Participant Information Sheet

Study title: Effect of Manual Therapy on Selected Biomechanical Outcomes of Gait in People with Knee Osteoarthritis
Sponsor: name and address: Mark Steptoe Research Grant-in-Aid, 2024 & School of Physiotherapy Research Grant-in-Aid, 2024, 325 Great King Street, PO Box 9054, Dunedin, New Zealand

Lead Researcher:	Sarfaraz Alam
Study Site:	Biomechanics Laboratory, School of Physiotherapy, University of Otago, Dunedin
Contact phone number:	029-020-64380
Ethics committee ref.:	2024 EXP 19143

You are invited to take part in a study on whether manual therapy intervention influences the biomechanical outcomes during gait in people with knee Osteoarthritis. Biomechanics during gait imply to analysis of movement of the body segments and acting forces on various joints while walking. Whether or not you take part is your choice. If you do not want to take part, you do not have to give a reason. If you do want to take part now but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, and what you would be required of you. It outlines the possible benefits and risks, and what may happen after the study ends. We will go through this information with you and answer any questions you may have. Before you decide if you want to participate, you may want to talk about the study with other people. Please feel free to ask family, whānau, friends, or healthcare providers.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of the Participant Information Sheet and the Consent Form to keep.

This document is ten pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Being part of this study is voluntary and you are free to withdraw at any time without experiencing any disadvantage.

WHAT IS THE PURPOSE OF THE STUDY?

The study aims to explore whether manual therapy influences walking biomechanics through improvement in clinical symptoms. This will help in improving the knowledge base of manual therapy and improve understanding of knee osteoarthritis clinical management. The study will include manual therapy intervention of the knee by the physiotherapist in people with knee osteoarthritis. Manual therapy is a physiotherapy technique in which physiotherapists apply selective manual forces on the joint surfaces through the hands to gain therapeutic benefits such as reduce pain, improve the range of motion of the joint, etc. There is evidence that manual therapy improves clinical symptoms such as pain, function, and range of motion of the joint.

HOW IS THE STUDY DESIGNED?

All participants will be initially screened via a web-based questionnaire to confirm potential eligibility. Potentially eligible participants will be asked to attend in-person sessions with the researcher to confirm their inclusion in the study. Our study will recruit a total of 20 participants in New Zealand based on inclusion and exclusion criteria.

Once your eligibility is confirmed, you will undergo baseline measurement I (initial assessment) on the same day of the enrolment into the study. You also need to undertake a weight-bearing x-ray of both knees at a specific radiology lab as directed by the research team. You will also be required to attend another baseline measurement (baseline II) at 4-week after the enrolment into the study. Following baseline II, within one week, you will be provided manual therapy of the knee by the physiotherapist for two sessions per week for three consecutive weeks. Manual therapy intervention will be tailored to the participant. The physiotherapist will explain the reasoning behind the manual therapy to the participant. As the study aims to explore the effect of manual therapy, it is important for you to attend all allocated appointments of the manual therapy sessions with the physiotherapist.

After completion of manual therapy intervention sessions, you will then be required to undergo an assessment at 8-week. At this 8-week assessment, you will also receive education about knee osteoarthritis and advice on how to self-manage it on an ongoing basis.

Each assessment (initial assessment, at 4 weeks, at 8 weeks) will take approximately 2 hours. There will also be a follow-up assessment at 6 months which will take 45 to 60 minutes. It is important that you commit to the required timeline, and management protocol and attend all assessments.

WHO CAN TAKE PART IN THE STUDY?

We are looking for people who have knee osteoarthritis to participate in this study. You do not need an X-ray or a previous diagnosis of osteoarthritis. We will confirm you have knee osteoarthritis by asking you questions and briefly examining your knee. You will be included in the study if:

- You have had pain in one knee (right or left) for more than 15 days in the last month.
- have a stiff knee and pain in walking.
- have knee stiffness and can’t get your knee fully straight or fully bend.
- are currently not having other treatments for your knee.
- You meet clinical criteria to classify you as having knee osteoarthritis.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You will participate in biomechanical assessment (lab-based), questionnaires, and physical tests to provide information that will help in the research aim. Initial assessment (baseline I), baseline II at 4-week, and post-intervention assessment at 8-week will include biomechanical lab-based assessment, a questionnaire related to osteoarthritis, physical measurements performed by a physiotherapist such as range of motion of the knee joint, and physical tests such as timed walking, timed stair climb, and a sit-to-stand test. Biomechanical lab-based assessment will be performed in the biomechanics lab, at the School of Physiotherapy. It consists of 12 infra-red cameras and two floor-mounted force plates that record the movement of the reflective markers and force placed on the plates by your feet, respectively. It doesn't record individual images or videos, so your privacy will be maintained. You will be asked to wear a singlet/sports bra (women) with shorts or remain in shorts only (men). The reflective markers will be placed on your skin on the specific landmarks as depicted in (Figure 1 & 2). Reflective markers are non-invasive, small, round-shaped markers that stick to the skin to reflect infra-red lights emitted from cameras which will be captured to analyze motion of the body (Figure 1 & 2). These landmarks require palpation by the physiotherapist to maintain the accuracy of the placement of the markers. You will be informed and asked for consent before placing any markers on the skin. Following the marker placement, one static trial will be performed in which you will be asked to stand still on both feet. Next, you will be made familiar with the testing procedure by performing several walking trials to achieve a steady walking speed. You will be then asked for the five successful walking trials at a self-selected walking speed, across the 7-meter walkway, barefoot to simulate your natural daily routine walking. The trial will be counted as successful once we have a minimum of five trials with clean foot strikes for both feet on the force plates will be acquired.

At the 6-month follow-up assessment, only questionnaires related to osteoarthritis, physical measurements, and physical tests will be performed as described above. Biomechanical lab-based assessment will not be performed at the 6-month follow-up.

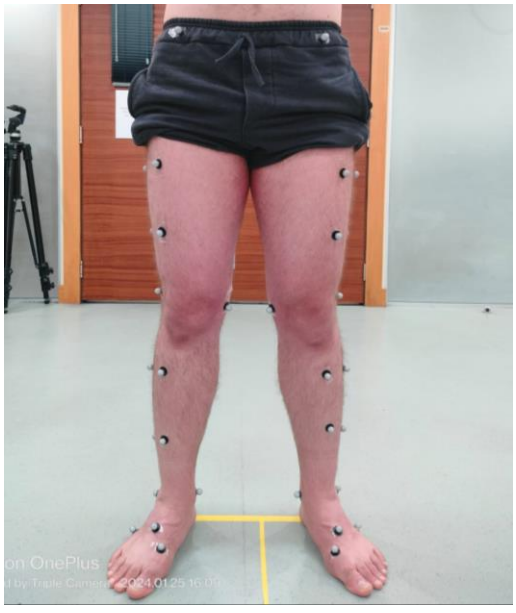

Figure 1 & 2.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There is a minimal risk of adverse effects of manual therapy. Occasionally, you may have an increase in pain. However, this could be managed with adjustment to the manual therapy and could settle within 24 hours. If, your knee shows signs of increasing inflammation such as swelling, heat, and/or redness greater than pre-treatment levels, then we will withdraw you from the study. Likewise, you can pull out of the study at any stage if you cannot tolerate the treatment. A follow-up with consultant in Dunedin hospital will be provided in the event of any adverse effects. Your GP will be notified in case of any significant adverse events.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Manual therapy has proven benefits of reduction in pain, improved function, and increased range of motion of the joint. All participants will also receive education about knee osteoarthritis and advice on how to self-manage it for a longer period.

WHAT ARE THE ALTERNATIVES FOR TAKING PART?

Treatment is available for your knee osteoarthritis from physiotherapists in private practice for which you must pay. You can also get free treatment funded by the government and available at the hospital.

You must be referred for this service by your GP, and there may be a waiting list. Your GP and pharmacist can advise you about pain medication. Lots of information on managing your knee osteoarthritis is available online. Look for national organizations such as Arthritis New Zealand or NZ Health Navigator for reliable information.

WILL ANY COSTS BE REIMBURSED?

Once you are included, you will undergo for an x-ray at a pre-specified radiology lab. A physiotherapist on the research team will provide manual therapy intervention sessions. There is no cost to you in being part of this trial. Participants will be given a $20 voucher at the initial assessment (baseline I) and an $80 voucher will be provided at the 6-month follow-up assessment session as a thank you for your participation.

WHAT IF SOMETHING GOES WRONG?

Ethical approval has been granted by HDEC: ref. 2024 EXP 19143

In the unlikely event you were injured in this study, you would be eligible to apply for compensation from ACC. This is like claiming for injury from an accident at work or home. It does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your coverage.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study, staff will record information about you and your study participation. This includes the results of any study assessments. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The physiotherapists, research team, radiologist and X-ray facility (Pacific Radiology, Dunedin) will have access to your identifiable information. Your GP will be notified of your participation in this study, and of any significant abnormal results obtained during the study via email and phone.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated from the research. Instead, you will be identified by a code. The clinical trial administrator will keep a list linking your code with your name so that you can be identified by your coded data if needed. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

If you agree, your coded information may be used for future research related to knee osteoarthritis or physiotherapy treatment. This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers. Your information may also be added to information from other studies, to form much larger sets of data. You will not get reports or other information about any research unrelated to the current study that is done using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information or withdraw consent for its use once your information has been shared for future research. You will also be asked if you are willing to be contacted and invited to participate in similar studies in the future conducted by the current research team. Any future study would have to be approved by an Ethics Committee and would involve accessing your contact information.

Security and Storage of Your Information.

Your identifiable information is held at the University of Otago during the study. After the study, it is transferred to a secure archiving site and stored for at least ten years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage for 10 years. All storage will comply with local and/or international data security guidelines. In addition to the Standards, researchers will also comply with other relevant regulations including Rule 9 of the Health Information Privacy Code. Particular attention will also be given to the need to use any cultural protocols for the destruction of information and to the principles of Māori Data Sovereignty in the case of Māori data.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymized information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small but may increase in the future as people find new ways of tracing information.

Your coded information may be sent overseas in the future, if required. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

Māori Data Sovereignty

Our study strongly supports the notion of data sovereignty of Māori population. We recognise the taonga of the data collected for this study. To help protect this taonga: i) We will de-identify the Māori data which reduces the likelihood of identification of a person by their name, place, or organization; ii) Also, we will have consent from each Māori participant to share their data internationally if required; iii) We allow Māori organisations to access de-identified study data, for uses that may benefit Māori.

A mandatory consultation process with Māori for research is followed in conjunction with ethics application.

Rights to Access Your Information.

You have the right to request access to the information held by the research team. You also have the right to request that any information you disagree with be corrected.

Please ask if you would like to access the results of your screening and safety tests during the study.

If you have any questions about the collection and use of information about you, you should ask the lead researcher Sarfaraz Alam.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing Sarfaraz Alam.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw unless you withdraw after the study analyses have been undertaken.

Please note: X-rays and X-ray reports will become part of the participant's clinical record (i.e. will remain identifiable) and cannot be withdrawn.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

You are a volunteer in this study and are free to withdraw from the research without experiencing a disadvantage. You can withdraw by informing your physiotherapist, the trial administrator, or the lead researcher (Sarfaraz Alam).

You have the right to access information collected about you as part of the study.

CAN I FIND OUT THE RESULTS OF THE STUDY?

A summary of the results will be written and circulated to study participants. This may be up to one year after you have finished the study.

We have put this study on a clinical trial register ANZCTR ref no. ACTRN12624000157572p. You can access details about the trial including the results via their website (http://www.anzctr.org.au/)using the reference number above.

WHO IS FUNDING THE STUDY?

This study is Funded by the Mark Steptoe Research Grant-in-Aid, 2024 & School of Physiotherapy Research Grant-in-Aid, 2024. This fund is awarded to Dr Cathy Chapple as a primary supervisor of the PhD student, Sarfaraz Alam.

WHO HAS APPROVED THIS STUDY?

This study has been approved by an independent group of people called the Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Southern Health and Disability Ethics Committee has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name: Sarfaraz Alam Position: PhD Candidate Department: School of Physiotherapy Phone: 029-020-64380 Email: Sarfaraz.alam@postgradotago.ac.nz	Name: Dr Cathy Chapple Position: Senior Lecturer Department: School of Physiotherapy Phone: 03 479 5235 Email: cathy.chapple@otago.ac.nz

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz
Website: https://www.advocacy.org.nz/

For Maori Health support please contact:

Katrina Anne Potiki Bryant (Ngai Tahu, Kati Mamoe, Waitaha, BPhty)
Kaiarahi Maori, Professional Practice Fellow
University of Otago School of Physiotherapy
Contact: (03) 4797473; (021)1140304 Email: katrina.bryant@otago.ac.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

CONSENT FORM

Effect of manual therapy on selected biomechanical

outcomes of gait in people with knee osteoarthritis

Please tick to indicate you consent to the following:

I have read the Participant Information Sheet, or have had it read to me in a language I understand, and I fully comprehend what it says.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
I consent to my information being sent overseas.	Yes ☐	No ☐
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.		
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I understand the compensation provisions in case of injury during the study.		
I know who to contact if I have any questions about the study in general.		
I understand my responsibilities as a study participant.		
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: