Real-time Sensorimotor Feedback for Injury Prevention Assessed in Virtual Reality

NCT# NCT02933008

Date: 06/03/2021

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

STUDY TITLE: Real-time Sensorimotor Feedback for Injury Prevention Assessed in Virtual Reality

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 175 people who are being studied, at Emory.

Why is this study being done?

This study is being done to learn more about how we can improve instruction and feedback to improve body mechanics during jumping and landing.

We are asking your child and other children that play sports to be in the research, because we want to know how injury prevention training with feedback works on young adolescent athletes.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for up to 21 times over the next 6-11 months. The researchers will ask you to do the following:

PRE-TESTING VISIT (prior to the start of the training program)

1. Medical History Questionnaire: your child will be asked to answer some questions about her past medical history including sports participation, her pubertal status, and any injuries she has sustained.
2. Anthropometrics and Biometrics: We will measure your child's height by having her stand up against a measuring tool on the wall. We will also measure your child's body weight and body fat percentage by having her stand on a scale.
3. Biomechanics Station: The testing session involves tests including jumping, landing, running and hopping. Reflective joint markers (or stickers) will be placed on your child's

body. Markers are attached with adhesive spray and taped to the skin. Motion of your lower body will be recorded by digital video equipment. Your child will be instructed to perform single leg landing tasks and also drop off a box and jump as high as she can. Your child will perform each test up to three times each.

4. Virtual Reality testing: At this station, your child will wear a headpiece on her head that will go over her eyes. With this headpiece on, your child will see a virtual environment similar to the sport she plays. Your child will be asked to perform a sport-specific maneuver that will involve jumping, cutting and landing. We may ask your child to complete a questionnaire about their experience in the virtual reality scenario.

NEUROMUSCULAR TRAINING VISITS (3x/week for 6 weeks)

Neuromuscular Training: The neuromuscular training will take place three times a week for 6 weeks. During this training, your child will perform exercises like squatting, lunging, jumping, and hopping.

Biofeedback training: During some of your child's neuromuscular training sessions, she will be asked to wear a pair of eye glasses (like a large pair of sunglasses) and perform exercises like squats and single leg squats. While your child is wearing the eyeglasses, she will see a rectangle shape. The rectangle shape represents your child's body movement and will be displayed on the eyewear in the lower right corner of her vision. Your child will be instructed to try to keep that image in a rectangular shape.

POST-TESTING STUDY VISIT

This testing will be identical to the pre-testing and will include (as described above):

- Anthropometrics and Biometrics
- Biomechanics Station
- Virtual Reality testing

This visit will occur after the completion of the neuromuscular training program.

POST-SEASON TESTING STUDY VISIT

In order to be complete this visit, your child must participate in the competitive sports season. This testing will be identical to the pre- and post-testing and will include (as described above):

- Anthropometrics and Biometrics
- Biomechanics Station
- Virtual Reality testing

Throughout the season, our study staff will work with the athletic trainer/coach at your child's school to track any injuries that are sustained during the season. If your child sustains an ACL injury during the season, we may request injury specific information (such as MRI images/reports, operative reports). We may also ask parents to complete weekly surveys throughout the season to track participation in practices/games and any injuries.

Your child will be "randomized" into one of 2 study groups. Being randomized means your child will be put into a study group by chance, like flipping a coin. Your child will have an equal chance of being in any one study group. Your child will be randomized into a true feedback group or a sham feedback group.

ALL of these procedures will be paid for by the study.

You will get $25 for completing the post-training study visit and $75 for completing the post-season study visit, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $100 total, if you complete all study visits.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include [some fatigue and/or delayed onset muscle soreness following the initial training sessions or during the training sessions may experience muscle fatigue, pre-syncope/nausea which are normal effects from high intensity exercise. There is also the chance that participants could sustain a muscular or ligamentous injury during the jumping or hopping tasks during testing or training. Other risks include loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs

You WILL NOT have to pay for any of the study procedures, in particular those that are not covered by your medical insurance.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Real-time Sensorimotor Feedback for Injury Prevention Assessed in Virtual Reality

IRB #: STUDY00001770

Principal Investigator: Gregory D. Myer

Sponsor: National Institutes of Health

If you are the legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child.

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?
In this research study we want to learn more about how we can improve instruction and feedback to improve body mechanics during jumping and landing.

We are asking your child and other children that play sports to be in the research, because we want to know how injury prevention training with feedback works on young adolescent female athletes.

What will I be asked to do?
The research staff will explain each visit to you and may give you a handout that explains each visit in more detail. You will be able to ask questions to make sure that you understand what will happen to your child.

If your child qualifies and decide you want your child to be in the study, your child will come to CCHMC up to 21 times over the next 6-11 months.

These are the things that will happen to your child while she is in the study:

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Throughout the season, our study staff will work with the athletic trainer/coach at your child's school to track any injuries that are sustained during the season. If your child sustains an ACL injury during the season, we may request injury specific information (such as MRI images/reports, operative reports). We may also ask parents to complete weekly surveys throughout the season to track participation in practices/games and any injuries.

Your child will be "randomized" into one of 2 study groups. Being randomized means your child will be put into a study group by chance, like flipping a coin. Your child will have an equal chance of being in any one study group. Your child will be randomized into a true feedback group or a sham feedback group.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.
The most common risks and discomforts expected in this study are:

- Fatigue/Delayed Onset Muscle Soreness following the training sessions (most will experience muscle soreness)
- Nausea/Pre-Syncope during the training sessions due to the high intensity type of exercises (~1%)
- Muscular or ligamentous injury during the jumping or hopping tasks during the testing or training (~3%)

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

The neuromuscular training may be a direct benefit to you (Core strength development, plyometrics training and weight lifting). This study is designed to learn more about biofeedback training and the impact on movement during sports that may reduce the risk of injury. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will get $25 for completing the post-training study visit and $75 for completing the post-season study visit, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $100 total, if you complete all study visits. Payment will be made in the form of a reloadable Mastercard Gift Card (Clincard). You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

What are my other options?

If you decide not to enter this study, that is your choice and will not impact any medical care received at Emory.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the

Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

The results of these study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Greg Myer at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. You can leave the research at any time; it will not be held against you. If you decide to leave the research, contact the study coordinator or the investigator so that they can terminate your study participation.

If you stop being in the research, data already collected may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Contact Information

Contact Dr. Greg Myer at [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at [redacted]:

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Name of Subject

Signature of Subject (18 or older and able to consent) Date **Time**

Signature of Legally Authorized Representative Date **Time**

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**