Participant Information Form

Project Title:

Why Does GLA:D work?
A pilot study investigating the link between biomechanical factors and a successful outcome following a movement retraining program for knee osteoarthritis.

Principal Investigator:

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Research Sites

Arthritis ACT 170 Hayden Drive BRUCE
The University of Canberra Sports Tek Lab
The Canberra Hospital Medical Imaging Department

Before you decide whether you wish to participate in this study, it is important for you to read and understand why the research is being done and what is involved. Please take the time to read the following information carefully and discuss with others if you wish.

What is the purpose of this study?

The purpose of this research is to investigate whether biomechanical changes occur following a movement retraining program such as GLA:D. Currently we do not understand the reasons why people get better with exercise interventions. This is a small study (known as a pilot study) which will explore changes in muscle patterns and joint load and movement and see if this is related to the improvement following the GLA:D intervention. Information we collect in this small study will be used to assist in a future larger study to work out whether the study is feasible. We will consider things like the convenience of the study to participants and how well we can replicate our measurements.

Why have I been invited to participate in this study?

You are eligible to participate in this pilot study as you have knee osteoarthritis, and you are deemed eligible for the GLA:D program for hip and knee osteoarthritis. The GLA:D program stands for Good Living Arthritis Denmark and is a program that consists of both education about osteoarthritis and specific exercise which is often called neuromuscular exercise.
By completing the GLA:D program, your knee will get stronger, and you will improve your knee function by learning to move better. Your walking may improve, and your pain may reduce. These changes may relate to reduced loading of your knee joint and reduce the likelihood you may require a total joint replacement in the future.

What if I do not want to take part in this study or if I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

You may withdraw from the study at any time and for any reason or no reason. Please tell the study team that you wish to withdraw from the study. Information that has been collected about you, prior to your withdrawal, will continue to be used in the data analysis. No new information will be collected or used after you have withdrawn from the study.

What does the study involve?

The study will take approximately 12 weeks to complete. You will complete the GLA:D program for your knee osteoarthritis. This consists of 2 education sessions and 12 small group exercise classes twice weekly for 6 weeks. You will be asked to complete the baseline and 3 month questionnaire as part of the normal GLA:D program. . For this study, you will not be registered with GLA:D Australia as part of their registry. All your information and data will be stored securely at the University of Canberra.

In addition to the GLA:D requirements you will be asked to complete further assessments of your knee. Participants who agree to participate in the research will be asked to complete these additional assessments:

1. A Pre-screening to determine your eligibility for study and information about study. This may be done face to face or over the telephone. Your consent for the study needs to be obtained before any further assessment occurs.
2. An initial gait lab analysis at SportTek Lab at the University of Canberra.
3. An initial imaging analysis using CT scan (Computed Tomography) and fluoroscopy at the Canberra Hospital. This assessment is expected to take 60-90 minutes.
4. A final gait lab and imaging analysis at the University of Canberra and the Canberra hospital. These assessments will occur after immediate completion of the GLA:D exercise program at 8 weeks

What will you be asked to do in the gait lab?

When you are in the gait lab at the University of Canberra, you will be assessed with a video while you walk, step up on to a step, rise from a chair and deep kneeling. Reflective markers will be placed on you to capture the movements of your joints. You will be asked to undress to shorts and a singlet. The researcher will palpate the surface anatomical landmarks and attach the markers and apply adhesive tapes. Then you will be asked to perform a walk, step up, sitting up from a chair repeated several times. You may be asked to repeat a few other tests that may have been missed with your GLA:D assessment such as a 30 second sit to stand test and a 40-metre walk test. Your knee range of motion and knee joint may be palpated to see if it is tender.

What will you be asked to do with the CT scan and fluoroscopy?

When you attend Canberra hospital imaging, you will have a CT scan of your knee. This involves lying down still and your leg place in a CT scanner. Following this, you will have a fluoroscopy of your knee. During this, you will be asked to kneel, rise from a chair, and complete a step up. The CT scan images, and fluoroscopy will be transferred to a computer program and a 4 D image is produced that shows how your inside of your joint moves during these tasks.

Are there risks to me in taking part in this study?

The following risks are associated with the study.

1. Injury or knee soreness following or during the exercise intervention. This is most likely to be a minor muscle complaint or minor knee pain and is usually due to getting used to an exercise intervention. All participants are screened prior to commencing the exercise intervention and your physiotherapist is trained to progress your exercises slowly, therefore these reactions to exercise are usually minimal.
2. Mild soreness following the gait lab and imaging. This is likely to be a mild muscle soreness due to being asked to complete a few assessment tests such as sit to stand, walking, kneeling and step ups.
3. Radiation exposure from the CT scan. Like any X-ray, there is some exposure to radiation. The level is quite low, and the risks are low of any problems following the scan. Please discuss this with the principal investigator if you are concerned.

If you suffer any injuries or complications because of this study, you should contact the study team as soon as possible, who will assist you in arranging appropriate medical treatment and follow up.

Who is organising and funding the research?

This study is being conducted by the study team headed by Jacqui Couldrick. The pilot study is being funded by the University of Canberra.

No investigator or member of research staff will receive a personal financial benefit from your involvement in this study. The study investigators have no personal conflict of interest relevant to the undertaking of this study.

How will my confidentiality be protected?

Only the researchers, Jacqui Couldrick and Professor Jennie Scarvell have access to your confidential information. Any identifiable information that is collected about you with this study will remain confidential and stored in a secure master file on a secure drive at the University of Canberra. The physiotherapist involved in taking you through the GLA:D program will be aware whether you are participating in this study. Any exercise records taken during your GLA:D exercise program at Arthritis ACT may have your name on this – however this information is securely locked in a cabinet with the room locked overnight. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law.
All reports and publications of the research will contain no information that can identify any individual and all information will be kept in the strictest confidence.

Where is my data stored?

The information collected will be stored securely on a password protected computer throughout the project and then stored at the University of Canberra for the required five-year period after which it will be destroyed according to university protocols.

Ethics Committee Clearance

The project has been approved by the ACT Health Human Research Ethics Committee. If you have any concerns or complaints about the conduct of this study, and do not feel comfortable discussing this with study staff, you may contact the Committee secretariat who is nominated to receive complaints about research projects. You should contact the secretariat on 6174 7968 or ethics@act.gov.au

Queries and Concerns

Queries or concerns regarding the research can be directed to the researcher and/or supervisor.
Contact details are at the top of this form. If you have any complaints or reservations about the ethical conduct of this research, you may contact the University of Canberra's Research Ethics & Integrity Unit team via telephone 02 6206 3916 or email humanethicscommittee@canberra.edu.au or researchethicsandintegrity@canberra.edu.au

If you would like some guidance on the questions you could ask about your participation please refer to the Participants' Guide located at http://www.canberra.edu.au/ucresearch/attachments/pdf/a-m/Agreeing-to-participate-in-research.pdf

Consent Form to Participate in Research Project

I, _____ *(name of participant)*

of _____ *(address)*

have been asked to consent to my participation in a research project entitled:

Why Does GLA:D work?

In relation to this study, I have read the Patient Information Sheet and have been informed of the following points:

1. Approval has been given by the ACT Health Human Research Ethics Committee.
2. The aim of the study is to **look at biomechanical changes that may occur following the GLA:D intervention for knee osteoarthritis.**
3. The results obtained from the study may or may not be of direct benefit to my medical management.
4. The study procedure will involve **biomechanical measures performed in a gait lab and CT scanning/fluoroscopy of my knee before and after my participation in the GLA:D intervention.**
5. I am aware of and have had explained all the study commitments required . My involvement in this study includes travel to various locations for measurement in addition to attendance at the GLA:D program. This includes:
    - *2 visits to the gait lab at the University of Canberra*
    - *2 visits for imaging*
    - *2 GLA:D education sessions and 12 group classes*
    - *2 assessments with a physiotherapist at beginning and end of the study at 3 months*
6. Should I have any problems or queries about the way in which the study was conducted, and I do not feel comfortable contacting the research staff, I am aware that I may contact the ACT Health Human Research Ethics Committee Secretariat, Canberra Hospital, Yamba Drive, Garran ACT 2605 (ph: 6174 7968)
7. I can refuse to take part in this project or withdraw from it at any time without affecting my medical care.
8. Participation in this project will not result in any extra medical or hospital costs to me. I am aware I still pay for the GLA:D program with Arthritis ACT.
9. I understand that while the results of the research will be made accessible to me, my involvement and my identity will not be revealed.
10. I understand the research data gathered for this study may be published or shared however with no identifying information will be used.

After considering all these points, I accept the invitation to participate in this study.

Name: (please print) _____**Date:** _____

Signature (Participant) _____

Investigator: (please print) _____**Date:** _____

Signature (Investigator) _____