NORTHLAND DISTRICT HEALTH BOARD
Te Poari Hauora Ā Rohe O Te Tai Tokerau

Participant Information Sheet

PROTO-KNEE External Validation Study

Formal Study title: Patient-focused prognostic tools used to predict outcomes in Total Knee Arthroplasty: a New Zealand validation study

Lead Study Doctor: Dr Michael English (Registrar)
Supervisor: Mr Marc Hirner (Orthopaedic Surgeon)

Study Locations: Northland and Bay of Plenty

Contact phone number: 0273635021

Ethics committee ref.: ##########

You are invited to take part in a study validating patient focused prognostic tools designed to be used before total knee joint replacement surgery. Two tools have been identified as possibly beneficial for New Zealanders, the 'PROTO-KNEE' tool (Melbourne, Australia) and the 'After my surgery' tool (York, UK). We hope to ensure they are accurate predictors of outcome for New Zealanders before recommending them for patients to use. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. 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'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

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 both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Participating in this study is entirely voluntary. You are under no obligation to be in the study, and declining will not have any impact on your medical/orthopaedic care in the future. We hope that after reading all the information, you will only agree to be in the study if you think you will be able to complete the follow up. However, if you want to withdraw from the study at any time, please just let us know.

What is the purpose of the study?

Osteoarthritis is a painful condition caused by degeneration of the cartilage in joints. Total Knee Replacement is effective for some people, but others can have a poor outcome such as having a painful knee replacement, stiffness, or not being able to do what they had wished to. The purpose of the study is to investigate the validity (or accuracy) of prognostic tools in helping patients make decisions when considering knee replacement surgery for osteoarthritis. The two prognostic tools identified involve gathering simple information about a person and their condition, and then comparing them to a large number of similar patients who have already had their replacement. The tools can then tell an individual how other patients similar to them faired (such as if they improved, stayed the same, or worsened). These tools have been tested in other countries, but not in New Zealand.

How is the study designed?

We will be recruiting approximately 200 people into the study. They will come from the Northland and Bay of Plenty regions. In this way we hope to capture a broader range of patients, surgeons, and types of replacement used.

We will ask you for simple health information such as age, gender, height, weight and how long you have had issues with your knee. Then you will complete two short questionnaires (taking about 5 minutes in total of your time) that ask about your activity levels, your limitations and pain. You will then go on to have your knee replacement. At 6 months and 12 months post surgery we will send out to you the two short questionnaires again to complete and return to us. Once you have done your 12month questionnaires, you are done!

We will pool together all of the data at the end of the study and go through each participant. We will then use the two prognostic tools and get them to make their predictions on each patient. We can then see how accurate the tools are by comparing the results of the tools to the two short questionnaires.

As these tools are not validated for our New Zealand population, we do not recommend that you use them before or after your knee replacement. This study is designed to try and change that for the future. We will aim to see if they are accurate and if they can be recommended for use.

Who can take part in the study?

You have been invited to participate because you have osteoarthritis in your knee and you are scheduled for unilateral (one side only) total knee replacement (arthroplasty).

You can not participate in the study if you have any of the following:

- Painful arthritis in your other knee that limits you
- Another cause of pain in your knee besides arthritis, such as an acute injury of the ligaments, gout, rheumatoid arthritis or a problem with the spine or hip that might be radiating pain down to the knee
- Booked for bilateral total knee arthroplasty (both knees to be replaced)
- Any injections into the knee in the last 3 months
- You have dementia or any other reason why it would be hard for you to fill out the surveys

There will be no restrictions on what participants can do during the study period.

What will my participation in the study involve?

You will complete the basic information questionnaire at the start of the study and the two short questionnaires. You will then go onto have your knee replacement as normal. At 6months and at 12months, you will be contacted to fill out the two short questionnaires again.

What are the possible risks of this study?

You will continue to have your knee replacement surgery as normal. Partaking in this study (or not partaking) does not influence the care that you will receive.

What are the possible benefits of this study?

We expect that the study will help prove that one or both of these prognostic tools are valid for use in the New Zealand population. These tools could then be recommended to patients that are considering knee replacement surgery and help them make a more informed decision recognising their predicted outcomes.

What are the alternatives to taking part?

If you do not take part in the study, then you do not have to. You don't have to provide a reason. You will continue to undergo your knee replacement surgery as scheduled.

Will any costs be reimbursed?

There will be no reimbursement or reward for taking part.

What will happen to my information?

During this study the study doctors/researchers will record information about you and your study participation. This includes the results of any study assessments. If needed, information from your hospital records and your GP may also be collected. 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 study doctors and the research assistant will have access to your identifiable information

Rarely, it may be necessary for the study doctors to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations.

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 by the study doctor. Instead, you will be identified by a code. The study doctor will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information, which may be sent and stored overseas:

- The sponsor, for the purposes of this study.
- People working with or for the sponsor, for the purposes of this study (this may include up to ten people such as
    - Other doctors and nurses working on the study
    - Scientists who help with the statistical analysis of the information from the study
- Regulatory or other governmental agencies.

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 the study. If you agree, your coded information may also be used for other medical and/or scientific research that is unrelated to the current study.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your coded information may be shared widely with other researchers or companies. 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 some research 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.

Security and Storage of Your Information.

Your identifiable information is held at Whangarei Hospital and Tauranga Hospital respectively during the study. After the study it is transferred to a secure archiving site and stored for at least seven years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor.

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.

Your information will not be sent overseas. However, we will work together with researchers from the University of Melbourne that developed this tool to help interpret the results.

This research includes basic information such as your ethnic group, 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. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

If you have any questions about the collection and use of information about you, you should ask the study doctor or research assistant.

Rights to Withdraw Your Information.

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

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?

If you wish to withdraw from the study, please inform the research assistant.

We will not be informing individuals of the outcome of the tools predictions on them. The study is to be used to validate the tools, and the tools should not be used until they are validated.

CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants who wish to find out the results of the study will be provided a plain English summary of the study results. They can also have access to the published scientific paper when it becomes available.

The study is registered in the Australia and New Zealand Clinical Trials Registry. It can be accessed via https://www.anzctr.org.au/TrialSearch.aspx. The trail number is ####.

WHO IS FUNDING THE STUDY?

The funding for this study is provided by the Wishbone Orthopaedic Trust. This is a charitable organization of New Zealand.

The study doctors work for the Northland district Health Board and the Bay of Plenty District Health Board.

WHO HAS APPROVED THE 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 Central Health and Disability Ethics Committee has approved this study.

The study has also been registered with the Australian and New Zealand Clinical Trials Registry: Ref. No. XXXXXXXXX

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:

Dr Michael English

michael.english@northlanddhb.org.nz

If you want to talk to someone who isn't 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@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Maori health support please contact:

Dr Joy Panoho
Workforce Equity Manager, Te Poutokomanawa, Maori Health Directorate

0218814008

Joy.panoho@northlanddhb.org.nz

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

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

Consent Form

Your letterhead

Validating patient-focused prognostic tools for Total Knee Arthroplasty in New Zealand

An interpreter is available on request to help you understand this form

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 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.		
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 ☐

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: