



## Participant Information Sheet

<b>Study title:</b>	<b>Influence of footwear on lower limb movement patterns in knee-healthy people and in people with anterior cruciate ligament reconstruction</b>	
<b>Principal investigator:</b>	<b>Gisela Sole Professor, School of Physiotherapy</b>	Contact phone number: 03-4797466

### Introduction

Thank you for showing an interest in this project. Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, before deciding whether or not to participate.

If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

### What is the aim of this research project?

Our first aim is to find out how people move who have undergone an anterior cruciate ligament (ACL) reconstruction of the knee. We will compare their leg movement patterns to a group of uninjured people. We will also compare the injured leg to the opposite, uninjured leg. Our second aim is to explore whether placing inserts into the shoes change the movement patterns. The inserts will be wedged either on the outer (lateral) side or the inner (medial) side. The results will help us to decide if changing footwear might be useful for people with ACL ruptures.

### Who is funding this project?

A University of Otago Research Grant is funding this project.

### Who are we seeking to participate in the project?

We are seeking two groups of participants:

- **Control Group:** men and women, 16 to 40 years old, who have not an ACL rupture in the past. These participants should take part in team sports, such as netball, rugby, soccer, volleyball, hockey, basketball or racket sports.
- **ACL Group:** men and women, 16 to 40 years old, who underwent a first-time ACL reconstruction within the past 6 months to 5 years. They should not have had an ACL rupture of the opposite leg in the past.

Both groups should not have had other injuries of the low back or legs that needed treatment by a medical doctor or physiotherapist in the past 6 months, or any diagnosed rheumatological, neurological or cardiovascular disorders.

## **If you participate, what will you be asked to do?**

We would first ask you to complete an online questionnaire (at home) about your age, ethnicity, work and sports. If you had an ACL rupture, you will be asked when you had the injury and how it happened, and when you had the reconstruction. All participants will be asked to rate how well your knee is currently, and how it might interfere with your daily life. We will then use the results of your questionnaire to confirm whether you can take part in the study.

If you agree, you will attend one session in the laboratory of the School of Physiotherapy, Dunedin. The session will take around 2 hours. If you are 16 or 17 years old, we will prefer that a parent/guardian/caregiver, or a person of your choice, attends the session. All participants will be welcome to bring a support person to the laboratory.

We will ask you to come with a pair of (short) shorts. Women/girls will be asked to wear a sports bra or sleeveless singlet. Men/boys will be asked to remove their shirt for the jumping/stepping tasks. There will be two researchers in the laboratory: a research assistant and a technician. Gisela Sole (the principal investigator) may also attend parts of the session.

We will measure your height and weight. We will also measure your foot posture while you stand. The research assistant will show you the movements you will be asked to perform. You will then be asked to practice them. You would perform four tasks: (1) hopping forwards as far as you can on one leg, (2) standing on one leg and reaching diagonally back with the other leg as far as you can (Y-balance test); (3) stepping down from a 30-cm box and hopping forwards, (4) stepping down a step, turning the other leg across the weight-bearing leg, and continue walking in a diagonal direction. We will assess both legs.

We will use 12 cameras and a force plate (that is in the floor) to measure your movement patterns during those tasks. We will fix a set of 45 small skin markers to your shoulder, back, pelvis (back and sides), hip and legs. We will use double-sided tape to attach the skin markers. We will also fix 5 wearable sensors that are smaller than a match-box on your shins, thighs and low back. We will use Velcro or elastic straps to keep them in place. Once the skin markers and the sensors are fixed on the skin, we will ask you to perform the above tasks. You will be asked to do those tasks wearing laboratory shoes, and with the inserts placed in them. The inserts are wedged with a 5mm raise on either the outer or the inner sides. You will likely not feel these while walking and jumping with them in the shoes.

We will then assess the thigh muscle strength (quadriceps and hamstrings). You will be seated. We will use a device to assess how hard you can push against the lever to straighten and bend your leg. We will assess both sides. We will give you the results of that assessment, and will explain them to you (and your parent/guardian). You may find those results useful for your rehabilitation.

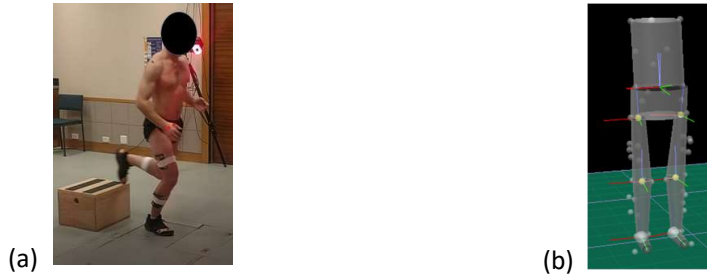


Fig 1. (a) Participant undertaking the step-down hop with reflective markers attached to leg, hip, shoulders and back. (b) Computer image of processed positioning of skin markers.

We will then assess the thigh muscle strength (quadriceps and hamstrings). You will be seated. We will use a device to assess how hard you can push against the lever to straighten and bend your leg. We will assess both sides. We will give you the results of that assessment, and will explain them to you (and your parent/guardian). You may find those results useful for your rehabilitation.

We will reimburse travel costs in the form of a grocery food voucher: \$120 for those coming from Southland or Central Otago, and \$50 for those within the wider Dunedin city area.

### **Is there any risk of discomfort or harm from participation?**

You may initially feel unfamiliar in the research laboratory. We will carefully describe the equipment to you, and what we will ask you to do. We will give you instructions and feedback for each step of the study and make sure that you feel comfortable. If your skin is sensitive to taping and plasters, we will ask you to let us know. In that case, you may prefer not to take part.

If you have had the ACL injury, you may feel some discomfort of that knee during some of the tasks. We will ask you to let us know if the discomfort is OK or whether you prefer not to undertake that task.

It is unlikely that you will get injured during the laboratory session. But should it happen, we will refer you to a medical doctor or physiotherapist of your choice. You would be eligible to apply for compensation from ACC. That would be just as you would if you were injured in an accident at work, school, home or sports.

You may have muscle stiffness for about 2 days after the session, as is normal with exercise. Should you have any soreness for more than 2 days after the session, or have any other concerns about having taken part, you will be asked to let the principal investigator (Gisela Sole) know, and you will be able to ask her for advice.

### **What specimens, data or information will be collected, and how will they be used?**

In the online questionnaire, we will collect data about your gender, age, occupation/school level, sports involvement, injury history, your knee injury and reconstruction (ACL Group), and questionnaires about how well the knee is. During the laboratory session, we will collect data related to the movement analysis and muscle strength. The skin markers will be recorded by the cameras and we will use that data to calculate the angles of your ankle, knee, hip and trunk. We will also estimate

with equations how much you load your joints during those movements. These data will be summarised for all participants. They will be compared between the ACL Group and the Control Group, and between the 3 footwear conditions: no insert, medial wedged insert, lateral wedged insert.

## **What about anonymity and confidentiality?**

We will not be able to share your results about the movement patterns with you. We will send you a summary of the results at completion of the study, if you indicate that you'd like to receive them.

Each participant will be allocated a code and the data will be stored anonymously with that code. Only the primary investigator (Gisela Sole), the research assistant and the research officer will be able to match your name to your data. The data will be stored securely by the researchers on University password-protected laptops and computers for 10 years. Your name and contact details may be deleted at the end of the study.

If you completed the online questionnaire but do not attend the laboratory session, we will delete your name and contact details. The data of the screening questionnaire will be used in the study.

We will not share your results with your orthopaedic surgeon, GP or physiotherapist. That applies even if they have given you information about this study. You may, however, choose to share those results of the muscle strength assessment with them as they may be useful for your rehabilitation.

We will publish the results of the study in a professional journal and present them at a conference. We will strive to preserve confidentiality and anonymity by using the participant codes and by storing the data securely.

We are collaborating with a researcher at Juntendo University, Japan, for part of this study. We will be asking your permission for the de-identified data of the Y-balance test (second task) and your demographic details (age, sex, date of injury and surgery) to be shared with Dr Shojiro Nozu and his two research mentors. They will analyse that specific data and report the results in the form of a journal publication. We will not share your name and contact details with them.

The data may be used in future research studies. That data will not provide your name or contact details. All data will be linked only to the participants' codes.

We will ask you for permission to add your name/contact detail to a database in the School of Physiotherapy. We would only use that if we undertake further studies specifically about ACL injuries, and would send you that information. There is no disadvantage to you if you do not want your name to be added to that list.

## **If you agree to participate, can you withdraw later?**

Taking part in the study is your choice. You may withdraw from the study at any time with no disadvantage to yourself. You may decide to withdraw during the laboratory session. In that case, we may be able to use the data we have collected up to that point. We would discuss that with you. If you withdraw from the study, you will also have the right to withdraw your data.

## Any questions?

If you have any questions now or in the future, please feel free to contact either David Jackson or Gisela Sole:

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<b>Co-investigators</b>	
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Dr Pierre Navarre Orthopaedic Surgeon Department of Orthopaedic Surgery, Southland Hospital / Department of Surgical Sciences, University of Otago	Email: <a href="mailto:Pierre.Navarre@southerndhb.govt.nz">Pierre.Navarre@southerndhb.govt.nz</a>

*This study has been approved by the University of Otago Human Ethics Committee (Health) (H21/003)  
If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email [gary.witte@otago.ac.nz](mailto:gary.witte@otago.ac.nz)). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.*



## **Influence of footwear on lower limb movement patterns in knee-healthy people and in people with anterior cruciate ligament reconstruction**

***Principal Investigator: Professor Gisela Sole***

*Email: [acl@otago.ac.nz](mailto:acl@otago.ac.nz); Tel: 03-4797466*

### **CONSENT FORM FOR PARTICIPANTS**

Following signature and return to the research team this form will be stored in a secure place for ten years.

**Name of participant:.....**

1. I have read the Information Sheet concerning this study and understand the aims of this research project.
2. I have had sufficient time to talk with other people of my choice about participating in the study.
3. I confirm that I meet the criteria for participation which are explained in the Information Sheet.
4. All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage.
5. I know that my participation in the project is entirely voluntary. I am free to withdraw from the project before its completion.
6. I know that as a participant I will have completed the online questionnaire, and perform several tasks in the laboratory. Those tasks include jumping tasks and stepping down from a step, and a thigh muscle strength assessment.
7. If I feel hesitant or uncomfortable with any tasks I may withdraw from the project without disadvantage of any kind.
8. I understand the nature and size of the risks of discomfort or harm which are explained in the Information Sheet.
9. I know that when the project is completed all information that identifies my name and contact details will be removed from the paper records and electronic files. The data will be placed in secure storage and kept for at least ten years.

10. I understand that the results of the project may be published in a professional journal and presented at a conference. The results will be presented in a format in which my personal data will not be identifiable. Any personal identifying information will remain confidential between myself and the researchers during the study. Information that identifies me will not appear in any spoken or written report of the study.
11. I will be offered a food voucher to partly cover travel costs. No commercial use will be made of the data.
12. I understand that other researchers may use the data, but they will not be able to link my data to my name and contact details.
13. I would like to be sent the results of the study via email. Yes \_\_\_\_\_ No \_\_\_\_\_
14. ACL Group: I provide the researchers permission to contact ACC. The researchers will ask ACC to confirm the date of my ACL rupture, surgery, and the number of physiotherapy sessions I had completed after surgery. Yes \_\_\_\_\_ No \_\_\_\_\_
15. I provide permission for my main demographic data and data related to the Y-balance test (one task that I will be asked to do in the laboratory) to be shared securely with the collaborators at Juntendo University, Japan. That data will not include my name or contact details. Yes \_\_\_\_\_ No \_\_\_\_\_
16. ACL Group: I agree that my name and contact detail is added to a database for future ACL injury studies. The researcher would send me information about such studies. I will be able to withdraw my details (via email to Gisela Sole) at any time with no disadvantage to me. Yes \_\_\_\_\_ No \_\_\_\_\_

Signature of participant:

Date:

Name of person taking consent

Date: