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Education, night splinting and exercise versus usual care on recovery and conversion to surgery for people awaiting carpal tunnel surgery: a protocol for a randomised controlled trial

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ABSTRACT

Introduction: Carpal tunnel syndrome (CTS) is a prevalent upper limb condition that results in significant individual and socioeconomic costs. Large patient numbers, long outpatient waiting times and traditional referral pathways in public health systems create delays in accessing treatment for this condition. Alternative care pathways aimed at streamlining access to treatment and reducing the need for surgical intervention warrant further investigation.

Methods: A randomised, single-blind controlled clinical trial will be conducted. 128 participants aged 18–75 years with CTS will be recruited from the carpal tunnel surgery waitlists of participating public hospitals. Suitable participants will be stratified for severity and randomly allocated to either receive therapy (education, provision of splints and a home exercise programme) or standard care (continuing on the waitlist without hand therapy intervention for the duration of the study). Outcomes will be measured at baseline and after 6 weeks and 6 months. Primary outcomes are conversion to surgery ratio and perceived effect via the Global Rating of Change Scale.

Secondary measures include patient satisfaction, and monitoring of symptoms and function using outcome measures including the Boston CTS Questionnaire, Disability of Arm, Shoulder and Hand Questionnaire, Patient-Specific Functional Scale, patient completed diagram of symptoms and Self-reported Leeds Assessment of Neuropathic Symptoms and Signs pain scale.

Discussion: This paper outlines the design and rationale for a randomised controlled trial that aims to assess the efficacy of an alternative care pathway for the management of patients with CTS while on the surgery waitlist. It is anticipated that the outcomes of this study will contribute to improved and expedited management of this common condition in a public hospital setting.

Ethics and dissemination: Ethics approval was granted by the Princess Alexandra Hospital Centres for Health Research (HREC/13/QPAH/434—SSA/13/QPAH/447) and the Medical Research Ethics Committee at the University of Queensland. Results will be disseminated via conferences and peer-reviewed publications.

Trial registration number: ACTRN12613001095752.

Strengths and limitations of this study

- The protocol describes a prospective randomised controlled trial to assess the efficacy of an alternative care pathway for the management of carpal tunnel syndrome.
- The trial uses a robust pragmatic design replicating usual clinical practice.
- The results of this study will contribute to improved and expedited management of carpal tunnel syndrome in a public hospital setting.

INTRODUCTION

Carpal tunnel syndrome (CTS) is a condition caused by compression of the median nerve as it passes through the carpal tunnel at the wrist.[1] CTS is the most common nerve entrapment[2] with an estimated prevalence of 3.8% in the general population,[3] and 7.8% in the working population.[4] Symptoms include paraesthesia, pain, weakness and loss of dexterity in the affected hand.[5] Although there are several risk factors associated with CTS (such as age, diabetes and sex), in many cases, there is no identifiable causal mechanism or comorbidity.[6] CTS is associated with a significant socioeconomic burden due to its impact on productivity, function, quality of life and significant costs associated with its management.[6 7]

CTS is managed either surgically or non-surgically, with stronger evidence in support

of surgery compared to non-surgical options.[8 9] Despite well-documented evidence regarding the significant socioeconomic impact, CTS is typically considered a low surgical priority in publicly funded health systems.[10] The reality of long public hospital waiting times and traditional referral pathways (general medical practitioner to surgeon to therapist) creates significant delays in gaining access to treatment. Not only are these substantial waiting times likely to result in extended periods of reduced quality of life,[11] they may also compromise long-term outcomes as delayed surgery has been shown to be associated with poorer prognosis.[12]

Guidelines endorsed by professional associations suggest a trial of non-surgical interventions for patients with mild or moderate CTS symptoms, with surgery being the treatment of choice where symptoms are severe or prolonged, or for those whose conservative management has been unsuccessful.[6 13] Commonly recommended non-surgical interventions include use of splints, nerve and tendon gliding exercises and activity modification.[5 6 14–16] These recommendations are largely based on clinical observations as there is limited research-based evidence to guide non-surgical treatments. Given the unconvincing evidence for conservative approaches and the resulting reliance on clinical trends to guide practice, further investigation into non-surgical interventions is warranted.

The number of surgical interventions performed in the UK for CTS has been predicted to increase from 66 833 per year in 2015 to 104 922 per year by 2030.[17] Given that a single carpal tunnel release in the UK is projected to cost between £830[18] and £2600,[19] the extrapolated total cost of carpal tunnel release surgery to the UK health budget will exceed £55 million in 2015. This level of expenditure creates incentives for publicly funded health systems to manage CTS efficiently. In an effort to manage surgery waitlists and reduce costs, retrospective studies in the UK and Australia have examined the effect of alternative care pathways and therapist-led clinics for patients with CTS on surgical waitlists.[20–22] Despite limited data regarding the cost or clinical effectiveness of conservative interventions,[15 16] these retrospective case audits have shown a clear reduction in CTS surgery waitlists. The potential benefits of these models of care therefore warrant further investigation.

The aim of this project is to evaluate the efficacy of an alternative care pathway compared to standard care on the need for surgery and patient-rated outcomes in the management of patients with CTS while on the surgical waitlists.

METHODS/DESIGN

A randomised controlled multisite clinical trial will be conducted in four publicly funded hospitals within Queensland, Australia. This trial will compare therapeutic intervention (education, provision of splints and a home exercise programme (ESX)) to the current standard care (continuing on the surgery waitlist without conservative intervention) in the management of patients with CTS (figure 1).

Participants

Patients with a diagnosis of CTS who are on the orthopaedic department outpatient waitlist of participating Queensland Health hospitals will be contacted by telephone. Those interested in participating in the study will be sent an information sheet outlining the study as well as a brief questionnaire to assess eligibility. Patients who meet the selection criteria (box 1) and agree to participate will be invited for a baseline assessment by an occupational therapist or physiotherapist employed within the Hand Therapy department of the participating hospitals. During this first appointment, informed written consent will be gained from each participant. This study has received ethical clearance and approval from the relevant hospital and university ethics review boards.

Baseline assessment

During the first appointment, a clinical examination will be completed. This examination will include a detailed medical and social history (occupation, sports, hobbies), demographic data (age, gender, weight, height review of the nature and onset of symptoms, and observation for thenar eminence wasting).

Interventions

Once consented and included in the study, the patients will be allocated to randomly receive standard care or a programme of ESX.

Education, splinting and exercise

ESX will be provided by either an occupational therapist or physiotherapist during a single appointment, and then continues as a patient self-applied home-based therapy programme while the patients are on the orthopaedic department outpatient waitlist.

Patients allocated to receive ESX will attend a 20–30 min group education presentation by an occupational therapist or physiotherapist on the same day as their baseline assessment. This presentation will cover education regarding the pathophysiology of CTS, treatment options (conservative management and surgery), posture and activity modification principles.[23] This information will also be provided in the form of an education booklet which participants will be encouraged to review at home.

Participants will also be provided with a splint. The Berger test[5] will be used to determine if lumbrical muscle excursion into the carpal tunnel may be contributing to CTS symptoms.[24–26] This test involves the participant actively holding the fingers in full flexion with their wrist in neutral position. If symptoms worsen within 30 s, the test is deemed to be positive.[5] Those with a negative Berger test will receive neoprene wrist

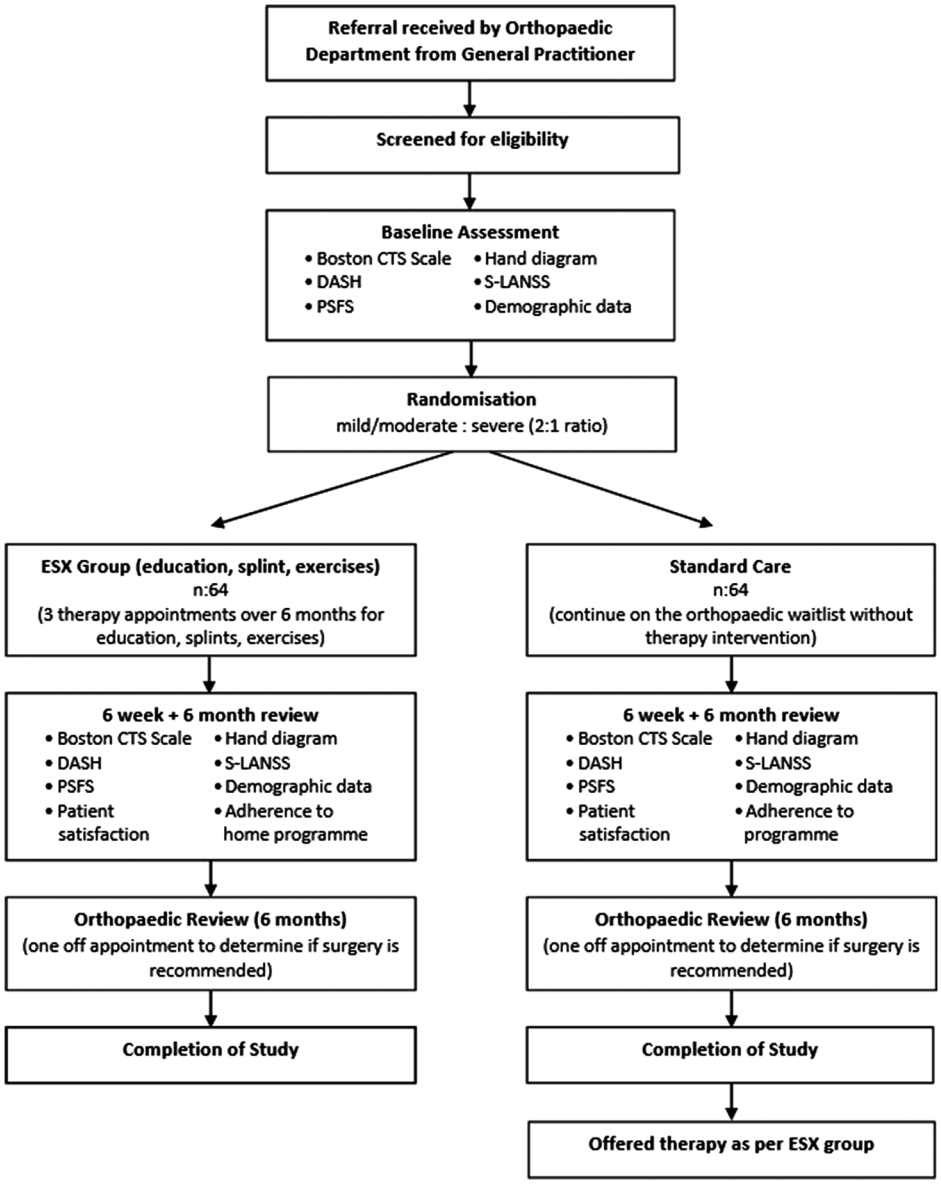

Figure 1 Study Outline. GROC, participant Global Rating of Change; DASH, Disability of the Arm, Shoulder and Hand; PFSF, Patient Specific Functional Scale; S-LANSS, Self-reported-Leeds Assessment of Neuropathic Symptoms and Signs.

supports with custom moulded thermoplastic stays that hold the wrist in a neutral position (figure 2A). Those with a positive Berger test will receive splints as described above but that extend distally to the level of the proximal phalanx and therefore limit metacarpal phalangeal joint flexion (figure 2B). Splinting has been shown to be of benefit in reducing symptoms[9 14] and patients will be requested to wear the splint during the night only.[27 28]

In addition to education and splinting, participants will be advised on a home exercise programme consisting of four exercises including median nerve and tendon-gliding exercises (figure 3A–C).[28–32] During the education session, therapists will assure that an accurate performance of these exercises is achieved by the patients. Nerve and tendon-gliding exercises have been shown to have a positive impact on symptoms[14] and reduce intraneural oedema in patients with CTS.[28] Patients are asked to perform 5–10 repetitions of each exercise five times a day in a manner that does not cause pain or increase symptoms. Participants who report an exercise-related increase of symptoms at any point during the study will be advised to contact the occupational therapist or physiotherapist. On doing so, the participant will be asked to trial a slightly modified version (such as completing exercises through a reduced range of motion) or to cease exercises completely if necessary.

Standard care

The standard care group will continue as per current practice to remain on the orthopaedic department outpatient waitlist for the length of the study (6 months) without receiving the education, splint or exercises described above. At the completion of the trial, the participants who underwent standard care (and have not had surgery) will be offered the option to receive the ESX intervention outlined above.

Box 1 Participant selection criteria

Inclusion criteria

- Referral to participating hospitals' orthopaedic department with a diagnosis of carpal tunnel syndrome (CTS);
- Diagnosis of CTS confirmed by nerve conduction studies;
- Clinical symptoms and signs consistent with CTS, such as altered sensation, numbness, paraesthesia or pain within the affected hand;
- Symptoms longer than 2 months;
- 18–75 years of age;
- Ability to comprehend the study, its requirements and provide consent.

Exclusion criteria

- Pregnancy-related CTS;
- Systemic disease other than diabetes;
- Osteoarthritis of the wrist or hand;
- Musculoskeletal conditions affecting the elbow, hand and wrist (such as de Quervain's tenosynovitis or trigger finger);
- Traumatic onset of CTS;
- Neurological conditions affecting the upper limb;
- Use of hand therapy interventions within the previous 3 months (splints or exercises);
- Steroid injection for CTS within the previous 6 months;
- Pending litigation or insurance claim.

Randomisation and allocation

The randomisation schedule will be generated using the Research Randomizer software (GC Urbaniak, S Plous. Research Randomizer (Version 4.0). Computer software. http://www.randomizer.org/2013 accessed 23 Sept 2013) and administered by an investigator who will not be involved with participant assessment, allocation or treatment. Allocation will be completed following consent and baseline assessment using sealed envelopes. Researchers completing the analysis and therapists completing the outcome measures will be blinded to allocation. Participants will be randomised into either mild/moderate or severe groups at a ratio of 2:1. For those with bilateral symptoms, the hand chosen to be included in the study will be allocated at random by flipping a coin, and both hands will be managed as per group allocation of the included hand.

Figure 2 (A) Night splint—wrist included in neutral position (used if participant has a negative Berger's test). (B) Night splint—wrist and *Metacarpal phalangeal joints* included in neutral position (used if participant has a positive Berger's test).

Stratification

Since it is expected that those with severe CTS will be less likely to respond to therapy, allocation will be stratified into mild/moderate or severe according to neurophysiological test severity according to the classification as suggested by Bland.[33] Severe CTS is defined as a score of 4 or above (severe, very severe and extremely severe, respectively) on the Bland classification.

Outcome measures

A battery of outcome measures will be used with the primary outcome measures being 'conversion to surgery' and the participant global rating of change. An investigator who is blinded to group allocation will administer the outcome measures at baseline and at 6 weeks and 6 months after enrolment in the study. The only exceptions to these time frames are 'conversion to surgery' which will only be evaluated at 6 months by an orthopaedic surgeon, and the participant global rating of change which will be evaluated at 6 weeks and 6 months.

Primary outcome measures

Conversion to surgery

Conversion to surgery is based on the surgeon's recommendation regarding whether or not the participant should have surgery. This decision will be made during a face-to-face appointment (as per standard practice) with the participant and an orthopaedic surgeon (either a Registrar or Consultant) at 6 months following randomisation, or earlier if rapid deterioration is identified. During this appointment, the surgeon will complete a form, which asks whether or not they would recommend surgery for that patient given their presentation and symptom severity at the appointment. Those identified as requiring surgery will be booked for carpal tunnel release as per standard practice at participating public hospitals. Those deemed to not require surgery will be discharged back into the care of their general medical practitioner. The percentage of participants requiring a carpal tunnel release in both groups will be compared. We will also seek participants' perspective whether they wish to proceed to surgery prior to their appointment with the surgeons. Comparison of conversion to surgery has been used in previous clinical trials to determine the success of non-surgical management.[34]

Participant Global Rating of Change

Participants will be asked to rate the change in their symptoms since starting the study on the global rating of change scale.[35] This scale measures perceived improvement on a 15-point Likert scale ranging from a very great deal worse

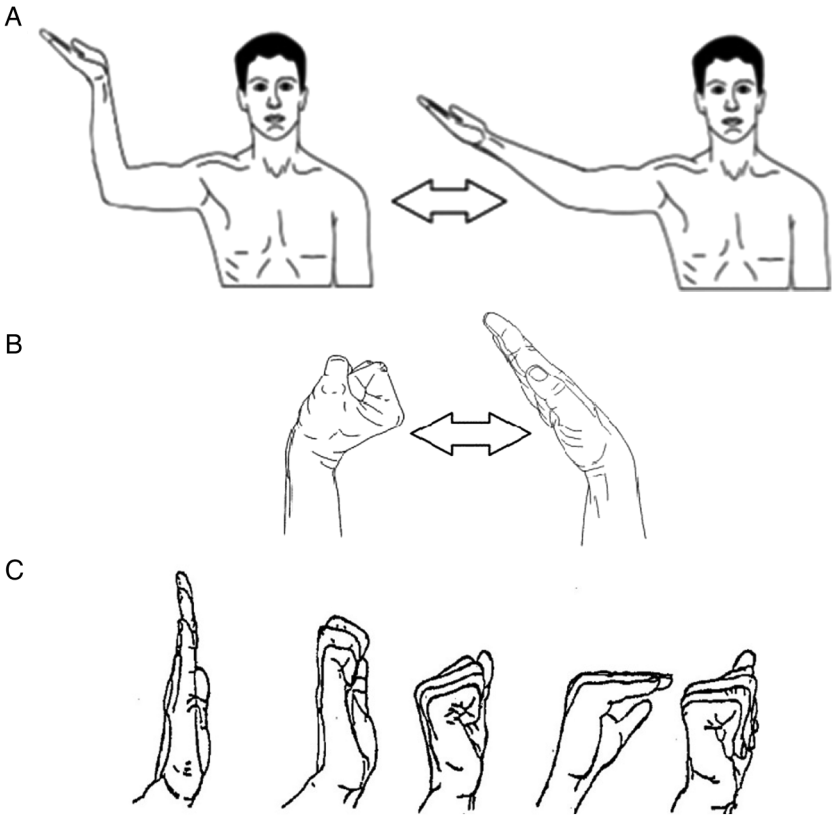

Figure 3 (A–C) Exercises performed by the ESX group (A) Median nerve-gliding exercises (forearm),[29] (B) median nerve-gliding exercises (wrist and fingers) and (C) tendon-gliding exercises[30] ESX, education, splinting and excercise. All exercises will be completed with 5–10 repetitions, 5 times per day in a pain-free manner.

to a very great deal better.[36] This questionnaire has previously been shown to have good reliability and validity in patients with musculoskeletal disorders.[37] As previously described, a score of ≥5 points (at least a 'good deal better') on this scale will be classified as 'improved'.[38 39]

Secondary outcome measures

Boston CTS Questionnaire

The Boston CTS Questionnaire is a two component, self-administered questionnaire. This questionnaire is CTS diagnosis specific, reliable, valid and responsive to change.[40 41] Both subscales result in a score between 1 (least severe) and 5 (most severe).

Disability of the Arm, Shoulder and Hand

The Disability of Arm, Shoulder and Hand (DASH) is a self-administered questionnaire that is responsive,[42] reliable and valid in patients with upper limb disorders[43] and CTS.[44 45] It comprises 30 questions with components relating to symptoms, functional status[46] and hand use. The final score ranges from 0 to 100 and a 10-point change in the total DASH score has been suggested as the minimal clinically relevant difference in repeat scores following carpal tunnel release.[47]

Participant completed hand and body diagram representing symptom distribution

Participants will be asked to mark symptom type and location on a diagram in order to monitor symptom distribution. This outcome measure is commonly used in patients with CTS[48] and will be used to evaluate symptom spread and the presence of extra-median symptoms.[49 50] Self-completed hand diagrams have been shown to be reliable in patients with CTS.[51]

The Patient-Specific Functional Scale

At baseline, participants will be asked to identify three important tasks that they are unable to do or have difficulty doing as a result of their hand problem. They will rate the difficulty they experience in completing that activity on a scale ranging from 0 (unable to perform the activity) to 10 (able to perform the activity at the same level as before the injury or problem). This scale has been established as reliable, valid and responsive in patients with musculoskeletal conditions[52] and upper extremity nerve injuries.[53] At the 6-week and 6-month time points, the patients will repeat the rating of the same activities on the 11-point scale.[54]

Self-reported Leeds Assessment of Neuropathic Symptoms and Signs

The Self-reported Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) scale is a seven question self-reported scale that aims to identify pain of neuropathic origin.[55] A value of ≥12 points on this scale is considered to be indicative of neuropathic pain. This questionnaire has been shown to be valid and reliable in

patients with neuropathic pain[55] and has previously been used in patients with CTS.[56]

Patient satisfaction with the treatment/management process

Since this study represents a change in care practices, patient satisfaction with the received treatment process will be included. The outcome measure to be used was adapted from Hall *et al*[57] and asks patients to rate their perceptions of treatment, satisfaction, function and progress on a seven question, 10-point Likert scale (see online supplementary appendix 1).

Adherence to home programme

Treating therapists will retrospectively monitor adherence to the above therapy programme at the 6-week and 6-month review appointments.[58] Adherence will be documented on a standardised form which details regularity of exercise completion and splint use, and if exercises could be correctly demonstrated to the therapist, they will also be recorded. Any deviations from the protocol, such as the receipt of any additional therapy or interventions for CTS, will be recorded; however, participants will continue within the study pathway as per randomisation.

Participant monitoring and management of adverse events

Following the 6-week review appointment, a therapist will discuss the progress of all participants (both standard care and ESX groups) with an orthopaedic consultant in the form of a brief case conference. This case conference will be used to provide an update regarding patient progress and, in particular, identify any participants with rapidly deteriorating symptoms for whom an orthopaedic review prior to the completion of the study may be indicated.

Participants will be encouraged to contact their treating therapist between appointments if any concerns arise regarding their home programme or if they experience an increase in symptoms. These concerns will be addressed by their treating therapist and details of the issue and outcome recorded. Any adverse events will be recorded and reported to the ethics committee as per institutional ethics committee requirements.

Training of therapists

All therapists involved in treating or assessing study participants will have completed training in regard to interventions and procedures. This training will include a self-directed review of the research protocol and reading three textbook chapters relating to contemporary rehabilitation of CTS.[5 59 60] To maintain consistency of practice, therapists will observe a member of the research team complete a clinical examination and ESX interventions and they will also complete these processes under guidance. Senior therapists and a site coordinator will be available to provide guidance in relation to the implementation of the research protocol and provide clinical assistance as needed.

Trial management

Data will be collected, managed, stored and confidentiality maintained as per Queensland Health policies. Investigators will meet regularly to monitor and discuss trial conduct. Additionally, this trial is subject to random audit by the approving research ethics committee. Protocol amendments will first be approved by the ethics committee and then disseminated to site investigators via meetings and updating of study resources and guidelines. All authors will have access to the final trial data set.

Sample size

The primary aim of this study is to detect a clinically important difference between the standard care and ESX groups in conversion to surgery rates. Power calculation revealed that 64 patients (stratified according to electrodiagnostic test severity into 43 mild/moderate, 21 severe) are required per group to detect a 25% lower conversion to surgery, assuming that the usual conversion rate is 69%[20] with a power of 80% at a 95% confidence level and allowing for a 5% loss to follow-up rate.

Planned data analysis

Appropriate descriptive statistics for all outcome measures and demographic characteristics across groups will be reported for baseline, 6 weeks and 6 months. Demographic and outcome measurement data at baseline will be assessed for comparability between groups. Comparative analyses between treatments will be performed using an intention-to-treat approach by an investigator blind to allocation. Outcomes will be analysed using linear mixed or logistic regression models, including respective baseline scores as a covariate, participants as a random effect, treatments as a fixed factor and covariate by treatment interaction at 6 weeks and 6 months. Regression diagnostics will be used to test data fit to assumptions. Hypotheses will be statistically tested at the 95% confidence limits.

DISCUSSION

Public health services are faced with the challenge of improving efficiency and managing increasing patient numbers with limited staffing and financial resources.[61] An ageing population and increased complexity of healthcare needs driven by the burden of chronic disease create significant challenges in provision of healthcare services.[62] Long waitlists for specialist orthopaedic appointments and surgery has been identified as a global issue.[61 63–65] This project aims to investigate the efficacy of an alternative care pathway that may assist in streamlining care and improve outcomes for patients with CTS who are on surgical waitlists.

Owing to limited clinical evidence for the non-surgical management of CTS, the ESX interventions were based on trends in clinical care and the success of similar clinical care models in retrospective reports. The choice of exercises followed evidence from previous studies which suggested beneficial biomechanical and neurophysiological

effects of these exercises in patients with CTS.[28 29] The relative ease of exercise completion and splint use may encourage patient self-management, thus limiting the number of therapy appointments required.

It has been suggested that conservative management for those with severe CTS is unlikely to reduce the need for surgery.[6] However, there is limited evidence relating to whether conservative management offers other benefits to those with severe symptoms, even if surgery is the end result. This information could be of significance for both patients and those managing their care. To assist in answering this question, participants with severe CTS will not be excluded from the study, but their group allocation will be stratified (mild/moderate and severe), allowing subgroup analysis. It is acknowledged that those with severe CTS are recommended to obtain care within a timely manner in order to prevent exacerbation of symptoms. In an effort to reduce this risk, the study follow-up time of 6 months is significantly less than current wait times (between 9 months and 6 years at the time of study commencement) to access specialist care at the sites included within this study. Additionally, participants will be monitored and managed as discussed earlier in this manuscript.

The surgeons' opinion on whether surgery is or is not required was chosen as the basis for the conversion to surgery outcome measures. Surgeons are the primary decision-makers in determining the need for surgery in the majority of settings. We will seek participants' perspective whether they wish to proceed to surgery prior to their appointment with the surgeons. This will allow evaluation of the relationship between surgeon and patient perspective in regard to need for surgery.

Since the care pathway being investigated uses clinically accessible interventions and outcome measures, it is anticipated that the results of this study will be applicable to the management of CTS in a wide range of hospital settings.

CONCLUSION

This paper outlines the design and rationale for a randomised controlled trial that aims to assess the effectiveness of an intervention clinic for the management of patients with CTS on the surgery waitlist. It is anticipated that the outcomes of this study will contribute to an improved and expedited management of this common condition in a clinical setting.

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Competing interests None declared.

Ethics approval Ethics approval was gained via the Princess Alexandra Hospital Centres for Health Research (HREC/13/QPAH/434—SSA/13/QPAH/447) and the Medical Research Ethics Committee at the University of Queensland.

Provenance and peer review Not commissioned; externally peer reviewed.

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