**Protocol for a single-centre pilot and feasibility randomised controlled trial (RCT):**

**Evaluation of an Innovative Hand Therapist-Led, Technology-Enhanced Group-Based (TEG) Model of Care following Carpal Tunnel Release Surgery**

**INVESTIGATORS**

**Chief Investigator:** Mrs Emma Taylor – Senior Hand Occupational Therapist

**Mentors and Principal Investigators:**

Dr Emmah Doig - STARS Education & Research Alliance Senior Conjoint Research Fellow

Prof Trevor Russell – Director of RECOVER Injury Research Centre

Dr Ridzwan Namazie – STARS Orthopaedic Consultant and Research Fellow

**Associate Investigators:**

Prof Nadine Foster – Director of STARS Education & Research Alliance

A/Prof Haitham Tuffaha – Health Economist, UQ Centre for the Business and Economics of Health

Mrs Tamsin Mahoney – STARS Director of Occupational Therapy

Dr Emma Ballard – Senior Biostatistician, QIMR Berghofer Medical Research Institute

Mrs Caroline Wegrzyn – STARS Orthopaedic Case Manager

Mrs Semele Robinson - consumer representative

**TABLE OF CONTENTS**

|  |  |
| --- | --- |
| **GENERAL INFORMATION** | **Page** |
| Title Page (including Investigators) | 1 |
| Table of Contents | 2 |
| **SECTION** |  |
| 1. **Introduction** | 3 |
| 1. **Aims** | 4 |
| 1. **Method** | 4 |
| * 1. Study Type / Design | 4 |
| * 1. Participants | 6 |
| * 1. Interventions / Procedures | 9 |
| * 1. Measurements | 10 |
| * 1. Analysis | 13 |
| * 1. Ethical Issues | 13 |
| * 1. Consumer Engagement | 14 |
| * 1. Resource requirements | 14 |
| * 1. Supervision | 15 |
| 1. **Dissemination of findings** | 15 |
| 1. **References** | 16 |

**1 INTRODUCTION**

Carpal Tunnel Syndrome (CTS) results from entrapment of the median nerve and is the most common entrapment neuropathy, affecting 3%-4% of the population. It accounts for at least 10% of patients referred to public orthopaedic departments, with carpal tunnel release (CTR) surgery one of the most-commonly performed elective procedures (1). CTS causes discomfort and pain, paraesthesia and numbness, which adversely affects daily activities, sleep, work capacity and quality of life (1, 2). Patients often try conservative treatments such as exercise, night splints or corticosteroid injections, but those who do not experience sufficient benefit are considered for CTR surgery. CTR surgery creates more space for the median nerve in the carpal tunnel by relieving pressure caused by the transverse carpal ligament.

Following CTR surgery, usual care consists of one-to-one, in-person, post-operative hand therapy with a written home program, with consistent recovery milestones observed in most patients (3, 4, 5). A group-based model of service delivery has the potential to be more efficient than one-to-one care, considering the large volume of CTR surgeries performed and relative consistency across patients in post CTR hand therapy provision, which in most cases involves suture removal, provision of education (wound, scar and pain management) and provision of a home program of exercise and advice aimed at improving hand function and resumption of activities of daily living.

A literature review of evidence for the effectiveness of group-based hand therapy following CTR surgery showed no previous studies. However, the therapeutic benefits of groups in other patient populations include peer-to-peer support, socialisation, learning, sharing of knowledge, enhanced progress, and instilling hope (6, 7, 8). Furthermore, commencement of home-based exercise and scar management is routine practice following CTR surgery, after the initial hand therapy appointment 10-14 days post-surgery (10,11). Whilst there is mixed evidence about, and a need for further research to establish, the effectiveness of app-based technologies for enhancing adherence to home programs, a recent RCT by Chung et al (9) found that a mobile phone-based, video-guided exercise app was superior to a standard paper-based home exercise program for improving adherence to exercise.

At the Surgical Treatment and Rehabilitation Service (STARS), CTR is the most common hand/upper limb surgical procedure, with 496 CTR surgeries performed between February 2021 to March 2023. Following CTR surgery at STARS, patients receive outpatient hand therapy in a hand therapist-led service. Sutures are removed, and education, exercises and scar management provided within 10-14 days following surgery (10, 11). A second appointment at 6 weeks involves review of progress, commencement of strengthening and further referral on an individual patient needs basis. The ambulatory care outpatient service at STARS has well established telehealth protocols and infrastructure, with a 30% telehealth activity target to enhance patient access to care. Furthermore, the STARS orthopaedic virtual model of care has been established to maximise the use of telehealth across the service.

Given the high volume of CTR surgeries, STARS has been piloting the delivery of group-based hand therapy, which has been initially driven by the increasing number of post-operative CTR hand therapy outpatient appointments (often multiple surgeries daily, on occasion up to 10 surgeries, necessitating the need to accommodate multiple hand therapy CTR surgery appointments on the same day). We have also been accommodating patients who prefer a telehealth appointment for their second, one-to-one, appointment at 6-weeks. Within the service, there has been positive patient feedback to date about the group-based approach and telehealth follow-up. Furthermore, patient feedback to date has indicated that an improvement to the current approach would be the availability of video instructions for home exercises via a mobile phone app.

Therefore, this research study will evaluate the feasibility and preliminary efficacy of this TEG approach for people post CTR surgery within a public hospital-based (STARS), hand therapy service. It is expected that the outcomes of this study will determine the feasibility and acceptability of the new model of care and determine the feasibility of a future fully powered randomised controlled trial (RCT) that will determine the clinical and cost-effectiveness of the model of care. The TEG model aims to increase efficiency and outcomes, use telehealth delivery to improve patient access and app-based video-guided exercise and monitoring to improve self-management, adherence, and outcomes.

This research is expected to increase knowledge about group-based hand therapy, technology use to enhance outcomes, as well as inform future research directions. Furthermore, the TEG model of care has the potential to be applied to other common elective hand surgeries that have a routine post-operative hand therapy approach. There is scope for it to influence practice beyond the STARS setting given the high volume of CTR surgeries performed Australia-wide (1).

**2 AIMS**

**Objectives:**

1. Explore the acceptability and feasibility of the TEG model of care for patients who have undergone CTR surgery
2. Determine the feasibility of a future, larger RCT
3. Describe and explore the differences between the clinical and cost outcomes between the TEG and usual care groups and obtain estimates to inform the sample size calculation for a future definitive RCT

Our hypotheses are that the TEG intervention will be acceptable and feasible for patients, and a future, larger randomised trial will be feasible to conduct. We will describe and explore the clinical and cost outcomes from this pilot RCT with due caution to not extrapolate results beyond the feasibility and pilot nature of the study.

**3 METHOD**

**3.1 Study Type / Design**

The research design is a single-centre, two-arm parallel group, independent assessor-blinded, pilot RCT. Participants will be randomised to receive either the TEG model of care or usual model of care.

**Figure 1: Consort Diagram**

## Screening

Assessed for eligibility

Inclusion: Adult 18 years+; CTS diagnosis and listed for CTR surgery; ; English language

Exclusion: Concurrent hand surgery; atypical CTS; surgery on same hand in prior 6 months; not attending post-CTR outpatient hand therapy in a face to face, in-person format at STARS; access to smart mobile phone or computer; unable to consent

## Pre-Intervention Assessment

## Analysis

Analysed   
 Excluded from analysis (give reasons)

Analysed   
 Excluded from analysis (give reasons)

## Post Intervention Assessment

## Allocation

Allocated to **usual care 1-1 intervention** (n=42)

 Received allocated intervention

 Did not receive allocated intervention (give reasons)

## Consent

Allocated to **TEG intervention** (n=42)

 Received allocated intervention

 Did not receive allocated intervention (give reasons)

Randomized (n=84)

Excluded

  Not meeting inclusion criteria

  Declined to participate

  Other reasons

**3.2 Participants**

**Inclusion/Exclusion Criteria:**

Inclusion criteria:

1. Patients with a clinical diagnosis of CTS (by treating surgeon) and listed for CTR surgery at STARS
2. Aged ≥18 years
3. Able to understand English

Exclusion criteria:

1. Patients who are not able to and not planning on returning to STARS for face to face in-person initial and review post-operative outpatient hand therapy appointments
2. Patients who do not have access to a smart mobile phone or tablet computer capable of hosting the app-based home therapy program and supporting telehealth video communications
3. Patients listed for CTR and concurrent hand surgical procedures (eg. Trigger finger release)
4. Atypical CTS that is likely to require an alternative (ie. more intensive) intervention such as a person with a concurrent condition (e.g. pre-existing chronic hand pain syndrome, trauma-related symptoms ie. hand/wrist fracture, or systemic inflammatory condition)
5. Prior hand / wrist surgery on the affected side within the last 6 months
6. Patients who are unable to provide full informed consent

**Figure 2: Identification, Approach, Eligibility screening, Recruitment, Consent and**

**Randomisation Flow Chart**

**Written information (flyer and PICF)** about the research study provided to all patients by nursing staff at the time they are booked and provided consent to receive CTR surgery at STARS

## Pre-Operative Appointment

During a routine telephone call by the STARS orthopaedic case manager:

* potentially eligible patients will be **approached** and provided with verbal / written information about involvement in study and interest in potentially participating will be determined
* interested potential participants **screened for eligibility** (inclusion / exclusion criteria)

A **working instruction** guiding recruitment and consent will be referred to, including:

* explanation of the study procedures including randomisation and follow-up requirements and explanation of the study purpose
* balanced explanation of the two interventions after surgery
* opportunity to ask and have questions answered
* willingness to be involved (verbal consent) will be sought – **consent form** will be either sent electronically or via post, & requested to be returned prior to surgery date

## Pre-CTR surgery (on average 3 weeks prior)

## Prior to CTR surgery date

**Written informed consent** to participate will be obtained before participating in the research (returned electronically or via post, depending on patients’ preference)

Consented participants will be **randomised** to either the TEG intervention or usual care intervention (using permuted block sizes of 2 and 4, 1:1 ratio to groups). Blinding of allocation to group will be undertaken using opaque sealed envelopes prepared by persons not associated with the trial.

Post randomisation, the nominated person performing the randomisation will inform the research hand therapist about which group the participant is allocated to and who will arrange and deliver the treatment

## CTR surgery date

## Initial post-CTR hand therapy appointment

The participant will be **informed of the allocation** only by the hand therapist who will deliver the treatment allocation

**Recruitment and Consent**

The identification, approach, eligibility screening, recruitment and consent and randomisation process is outlined in Figure 2. Recruitment flyers will be displayed in relevant STARS areas where potentially eligible participants may see them including STARS electronic noticeboards. All patients who receive CTR surgery at STARS attend a pre-operative appointment at a STARS orthopaedic clinic, where written consent for surgery is gained. All patients who are booked and provide consent to receive CTR surgery at STARS will be offered written information about the research study (flyer and PICF) at their STARS orthopaedic clinic appointment by nursing staff to raise awareness about the study. A brief working instruction will be followed by nursing staff to explain the research study when offering this information to patients. During a routine telephone call by the STARS orthopaedic case manager to inform patients of their scheduled surgery date and provide instructions to prepare for surgery (on average 3 weeks prior to surgery), potential participants will be screened for eligibility with reference to the inclusion and exclusion criteria. If eligible, patients will be invited to participate in the study.

A working instruction will be followed by the orthopaedic case manager to provide the potential participant with information about the study, screen for eligibility, and provide the potential participant the opportunity to ask questions and have those answered. The potential participant will be informed that they will be shown how to access and use the app-based home therapy program should they be randomly assigned to the TEG group. The STARS orthopaedic case manager will liaise with the STARS research hand therapist to clarify and confirm eligibility against inclusion and exclusion criteria as required. The potential participant will be provided with verbal and written information (PICF) about involvement in the study in a form that is accessible and preferred by the patient (eg. Email, hard copy by mail). If the participant reports that they already have the PICF that was provided at their STARS pre-operative orthopaedic appointment, the PICF will not be re-sent. Should potential participants contact a research team member in response to receiving information about the study/seeing a flyer, this step will be completed by a member of the STARS research team.

Written informed consent will be obtained from willing and eligible patients before participation. During the routine telephone call, the orthopaedic case manager will provide participants with a variety of options for providing consent including:

* 1. Being provided an electronic version of the consent form that the participant can return scanned or photographed via email
  2. Being provided with a consent form in the mail for signature and return via email (scanned or photographed) or via mail by a stamped, self-addressed envelope

All email or postal correspondence from the orthopaedic case manager with participants (eg. When sending PICF) will be as per the appended scripts. Participants will be asked to return their signed consent form prior to their surgery date. A record of the consent process will be stored on the patient’s electronic medical record (ieMR) at STARS. Any hard copy consent forms will be scanned, and the hard copy stored in a locked filing cabinet at STARS. The scanned consent form along with participant logs, will be stored electronically in a dedicated Research Folder within secure QLD Health electronic systems accessible only by members of the research team. This will be kept separate from any patient data, which will be labelled with a participant ID number (as per the participant log) and stored in a de-identified form on TEAMS and UQ Research Data Manager.

A copy of the signed consent form will be offered to and provided to the participant if they would like a copy. Participants will be informed that they have the right to withdraw at any time without any consequence to any current or future care they receive at STARS. Participants will also be informed that if they withdraw their consent during the research project, researchers will not collect additional information about them, but information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

To establish feasibility of recruitment and reasons for ineligibility, a screening log will be completed and stored. This will include, for each person screened: name and UR number, invited and screened, the date invited, whether eligible or not, reason for ineligibility (if applicable), whether consent to participate was provided or not. This data is needed to enable the number of participants screened, approached, eligible (and reason for exclusion), and randomised to be determined (SEAR data).

**Sample size**

Considering an average of 20 CTR surgeries per month are undertaken at STARS it is estimated that 14 participants (approx. 70%) could be recruited each month (allowing for those who are potentially ineligible, decline to participate, cancel their surgery or appointments, and variations in surgical list sizes). With a 6-month recruitment window, it is anticipated that 84 participants could be recruited but this is part of the feasibility assessment of this study. For the TEG approach the smallest number per therapy group will be one, so that all participants eligible and wanting to participate can be accommodated during randomisation. This considers variations in surgical list sizes, and the need for sufficient CTR surgeries in close time-blocks to be able to provide the 10–14-day post CTR surgery appointment in a group. Participants that provide consent to be involved in the study will not be randomised until after their CTR surgery. A sample size of 84 (42 per arm) is sufficient to assess acceptability and feasibility (18).

**Randomisation**

A randomisation schedule of permuted block sizes of 2 and 4 will assign patients in a 1:1 ratio to groups. Blinding of allocation to group will be undertaken using opaque sealed envelopes prepared by persons not associated with the trial. Patients will only be randomised following confirmation of eligibility, consent and after their CTR surgery.

Post-randomisation, the nominated person performing the randomisation will inform the research hand therapist about which group the participant is allocated to and who will arrange and deliver the treatment. The participant will be informed of the allocation only by the hand therapist who will deliver the treatment allocation at the initial hand therapy appointment.

**3.3**  **Interventions / Procedures**

Both the usual care and TEG intervention are manualised interventions that will be delivered by accredited, qualified hand therapists who have been trained to deliver the intervention according to the intervention protocol.

A dated treatment case report form will be kept by the hand therapist including a post intervention checklist designed to record fidelity to allocated treatment intervention, recording any deviations from the protocol (eg. Post-operative complications requiring additional Orthopaedic surgeon review or additional hand therapy review appointments) and information related to clinician’s perceived feasibility of the intervention approaches (challenges, perceived benefits etc).

**Usual care**

The initial appointment occurs within 10-14 days post-operation in an in-person, one-to-one format for 30 minutes. During this appointment sutures are removed, and education is provided regarding carpal tunnel surgery, post-operation recovery and the hand therapy program involved. Additionally, range of motion (active tendon gliding, thumb and wrist) exercises and median nerve sliding exercises are prescribed three times a day to encourage early movement after surgery. Scar management including scar massage with non-slip matting 3 times a day, and silicone sheeting worn at night is commenced to reduce scar adherence and assist scar maturation.

A written home therapy program is prescribed, including provision of education, exercise and scar management patient handouts with text and photographic descriptions. A written log designed to prompt completion of the home program each day is provided at the first appointment (and will also be used to monitor adherence to the home program).

The second appointment is scheduled at six weeks post-CTR surgery in an in-person, one-to-one format for 30 minutes. During this appointment, review of progress occurs regarding pain, oedema, scar healing, range of motion and functional use. Strengthening is commenced using theraputty exercises 2 times a day.

**TEG model of care**

The first appointment occurs within 10-14 days post-CTR surgery in an in-person format. However, in contrast to usual care, it occurs in a group setting comprising up to four patients for 30 minutes to one hour. During this appointment, sutures are removed for each patient and education is provided as a group regarding carpal tunnel surgery, post-operation recovery and the hand therapy program involved. During suture removal, infection control measures will include the use of separate tables, social distancing, separate wound care packs, aseptic non-touch technique (ANTT) and handwashing between each patient. Range of motion (active tendon gliding, thumb and wrist) exercises and median nerve sliding exercises are prescribed as a group three times a day to encourage early movement after surgery and reduce scar adherence. Scar management including scar massage with non-slip matting 3 times a day, and silicone sheeting worn at night is commenced as a group.

In contrast to usual care, a home therapy program is prescribed using a mobile telephone / computer-based app comprising of interactive videos, reminders and prompts to increase self-monitoring to the home program.

The second appointment is scheduled at six weeks post-operation in a one-to-one format. In contrast to usual care, this appointment will routinely occur via a telehealth or telephone (depending on patients’ preference) 30-minute appointment. Progress is reviewed regarding pain, oedema, scar healing, range of motion and functional use. Strengthening is commenced using theraputty exercises 2 times a day.

**3.4** **Measures**

Independent assessor/s employed to co-ordinate and provide support to participants in completing baseline and follow-up intervention measures will be blinded (assessor blinded trial). No further measures to blind participants, clinicians or the research team will be implemented.

Baseline intervention measures will be collected after the participant’s CTR surgery and prior to their initial appointment which is 10-14 days post-CTR surgery. Follow-up measures will be collected within 1 week after the participant’s 6-week post-CTR surgery hand therapy appointment. All measures will be collected from participants by a blinded assessor in-person, by telephone call or electronically (depending on patients’ preference). Responses to the battery of measures will be captured using REDCap (Research Electronic Data Capture) as it is a secure web application for building and maintaining online surveys and databases and is specifically designed to support research studies. Metro North REDCap can be accessed from the Qld Health network. All correspondence by email to participants when sending measures for completion by the independent assessor will be as per appended script. Baseline measures will include demographic and injury information and health outcomes and will take approximately 10 minutes to administer. Follow-up measures will include acceptability, feasibility and satisfaction measures, health outcomes and close and open-ended questions about health-care use and perceptions of the intervention and will take approximately 20 minutes to complete.

**Demographic and injury information:**

Relevant demographic information including age, gender, years of formal education, occupation, and cultural background will be collected directly from the patient by the blinded assessor. Background injury information related to patients’ CTS will also be collected including duration of the complaint, dominant hand involvement, history of direct relatives with CTS, and whether they participate in a manual job or hobby (eg. high hand use).

**Acceptability:**

Acceptability of the TEG model of care and usual care model will be examined using the Acceptability of Intervention Measure (AIM), a 4 item, 5-point Likert scale, designed to measure acceptability of interventions (17).

**Feasibility:**

Feasibility of the TEG model of care and the trial design will be assessed by the number screened, eligible, approached and randomised (16), number of intervention sessions (group, one-to-one), number of participants in each group, number of ‘did not attend’ appointments, length of time spent at each appointment, resource needs and administrative time, follow-up rates and data completeness. Feasibility of the TEG model of care will be examined by recording number choosing phone/videoconferencing (telehealth mode as well as close and open-ended questions (listed below). The Feasibility of Intervention Measure (FIM), a 4 item, 5-point Likert scale, designed to measure feasibility of interventions, will also be administered (17).

**Satisfaction:**

The Patient Satisfaction Questionnaire Short Form (PSQ-18) is an 18-question patient satisfaction survey, divided into 7 subscales. Each item is rated on a 5-point Likert scale ranging from 1 (strongly agree) to 5 (strongly disagree). The general satisfaction subscale (2 questions) and the time spent with hand therapist subscale (2 questions) will also be administered.

The following closed and open-ended questions will be included to further explore participants perceptions about aspects of their intervention (either the TEG or usual care) as well as determine other healthcare use related to CTS during the trial period.

1. Did you attend other health care appointments (in addition to STARS hand therapy appointments) since your CTR surgery? (yes/no). If yes, please describe the type of appointments (eg. Physiotherapy) and how many appointments (eg. Each week for 1 hour)

1. Did you like receiving your first therapy appointment in a group / on a one-to-one basis? (Yes/No). Describe what you liked/didn’t like about the group-format/one-to-one format (eg. Would you change anything)
2. Did you like using the mobile phone app / written paper handouts to follow your hand therapy program? (Yes/No). Describe what you liked/didn’t like about the mobile phone app/written paper handouts (eg. Would you change anything)
3. Did you like having your follow up appointment via tele-rehabilitation (telehealth or phone) / face-to-face? (Yes/No). Describe what you liked/didn’t like about tele-health or phone/face-to-face
4. Are there any other comments you would like to make about the hand therapy you received at STARS after your recent CTR surgery?

**Health Outcomes:**

Pain: will be measured using the Numerical Rating Scale (NRS), a validated commonly used patient-reported outcome measure (PROM) for patient with CTS (22). It is used to assess pain severity at a moment in time using a 0 to 10 scale, with zero meaning ‘no pain’ and 10 meaning ‘the worst pain imaginable’ (19).

Health related Quality of Life: will be measured using the EQ-5D-5L, a generic measure of health-related quality of life that produces a single index value for health status that can be used for the purpose of clinical and health economic evaluation (20). The EQ-5D-5L consists of questions relating to five health domains (mobility, self-care, usual activities pain/discomfort, anxiety/depression) and respondents’ self-rate their degree of impairment using five response levels (no problems, slight problems, moderate problems, severe problems, and extreme problems).

Upper limb function: will be measured using the Boston Carpal Tunnel Questionnaire (BCTQ), the most used validated PROM for patients with CTS (22). It is an 11-item questionnaire, using a 5-point Likert scale, to measure symptom severity and functional status. When the items are summed and averaged, this produces an overall score with 1 being the best outcome.

The Patient Specific Functional Scale (PSFS) will also be used to measure upper limb function. It is a PROM used to quantify activity limitation and measure functional outcome for CTS. It is valid, reliable, responsive, and acceptable to patients (23). Patients are asked to identify up to 5 activities they are having difficulty with due to their condition and asked to rate the current level of difficulty on an 11-point scale, with 0 representing unable to perform the activity and 10 representing able to perform the activity at the same level as before the injury or problem. The total score is the sum of the activity scores divided by the number of activities listed, with the minimum detectable change for the average score for CTS being 2 points.

Adherence: to the home therapy program will be determined using the patient-completed home-program written log designed to prompt and monitor daily completion of prescribed home program activities. The method of return of the log at program completion with be based on the participant’s preference, being either by scanning or photographing and emailing, or by return using a stamped, self-addressed envelope provided by the hand therapist. Adherence to the TEG intervention will also be determined using the home therapy program app. Participant adherence data will be manually copied or downloaded from the app clinician portal, labelled with a participant ID number, and stored in a password protected excel file. This file will be stored in a de-identified form on TEAMS and UQ Research Data Manager, and only be accessible to members of the research team

**A summary of measures completed by each group at each time-point including approximate time required is summarised in the table below:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | UL: BCTQ and PSFS | Pain: NRS | EQ-5D-5L | Acceptability (AIM) | Feasibility  (FIM) | Satisfaction  Scale | Closed and open-ended questions | Approx Time |
| 5 mins | 1 min | 4 mins | 2 mins | 2 mins | 2 mins | 4 mins |
| Usual Care group | Baseline | ü | ü | ü |  |  |  |  | 10 mins |
| Follow-up | ü | ü | ü | ü | ü | ü | ü | 20 mins |
| TEG Group | Baseline | ü | ü | ü |  |  |  |  | 10 mins |
| Follow-up | ü | ü | ü | ü | ü | ü | ü | 20 mins |

**Cost data collection:**

Administration officer and hand therapist administrative time, treatment time, other health resources utilised (eg. equipment, app), and patient-related costs including out-of-pocket expenses and opportunity costs (eg. time away from work) will be collected.

**3.5 Analysis**

The comparison of interest is between the TEG model of care and usual care. Categorical variables will be summarised by frequency and percent and continuous variables by mean and standard deviation (SD) or median and interquartile range (IQR). Categorical variables will be examined using Pearson’s Chi-squared test or Fisher’s exact test and continuous variables by a student t-test or Mann-Whitney U test. A two-sided p-value < 0.05 will be considered significant. Incremental cost-effectiveness ratio will be estimated, which is the difference in costs divided by the difference in effects between TEG and usual care. Uncertainty around the ICER will be estimated using bootstrapping, the value of information analysis will be conducted to inform the value and efficient design of a larger study.

The study statistician will receive anonymised exported data sets for data checking and analysis. The chief investigator and study statistician have responsibility to ensure the integrity of the data and that all confidentiality procedures are followed.

**3.6 Ethical Issues**

Participants will be provided with information about the research study prior to, and when they are invited to participate in the study. They will be given the opportunity to ask questions and have them answered. Written informed consent will be obtained prior to participation in the study. Participants will be informed that participation in the research study is voluntary, and that they have the right to withdraw at any time without any consequence to any current or future care they receive at STARS. Participants will be informed that if they withdraw from the study at any stage, they will continue to receive usual care hand therapy following their carpal tunnel release surgery. Participants will also be informed that if they withdraw their consent during the research project, researchers will not collect additional information about them, but information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

STARS cultural liaison staff will be contacted to provide cultural support and facilitate involvement of all participants who identify as Aboriginal and/or Torres Strait Islander origin and/or participants of other cultural origin. For the TEG intervention 6-week post-CTR telerehabilitation appointment, participants will be offered the option of telephone if they are not confident with using telehealth. This is an aspect that will be considered when measuring the feasibility of the TEG model. A blinded independent assessor will support participants to complete baseline and follow-up intervention measures in-person, by telephone call or electronically (depending on patients’ preference).

Ethical approval and governance approvals will be sought from the Metro North Health Research Ethics Committee. All required resources (eg. patient facing information, study databases, participant logs) will be developed in readiness for recruitment to begin once all necessary ethical and institutional approvals are received. Any identifiable data will be securely stored in Qld Health servers (eg. Redcap) accessible only by members of the research team. Deidentified data will be stored in the University of Queensland Research Data Manager (UQRDM)for 25 years and then destroyed.

**3.7 Consumer Engagement**

Consumers who have had CTR surgery have been involved in pilot groups and have contributed to the development of this research protocol. 14 consumers who participated in group-based hand therapy post CTR at STARS were provided a summary of the research question and asked for input on how valuable they think researching this topic is. 93% of consumers rated researching this topic as either highly or very highly valuable. One consumer commented ‘I find research very valuable as it will hopefully help improve my recovery and make a difference to my care’.

Furthermore, Semele Robinson, a consumer with lived experience has received both group-based and 1-to-1 hand therapy post consecutive CTR surgeries. Semele is a member of the STARS consumer research group and has been involved in the design of this study by participating in a research Thinktank meeting. Semele has also been involved in the development of a Health Practitioner grant application to support this research project, which was successful and is a consumer co-investigator on the project. She has been involved in the development of the Participant Information Sheet and Consent form for ethics approval.

**3.8** **Resource Requirements**

Dr Emmah Doig will provide mentoring and support to the chief investigator Emma Taylor. Professor Trevor Russell will provide mentoring and brings expertise in the delivery of telerehabilitation and use of app-based technology to enhance interventions. Dr Ridzwan Namazie and Mrs Tamsin Mahoney bring expertise in the management of patients with CTS and will provide recruitment and research support. As the STARS orthopaedic case manager, Mrs Caroline Wegrzyn will coordinate participant screening, recruitment and consent. Professor Nadine Foster will bring expertise in the design and conduct of RCTs. At patients’ STARS orthopaedic clinic appointment, clinic nursing staff will offer patients written information about the research study (flyer and PICF) who have been booked and provide consent to receive CTR surgery at STARS. Associate professor Haitham Tuffaha will provide support in the design and analysis of economic data, and Dr Emma Ballard will provide support in statistical analysis. Mrs Semele Robinson as a consumer will bring a valuable patient perspective to the research design, design of patient facing information and usability of telerehabilitation and app-based technology.

Mrs Tamsin Mahoney as the STARS Director of Occupational Therapy is an associate investigator and is in full support of this research project. STARS is a fully digital, research-active hospital, with the STARS Education and Research Alliance, a 20-year partnership formed between Metro North Health and the University of Queensland.

The Health Practitioner Research Scheme (HPRS) budget of $29,994 (awarded 22/12/2022, reference AH003285, funding timeframe July 2023 to June 2024) (includes clinical backfill HP4.4 @ 0.45 FTE for 4 months) will be utilized for the chief investigator to undertake data analysis, write up and dissemination of research findings. The grant budget also includes consumer remuneration for attendance at monthly research team meetings via TEAMS, involvement in the construction and development of patient facing information, and in recruitment and dissemination activities. Additionally, the budget includes employment of a blinded independent assessor to co-ordinate and provide support to participants in completing baseline and intervention measures.

**3.9 Supervision and Research Team Meetings**

The chief investigator (Emma Taylor) will be formally supervised by mentors Dr Emmah Doig (STARS Education & Research Alliance Senior Conjoint Research Fellow), Professor Trevor Russell (Director of RECOVER Injury Research Centre), and Dr Ridzwan Namazie (STARS Orthopaedic consultant and Research Fellow). Supervision will occur regularly, with email correspondence as required.

The research team will meet monthly via TEAMS, and via email correspondence as required. This will include discussions regarding research project progress, opportunity for feedback and ongoing review.

**4 Dissemination of Findings**

Abstracts will be submitted to, and research findings will be presented at, relevant national and international conferences (eg. Australian Hand Therapy Association (AHTA) national conference). The RCT protocol and main report detailing research findings will be submitted for publication in international peer reviewed journals. Findings and outcomes will be presented to Queensland Health staff and community members (including recruited participants) at the completion of the project.

If research study findings support the feasibility and acceptability of the TEG model of care, it will be considered for use as standard hand therapy following CTR surgery at STARS, in addition to usual care. The TEG model aims to increase efficiency and outcomes, use telehealth delivery to improve patient access and app-based video-guided exercise and monitoring to improve self-management, adherence, and outcomes.

Furthermore, the TEG model of care has the potential to be applied to other common elective hand surgeries that have a routine post-operative hand therapy approach. There is scope for it to influence practice beyond the STARS setting given the high volume of CTR surgeries performed Australia-wide (1).

It is expected that the outcomes of this study will also determine the feasibility of a future fully powered randomised controlled trial (RCT) that will determine the clinical and cost-effectiveness of the model of care.

**5** **REFERENCES**

|  |
| --- |
| 1. Genova, A.,Dix, O., Saefan, A., Thakur, M., & Hassan, A. (2020). Carpal tunnel syndrome:   a review of the literature. *Cureus.* DOI 10.7759/cureus.7333 |
| 1. Wipperman, J., & Goerl, K. (2016). Carpal tunnel syndrome: diagnosis and management.   *American Family Physician*. 94: 993-999. DOI  <https://www.aafp.org/afp/2016/1215/p993.html> |
| 3. Multanen, J., Uimonen, M.M., Repo, J.P., Hakkinen, A., & Ylinen, J. (2021). Use of  conservative therapy before and after surgery for carpal tunnel syndrome. *BMC*  *Musculoskeletal Disorders*. 22: 484. DOI <https://doi.org/10.1186/s12891-021-04378-3> |
| 4. Nathan, P.A, Meadows, K.D., & Keniston, R.C. Rehabilitation of carpal tunnel surgery  patients using a short surgical incision and an early program of physical therapy (1993).  *American Journal of Hand Surgery*. 18: 1044-1050. DOI 10.1016/0363-5023(93)90401-N. |
| 5. Fufa, D. (2017). Recovery milestones for carpal tunnel release surgery. *Sports-health. 43:*  *25-26.* |
| 6. Howe, M.C., Schwartzberg, S.L. (2001). A functional approach to group work in  Occupational Therapy. Sydney, Lippincott Williams. |
| 7. Malec, J.F. Comprehensive brain injury rehabilitation in post-hospital treatment setting. In:  Sherer M, Sander A, ed. |
| 8. Yalom, I.D., & Leszcz, M. (2005). The theory and practice of group psychotherapy. New  York, Basic Books. |
| 9. Chung et al.(2020). Pilot study on comparisons between the effectiveness of mobile video-  guided and paper-based home exercise programs on improving exercise adherence, self-  efficacy for exercise and functional outcomes of patients with stroke with 3-month follow-  up: a single blind randomized controlled trial. *Hong Kong Physiotherapy Journal*. 40(1):63-  73. |
| 10. Sauders, R.J., Astifidis, R.P., Burke, S.L., Higgins, J.P., & McClinton, M.A. (2016). Hand  and upper extremity rehabilitation: Chapter 4 - wound care and suture removal. Sydney,  Elsivier. |
| 11. MacFarlane, R.J., Donnelly, T.D., Khan, Y., Morapudi, S., Waseem, M., & Fischer, J.  (2014). Clinical outcome and wound healing following carpal tunnel decompression: a  comparison of two common suture materials. *BioMed Research International.* DOI  http://dx.doi.org/10.1155/2014/270137 |
| 12. Albergoni, A., Hettinga, F.J., La Torre, A., Bonato, M., & Sartor, F. (2019). The role of  technology in adherence to physical activity programs in patients with chronic diseases  experiencing fatigue:a systematic review. *Sports Medicine - Open*. 5(41). DOI  https://sportsmedicine-open.springeropen.com/articles/10.1186/s40798-019-0214-z |
| 13. Gummeson, C., Ward, M.M., & Atroshi, I. (2006). The shortened disabilities of the arm,  shoulder and hand questionnaire (QuickDASH): validity and reliability based on  responses within the full-length DASH. *BMC Musculoskeletal Disorders*.1;7 (1):44. |
| 14. Budtz, C.R., Andersen, J.H., Andersen, N.D., & Christiansen, D.H. (2018).  Responsiveness and minimal important change for the quick-DASH in patients with  shoulder disorders. *Health and Quality of Life Outcomes.*16:266. DOI  <https://doi.org/10.1186/s12955-018-1052-2> |
| 15. Newman-Beinart, N.A., Norton, S., Dowling, D., Vari, C., Weinman, J.A., & Godfrey, E.L.  (2016). The development and initial psychometric evaluation of a measure assessing  adherence to prescribed exercise: the exercise adherence rating scale (EARS).  *Physiotherapy.* 103(2): 180-185. DOI <https://doi.org/10.1016/j.physio.2016.11.001> |
| 16. Wilson, C., Rooshenas, L., Paramasivan, S., Elliott, D., Jepson, M., Strong, S., Birtle, A.,  Beard, D.J., Halliday, A., Hamdy, F.C., Lewis, R., Metcalfe, C., Rogers, C.A., Stein, R.C.,  Blazeby, J.M., & Donovan, J.L. (2018). Development of a framework to improve the  process of recruitment to randomised controlled trials (RCTs): the SEAR (Screened,  Eligible, Approached, Randomised) framework. *Methodology*. 19:50. DOI  10.1186/s13063-017-2413-6. |
| 17. Weiner, B.J., Cara Lewis C.C., Stanick C., Powell B.J., Dorsey C.N., Clary A.S., Boynton  M.H., Halko H (2017). Psychometric assessment of three newly developed  implementation outcome measures. *Implement Science.* 29; 12(1): 108. DOI  10.1186/s13012-017-0635-3. |
| 18. Teare, M.D., Dimairo, M., Shephard, N., Hayman, A., Whitehead, A., & Walters, S.J.(2014). Sample size requirements to estimate key design parameters from external pilotrandomised controlled trials: a simulation study. *Trials*. 15(264). |
| 19. Stjernberg-Salmela, S., Karjalainen, T., Juurakko, J., Toivonen, P., Waris, E., Taimela, S.,  Ardern, C.L., Jarvinen, T.L.N, & Jokihaara, J. (2022). Minimal important difference and  patient acceptable symptom state for the Numerical Rating Scale (NRS) for pain and the    Patient-Rated Wrist/Hand Evaluation (PRWHE) for patients with osteoarthritis at the base  of thumb. *BMC Medical Research Methodology.* 127 (22). |
| 20. Feng, Y-S., Kohlmann, T., Janssen, M.F., & Buchholz, I. (2021). Psychometric properties  of the EQ-5D-5L: a systematic review of the literature. *Quality of Life Research.* (30): 647-  673. |
| 21. Horn, K.K., Jennings, S., Richardson, G., Van Vliet, D., Hefford, C., & Abbott, J.H. (2012).  The Patient-specific functional scale: psychometrics, clinimetrics, and application as a  clinical outcome measure. *Journal of Orthopaedic and Sports Physical Therapy*. 42 (1):  30-42. |
| 22. Mertz, K., Lindsay, S.E., Morris, A., & Kamal, R.N. (2020). Outcome metrics in the  treatment of carpal tunnel syndrome: a systematic review. *Sage Journals.* 17(4). |
| 23. Roe, A., Eppler, S., Koltsov, J., Shapiro, L., Yao, J., Sanjeev, K., Gil, J., & Kamal, R.  (2021). Is the patient-specific functional scale reliable and valid for carpal tunnel  syndrome: preliminary reports. (NB: Presented at Orthopaedic conference, not yet  published). |