**Participant Information Sheet & Consent Form**

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| Title | Evaluation of an innovative hand therapist-led, technology-enhanced, group-based (TEG) model of care following carpal tunnel release (CTR) surgery  |
| Short Title | Pilot and feasibility RCT – Evaluation of TEG model of care following CTR surgery |
| Principal Investigators | Emma Taylor (chief investigator), Dr Emmah Doig, Prof Trevor Russell, Dr Ridzwan Namazie |
| Associate Investigators | Prof Nadine Foster, A/Prof Haitham Tuffaha, Tamsin Mahoney, Dr Emma Ballard, Caroline Wegrzyn |
| Location |  Surgical Treatment and Rehabilitation Service (STARS), Metro  North Health |

**What does my participation involve?**

Thank you for your interest in being part of this research – *‘Pilot and feasibility randomised controlled trial – evaluation of an innovative hand therapist-led, technology-enhanced, group-based (TEG) model of care following carpal tunnel release (CTR) surgery’*. You are invited because you have been booked and given consent to have CTR surgery.

At STARS, after CTR surgery, people receive two sessions with a hand therapist, the first at 10-14 days after surgery. This appointment happens either one-to-one or in a group with other people who have also had CTR surgery recently. This is usually decided upon based on how many surgeries are carried out and how many people require post CTR surgery hand therapy. The second appointment after CTR surgery happens at 6 weeks after surgery. This is usually in-person at STARS and one-to-one. Feedback from STARS patients since we have been providing some group hand therapy sessions is that they are happy with working in a group and that follow-up telehealth or telephone appointments are preferred by many people due to convenience. We also know, based on research evidence, that some people like and can follow their home exercise program better if they have pictures and videos on their phone to refer to. There is no previous research that has formally looked at how effective group-based hand therapy is after CTR surgery and no research looking at what patient’s think about it.

The purpose of this research is to see if the TEG model of hand therapy (which involves a group-based appointment at 10-14 days, use of an app on your mobile phone with pictures/videos to help follow your home program, and a telehealth or telephone, one-on-one appointment at 6-weeks) is practical and acceptable to patients, in comparison to usual care hand therapy (which involves in-person, one-on-one appointment at 10-14 days, a paper-based exercise program, and a 6-week review appointment) following CTR surgery. If the TEG model of hand therapy is feasible and acceptable to patients, we hope to continue using this for patients following CTR surgery. This research will also help us understand whether further research to compare the effectiveness of the approaches is feasible and warranted.

This Participant Information Sheet & Consent Form tells you about the research project. It explains the assessments and research involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully and ask any questions about anything that you don’t understand or want to know more about.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it, you are telling us that you:

* Understand what you have read
* Consent to take part in the research project
* Consent to the assessments and research that are described
* Consent to the use of your personal and health information as described

You will be given a copy of this Participant Information and Consent Form to keep.

**What is the purpose of this research?**

The purpose of this research is to see if the TEG model of hand therapy (in-person group first appointment and telehealth or telephone one-to-one follow-up appointment) is practical and acceptable to patients, in comparison to usual care hand therapy (in-person, one-to-one first and follow-up appointments) following CTR surgery. Research has shown the benefits of group therapy for people receiving rehabilitation including peer support, socialisation, learning, sharing of knowledge and giving hope. There is evidence that patients follow home therapy programs more successfully using mobile phone apps with video-guided exercises than paper-based handouts.

This research has been started by a group of therapists and researchers from the Surgical Treatment and Rehabilitation Service (STARS), Metro North Health and the University of Queensland. This research is funded by a Health Practitioner Research grant from Metro North Health.

**Procedures**: If you agree to take part, you will be asked to sign a consent form before being part of the research. You will be asked to return your signed consent form before the date of your surgery.

Once your signed consent form is received, you will be randomly allocated to either the usual care or the TEG model of hand therapy. You will need to be able to return to STARS in-person for both your first, and possibly your second hand therapy appointment, depending on which group you are randomised to. You will be told what group you have been randomly assigned to and what is involved at your first hand therapy appointment. After your CTR surgery and prior to attending your first hand therapy appointment, we will ask you some information about you (your age, gender, years of education, occupation, hobbies and cultural background) and your carpal tunnel syndrome (CTS) (how long you have had CTS, on which hand your CTR surgery occurred, and family history of CTS). You will also be asked to complete some questionnaires about your hand function, pain and quality of life. To complete these, depending on your preference, we will either do them over the phone with you or send them to you electronically by email to complete on your own. This will take approximately 10 minutes.

The **usual care** model of hand therapy involves:

1. An initial appointment occurs within 10-14 days post-operation. It is an in-person, one-to-one session of 30 minutes duration. During this appointment, your stitches will be removed, and you will be given education about carpal tunnel surgery, post-operation recovery and the hand therapy program involved. You will also be given exercises and scar management.
2. You will be given a paper-based home therapy program including patient handouts with text and photographic descriptions. You will be given a written log and asked to complete it each day to help you keep track of how often you complete your home program.
3. A follow-up appointment is scheduled at six weeks post-operation. It is an in-person, one-to-one session of 30 minutes duration. During this appointment, you will be given further education, your post-operative recovery will be reviewed, and you will be given strengthening exercises.

The **TEG** model of hand therapy involves:

1. An initial appointment occurs within 10-14 days post-operation. It is an in-person, group session of 30-60 minutes duration. Please note that in some cases you may receive your initial appointment one-to-one if there are not enough patients needing hand therapy following CTR surgery at the same time. During this appointment, your stitches will be removed, and you will be given education about carpal tunnel surgery, post-operation recovery and the hand therapy program involved. You will also be given exercises and scar management.
2. You will be given a phone-based app home therapy program including video-guided exercises and a way to track how often you complete your exercises. You or your family member/carer will be shown how to use the app. You will be given a written home-program log and asked to complete it each day to help you keep track of how often you complete your home program.
3. A follow-up appointment is scheduled at six weeks post-operation. It is a one-to-one telehealth or telephone session of 30 minutes duration. During this appointment, you will be given further education, your post-operative recovery will be reviewed, and you will be given strengthening exercises.

All participants will be asked to complete some questionnaires soon after their follow-up appointment including the questionnaires you did at the beginning of the study (about hand function, pain and quality of life) and some additional questions about your satisfaction and views on how acceptable and feasible the program was. Some of the questionnaires can be completed over the phone with you or be sent to you electronically by email to complete on your own, depending on your preference. This will take approximately 20 minutes. You will also be asked to return a copy of your completed home-program written log either by email or by post (depending on your preference).

**Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. You will receive the best possible care regardless of whether you take part or not or take part and then withdraw.

**Possible benefits?**

There will be no clear benefits to you from your participation in this research. We cannot guarantee or promise that others will receive benefits from this research, however possible benefits may include a better understanding of hand therapy models for patients after CTR surgery and identifying if the TEG model is practical and acceptable to patients. The TEG model of hand therapy may potentially benefit patients’ recovery after CTR surgery.

**Possible risks and disadvantages?**

If you receive the TEG model of hand therapy, this study will require an additional time commitment for the first appointment with a duration of 30-60 minutes (depending on the number of patients in the group) instead of 30 minutes for usual care. Completion of research measures prior to and at the end of your hand therapy program will require additional time. You will be required to complete some assessments prior to your first appointment (additional time commitment of up 10 minutes) and soon after your second hand therapy appointment, including some questions about your experience of the program after your second hand therapy appointment (additional time commitment of up to 20 minutes).

**What if I withdraw from this research project?**

Your participation in this research is voluntary and you are free to withdraw from the study at any time without needing to provide any explanation, and you would not receive any penalty as a result of your withdrawal. Should you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them when you withdraw from the research project.

**What happens when the research project ends?**

A summary of the research findings will be provided to you should you request it. You may also access publications arising from the research. If you would like a researcher to send you a summary of the findings or academic publications, please speak with a member of the research team.

**What will happen to information about me?**

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research study that can identify you will remain confidential. Data will be stored separately to any identifying information, saved in a password protected, secure electronic database only accessible by members of the research team. All findings will be reported in pseudonyms (a pseudonym is the use of a name that is not your own name so that will not be identified). Audio-recordings will be stored in a password, protected, secure electronic database and deleted from audio-recording devices. Audio-recorded data will be transcribed verbatim and any identifying information removed from the transcription. Data will be stored in a non-identifiable form for 25 years and then destroyed.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be presented in such a way that you cannot be identified, except with your permission. In accordance with relevant Australian and/or Queensland privacy or other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree can be corrected. Please contact the research team member listed at the end of this form if you would like to access your information.

If you have any problems as a result of this research, please contact the Principal Investigator Mrs Emma Taylor (email: emma.taylor@health.qld.gov.au). To contact by telephone, please call (07) 3647 6324. You are free to discuss participation in this study with the researchers at any time using this contact information.

**Who is organising and funding the research?**

This study received funding from Metro North Health. The funding is a Health Practitioner research grant scheme.

**Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been reviewed and approved by the Metro North Health HREC (EC00168). This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Should you wish to discuss the study in relation to your rights as a participant, or should you wish to make an independent complaint, you may contact:

Name: Research Governance Manager

Position: Metro North Health

Phone: 07 3647 9550

Email: MetroNorthResearch-RGO@health.qld.gov.au

**Participant Consent Form** – *Adult providing own consent*

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**Declaration by Participant**

I have read the Participant Information Sheet, or someone has read it to me in a language that I understand. I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that the project involves randomisation of participants.

I have been informed that the confidentiality of the information will be maintained and safeguarded.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) ­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Declaration by Senior Researcher\***

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation.

Name of Senior Researcher\* (please print) ­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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\* A member of the research team must provide an explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Withdrawal of Consent Form** – *Adult withdrawing own consent*

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**Declaration by Participant**

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ no longer wish to participate in the

research study named above.

I understand the medical information I have already supplied may still be reviewed but no new information can be reviewed.

Name of Participant (please print) ­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Declaration by Senior Researcher\***

I confirm that the participant no longer wishes to participate in the research project.

Name of Senior Researcher\* (please print) ­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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\* A member of the research team

Note: All parties signing the consent section must date their own signature.