Neuromuscular Intervention Targeted to Mechanisms of ACL Load in Athletes

NCT03190889

October 28, 2024

MAYO CLINIC

Name and Clinic Number

Approval Date: **November 18, 2020**
Not to be used after: **March 9, 2021**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Neuromuscular Intervention Targeted to Mechanisms of ACL Load in Athletes

IRB#: 17-001833

Principal Investigator: Nathaniel Bates, PhD and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep.

If you are signing this consent form for someone else, "you" in the consent form refers to the participant.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Nathaniel Bates, PhD	**Phone:** (507) 538-6953 **Institution Name and Address:** Mayo Clinic Square 600 Hennepin Avenue #310 Minneapolis, MN 55403	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

A description of this clinical trial will be available on http://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.

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1. Why are you being asked to take part in this research study?

Study Eligibility and Purpose

You are being asked to take part in this research study because you are having anterior cruciate ligament (ACL) reconstruction surgery and will undergo rehabilitation following surgery.

Number of Participants

The plan is to have about 75 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this study is to determine if there are varying risk levels for second ACL injury, and determine the effects of different rehabilitation programs on performance measures associated with an increased ACL injury risk.

3. Information you should know

Who is Funding the Study?

This study is being funded by the National Institutes of Health.

4. How long will you be in this research study?

You will be in this research study for approximately 6 years.

5. What will happen to you while you are in this research study?

If you agree to participate, you will be asked to:

- Participate in two testing sessions which will last approximately 2 hours,
- Participate in a specialized rehabilitation program following clearance after ACL reconstruction which will be performed twice a week for six weeks (onsite and offsite options),
- Record how much time you spend participating in sports activities after clearance from your physician.

Additionally, we will communicate with you to determine if you have sustained additional leg injuries after a discharge to sports activities.

Your testing will take place at the Sports Biomechanics Lab and Mayo Clinic Sports Medicine Center in either Rochester or Minneapolis, MN, based on which location is most convenient for you. You will participate in two testing sessions consisting of Demographics and Medical History, Self-Report Questionnaires, Anthropometrics (i.e. the size and composition of your limbs), Skeletal Maturity, Strength, Balance, Clinical Testing, and Motion Analysis.

Details of the testing sessions include:

Demographics and Medical History
You will be given a short survey asking you to provide demographic information (e.g. age, gender, sports participation) along with previous injuries you may have sustained.

Self-Report Questionnaires
You will complete 6 questionnaires that ask about your knee symptoms, and ability to complete a variety of daily and sporting tasks.

Anthropometrics
Anthropometrics, which refer to the size and composition of your limbs, will be collected. Your height and weight will be recorded and body mass index (BMI) will be calculated. A scale, which administers an imperceptible amount of electrical current, will be used to analyze your body composition (i.e. body fat %). The lengths of your limbs will be measured using a standard tape measure. The height of the arch of your foot will be measured with a height gauge.

Finally, your quadriceps angle (Q-angle) will be measured. The Q-angle measures the angle created by the imaginary lines connecting the hip to the knee and the knee to the ankle when viewed face-on.

Skeletal Maturity
You will be asked to complete a questionnaire that asks about several indicators of pubertal maturation including growth spurt, menarchal status, body hair, and sweating tendencies.

Strength
We will test your hip and knee strength in both legs. Velcro straps will be used to make sure you are securely positioned, and your leg will be positioned in a testing device that measures how hard you push. You will be asked to push as hard as you can, but not to the point of discomfort. We will measure the strength of both hips while you are lying down. We will measure the strength of both knees while you are seated.

Balance
Your balance will be measured by having you stand on one leg on a platform designed to measure the amount of body movement you use to maintain your balance.

Clinical Testing
Hop tests: You will be asked to hop on one leg as far as you can, and as quickly as you can. This will include a single hop for distance, three consecutive hops in a straight line for distance, three hops crossing a line for distance, and hopping 6 meters as quickly as possible. You will perform these hopping tasks on both legs.

Knee laxity: We will measure how much your shin moves relative to your thigh. During this test you will be lying down. A standardly used clinical device will be secured to your leg while an examiner pulls your shin bone forward. This is a test that is routinely utilized in clinical practice to assess knee laxity.

Motion Analysis
Motion analysis testing will use cameras to record how you move during 3 jumping activities that will be performed on both legs. For the testing reflective markers will be attached to your feet, legs, pelvis, trunk, and arms with adhesive spray and double-sided tape. These are all non-invasive tests. During the drop vertical jump test (DVJ) you will drop off of 1 12 inch box with both feet and land on the ground with both feet. Immediately after landing, you will perform a maximum vertical jump. During the single-leg drop (SLD) test, you will stand on one foot on the box with the other foot tucked behind you. You will drop down onto the ground, landing on same foot. During the cross over drop (COD) you will stand on one leg on the box with the other foot tucked behind you. You will drop onto the ground landing on the opposite leg. During the countermovement jump (CMJ) you will stand on the floor with feet shoulder width apart. You will squat down and execute a maximal vertical jump in one fluid movement.

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Specialized Rehabilitation

If you are eligible for the study, you will randomly be assigned to one of three specialized rehabilitation groups: home, clinical, and experimental training. Neither you nor the Principal Investigator can choose your study group. You will have a 1 in 3 chance of being assigned to any group. This specialized rehabilitation will take place during the late stages of rehabilitation after surgery. This will take place twice a week for six weeks. Depending on the rehabilitation group to which you are assigned, this will take place either at your home or at the Mayo Clinic Sports Medicine Center. However, if you live at a distance from Mayo Clinic and cannot participate in the weekly onsite training but able to participate in both testing sessions, you will be randomized into one of the offsite training groups.

Optional Storage of Data

All data collected during testing will be retained indefinitely in a secured data repository for future analysis. To protect your identity, we will replace your personal identifying information (name, date of birth, sport, etc.) with a unique code. All coded electronic data will be stored on a private, secure network that is password protected, and only viewable by the principal investigator, co-investigator, and key personnel who have been approved by the Institutional Review Board at the Mayo Clinic. All hard copy data will be stored behind lock and key. These coded, electronic and hard copy data may be used for future research. You may opt out of having this data stored by checking the appropriate box below and initialing next to the box:

Option A: Your permission for Mayo Clinic to use and share your health information, study data, and video recordings lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

☐ Yes ☐ No Please initial here: _____Date: _____

Option B: Your permission for Mayo Clinic to use and share your health information, study data, and video recordings lasts forever, unless you cancel it.

☐ Yes ☐ No Please initial here: _____Date: _____

Option C: You do not give permission for your study data and video recordings to be used in the repository.

☐ Yes ☐ No Please initial here: _____Date: _____

Injury Reporting
We are interested in understanding how rehabilitation may impact future injuries. Injuries will be monitored using a weekly tracking form completed and submitted electronically by you. You will either log in to a secured online database or complete the provided forms or you may contact the research staff to relay this information, which will then be appropriately documented by the research team.

If you sustain an injury while in this study, your injury will be addressed by your physician.

Injury Surveillance
Research staff may contact you via phone call annually for up to 6 years following enrollment to update athletic injury and participation history.

6. What are the possible risks or discomforts from being in this research study?

The risk of breach of your confidentiality is minimal. Your data will be maintained in a securely-protected and encrypted database only accessible to the research team. Personal and demographic data will be blinded to the entire research team with the exception of the testing coordinator who will enter data and assign a reference code to your data.

The questionnaires you complete ask you to rate your ability to complete a variety of daily, work, and recreational activities. We hope that you will complete the entire questionnaire, but you can skip any questions you don't want to answer.

The risk of physical injury or muscle fatigue discomfort to you during testing is minimal. There is a minimal risk of injury from a fall or improper landing during the box drop tests performed during motion analysis testing. These movements are common sport activities and ones that can be completed safely in a controlled laboratory environment, posing no more risk than you would assume during normal sports participation. You may experience some muscle soreness during strength testing, but this should not be any different than soreness you experience associated with sports participation.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

9. What are the possible benefits from being in this research study?

Others with an ACL injury may benefit in the future from what we learn in this research study.

This study may not make your health better. However, it is possible you may have improved strength and neuromuscular movement patterns from participating in the rehabilitation group to which you are assigned.

10. What alternative do you have if you choose not to participate in this research study?

You do not have to be in this study to receive treatment for your condition. You may continue to participate in traditional rehabilitation as prescribed by your physician.

11. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures that are done just for this research study. These tests and procedures are:

- Motion Analysis Testing
- Skeletal Maturity
- Anthropometrics
- Injury Reporting
- Injury Surveillance

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

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

You will receive $95 for each study visit you complete.

13. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Your information will be secured in locked cabinets, and password protected computer storage servers that only study personnel have access to. Your data will not be presented individually. Your data, when reported, will be part of a group with no individual identification.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

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With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts forever, unless you cancel it.

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. Mayo Clinic will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Mayo Clinic 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 Mayo Clinic 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.

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ENROLLMENT AND PERMISSION SIGNATURES

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

Printed Name | Date (mm/dd/yyyy) | Time (hh:mm am/pm)

Signature

Signature of Parent(s)/Guardian for Child:

I give permission for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Printed Name of Child

Printed Name of Parent or Guardian | Date (mm/dd/yyyy) | Time (hh:mm am/pm)

Signature of Parent or Guardian

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name | Date (mm/dd/yyyy) | Time (hh:mm am/pm)

Signature