ROYAL NORTH SHORE HOSPITAL

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

CLINICAL TRIAL

EFFECT OF COMBINED CONSERVATIVE THERAPIES ON CLINICAL OUTCOMES IN PATIENTS WITH THUMB BASE OSTEOARTHRITIS: A RANDOMISED, CONTROLLED TRIAL (COMBO)

Invitation

You are invited to participate in a research study aimed at comparing two different treatments for people with osteoarthritis at the base of the thumb. Currently, treatment of osteoarthritis is primarily aimed at easing symptoms. For this purpose, there is a range of non-drug and drug options available but the optimal strategy to treat this condition is still largely unknown. With this is mind, this study aims to investigate and compare the effects of two treatment approaches on clinical outcomes such as pain, stiffness and hand function in persons with osteoarthritis at the base of the thumb.

The study is being conducted by Professor David Hunter, Florance and Cope Chair of Rheumatology, Professor of Medicine, University of Sydney.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

The purpose is to investigate and compare the effects of two distinct treatment approaches involving non-surgical therapies for people with osteoarthritis at the base of the thumb.

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because you fulfill the research criteria and/or because you have participated in previous trials and expressed your willingness to be involved in future studies. This Participant Information Sheet tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

3. 'What if I don't 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 or not you will 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.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. The COMBO study is a 12-week study over this period you will be assessed at 2, 6 and 12 weeks. After 6 months from the completion of the study, participants will be contacted by phone or through an online survey to assess: 1) Participants' choice in continue using the interventions; 2) The frequency of intervention use (as recommended by the physiotherapist vs. less than the recommended by the physiotherapist); 3) Pain at the base of the thumb and hand function.
This study does not involve surgery, and the only medicine which may be used is a topical medicine (i.e diclofenac gel/cream). You are permitted to take paracetamol (up to 3000mg per day) in episodes of worsening pain due to any cause and you will be allowed to continue using any pain medication if taken with stable regimen.
A researcher will contact you in order to schedule the screening visit when some information will be collected to confirm your eligibility in the study. If you agree to participate in this trial, we will arrange for you to undergo an x-ray of both hands at Castlereagh Imaging (St. Leonards), free of charge. You will also undergo to a diagnostic ultrasound of your thumb(s) at RNSH during your first study visit. No other x-rays or laboratory test are necessary for this study.

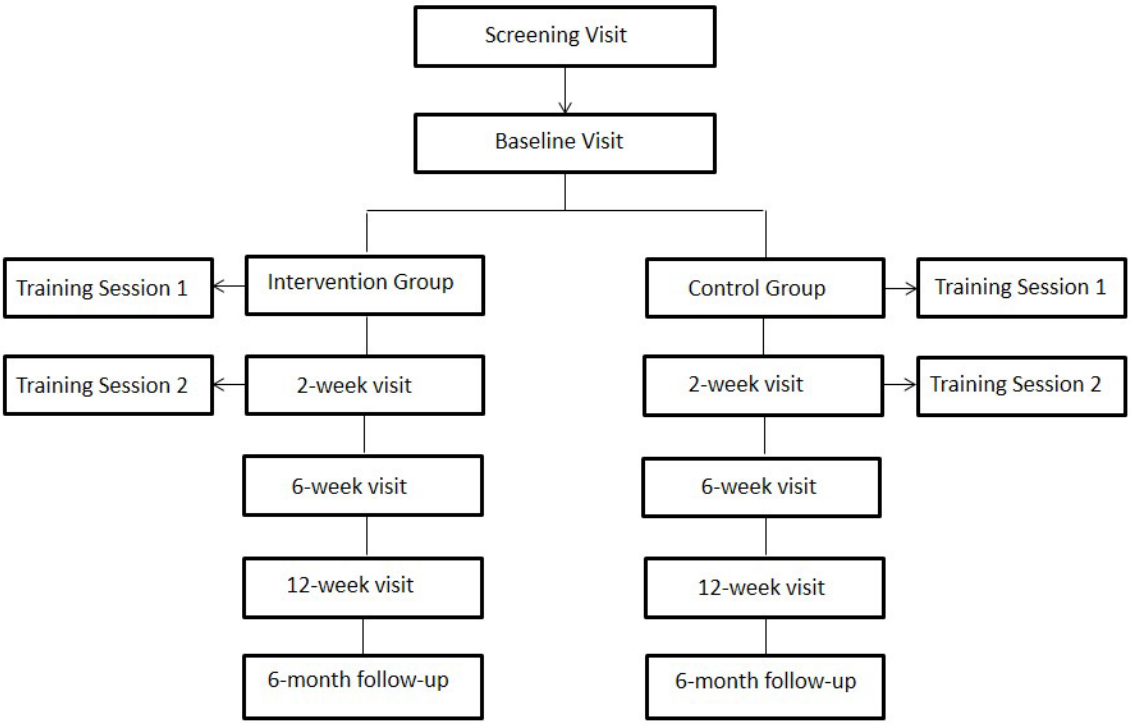
If you agree to participate in this trial, you will then be asked to provide further measures/information such as your medical history, medications in use, weight and height and information about your arthritis at the base of your thumb.

After the screening assessment, your eligibility will be determined. If you are considered as not eligible, the research coordinator will inform you in person or contact you by telephone.

If you are eligible, you will be randomised to either one of the two groups of treatment. Randomisation (random allocation to a treatment group) is used in order to enable comparisons between groups of patients with similar characteristics receiving different treatments. To do this, study participants are put into groups and given different treatments, and the results are compared to see whether one treatment is better. To ensure the groups are similar to start with, a computer allocates each study participant into one of the groups randomly, like the flip of a coin. Neither the therapist nor the study participant can decide which treatment the participant will receive.

Both groups will have two appointments (training sessions) with health care professional that is specialised in osteoarthritis care. They will give you instructions on the treatments for the study. The first one will be at the beginning of the study (baseline visit) and the second one will be at 2 weeks.

Please see the study flow chart:



You will be allocated into one of the two groups. Both treatment groups involve non-surgical treatments for managing the osteoarthritis of the base of the thumb and, at this point, it is not known which strategy is best.

The research coordinator will contact you in order to schedule the baseline visit when you will be informed about which group you will belong to. At your baseline visit, you will be asked a few questions about your general health and symptoms related to your arthritis at the base of the thumb. You will also have your pinch and grip strength measured. Each study visit is estimated to last 30-45 min approximately, however the first visit is expected to last up to 2 hours in total due to the baseline imaging procedures and intervention delivery.

5. 'How is this study being paid for?'

This study is being funded by a grant from the National Health and Medical Research Council (NHMRC).

6. 'What are the alternatives to participating in this study?'

If you decide not to participate in this study, and you wish to continue treatment, you will still

receive treatment for your condition. It is important that you discuss the alternatives to participating in this study with your doctors or health care provider.

7. 'Are there risks to me in taking part in this study?'

In spite of all reasonable precautions, you might develop medical complications from participating in this study. In addition, there may be risks associated with this study that are presently unknown or unforeseeable.

You may be required to use topical anti-inflammatory (i.e., diclofenac gel/cream) throughout the study. Local skin rashes may occur with this drug; however, they are mostly minor local skin reactions. If you have local side effects, you will stop the use of the drug and you will be followed to certify resolution of the rash. Other potential side effects associated with diclofenac are related to cardiovascular problems (e.g., increase in blood pressure, heart attack, stroke), gastrointestinal problems (e.g., ulceration, perforation, bleeding) and impairment of kidney function. However, these side effects are not common and risks are much lower with diclofenac gel/cream compared to oral diclofenac (tablets). Your blood pressure will be monitored throughout the study and if you have symptoms suspected to be associated with the drug, you will be assessed by a doctor and may be referred for further medical evaluation.

Tests for pinch and grip strength may cause discomfort over the affected joint during the test. You will be instructed to do the test only until the maximum that you can tolerate.

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a radiation dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.001 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal.

We do not expect any serious side effects from the treatments included in this study.

8. 'What happens if I suffer injury or complications as a result of the study?'

If you suffer any injuries or complications as a result of this study, you should contact the study coordinator as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

9. 'Will I benefit from the study?'

This study aims to further medical knowledge and may improve future treatment thumb base osteoarthritis; however it may not directly benefit you.

10. 'Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything. You will be reimbursed for your time and parking expenses, for each completed study visit, with a free parking ticket and with a Coles/Myer gift card.

11. 'How will my confidentiality be protected?'

Of the people treating you, only the research coordinator Sarah Meneses and the Principal Investigator (Professor David Hunter) will know whether or not you are participating in this study. 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. Only the researchers named above, the Human Research Ethics Committee (HREC) for monitoring purposes and those persons monitoring the conduct of the study on behalf of the sponsor (the University of Sydney) will have access to your details and results that will be held securely at Royal North Shore Hospital and on a University of Sydney server.

12. 'What happens with the results?'

If you give us your permission by signing the consent document, we plan to discuss/publish the results in journals, presentations in conferences, symposia, congress and scientific meetings in general. No information which could lead to your identification will be included in the dissemination of results.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

13. 'What happens to my treatment when the study is finished?'

You may be able to continue your program following completion of this study if it found to be of benefit to you. This decision should be made in consultation between you and your treating doctor about the most appropriate treatment for you at that time. You will be able to keep any materials you received during the study free of charge.

14. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researcher coordinator (Sarah Meneses) will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on number 02 9463 1855.

15. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Northern Sydney Local Health District HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 9926 4590 and quote HREC reference number

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.

ROYAL NORTH SHORE HOSPITAL

CONSENT FORM / CLINICAL TRIAL

EFFECT OF COMBINED CONSERVATIVE THERAPIES ON CLINICAL OUTCOMES IN PATIENTS WITH THUMB BASE OSTEOARTHRITIS: A RANDOMISED, CONTROLLED TRIAL (COMBO)

1. I,.....of.....

   ..... agree to participate as a subject in the study described in the Participant Information Sheet set out above **(or: attached to this form).**

2. I acknowledge that I have read the Participant Information Sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the investigators or **Royal North Shore Hospital.**

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact the Research Coordinator, Sarah Meneses on 02 9463 1893 who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Complaints may be directed to the Research Office on Level 13, Kolling Building, Royal North Shore Hospital, St Leonards NSW 2065

Phone 02 9926 4590 | email NSLHD-research@health.nsw.gov.au

Signature of participant **Please PRINT name** **Date**

_____

Signature of witness **Please PRINT name** **Date**

_____

Signature of investigator **Please PRINT name** **Date**

_____

ROYAL NORTH SHORE HOSPITAL

CLINICAL TRIAL

EFFECT OF COMBINED CONSERVATIVE THERAPIES ON CLINCAL OUTCOMES IN PATIENTS WITH THUMB BASE OSTEOARTHRITIS: A RANDOMISED, CONTROLLED TRIAL (COMBO)

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Royal North Shore Hospital or my medical attendants

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to:

Professor David Hunter

Royal North Shore Hospital

Level 7, Clinical Administration 7C

St Leonards NSW 2065