Preventing Posttraumatic Osteoarthritis With Physical Activity Promotion

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

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IRB Study # 21-0614
Title of Study: Preventing Posttraumatic Osteoarthritis with Physical Activity Promotion
Principal Investigator: Brian Pietrosimone
Principal Investigator Department: Exercise and Sport Science
Principal Investigator Phone number: (919) 962-3617
Principal Investigator Email Address: pietrosi@email.unc.edu
Study Contact Telephone Number: (919) 962-2025
Study Contact Email: liseecar@email.unc.edu

CONCISE SUMMARY

Individuals with a history of anterior cruciate ligament reconstruction (ACLR) are at a heightened risk for developing osteoarthritis. The heightened risk for developing osteoarthritis may be caused by either too little force applied to the knee throughout the day as a result of lack of physical activity. Physical activity promotion is a focus of current clinical guidelines for prevention of osteoarthritis progression following a musculoskeletal injury. In order to develop effective treatments that can change the number of steps and resulting force applied to the knee during daily activities, we must first determine if changing the number of daily steps beneficial for the knee following ACLR. Therefore, the purpose of this study is to see if changing daily steps over 8 weeks will change cartilage composition.

You are being asked to be in the study because you are between the ages of 18-35 and you have torn your ACL and had it surgically reconstructed between 6 months and 5 years ago, and have completed all other forms of formal physical therapy and therapeutic exercise regimens.

Throughout the course of the study you will attend 4 visits ranging from 15 minutes to 2 hours. You will wear a physical activity monitor on your waist for 7 days, undergo magnetic resonance imaging (MRI) of your surgical knee, undergo walking biomechanics assessment, fill out surveys about your knee. If you meet our screening criteria, you will wear a Fibit monitor on your wrist for 10 weeks. During the last 8 weeks of wearing the Fitbit monitor, you will undergo exposure to physical activity promotion by receiving personalized daily step count goals through text messages on your phone or through email. After the 10 weeks, you will wear a physical activity monitor on your waist for 7 days, undergo magnetic resonance imaging (MRI) of your surgical knee, and fill out surveys about your knee.

Research is designed to benefit society by gaining new knowledge. You may not benefit personally from being in this research study. Using a physical activity monitor, like a Fitbit, has the potential to enhance the amount or intensity of physical activity in which you participate.

While all participants may not experience an improvement in their activity participation, it is possible that participation in this study may benefit you. You may experience mild discomfort from the MRI assessment.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
Individuals with a history of anterior cruciate ligament reconstruction (ACLR) are at a heightened risk for developing osteoarthritis. The heightened risk for developing osteoarthritis is likely caused by either too little force applied to the knee throughout the day as a result of lack of physical activity. Physical activity promotion is a focus of current clinical guidelines for prevention of osteoarthritis progression following a musculoskeletal injury.

In order to develop effective treatments that can change the number of steps and resulting force applied to the knee during daily activities, we must first determine if changing the number of daily steps beneficial for the knee following ACLR. Therefore, the purpose of this study is to see if changing daily steps over 8 weeks will change cartilage composition.

You are being asked to be in the study because you are between the ages of 18-35 and you have torn your ACL and had it surgically reconstructed between 6 months and 5 years ago, and have completed all other forms of formal physical therapy and therapeutic exercise regimens.

Are there any reasons you should not be in this study?
You should not be in this study if:

- You have undergone ACLR revision surgery due to a previous ACL graft injury.
- Had a multiple ligament surgery was indicated at the time of your ACLR surgery.
- Had a lower extremity fracture was suffered during the ACL injury.

- You were diagnosed with osteoarthritis in either knee.
- You have a cochlear implant, metal in body, claustrophobia, or history of seizures.

How many people will take part in this study?
Approximately 30 people at the University of North Carolina at Chapel Hill will take part in this study.

How long will your part in this study last?
Participants will be actively involved with the study for 3 months. Participants will attend 4 visits at the MOTION Science Institute at Fetzer Hall. The first and last visit will last 15 to 30 minutes. The other two visits will last 1.5 to 2 hours.

What will happen if you take part in the study?

Visit 1
At the first visit, the study coordinator will talk with you at this visit to ensure that you are a candidate for this study. You will also be asked to fill out a brief survey about you knee quality of life. Finally, you will be outfitted with a physical activity monitor around your waist which you will wear during all waking hours (except in water or sleeping) for the next seven days. This monitor is easy to wear around your hip and will keep track of your activity throughout the week. You will also complete a walking motion capture assessment described below. This visit will take approximately 45 minutes.

- Gait Biomechanics Assessment – 15 minutes to complete
    - We will place sensors on your legs, hips, and abdomen that will allow us to measure movements of your joints during walking. You will be asked to walk forward along a 20-foot walkway at a comfortable, self-selected speed while movements of your legs are collected. You will be asked to walk over a device that will measure how hard you are stepping on the ground. You will perform at least 5 practice trials to ensure that you are comfortable walking with the sensors. You will then perform 5 trials that will be recorded.

Visit 2
You will return the waist-worn activity monitor to Fetzer Hall at the MOTION Science Institute. If you meet our average steps per day inclusion criteria you will continue with the study visit procedures described below and the physical activity promotion exposure. If you do not meet this criterion then you will stop participating in the study.

- Knee Injury History Form and Demographics – 10 minutes to complete
- Questionnaires about your knee pain and ability to function – 20 minutes to complete
- Fitbit Initialization – You will be outfitted with a Fitbit monitor and be connected to a member of the Michigan State University study team using a HIPAA compliant video conferencing platform. The investigator from Michigan State University will guide you through monitor initialization and sync the monitor with your personal mobile device or email. This will take approximately 30 minutes to complete.

- Magnetic Resonance Imaging (MRI) – You will be asked to obtain an MRI at another building on campus called the UNC Biomedical Research Imaging Center. This will take approximately 1 hour to complete.

Physical Activity Promotion
You will wear the Fitbit monitor on your wrist for 10 weeks. During the first 2 weeks, you will not receive text messages for daily step counts. If you fail to wear the Fitbit monitor during this period of time you will be contacted by a study member of the research team and will not continue with the study. If you wear the Fitbit monitor, you will continue with the physical activity promotion. For the next 8 weeks, you will receive an SMS message each morning containing a personalized step count goal for the day at 8 AM EST and a link that you will click to confirm receipt of the goal.

Visit 3
You will return the Fitbit to Fetzer Hall at the MOTION Science Institute. You will complete the following tasks:

- Questionnaires about your knee pain and ability to function – 20 minutes to complete
- Activity Monitoring – You will be outfitted with a physical activity monitor around your waist which you will wear during all waking hours (except in water or sleeping) for the next seven days. This monitor is easy to wear around your hip and will keep track of your activity throughout the week. This will take 10 minutes to complete
- Magnetic Resonance Imaging (MRI) – You will be asked to obtain a MRI at another building on campus called the UNC Biomedical Research Imaging Center. This will take approximately 1 hour to complete.

Visit 4
You will return the waist-worn activity monitor to Fetzer Hall at the MOTION Science Institute. This visit will take approximately 15 minutes to complete.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?
There is a small risk that you will experience pain, discomfort, or injury from magnetic resonance imaging (MRI).

There is a less likely risk of mild, transient joint and/or muscle soreness from biomechanical, testing and a very small risk of injury during biomechanical testing.

There is a rare chance there will be a breach of confidentiality during this study. All data will be de-identified and stored on password-protected computers. You will be identified only by this participant ID to which your personal information will not be linked. No form of dissemination of this study's findings will include any of your identifiable information.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

Women who are pregnant will be excluded by self-reporting by the participant.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

The imaging we are using in this research study is not the same quality as imaging that you may have as part of your health care. The images will not be reviewed by a doctor who normally reads such images (such as a radiologist). As a result, you may not be informed of any unexpected findings. The results will not be placed in your medical record. Occasionally the technologist or principal investigator may notice something abnormal on the imaging. If this does occur, the images will be reviewed by a qualified doctor to determine if there is anything of clinical importance. If something is found to be important then you, and/or your primary care provider will be notified. Any further follow up and costs associated with the incidental finding will be your responsibility. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate).

Do you wish to be informed in case of clinical/relevant unexpected findings? Please initial in the box below if you do not wish to be notified of clinical/relevant unexpected findings. If you do not initial in the box, you will be notified of any findings.

_____ I do not wish to be notified.

How will information about you be protected?
Once you are entered into the study, you will be assigned a subject number that only the investigators to the study will know. Your name will never be recorded on any study visit documentation, and all of your records will be stored in a locked filing cabinet to ensure no one will know you were a subject in this study or be able to access your file from this study. Only study personnel will have access to locked documents from the study.

Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this

research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety. Individuals with oversight of research responsibilities at Michigan State University may have access to the research records.

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

As the purpose of this research is to study physical activity promotion delivered by text messages on your phone or email, by signing this consent on the last page of this form you are giving permission for the study team to contact by the mechanism identified below that you provide. This communication may contain personal information about you and may be sent or received by the study team member's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team.

This information may include information such as reminders and notification requests to contact the study team. If you do not want to receive un-protected communication that may contain personal information, then you should not consent to participate in this study.

If you have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities concluded, or you withdraw from the study, you will no longer receive un-encrypted (un-protected) communication specific to this study.

The study team may use the following cell phone and email to send communication:

EMAIL: _____
(List Email)

CELL PHONE NUMBER: _____
(List Cell Phone Number)

You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.

"What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information."

Who is sponsoring this study?

This research is funded by North Carolina Translational Clinical Sciences Institute and the National Institute of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of

withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?
You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?
If you enroll in this study, you will have costs, which include transportation to and from the data collection session.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

_____ _____

Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form) Date

_____

Printed Name of Witness