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The effectiveness of the Push Brace™ orthosis and corticosteroid injection for managing first carpometacarpal joint osteoarthritis: A factorial randomised controlled trial protocol

Susan E Peters[1], Bhavana Jha[1], Gregory B Couzens[1,2], Wilma Walsh[3], David Lisle[4] and Mark Ross[1,2,5]

Abstract

Introduction: Various conservative treatments for first carpometacarpal joint osteoarthritis have been reported. We aim to investigate the short-term effectiveness of conservative management interventions used to improve pain and function for adults with first carpometacarpal joint arthritis in a randomised controlled trial.

Methods: A pragmatic 2×2 factorial randomised controlled trial will be conducted. This randomised controlled trial will have one control group (hand therapy) and three intervention groups. Interventions will include Push Brace™ orthosis and hand therapy, ultrasound-guided intra-articular corticosteroid injection and hand therapy and a combination of all three interventions. A total of 276 participants will be recruited for the trial. The primary outcomes will be pain (reported using a Visual Analogue Scale) and function (using the Patient Rated Wrist/Hand Evaluation). Secondary outcomes will include osteoarthritis specific function, pinch strength, global change and quality of life. Adverse events and complications will be reported. Outcomes assessments will be completed prior to the intervention and at 3, 6, 12 and 24 months post-intervention. The trial will be conducted at a private hand surgery clinic in Queensland, Australia.

Conclusions: Results from this trial will contribute to the evidence on conservative management of first carpometacarpal osteoarthritis.

Keywords

Conservative management, carpometacarpal joint, orthosis, corticosteroid injection, exercise, joint protection

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Introduction

Osteoarthritis (OA) of the carpometacarpal (CMC) joint is a common problem that can lead to chronic pain impacting on function and quality of life. It has a prevalence of 23%–39% in adults over the age of 60.[1] Large amounts of force are transmitted through the joint during pinching and grasping functions. Consequently, these joints become vulnerable to OA.[2] Symptoms of pain, muscle weakness, deformities and instability reduce the function of the entire hand, causing significant impairment and disability.[3]

[1]Brisbane Hand and Upper Limb Research Institute, Brisbane, Australia
[2]Orthopaedic Department, Princess Alexandra Hospital, Woolloongabba, Australia
[3]Extend Rehabilitation, Brisbane, Australia
[4]Brisbane Private Imaging, Brisbane Private Hospital, Brisbane, Australia
[5]University of Queensland, St Lucia, Australia

Corresponding author:
Susan E Peters, Brisbane Hand and Upper Limb Research Institute, 9/259 Wickham Terrace, Spring Hill, Brisbane, OLD 4000, Australia.
Email: research@upperlimb.com

Conservative management

Most people who suffer from first CMC joint OA, irrespective of the severity of the disease, are believed to benefit from a period of conservative management.[4] These interventions focus on modifying the symptoms and may include oral medications, provision of orthosis, intra-articular corticosteroid (CS) injections, exercise prescription, application of thermal modalities and patient education regarding the principles of joint protection and activity modification.[5] Routine management offered as a first line of treatment to patients by both general practitioners and orthopaedic specialists includes a period of conservative management of up to three months before recommending surgery. CS injections into the CMC joint, a thumb orthosis and hand therapy are three of the most commonly offered interventions, either as stand-alone treatments or in combination.[6–8] There is a paucity of high-quality clinical trials with large samples, which have investigated the effectiveness of these interventions.[9]

Evidence on orthosis

Provision of a thumb orthosis is the preferred intervention recommended by medical practitioners and therapists.[8] The objective of an orthosis is to provide rest, external joint support, positioning and a reduction of the stresses on the supporting ligaments.[10] There is evidence to support the role of orthotics in providing symptomatic pain relief.[11] However, studies investigating the effectiveness of orthoses for thumb CMC joint arthritis have had mixed outcomes with no clear evidence supporting the superiority of any particular design.[7,12,13]

Splinting using a Push Brace™ orthosis is an emerging conservative management approach. The Push Brace™ (Nea International Push Braces, Maastricht, the Netherlands) is a custom-fitted off-the-shelf orthosis that provides support to the thumb CMC joint whilst not impeding mobility of the other hand and wrist joints. It is thought to be better tolerated by the patient whilst improving pain-free function, by supporting the thumb in a functional position. It is adjustable to the thenar eminence contour and can be easily applied and removed.[14] Despite the Push Brace being the orthosis of choice by many medical practitioners and therapists at our hospital, there have been no studies published on its efficacy.

Evidence on intra-articular CMC joint injections

Another conservative management, intra-articular CS injection is frequently offered by medical practitioners to ease pain by reducing the inflammation within the thumb CMC joint. Eighty nine percent of hand surgeons stated that they recommend CS injections for patients with thumb CMC joint arthritis and have anecdotally reported a positive response in pain reduction.[6] However, few trials to date have studied the effectiveness of CS injections compared to other interventions or a control/placebo group. The majority of studies on which surgeons have based their recommendations have focused on lower limb joints[15] or surgeon experience.[6] A double-blinded randomised trial by Meenagh et al.[15] investigated CS injections into the CMC joint and found no significant difference over a sham injection in a small sample of patients. However, they identified that their cohort had moderate to severe OA, and their injections were not ultrasound guided. They recommended further studies to evaluate the effectiveness of these injections, especially for patients in the early stages of OA. Correlations between relief of symptoms and severity of arthritis have further been demonstrated by Day et al.[16] and Khan et al.[17] Maarse[18] demonstrated short-term benefits in 78 patients following CS injection with no control group comparison. Thus, it is still unknown whether CS injections lead to better patient outcomes than other interventions or a control, despite its frequent recommendation as a treatment.

Evidence on hand therapy

Hand therapy is one of the most common treatments recommended by health care providers for patients with thumb CMC joint OA, regardless of the severity of the disease. This usually consists of advice regarding joint protection and activity modification, managing their pain and stiffness, including use of thermal modalities, prescription of basic hand exercises to maintain joint integrity and for improving function. There is moderate evidence for its effectiveness in this client group,[7] with benefits reported on improving function in a randomised controlled trial (RCT).[19]

Justification for a trial

The relative merit of orthotic use (Push Brace™), CS injection or a combination of both is a critical clinical question. Patients are informed by their treating specialists and therapists on which treatments to try. However, little evidence exists on which these decisions are made. This study will aim to answer the research question: Do patients receiving a combination of the Push Brace™ orthosis, an intra-articular CS injection and hand therapy have significantly greater improvement in pain and function, as compared to those receiving just the Push Brace™ orthosis, or an intra-articular CS injection, or the control treatment of hand therapy in adults with primary idiopathic CMC joint OA of the thumb?

Methods

The purpose of this trial is to investigate the effectiveness of conservative management interventions used to improve pain and function for adults with CMC joint arthritis in a RCT. Interventions will include the Push Brace™ orthosis, CS injection, hand therapy (control) or a combination of these interventions.

A four-group, assessor-blinded, pragmatic, RCT will be implemented. The trial is a 2 × 2 factorial design, with the Push Brace™ orthosis and the injection being the two independent variables (Figure 1). We have chosen a factorial design because it is an efficient way to evaluate more than one intervention in a single trial.[20] As CMC joint orthosis and CS injection are commonly prescribed both as isolated interventions and in combination, a factorial study design randomising to intervention was considered to be most appropriate.

Setting

Australia's health care system is a complex patchwork of public and private health care arrangements. For simplicity, it can be viewed as a universal health care system (Medicare), supplemented by a private health insurance system. This also means that care is provided by either public or private hospitals or by private health care professionals often in private clinics. Private health insurance is not mandatory. It is available to those people who opt to purchase a health insurance policy and can have varying levels of cover. Generally, private patients have more control over the provider of the health service including choosing their doctor or hand therapy provider, and generally have shorter waiting times for elective treatments than those accessing public health care. The amount of general expenditure in the private health system is approximately 38% of all health care expenditure in Australia.[21] For those who have private health insurance, reimbursement for certain health care services at a set rate can be made by the patient, in addition to those provided by Medicare. General practitioners usually act as the gatekeepers to the private health system, with a referral being a mandatory requirement for seeing a surgeon. General practitioners can also order diagnostic tests and write prescriptions. However, a referral is not necessary to receive hand therapy or physiotherapy treatment.

The trial will take place at the Brisbane Hand and Upper Limb Clinic, Brisbane Private Hospital, Brisbane, Australia. This is a private clinic, in which hand surgeons, physiotherapists and occupational therapists provide hand therapy services. Those without private health insurance can still access these health care providers, however, would not be able to claim any reimbursement from a private health insurer. As a result, the majority of the consumers receiving treatment from this clinic would have private health insurance. For the purpose of this trial, participants will not have any out-of-pocket expenses for either the orthosis or injection.

Ethics

Ethical aspects of this trial were reviewed and approved by the Mater Human Research Ethics Committee, Brisbane, Australia (Ref: HREC/14/MHS/140) and is registered with the Australian New Zealand

Push Brace™ Orthosis

Corticosteroid Injection	No Orthosis	Orthosis	totals
No Injection	Hand Therapy (n=69)	Orthosis + Hand Therapy (n=69)	138
Injection	Injection + Hand Therapy (n=69)	Orthosis + Injection + Hand Therapy (n=69)	138
totals	138	138	276

Figure 1. 2 × 2 factorial trial design.

Clinical Trials Registry (ANZCTR) (Ref: ACTRN12614000671662).

Data monitoring

Adverse events are expected to be minimal, and the interventions are not considered to be high-risk interventions (and are commonly prescribed for this patient population); hence, no independent data monitoring committee will be established.

However, we have several systems in place to monitor the conduct of the study including:

1. The medical advisory committee of the Brisbane Private Hospital will monitor progress of the trial and adverse event reporting;
2. The Mater Human Research Ethics Committee requires reporting of severe adverse events within 24 hours, as well as completion of annual progress reports;
3. We have assigned an external independent orthopaedic surgeon with research experience, to provide monitoring of implementation of the study protocol and processes. This surgeon is not otherwise directly involved in the study.

Participants

Participants will include adults who have been diagnosed with first CMC joint OA. As this is a study looking at symptom modification following conservative management, a minimal level has been set for the severity of symptoms. As there is no current consensus for entry level of symptoms for clinical trials, these have been based on recommendations by Maheu et al.[22] as described in the inclusion criteria.

Participants will be eligible for inclusion in the study if they are:

i. Male or female participants, aged 18 years and over;
ii. Have a clinical diagnosis of primary/idiopathic first CMC joint arthritis;
iii. Report a minimal level of symptom – either a pain score of at least 30 mm on a 100 mm Visual Analogue Scale (VAS) or a ≥ 22 (out of a maximum of 90) on the Australian/Canadian Hand Osteoarthritis Index (AUSCAN^{TM}) NRS 4.1 function subscale.

For patients seeking treatment for symptoms in both hands, treatment will be provided to both hands. For the purpose of the study, only the hand with the greater level of symptoms at baseline assessment will be included in the study. Patients commonly report one hand to be more symptomatic than the other. In the rare chance that symptoms are exactly the same, we will select the dominant hand for analysis.

Radiological confirmation of first CMC joint arthritis will be performed by an orthopaedic surgeon for all participants as per standard care. However, absence of radiological changes will not be an exclusion criterion as a correlation between radiological changes and symptoms is not always evident.[23]

Participants will be excluded from the study if they present with:

i. Inflammatory joint conditions, including rheumatoid arthritis and gout. These systemic illnesses have a different underlying pathology and are often required to be managed differently. There is also significant fluctuation in symptoms in these patients due to episodes of acute exacerbations. This may influence the outcomes reported by the patients;
ii. Significant Dupuytren's disease resulting in severely impaired function as it will be difficult to differentiate between the causes of the participants' functional limitations;
iii. History of previous conservative management of first CMC joint arthritis including use of splint and/or, a history of CS injection within three months prior to group allocation as their outcomes may be influenced by previous experience;
iv. Previous soft tissue injury or fracture of the thumb or wrist joints that has resulted in the participants having significant functional limitation;
v. Pregnancy due to the risks associated with the CS injections;
vi. Medical dependency that may interfere with ability to return for assessments or compliance.

Recruitment

Figure 2 shows a flowchart illustrating the expected flow of participants through recruitment, assessment and intervention. The trial will be advertised to the relevant services, and recruitment will take place via referral to the Brisbane Hand and Upper Limb Clinic at the Brisbane Private Hospital. All participants will be assessed and screened for eligibility by an orthopaedic surgeon. All willing potential participants who meet the eligibility criteria will be provided with an information leaflet about the trial. Informed written

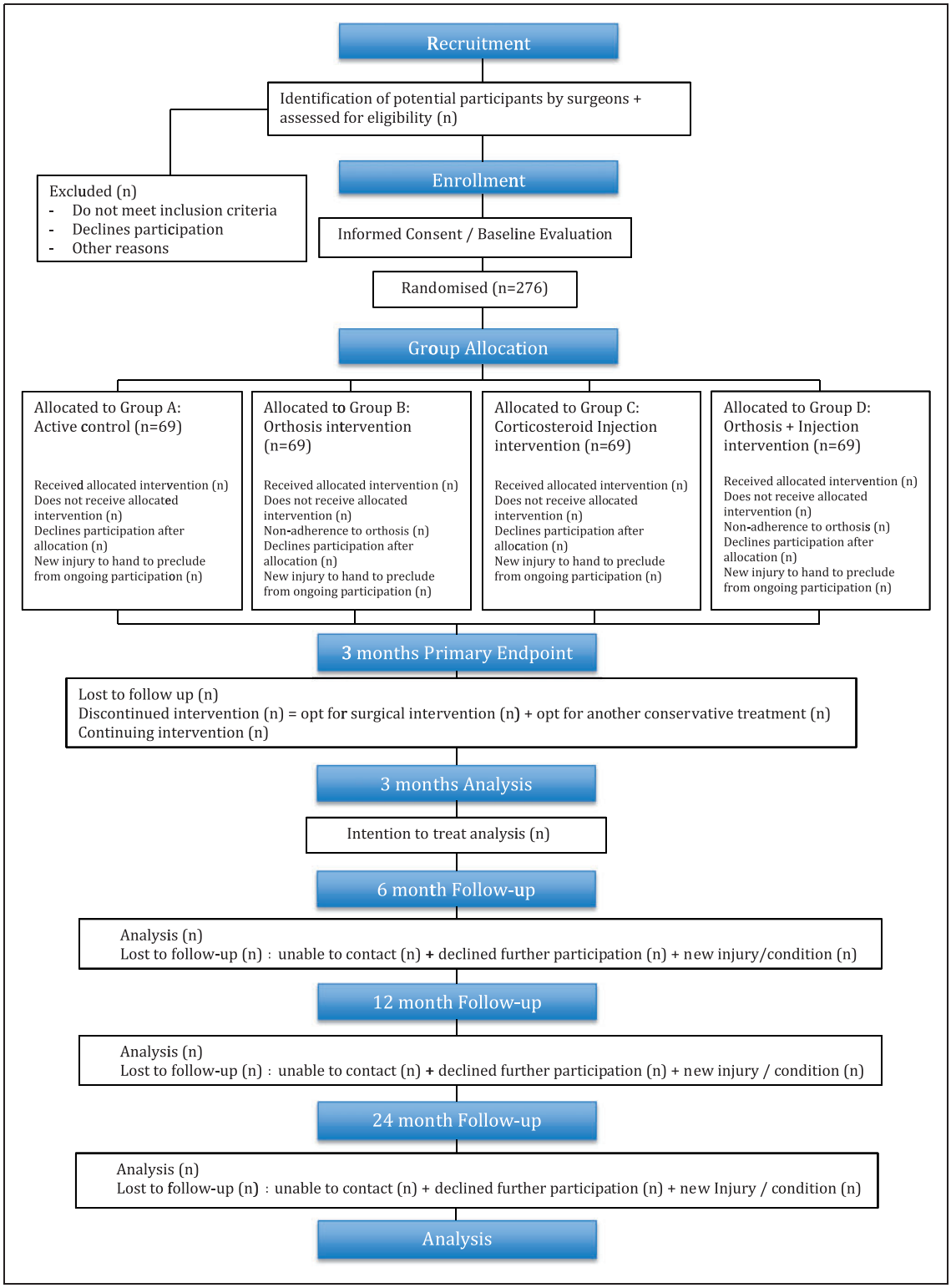

Figure 2. Diagram of expected flow of participants.

consent will be obtained prior to enrolment into the trial. Recruitment is anticipated to take 24 months based on historical data and an 80% recruitment rate.

Interventions

This study will have an active control group and three intervention groups:

Control Group A: Hand therapy
Intervention Group B: Push Brace™ orthosis + hand therapy
Intervention Group C: CS injection to the first CMC joint + hand therapy
Intervention Group D: Push Brace™ orthosis + CS injection to the first CMC joint + hand therapy

Hand therapy. All participants, irrespective of the group they are allocated to, will receive hand therapy. The control group will only receive hand therapy. Participants will receive a standardised exercise programme and advice on pain management including thermal modalities, joint protection and activity modification, both verbally and in written format (Table 1).

Push Brace™ orthosis. All participants in Group B and Group D will be fitted with the Push Brace™ orthosis, as per sizing instructions provided by the manufacturers, by a qualified occupational therapist or physiotherapist.

Corticosteroid injections. All participants in Group C and Group D will receive a single dose of ultrasound-guided intra-articular CS injection, provided by radiologists at Brisbane Private Imaging (Brisbane Private Hospital, Brisbane). A standard procedure will be followed. A mixture of Celestone Chronodose™ (Merck Sharp & Dohme Pty Ltd, Australia) containing 1 ml of betamethasone 5.7 mg and Marcain™ (AstraZeneca Pty Ltd, Australia) containing bupivacaine hydrochloride monohydrate will be used.

Sample size

A total of 276 participants will be recruited in the study (69 allocated to each group). Sample size calculations were performed for both the primary outcomes of (i) pain (measured using the VAS) and (ii) function (measured using the Patient Rated Wrist/Hand Evaluation – PRWHE). We estimate a loss to follow-up rate of 30%. The final sample size calculation was based on the PRWHE, which yielded the largest number of participants required to power the study, based on a minimal clinically important difference (MCID) of 15 and standard deviation of 25. Analysis of variance (ANOVA) (four groups) between factors with repeated measures was chosen, using a power of 80% and a type-I error rate of 0.025. Using G-Power 3.0[24] and considering

Table 1. Hand therapy standardised programme.

Therapy modality	Components
Exercise	1. Touch the tip of your thumb to the tip of your index finger, middle finger, ring finger and little finger, and then slide the tip of your thumb down your little finger as far as able without causing pain. 2. Move thumb away from palm to make a 'C' shape and then bring it back to starting position. 3. Move thumb away from palm – draw a circle in the air about the size of a 20-cent piece, moving in an anti-clockwise direction. Instructions: Move to the position where you feel a stretch but no pain. Hold this position for a count of 5. Repeat 5–10 times, 4 times a day. If it is painful, start with fewer repetitions and build up the repetitions gradually over time.
Principles of joint protection	1. Respect pain 2. Balance activities with rest 3. Use larger joints and muscles where possible 4. Modify activities to make it more efficient 5. Avoid prolonged gripping and postures 6. Avoid tight pinching and gripping activities which twist and deform the joints 7. Use assistive devices
Thermal modalities	A hot pack can be applied or hand can be immersed in a bowl of warm water for 20 min prior to commencement of exercises.

a loss to follow-up of 30%, each study group must enrol a minimum number of 69 participants.

Randomisation

Block randomisation will be performed in block sizes of 8. The randomisation sequence will be computer generated and concealed in sequentially numbered, sealed, opaque envelopes by a person, not otherwise associated with this research. Each envelope will contain a sheet of paper with the intervention group listed.

Once a participant has given consent and completed their pre-treatment assessment, they will be randomised and allocated to an intervention group. This will be done by a research assistant who will not be blind to allocation for the duration of the study. They will open an envelope and reveal the allocation to the participant. They will then make the necessary referrals for the different interventions.

Outcome measures

A suite of outcome measures recommended and previously used in research for this patient group will be used[22,25,26] (Table 2). These outcomes will be administered by a blinded assessor. However, due to the nature of the intervention, participants will not be blinded. Two primary outcome measures will be used. These will include the following.

Visual Analogue Scale (VAS). VAS will be used to assess pain. VAS is a commonly used tool for measuring pain intensity in clinical and research setting. Evidence supports its validity and reliability across many populations.[27–29] Participants will be requested to mark with a single slash (/) their response on the 100 mm line, which will be anchored at both ends with word descriptors.

Patient-Rated Wrist/Hand Evaluation. The PRWHE is a 15-item questionnaire designed to measure wrist pain and, specifically, disability in activities of daily living. It is a widely used and validated instrument specifically for this clinical population.[25] In addition to the individual subscale scores of pain and function, a total score can be computed on a scale of 100 (0 = no disability), where pain and functional problems are weighted equally. Participants are requested to rate 15 questions on a numeric score of 0 to 10.

Secondary outcome measures

Secondary outcome measures will include:

- Osteoarthritis specific function measured using the AUSCAN™ Hand Osteoarthritis Index NRS 4.1;
- Disability measured using the Disabilities of Shoulder, Arm and Hand short form (QuickDASH);

Table 2. Summary of outcome measures and evaluation time-points.

		Evaluation time-points				
Outcome	Assessment tool	Baseline	3 Months	6 Months	12 Months	24 Months
Pain	VAS[a] PRWHE[a]	Clinic	Clinic	Clinic	Clinic/Postal	Clinic/Postal
Function	PRWHE[a] AUSCAN™ Hand Osteoarthritis Index NRS 4.1	Clinic	Clinic	Clinic	Clinic/Postal	Clinic/Postal
Disability	QuickDASH	Clinic	Clinic	Clinic	Clinic/Postal	Clinic/Postal
Improvement in symptom/function	Global Rating of Change Score	X	Clinic	Clinic	Clinic/Postal	Clinic/Postal
Satisfaction	VAS	X	Clinic	Clinic	Clinic/Postal	Clinic/Postal
Grip strength	Jamar Dynamometer	Clinic	Clinic	Clinic	X	X
Pinch strength	Hydraulic Saehan Pinch Gauge	Clinic	Clinic	Clinic	X	X
Thumb range of movement	Kapandji Index	Clinic	Clinic	Clinic	X	X
Health-related quality of life	EQ-5D-3L(Australian)	Clinic	Clinic	Clinic	Clinic/Postal	Clinic/Postal
Adverse events	Study-specific generated checklist	Clinic	Clinic	Clinic	Clinic/Postal	Clinic/Postal

[a]Primary outcome measure.

- Change in symptom and function measured using the Global Rating of Change;
- Patient satisfaction measured using a 100 mm VAS;
- Grip strength measured using the Jamar Dynamometer;
- Pinch strength measured using the Hydraulic Saehan Pinch Gauge;
- Thumb opposition measured using the Kapandji Index;
- Health-related quality of life measured using the EuroQol (Australian Version) (EQ-5D-3L);
- Adverse events using a study-specific generated checklist.

Patient demographic information and baseline functional status will be collected after consent but prior to randomisation. This will include age and gender, hand dominance, primary occupation, identification of current and past activities that involves intensive use of the hand, general medical history including hypermobility (as defined by the Beighton Score[30]), history of smoking, OA history, including involvement of other joints, duration of symptoms, current and previous medications, surgical history of both wrists and hands and history of any alternative treatments used for symptoms relief by the patients, including supplements.

Participants will be advised to continue any routine alternative therapies and/or supplements that they have been using for the duration of the study.

Adverse events

Any adverse events occurring during the trial will be closely monitored and followed up until the complete resolution of symptoms. This will include all reactions listed for the medications and any reactions to the orthosis. These will be checked at each assessment stage and recorded on the adverse events/complication forms. Adverse events may include:

- Increased levels of reported pain;
- Any adverse reaction from the intra-articular CS injection;
- Any adverse reaction from the use of the Push Brace™ orthosis;
- Chronic regional pain syndrome.

Patient feedback will also be taken on the usefulness and compliance with the Push Brace™ and hand therapy advice provided to them. This information will be collected confidentially and used for data analysis without being available to the referring surgeons. A coding system will be used to maintain confidentiality.

Data collection

OA is a condition with significant symptom variability. The post-intervention data collection will be completed at the primary end-points of three and six months to provide sufficient time for detection of a clinically important difference. Data will also be collected at 12 and 24 months to evaluate the longer term therapeutic effect as recommended by Maheu et al.[22]

Blinding

Due to the nature of the treatments provided, it is not possible to blind the radiologists and hand therapists providing the treatments. The primary outcome measures are the patient-rated VAS and the PRWHE, and therefore, blinded assessment is also not possible. However, secondary outcomes will be collected by research assistants who will remain blinded to the group allocation. Data analysis will be performed blinded to the group allocation.

Participant retention and study completion

Patients will be evaluated at three months following a trial period of conservative management. Those patients who demonstrate a reduction of symptoms are advised to continue with the conservative management until they experience any further aggravation in their symptoms and are reviewed again by the surgeon at an interval of further three months (i.e. six months from commencement of treatment). Those patients who demonstrate no benefits from conservative management are able to consider other treatment options including surgery at this stage, in line with normal treatment recommendations for the patient populations.[4]

Assessments will be completed in person at baseline, three and six months; and either in-person or via a telephone follow-up or postal questionnaire for the 12 and 24 month intervals.

Statistical analysis

All analyses will be conducted using an intention to treat approach. Baseline demographic and clinical data will be reported using descriptive statistics and will be tabulated. Between groups differences in baseline data will be examined using unpaired conventional tests of hypothesis depending on the nature of the data. Between group and within group differences in outcome measures over time will be examined using a priori unpaired and paired conventional tests of hypothesis depending on the nature of the data. Linear mixed effects models will be used to examine the within and between group variability of the four groups.

Bonferroni adjustments for multiple comparisons will be made where appropriate to mitigate risk of type-1 error. The complication rates will be reported in terms of frequency. The frequencies of complications will be compared using statistical analysis such as the Pearson chi-square statistic.

Discussion

This randomised clinical trial is due to be completed in December 2017.

This trial examines whether a combination of hand therapy and an orthosis (using a Push Brace™), hand therapy and ultrasound-guided CS injection, or a combination of all three is more effective in managing pain and improving function, than an active control of exercise and joint projection education. This trial will build on the current evidence base. Whilst previous studies have examined the efficacy of orthosis[11–13] and CS injection[15–18], there is a lack of high-quality studies examining the effectiveness of these interventions in a RCT.

This trial uses a pragmatic approach to evaluate best-practice for conservative treatments commonly recommended for the management of CMC joint OA of the thumb. If one intervention is found to be more effective, this would assist clinicians and consumers to make evidence-based decisions regarding treatment for first CMC joint OA. If there is no difference found between the interventions and all are found to be effective in improving pain and function, this enables clinicians and their patients to make an informed choice based on patient adherence and cost-related factors.

Conflict of interest

None declared.

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Trial registration

Australian New Zealand Clinical Trial Registry, Ref: ACTRN 12614000671662.

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