Participant Information Sheet

Study title:	Frequency of manual therapy for people with knee osteoarthritis: The Opti-OK Trial
Sponsor:	Dr Martin Gagnon, Centre for Innovation, University of Otago, Level 1 (East Wing), 87 St David St, Dunedin 9054, New Zealand
Lead Researcher	Dr Cathy Chapple
Study Site	School of Physiotherapy, University of Otago, Dunedin
Contact phone number:	0800 687 489 (0800 OUPHTY)
Ethics committee ref:	Southern Health and Disability Ethics Committee 21/STH/81

You are invited to take part in a study on whether frequency of physiotherapy appointments affects response to treatment for people with knee osteoarthritis. 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 have to do. 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 eight pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWL 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?

Treatment consists of manual therapy when the physiotherapist puts their hands around your knee and imparts a physical force to make the joint surfaces move. Physiotherapy treatment using manual therapy is effective for patients with knee osteoarthritis. However, we do not know if treatment once per week or twice per week is more beneficial or which is more cost-effective. The aim of this research is to identify the treatment frequency that gives the best clinical outcome and is value for money. Ultimately, this will help with planning and delivery of knee osteoarthritis treatment.

HOW IS THE STUDY DESIGNED?

Our study will recruit 180 people in New Zealand after an initial assessment to determine eligibility. Eligible people will be randomized to one of the following three groups, meaning there is an equal chance of being in any one of the groups. You do not choose the group you are in. Sixty people are required for each group.

As the study is about treatment frequency, it is important you can commit to the allocated appointment frequency, and that you are able to attend for all three follow-up assessments.

A NZ registered physiotherapist will deliver the manual and exercise therapy. A different researcher will conduct all assessments and will not know your treatment group. This "blinding" of assessors is important to reduce bias in the study.

- Group A will have manual therapy **once** per week for **six** weeks. (45 min each)
- Group B will have manual therapy **twice** per week for **three** weeks. (45 min each)
- Group C is the control group and will not have manual therapy at all.

All groups will get an exercise programme that is tailored to individual needs. Groups A and B will get this in their final treatment session. Group C will have a treatment session booked after their Week 7 follow-up assessment to teach them the exercises. A week after being taught the exercises, the physiotherapist will contact each participant to check on progress and answer any queries. You will be encouraged to continue with your exercises until the trial is ended, and every week asked to complete an exercise diary, which is a log of exercise completion.

All groups will also receive education about knee osteoarthritis and advice on how to self-manage it for a longer period of time.

At the initial assessment you will be asked to complete some questionnaires about your knee osteoarthritis, and how it affects you, how it affects your finances, and how it affects your health. We will also measure the amount of movement in your knee and ask you to do some physical tests such as timed walking, timed stair climb and a sit-to-stand test. Initial assessment will take about 60 minutes. There will be three follow-up assessments (four weeks, seven weeks, and six months after you enrol in the trial), when you will complete the same questionnaires and physical tests. These follow-ups should take about 30 mins each.

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 your knee for most days in the past month (more than 15 days).
- Your knee is stiff and you are unable to fully straighten it.
- You meet clinical criteria to classify you as having knee osteoarthritis.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Manual therapy is a common treatment used by physiotherapists. It can relieve pain and increase movement in your knee. The advice and exercise all participants will receive is considered "best-practice" treatment and recommended by numerous international guidelines. All treatment is free.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There is very low risk of any adverse reaction. During the initial assessment, we will check you are safe to participate in the study. Occasionally the treatment may increase pain in the knee. Your physiotherapist can adjust the treatment to reduce this. It is common after starting a new exercise programme that muscles will feel sore. This usually lasts less than a day and is a good sign that muscles are getting stronger. We will withdraw you from the study if there is prolonged soreness following treatment. Likewise, you can pull out of the study at any stage if you cannot tolerate the treatment.

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 on-line. Look for national organisations such as Arthritis New Zealand or NZ Health Navigator for reliable information.

WILL ANY COSTS BE REIMBURSED?

You will not have to pay for any of your physiotherapy treatment. Participants will be given a $20 voucher as a token thank you for participation for each of the four assessment sessions. Funding is from the Stanley Paris Research Fellowship.

WHAT IF SOMETHING GOES WRONG?

Ethical approval has been granted by HDEC: ref. 21/STH/81
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 at 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 cover.

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). Only the physiotherapists, and research team will have access to your identifiable 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 indefinitely. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised 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.

This research includes basic information such as your ethnic group, geographic region, age range, and sex. It is possible that this research could one day help people in the same

groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is 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 Dr Cathy Chapple.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing Dr Cathy Chapple.

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.

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 disadvantage. You can withdraw by informing your physiotherapist, the trial administrator or the lead researcher (Dr Cathy Chapple).
- 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 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 trials register ANZCTR ref no ACTRN12621000398808p. You can access details about the trial including the results via their website using the reference number above.

http://www.anzctr.org.au/

WHO IS FUNDING THE STUDY?

This study is funded by the Stanley Paris Research Fellowship and was awarded to Dr Cathy Chapple, School of Physiotherapy, University of Otago.

WHO HAS APPROVED THIS STUDY?

This study has been approved by an independent group of people called a 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 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
(03) 4797473
(021)1140304
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

Frequency of manual therapy for people with knee osteoarthritis: The Opti-OK Trial

Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	☐	
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. 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 health 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.	Yes ☐	No ☐
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 ☐
I am willing to be contacted for future similar research	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: _____