Variability and Specificity in Reactive Stabilization Movements to Diverse Slip Perturbations
NCT03755336
02-08-2023

ADULT CONSENT - NON-CLINICAL BIOMEDICAL

Title of this Research Study

Invitation
You are invited to take part in this research study. Participation in this research is voluntary. You have a copy of the following, which is meant to help you decide whether or not to take part:

- Informed consent form
- "What Do I need to Know Before Being in a Research Study?"
- The Rights of Research Subjects

Summary of the study:

This research study includes 3 visits in a week and each visit will take no more than 3 hours to complete. During the study we will have you complete a number of walking trials in the laboratory while wearing a device over your shoes. The device is designed to cause both of your feet to purposely slip simultaneously at random times. Reflective markers will be placed on your arms, legs, torso, and head to measure your movement. You will have a harness on at all times to keep you from falling. You will also be asked to complete a short physical activity questionnaire and fall history log at the first visit and 6 months after the last visit through a phone interview. Lastly, we will measure your upper and lower body muscle strength before and after the training program (1st and 3rd visits). The risks associated with the research include muscle soreness or muscle strain. You are not expected to benefit but the research may help us learn more about how people recover from slipping.

Why are you being asked to be in this research study?
You are being asked to be in this research study because you are between the ages of 19-35 years old or are 65-79 years old and, to the best of your knowledge, you are free of conditions that may affect your gait pattern.

If you are pregnant you may not be in this study.

What is the reason for doing this research study?
The purpose of this study is to understand how responses to slips vary and how and whether those responses improve with learning.

What will be done during this research study?
If you agree to participate in this research study, you will be screened for participation by completing a short medical history. This is to make sure you meet the qualifications to participate. You will also complete a short physical activity questionnaire and fall history log at the first visit and 6 months after the last visit through a phone interview.

You will be asked to wear comfortable walking shoes and a form-fitting suit. You will then have your height, body weight and leg and arm measurements recorded. Next, small markers (Styrofoam balls about the size of a marble) will be placed on your arms, legs, torso, and head. These markers are used by a motion capture system to record your movements. The motion capture cannot see any image of you it can only see the reflective markers. You will be asked to walk on a treadmill for 5 minutes. Then you will be asked to perform walking trials across the laboratory while wearing a safety harness attached to a gantry on the ceiling. You will also wear a device over your shoes that will unexpectedly cause a reduction in friction and may lead to a slip (e.g. similar to slipping on ice). After this event, you will have a 5-minute rest. The walk-slip-rest pattern will happen 12 times.

You will be asked to perform this procedure on 3 different times within one week. Each visit should take no more than 3 hours.

You will also be asked to complete muscle strength tests during the first and last visits. The test will measure your upper and lower body muscle strength before and after the training program.

What are the possible risks of being in this research study?
Potential risks of being in this research study are not higher than would be involved during normal physical activity. You will wear a fitted safety harness to prevent falling to the ground. However, you may react to the slip with rapid movements that cause muscle soreness, muscle strain, or slight discomfort from the safety harness.

It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

There is a minor risk of loss of confidentiality of your study data.

What are the possible benefits to you?
You are not expected to get any benefit from being in this research study.

What are the possible benefits to other people?
The study may provide additional information about fall prevention.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to participate.

What will being in this research study cost you?
There is no cost to you to be in this research study.

Will you be paid for being in this research study?
A $60 Amazon gift card will be given to you as compensation for your time. For accounting purposes, in order to compensate you for your participation we must ask that you provide your social security number. You can choose not to provide this information and still participate in the study but we will be unable to compensate you.

Who is paying for this research?
The research is being paid for by grant funds from The Center for Research in Human Movement Variability at UNO. The Center receives money from the National Institutes of Health to conduct this study.

What should you do if you are injured or have a medical problem during this research study?
Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem or some other kind of problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

How will information about you be protected?
In the course of this study we will collect information about you. The information may include things that could be used to find out who you are (like your name, phone number, birth date, address). This is called identifiable private information. During and after the research we will keep your research records as confidential as possible.

All necessary steps will be taken to protect your privacy and the confidentiality of your study data. All forms will be kept in a locked file room in the Biomechanics Research Building. No identifiable information will be associated with the data files.

At some time in the future, we may take the identifiers off the information. It is possible that this information without identifiers could then be used for other research studies by us, or by another investigator, without asking you for your permission.

Who will have access to information about you?
By signing this consent form, you are allowing the research team to have access to your research data. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your research data will be used only for the purpose(s) described in the section What is the reason for doing this research study?

You are also allowing the research team to share your research data, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
    - The HHS Office of Human Research Protections (OHRP)
    - National Institutes of Health (NIH)

You are authorizing us to use and disclose your research data for as long as the research study is being conducted. Per Nebraska law, the data collected as part of your participation will be retained for a minimum of 7 years after the completion of this research study. You may cancel your authorization for further collection of research data for use in this research at any time by contacting the principal investigator in writing. However, the information which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

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

This research is covered by Certificate of Confidentiality (CoC) from the National Institutes of Health. A CoC means that the researcher in most cases cannot reveal identifiable information about you to others without your permission. He or she can report things like potential child abuse or intent to hurt self or others. He or she can report contagious diseases, and can share information with agencies paying for the research. He or she can also share the information with other scientific researchers, as allowed by federal regulations protecting research subjects. A CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research

How will results of the research be made available to you during and after the study is finished?
In most cases, the results of the research can be made available to you when the study is completed , and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address: 6160 University Drive
Omaha, NE 68182-0860

What will happen if you decide not to be in this research study?
You can decide not to be in this research study. Deciding not to be in this research will not affect your relationship with the investigator or the Institution. You will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?
You can stop participating in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff. Deciding to withdraw will otherwise not affect your relationship with the investigator or this institution. You will not lose any benefits to which you are entitled. Any research data obtained to date may still be used in the research.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want to continue being in the study.

What should you do if you have any questions about the study?
You have been given a copy of "What Do I Need to Know Before Being in a Research Study?" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

What are your rights as a research subject?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems,

concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463.
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject _____ Date _____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent _____ Date _____

Authorized Study Personnel

Principal

* Hunt, Nathaniel
alt #: 402-417-3790
degree: PhD

Secondary
* Ouattas, Abderrahman
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Participating Personnel
* Rasmussen, Corbin
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