & position: _____

Name of Participant ("Study Subject"):

This consent form is designed to provide you with information to help you make your decision to participate in this study. This consent form may contain words that you do not understand. Please ask your study doctor or the study staff to explain any words or information that you do not clearly understand. You may take a copy of this consent form to review and discuss with family or friends before making your decision.

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant. Your decision to be in this study is voluntary. If you decide, at any point during the study, that you no longer wish to be in the study, you may leave the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Background and Purpose

This study involves the use of an investigational shoe insole device (also referred to as a foot insole device) similar to various shoe insoles or inserts you can buy at a store or pharmacy. Healthy participants will wear this insole device in their own athletic/tennis shoes over the course of one week. There are two key purposes of this study: 1. To determine how using this insole device for 1 week may effect a healthy individual's balance and postural sway while standing; and 2. To determine how using this insole device for 1 week may effect how an individual walks (gait), how hard they hit the ground as they walk, and foot pressure patterns with each step. Each individual's balance, postural sway, and walking gait (how you walk) will be analyzed before and after wearing the shoe insole device for the one-week time period.

Participation in the Study

This study is for healthy men and women aged 18 to 40 years. Certain individuals cannot participate in this study because of medical conditions they have at the present time or have had in the past. Please let the person who is discussing this study with you know if you have any of the following:

- Moderate or severe obesity (body mass index greater than 35kg/m^2)
- Known diagnosis of cardiovascular, orthopaedic, or neurological conditions, uncontrolled diabetes, or any condition that impacts normal walking ability
- Any current ankle, knee, hip, or low back pain
- Currently using any knee or ankle brace on a regular basis for joint pain
- Severe back pain, prior spinal fusion or spinal deformity that would affect gait
- Major cardiac or pulmonary conditions and any orthopedic limitation that precludes your ability to independently walk for 10 minutes or longer
- Any major orthopedic injury within the prior 12 months

What will be done only because you are in this research study?

This study will require two (2) visits (a baseline visit and one follow-up visit) to the Sports Performance Center at the UF Orthopaedics and Sports Medicine Institute. You will also be asked to use the foot device in your own athletic/tennis shoes at home over the course of seven (7) days. The insoles should remain in the same pair of shoes for the entire week (do not put the insole device in a different pair of shoes). Once you have completed the 7-day home program, you will return to the Sports Performance Center to complete your final follow-up visit.

On your initial baseline visit, you will first be asked to complete a short questionnaire asking about your background and health history. You will then complete a series of simple balance and walking tests to assess your stability and your gait patterns (how you walk).

Your walking gait will be evaluated using the GaitRite gait mat. The gait mat is a long strip of rubberized carpet (26 feet long) with sensors embedded within it. The sensors provide information about how you walk, step length, step width, and the pressures across your foot with each step. You will walk across the mat 6 times.

A second walking gait test will be performed while walking on a treadmill with your athletic/tennis shoes on – these should be the same ones you wore to the initial study visit. You will be fitted with several silver, reflective dot-like markers on your arms, legs, and torso. These markers will be worn while you walk on the treadmill at a set speed of 3.2 miles per hour. The markers will reflect light given off by special cameras around the treadmill and testing area. The reflected light will be used to create a 3-D model of you as you walk. This 3-D model can then be analyzed to provide information about your walking gait and forces through your body as you walk. The gait mat and treadmill walking tests will take about 15-20 minutes total.

While the reflective markers are still on you, we will also have you perform a series of balance tests – standing with both feet together, standing on just your dominant leg (the leg you use to kick a ball), and standing with your feet in a tandem position (one foot behind the other). The balance tests will be performed while standing on a force platform that is in the lab floor. Each balance test will about 30 seconds to complete.

Once the walking assessments and balance tests are complete, you will be provided with the foot device and a 7-day home program for use. We will review this program with you. You will be asked to use the foot device in your own shoes for 1 hour per day for the first 2 days then increase by hour per day each subsequent day (please see the table below). The study team will give you a log to write down the amount of time you actually used the device each day. At the end of home program, you will return to the Sports Performance Center to repeat all the walking assessments and balance tests just like on the first visit. You will be asked to return the completed log of foot device use to the study team in your final visit.

Day	Duration of Use
1	1 hour
2	1 hour
3	2 hours
4	3 hours
5	4 hours
6	5 hours
7	6 hours

What are the possible discomforts and risks?

The risks of participating in this study are minimal. The foot device is very similar to commercially available shoe inserts. The inserts may be a little thicker than the insert that originally came in your shoes, so your shoes may fit a little differently. This may be slightly uncomfortable at first, but as you use the inserts, this feeling should go away. A second anticipated discomfort is the development of mild muscle soreness in the legs and lower back from wearing the foot devices. Soreness often occurs with the start of any new therapy program where muscles adjust to being used in a new way. Any related muscle soreness should go away within 48 hours.

The small markers that are used in this study are placed on your skin with double sided tape. It is possible that you may feel some irritation on the skin where the markers were placed when the markers are removed.

Although a minimal risk, completing surveys may cause stress to some participants who may believe that they are not providing correct answers to the research team. To reduce this stress, the investigators will reassure each participant that all survey answers are based on what the participant is feeling, with no "correct" answer.

How could the researchers benefit from this research study?

The sponsor is paying the University of Florida for conducting this research study. In general, presenting research results helps the career of a scientist. Therefore, the study doctor may benefit if the results of this study are presented at scientific meetings or in scientific journals.

If you choose to take part in this study, will it cost you anything?

Study Devices
The foot insole will be provided at no cost to you while you are participating in this study.

Study Services
The Sponsor will pay for or provide all study services/activities required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact the Principal Investigator, Dr. Heather Vincent, at 352-273-7459 or Study Coordinator, Dr. Sharareh Sharififar, at 352-273-7410.

Items/Services Not Paid for by the Sponsor
Any other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

Will you be paid for taking part in this research study?

You will be paid a total of $125 for participating in this study. You will receive $25 upon completion of the initial study visit and $100 upon completion of the 7-day home program, follow-up study visit, and return of all study-related materials.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. If the payments total $600 or more or you are a nonresident alien, payment will be processed through the University of Florida Accounts Payable department and the University must report the amount you receive to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

The study team will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

What if you are injured because of the research study?

If you are injured as a direct result of your participation in this study, the Sponsor will pay for all reasonable and necessary medical expenses required to treat your injury, so long as:

1. The injury occurs during your participation in the study.
2. The injury results directly from the study device or study required procedures that you would not have received as part of your routine medical care.
3. The injury is not the result of the natural course of your disease or some other underlying condition.
4. The study doctor and/or study staff have followed the study procedures.

The sponsor and the Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. Heather Vincent at 352-273-7001 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

Do you have to be in this study?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you leave this study for any reason, please contact the Principal Investigator, Dr. Heather Vincent at 352-273-7459, or Study Coordinator, Sharareh Sharififar at 352-273-7410. They will tell you how to stop your participation safely.

Can you be withdrawn from this research study?

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- If you do not consent to any future changes that may be made in the study plan;
- If you do not adhere to the outlined study procedures;
- Or for any other reason.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

If you agree to participate in this study, the study doctor will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the study doctor needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Records about your study visits
- Records about the study devices
- Questionnaires and surveys
- Results from your study-related gait and balance assessments

This information will be stored in locked filing cabinets or in computers with security passwords.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will include only information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, or any other photographs, numbers, codes, or so forth that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, throughout your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To determine the effectiveness of the study device with improving balance and walking gait measures in healthy, young adults over a 7-day period.
- To evaluate a possible new use for the study device
- To determine the causes or effects of the study condition

Once this information is collected, it becomes part of the research record for this study.

Only certain people have the legal right to collect, use, and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study doctor, and research staff associated with this project
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures
- The University of Florida Institutional Review Board

Your PHI may be shared with:

- The study sponsor, Villency Design Group, LLC, and its designees
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments
- Western Institutional Review Board
- Your insurance company for purposes of obtaining payment

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it

could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

Your PHI will be used and shared with others until the end of the study. At the end of the study all PHI will be removed from the data set. This de-identified information could be used forever since it will be stored for an indefinite period of time in a secure database.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use, and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the study doctor.

Who would you call if you have any questions?

If you have any questions, concerns or complaints about this study or your participation, or feel you have experienced a research-related injury, contact Dr. Heather Vincent at 352-273-7459 or 352-273-7001 (24-hour number), or Sharareh Sharififar at 352-273-7410.

If you have any questions about your rights as a research subject, or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, WA 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

or

The University of Florida liaison in Gainesville at (352) 273-9600.

WIRB® is a group of people who perform independent review of research.

WIRB® will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB® if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Consent to participate in this research study

I have been informed about this study's purpose, procedures, possible benefits and risks. I have also been told alternatives to being in the study and how my protected health information will be collected, used, and shared with others. I have been given the opportunity to ask questions. My questions have all been answered satisfactorily. I agree to be in this research study. I have received a copy of this form.

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

Subject Signature and Authorization	Date

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study, the alternative to being in the study; and how the subject's protected health information will be collected, used, and shared with others:

Signature of person conducting informed consent discussion	Date