Participant Information Sheet

Study title:	**Extensor tendon study**		
Locality:	**Dunedin Hospital**	Ethics committee ref.:	**15/STH/63**
Lead investigator:	**Miranda Bűhler**	Contact phone number:	**Wk 03 4709347** **Mob 027 299 3979**

You are invited to take part in a study on splinting for extensor tendon rehabilitation. 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. You do not have to decide today whether or not you will participate in this study. 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 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the study is to compare two splinting and rehabilitation treatments following extensor tendon repair on the back of the hand. The study will provide information about outcomes following treatment, and the cost-effectiveness of treatment including costs to patients such as time off work. Information from the study will help surgeons and therapists to decide which method of splinting and rehabilitation gives the best outcome at the least cost to patients, society and the health care system.

The treatments used in the study are well documented and known to be safe. However it is not yet known which splinting and rehabilitation treatment will result in the best outcome.

If you agree to participate in this study, you will be randomly allocated to a treatment group. Random allocation ensures that participants in each of the treatment groups are similar, and we can be more certain that the findings of our study are due to the treatment method and not due to some other reason. The clinicians that care for you will know which treatment you receive, however the researcher that assesses your progress to collect information for

the study will not know which treatment group you are in. This 'blinding' of the assessor will prevent them from influencing the results, which they may consciously or unconsciously do depending on their personal opinions of the treatments. Likewise, if you agree to participate you will also be partially-blinded – we will not explain to you the full purpose of the study in order that your own opinions do not influence the study findings.

Funding for the study comes from the Healthcare Otago (HCO) Trust, and from the New Zealand Association of Hand Therapists (NZAHT). The investigators are affiliated with the Southern District Health Board (SDHB) and with the University of Otago Dunedin School of Medicine (DSM). You can contact the Primary Investigator Miranda Bűhler, or Co-investigator Josh Woodside by telephone or email at any time (contact details on title above, or page 4 below.

This study has received ethical approval from the Lower South Regional Ethics Committee, Ethics reference number 15/STH/63.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been chosen to participate in this study because you have recently injured the extensor tendon(s) to one or more fingers on the back of your hand, and have had the tendon(s) surgically repaired at Dunedin Hospital.

In this study, a Hand Therapist will fit you with one of two types of splints commonly used to rehabilitate surgically repaired extensor tendons. You will then continue your treatment according to one of two rehabilitation programmes and see your local therapist as per usual.

The time involved in participation, over and above the usual treatment time you will spend with your therapist will be, 1) a 30 minute initial interview, 2) a 30 minute assessment at 6 weeks, and 3) a 30 minute assessment at 12 weeks.

At the initial interview the Principal Investigator or a Co-investigator will first go through this information sheet with you and seek your written consent to participate in the study. If you agree to participate, they will then ask you about your personal details including your age, gender, ethnicity and general health; your work history; and the details of your tendon injury.

At the 6 week assessment, an independent Hand Therapist will measure your finger range of motion using a small metal hinged protractor, ask you about any complications, and ask you to complete six short questionnaires. The questionnaires ask about your symptoms and any difficulties you have with everyday activities, your return to work (paid or unpaid), your satisfaction with splinting, treatment and outcome, your adherence to splint wearing, costs you have incurred due to your injury such as transport and GP visits, and your general health status.

At the 12 week assessment an independent Hand Therapist will again measure your finger range of motion. They will also measure your grip strength using a hand-held dynamometer. You will be asked again about complications, and asked to complete five questionnaires – all those described above but not the questionnaire about adherence to splinting.

All questionnaire responses will be kept confidential and will not be passed on to your treating clinician.

Health information will be collected from you during the initial interview. Health information regarding your surgical treatment, complications, and the number and duration of Hand Therapy and Orthopaedic appointments will also be collected indirectly by accessing medical records.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

There are no forseeable risks, side-effects or discomforts associated with study participation.

The investigator is not responsible for ensuring that care is provided to participants during the study – this responsibility lies with the Southern DHB.

WHO PAYS FOR THE STUDY?

Participants of this study may incur additional transport costs and time off work to attend the 6- and 12 week assessments.

Reimbursement provided in recognition of participation will be made in the way of petrol vouchers at the rate of $20 for each of the two follow-up assessments attended. For those participants who live more than 20 km from Dunedin Hospital or Wanaka Physiotherapy Clinic and for whom the follow-up assessment does not coincide with a follow-up Hand Therapy or Surgical appointment and travel costs are not covered by ACC, petrol vouchers will be provided at the rate of 50c per km travelled to and from the follow-up session.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. 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 won't affect your cover.

WHAT ARE MY RIGHTS?

Your participation in the study is voluntary and you are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage

If you agree to participate in the study you will have the right to access information about you collected as part of the study. You will be told of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on your health

Assessment data will be anonymised using a coding system and participants' information will remain confidential.

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

All study information will be stored securely in a locked file cabinet and in a secure computer in an office in the Physiotherapy Outpatient Department, Dunedin Hospital. All data will be kept for a minimum of 10 years and may be made available for further use in a de-identified form, if ethically approved.
On completion of the study, findings will be communicated to Hand Therapists and Hand Surgeons in New Zealand by presentations at professional conferences, and internationally by articles submitted to the Journal of Hand Therapy. Participants will be informed of the study findings by a short written report mailed out. The study is expected to be completed by the end of 2017.

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:

Miranda Buhler, Hand Therapist (Principal Investigator)
Physiotherapy Outpatient Dept., Dunedin Hospital
Tel Wk. 03 470 9347 Mob. 0272993979
Email Miranda.buhler@southerndhb.govt.nz

Or:

Josh Woodside, Hand Therapist (Co-investigator)
Physiotherapy Outpatient Dept., Dunedin Hospital
Tel Wk. 03 470 9347 Mob. 0272830688
Email Joshua.woodside@southerndhb.govt.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

Free Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

If there is a specific Maori issue or concern please contact: 0800 555 050

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

An interpreter can be provided if you need one. Please ask the researcher.

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.	Yes ☐	No ☐
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	No ☐
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.	Yes ☐	No ☐
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.	Yes ☐	No ☐
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.	Yes ☐	No ☐
I consent to the research staff collecting and processing my information, including information about my health.	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 other current health providers including my Hand Therapist 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 Ethic 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.	Yes ☐	No ☐
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.	Yes ☐	No ☐
I understand the compensation provisions in case of injury during the study.	Yes ☐	No ☐

I know who to contact if I have any questions about the study in general.	Yes ☐	No ☐
I understand my responsibilities as a study participant.	Yes ☐	No ☐
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: