THE BRISBANE HAND & UPPER LIMB RESEARCH INSTITUTE

Participant Information Form

Brisbane Hand and Upper Limb Research Institute, Brisbane Private Hospital

Project Title: Conservative management of 1st CMC joint osteoarthritis: a randomised controlled trial.

You are being asked to participate in a study exploring the outcomes of various conservative treatments provided for the management of arthritis at the base of your thumb.

Who is doing the Research?

Primary Investigators:

Associate Professor Mark Ross	Orthopaedic Surgeon
Dr Greg Couzens	Orthopaedic Surgeon
Dr David Lisle	Consultant Radiologist
Dr Benjamin Hope	Orthopaedic Surgeon
Dr Andrew Mayo	Orthopaedic Surgeon

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What is the purpose of this research project?

Conservative non-surgical treatments are routinely offered by health care professionals to manage pain and symptoms; and improve function of the hand and quality of life. Patients are commonly offered treatments, which may include hand therapy; a thumb splint; a corticosteroid injection; or a combination of these treatments.

The aim of this project is to investigate the clinical effectiveness of various non-surgical treatments to manage pain and improve function for osteoarthritis at the base of the thumb. This study is comparing the outcomes of the following treatments: Push Brace™ splint; corticosteroid injection; hand therapy program; or a combination of these treatments. These treatments are all thought to manage symptoms of pain, and improve function and quality of life. However, we do not know which of these treatments is more effective than the other.

This research is important as very little is known on the most effective forms of treatment for osteoarthritis in the thumb. The results of this study will help to inform health care providers on the most effective treatments for their patients.

What does participation in this research project involve?

If you consent to participate in this study, you will be allocated to one of the treatment groups listed below:

Group A: will receive hand therapy (exercise, joint protection, activity modification)
Group B: will receive a Push Brace™ splint + hand therapy
Group C: will receive a corticosteroid injection to the thumb joint + hand therapy
Group D: will receive a Push Brace™ splint + corticosteroid injection to the thumb joint + hand therapy

Your participation will involve the following:

1. We will complete an assessment prior to the treatments being provided. In this assessment we will ask questions about your pain and function. We will measure range of motion in your hand, and test your hand strength. All assessments are routinely used in clinical practice at present. No additional assessments will be made for research purpose only. This will take approximately 20 minutes.
2. You will then be randomly allocated to one of the treatment groups. We will organise appointments for you to have the treatments based on the group you are allocated to.
    - Everyone will receive a 15 minute hand therapy session
    - If you require a splint, this will be fitted at the end of your hand therapy appointment by one of the hand therapists. This will take approximately 5 mins.
    - If you require an injection, this will be organised for you at the Brisbane Private Imaging, which is located within the hospital. The injection appointment will take approximately 20 minutes.
3. We will repeat the assessments of your pain, function, mobility and strength at 3 and 6 months at the hospital (i.e. at the same time as your regular follow-up visit with your surgeon). We will organise these appointments for you. We will also review your pain and function at 1 and 2 years following your intervention. This can be completed either when you attend the hospital or by a phone or mailed questionnaire.

This study will also use information that your treating surgeons routinely collect as part of your standard care. This will include information from your medical chart, any assessment you complete when you see your surgeon or any test results such as x-rays of your hand.

If you do not receive any benefit from the treatment you are allocated to, you will have the option to change your course of management after your three-month review in consultation with your surgeon. At this stage you will be provided with a splint or an injection if it is deemed appropriate. Injection will be bulked billed and splint will be provided free of cost. If it is felt by your surgeon that surgery is required, the surgeon's routine costs will apply.

What are the benefits of participation?

You will not be paid to take part in this research study. There will however be no extra costs to you outside of what would be normal for your surgeon's appointments and your treatments.

The hand therapy session will cost $55. If you are allocated to have an injection, this will be bulk billed (no cost for you). If you get allocated to the splint groups, this will be provided to you free of charge. If you are not involved with the study, you will be required to pay for the treatments, as is the case for usual care.

You will be contributing valuable information about the effectiveness of the currently prescribed treatments, which might indirectly assist others that suffer from arthritis of the thumb joint.

What are the possible risks?

There are no risks involved from participating in the research, beyond the inconvenience of having to complete the assessments. You will require no additional x-rays.

None of the interventions being tested are new or experimental treatments, and are offered routinely to patients with thumb osteoarthritis. However, there are some very minor risks involved with the treatments, which you should discuss with your treating surgeon before consenting to participate in this study. This could be risks from having an injection into your joint. Potential risks involved with a corticosteroid injection may include infection, bruising or bleeding or an allergic reaction (local or central) to the medication. Although the

mentioned reactions have been documented, the likelihood of occurrence is extremely rare. Adverse reaction from the splint may include redness, irritation, pressure point or skin maceration if splint is not dried properly. You will be provided with information and support depending on which group you are a part of.

Your treating surgeon would have already discussed the risks and benefits of all of these treatments with you. If you are unsure what these treatments involve, please do not hesitate to ask.

Do I have to take part in this research project?

Involvement in this study is voluntary. You have the ability to decline from being part of this study at any time. This will not affect your future treatment in any way. If you do not participate in the study, all treatments that are offered to you will be at the standard rates. Hand therapy treatment and the splint provided will be at the discretion of your hand therapist.

How will I be informed of the results of this research project?

A summary of the results of our research will be outlined on our website once they become available. Our website address is www.upperlimb.com/research. If you want any more information you can contact us and request a full copy of the results.

What will happen to information about me?

Any information obtained in connection with this research project, which can identify you, will remain confidential. It will only be disclosed with your permission, except as required by law. Your data will be stored securely on-site at the Brisbane Hand and Upper Limb Research Institute Office. The investigators in this study will use and access your medical records from your surgeon. Data from this study may be published in journals or books and may be used for educational purposes or presentations. However, your name and other identifying information will not be used. The information collected from this study may be used for future research, for which we will seek appropriate ethical approval from the Mater Human Research Ethics Committee.

The information you provide in electronic format will be stored in an online survey platform (SurveyGizmo) and held off-shore. However, no identifying details (e.g. your name or date of birth) will be stored in this platform and the only identifier will be the number you are assigned as study participant.

How can I access my information?

In accordance with relevant Australian privacy laws, you have the right to access the information collected and stored by the researchers about you, in the same way you access information from your treating doctors.

Is this research project approved?

The ethical aspects of this research project has undergone approval by the Mater Human Research Ethics Committee. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies. Participants may contact the Mater Health Services Research Ethics Coordinator on (07) 31635185, regarding any concerns about the conduct of the research.