Pre-print Manuscript

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Journal title: Physical Therapy Reviews
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First published version available online: 13-MAY-2020
DOI information: 10.1080/10833196.2020.1763662

This is a PDF file of an un-revised, unedited pre-print version of a manuscript accepted for publication. The Version of Record of this manuscript has been published and is available in Physical Therapy Reviews 13 May 2020 http://www.tandfonline.com/10.1080/10833196.2020.1763662

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The article can already be cited using the year of online availability and the DOI as follows:

M. Buhler, C. M. Chapple, S. Stebbings, J. Adams, D. Gwynne-Jones & G. D. Baxter (2020): Splinting for thumb carpometacarpal osteoarthritis: protocol for a feasibility randomized controlled trial, Physical Therapy Reviews, DOI: 10.1080/10833196.2020.1763662

Splinting for thumb carpometacarpal osteoarthritis: protocol for a feasibility randomised controlled trial

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Splinting for thumb carpometacarpal osteoarthritis: protocol for a feasibility randomised controlled trial

Background: Evidence for the use of splints to reduce pain and improve function and quality of life in thumb carpometacarpal osteoarthritis (CMC OA) is sparse and poor despite recommendations by international guidelines.

Objective: To outline the protocol for a study designed to determine the feasibility of conducting a fully powered pragmatic randomised controlled trial (RCT) comparing soft splint vs no splint for thumb CMC OA.

Methods: The proposed pragmatic, assessor-blinded, and partial participant blinded parallel-group feasibility RCT will recruit 30 adults with thumb CMC OA and randomise to: splint intervention or usual care control. Randomisation will be stratified by hand dominance. Primary feasibility outcomes are recruitment rate over a 4-month period, retention rate at 6 months, intervention acceptability, and rate of adverse events. Study costs, intervention fidelity, and clinical outcomes will also be evaluated. Measurements will be collected at baseline, 4 weeks, and 6 months post-initiation of treatment. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12618001639213.

Major Findings: N/A

Conclusions: If shown to be effective, soft off-the shelf splints would be a good first-line non-pharmacological, non-surgical option for thumb CMC OA as prescribed by health professionals or accessed directly by patients. This feasibility study will inform a future, fully powered RCT as evaluated by success of the recruitment strategy; assessment time and acceptability; implementation and evaluation of 'usual care'; and intervention procedures and adherence.

Key words: thumb; carpometacarpal; trapeziometacarpal; osteoarthritis; splinting; randomised controlled trial; feasibility study

Introduction

Symptomatic thumb carpometacarpal osteoarthritis (CMC OA) has an estimated age-adjusted prevalence of 22% in the UK community-dwelling population aged 50 years and over [1]. In the Swedish population aged 20 years and over, the rate of doctor-diagnosed thumb CMC OA is 1.4%, with prevalence 3-4 times higher in women than in men [2]. Over a 15-year period, one in 20 Swedish women presented to a physician with thumb CMC OA. In a North American population, the life time risk of developing symptomatic hand OA by age 85 is 40% [3]; the thumb CMC joint is the single most commonly affected site [1, 4] and contributes more to pain and disability in hand OA than other hand joints [4, 5]. Thumb CMC OA presents a substantial individual and societal burden and an aging population heralds a rapidly rising prevalence.

We recently completed a qualitative study to investigate the perspectives of patients with thumb CMC OA and identified the following key concerns: pain that interrupts sleep; limited ability to perform power grip and precision tasks; and limited ability to participate in work, caregiving, recreational and physical activities, and activities of daily living. Negative thoughts and feelings included frustration, anger, worry, concern about the future, and the burden of medication; and an altered sense of self, related to ageing [6]. Impact was greater where the dominant hand was involved [6].

Despite the high prevalence and significant impact of thumb CMC OA, there is a lack of high-quality evidence to support clinicians, patients, and policy makers in decision-making about interventions for the condition. Surgical intervention can provide relief but is usually reserved as the last option; joint replacement has not proven as successful as that for hip or knee OA [7, 8]. Pharmacological treatments carry risk such as adverse gastrointestinal, cardiovascular, and renal events resulting from nonsteroidal anti-inflammatory drugs, especially in the older population [9],

and injection therapies have not shown demonstrable efficacy [10]. Therefore, interventions that reduce the need for drug therapy or surgical intervention are highly desirable. Splinting is a non-pharmacological, non-surgical, biomechanical intervention to provide external support to the CMC joint, to reduce pain, prevent contracture, and maintain hand function [11]. Clinicians commonly prescribe splints [12, 13] and previous clinical studies have shown positive results, with significant reductions in pain and reduced demand for surgery [14, 15, 16]. However, because the strength and quality of the existing published evidence for splinting in thumb CMC OA is variable and often of poor quality, international treatment guidelines can make only weak recommendations for their use in splints for thumb OA [10, 17]. Although a recent guideline update advocates long-term use of splints [18], this is primarily based on an older single study of participants wearing a thermoplastic splint at night for 12 months [14, 19], a protocol not widely used nor well aligned to currently proposed mechanisms of effect [11, 13, 20, 21, 22].

The role of biomechanical interventions such as splints has been highlighted as a key area of osteoarthritis management in need of more research [7]. Our recent systematic review found splints to be a safe intervention; however, only low-quality evidence supports their use, and only in the medium-term (3-12 months) [20]. Furthermore, splints are made from a variety of materials and designs; currently, there appears to be no difference between splint types although this is based on very low-quality evidence [20].

One possible splinting solution is a soft neoprene splint, available off–the-shelf and easily fitted, making it a cheaper and more accessible option than other splints, and often preferred by patients [23, 24]. However, no study comparing a soft, off-the shelf splint with a no-splint control has yet been completed [20]. To conduct an effectiveness trial to a high standard, there is a need ensure that trial design minimizes research waste and optimizes quality of findings. To achieve this, study

elements are best assessed by feasibility study [25, 26]. Therefore, the primary aim of this study is to determine the feasibility of conducting a fully powered pragmatic randomised controlled trial (RCT) comparing soft splint vs no splint control for thumb CMC OA.

Specific criteria to determine feasibility are: recruitment of 30 participants in a 4-month period; retention >85% at 6 months; >90% find the intervention acceptable; and determine rate of adverse events [Table 1].

Secondary aims are: 1) to confirm the time required for assessor and clinician in the full study; 2) achieve intervention implementation in over 80% of prescribed time; 3) satisfactory quality-control audit of intervention; 4) determine success of recruitment and randomization; 5) explore whether treatment effects/outcomes are consistent with expectations based on previous literature. Data will be collected and analysed to investigate the impact of the splint vs no splint on patient-reported pain, function, quality of life, and use of other treatments including medication, and on physical performance variables (although due to small sample size these will be preliminary data only and unlikely to reach significance). We also aim to explore the potential role of imaging (X-ray and ultrasound) in evaluating participant characteristics at baseline and the ability of imaging to identify a subgroup of participants who may be more responsive to treatment.

Methods:

Study design

Pragmatic, assessor-blinded, and partial participant blinded parallel-group feasibility RCT with randomisation stratified by hand dominance. The proposed study will establish the feasibility of conducting a fully sized future trial designed to assess the superiority of a soft prefabricated splint intervention vs no splint intervention at the 4-week follow up. Measurements will be collected at baseline, 4 weeks, and 6 months post-initiation of treatment. The nature of the intervention offered

will not be revealed to participants until after the 4-week follow up to avoid bias in how they perceive the intervention at the primary end point; i.e. participants will remain blinded to the study hypothesis until after the 4-week follow up. The protocol adheres to the SPIRIT 2013 Statement [27], which defines standard protocol items for clinical trials, and is informed by the CONSORT 2010 Statement extension for randomized pilot and feasibility trials [28]. A sample size of 30 participants is considered sufficient for a feasibility study [29, 30].

This trial has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12618001639213. The trial can be viewed at http://www.ANZCTR.org.au/ACTRN12618001639213.aspx

Setting

The study will be conducted in health settings in two centres in the South Island of New Zealand (Dunedin and Invercargill). A clinical research administrator at the hosting research centre will manage recruitment processes and provide administrative support for the study. An independent research assistant blinded to participants' allocation will conduct the baseline, 4-week, and 6-month assessments. A registered hand therapist/physiotherapist with 17 years clinical experience (MB) will implement the intervention.

Participants

We aim to recruit adults with symptomatic CMC OA – either physician diagnosed, or history suggestive of thumb CMC OA with clinical signs and no other specific diagnosis (Table 2).

Currently, no specific clinical classification criteria for thumb CMC OA exists. Therefore, an accepted method for identifying history suggestive of hip/knee OA [31] will be adapted for use in the thumb, along with clinical assessment adapted from the American College of Rheumatology

criteria for generalised hand OA [32]. If an eligible participant presents with bi-lateral thumb pain, only the self-nominated ‘worst’ thumb will be included.

Participants will be recruited between April and July 2019 from community and health settings, including secondary public health services in the two centres. Recruitment will be by way of advertisement or clinician invite. The recruitment strategy will aim to optimize the number of indigenous New Zealand Māori participants by recruitment through Māori health providers, recruitment of those who may not have previously sought treatment, through newspaper, community, and GP adverts, and by recruiting in the second centre of Invercargill where a higher proportion of the population are of Māori descent compared to that in Dunedin [33]. Potential participants will contact the research administrator for a Patient Information Sheet or download this from the study website.

Randomisation and allocation concealment

The randomisation schedule will be prepared by the clinical research administrator by computerized sequence generation and concealed in series of opaque envelopes according to three randomisation blocks (dominant vs nondominant vs ambidextrous). Following the consent process and baseline assessment, the next envelope in sequence in the relevant block will be opened by the clinician to reveal group allocation. Study procedures are outlined in Figure 1.

Blinding

It will not be possible to fully blind participants or the treating clinicians to group allocation due to the nature of the study intervention. However, to provide partial blinding, the study hypothesis will not be revealed to participants until after the 4-week follow up visit. Information provided to participants will explain that the exact nature of the treatments offered to the opposite group will

be concealed from them until after the 4-week follow up so that their perceptions about the intervention do not influence the study findings at this time period.

Instruction will be given to the treating therapist, assessors, and all health professionals and administration staff involved in participants' care to conceal this information until after the 4-week follow up. Outcome assessors will not be involved in participant care and will be blinded to group allocation. Participants' splints will be removed prior to assessment and participants will be instructed not to disclose information about their treatment.

Intervention

Participants randomized to the intervention group will be fitted with a soft neoprene hand-based splint (Procool T/R Splint Bound, @Therapy), issued a second (for one to wash, one to wear) and instructed to wear the splint 20 hours out of 24 for 4 weeks. An explanation of the rationale and wearing schedule for the splints will be given.

A simple behavioural intervention will accompany the splint prescription comprising dedicated time for skill acquisition and practice within the treatment session for donning and doffing the splint; providing feedback and encouragement; and fostering self-efficacy through problem solving to incorporate the splint in everyday life [34]. Minor modifications may be made to the splint (shorten or alter shape of the thumb exit space by cutting; alter length of strap through web space or wrist using NRX Strap, @Therapy or OneStrap, Mitre10 Mega) for optimal fitting while maintaining splint aesthetic and integrity. Splint intervention procedure will comprise a one-off face-to-face consult anticipated to take maximum 20 minutes per participant and follow a 1-sided A4 information sheet specific to the left (Supplementary 1) or right (Supplementary 2) hand. Participants will be asked to complete a daily log to record the number of hours splint worn and any reasons for not wearing the splint (for those in the intervention group),

implementation of usual care, , any concerns or problems, and any change in medication, according to a template form (Supplementary3). The 4-week timepoint will mark the end of the intervention period.

Standardised usual care

Both groups will receive a standardised package of recommended best-practice usual care – verbal and written education about thumb CMC OA and joint care principles, simple hand exercises, and advice to increase general activity levels (walking or pool) [7] following a 2-sided A4 information sheet specific to the left (Supplementary 4) or right (Supplementary 5) hand with additional verbal cues (Supplementary 6), plus continue with usual physician care. The same behavioural approach will be taken as for the splint intervention. The standardised usual care package will be delivered at a one-off face-to-face consult anticipated to take 25 minutes per participant, by the same person delivering the intervention (MB). Participants in the no splint group will be asked to log daily as above, with the exception of splint wearing (Supplementary7).

If participants in either group require assistance during the 4-week treatment period, they may contact the research administrator for the treating therapist to make an arranged call to the participant. If any issue is unable to be resolved by telephone consult, then a follow up treatment session will be arranged. Participants will not be offered additional treatment after the 4-week intervention period is complete; participants randomized to the best-practice usual care group will not be offered the splint intervention as there is currently insufficient evidence to demonstrate that this intervention is effective.

At the completion of the 4-week intervention period and following the 4-week follow-up assessment, the treating therapist will telephone or email (as preferred) each participant to ask

about any adverse events, counsel the participant regarding intervention received by the other group, reiterate that the treatment period is complete, and advise that any of the standardized usual care and/or splint intervention may be continued at the participant's discretion.

Intervention development

The splint intervention and standardized usual care were developed through two stakeholder focus groups (n=6, n=2) and a single one-to-one interview (n=1) run by the first author (MB) with experienced Hand Therapy New Zealand-registered hand therapists (physiotherapists and occupational therapists) working in public and private practice settings in New Zealand. The development of the standardised usual care package was informed by a previously published resource widely used in hand therapy clinical practice [35] and best available evidence [36] and expert opinion [37] regarding specific exercise programmes for thumb base OA.

Intervention fidelity

Measures to optimize adherence to the intervention and standardized usual care include: ensuring the splint is comfortable, well fitted and aesthetically acceptable; advising how to successfully adapt activities without compromising the splint regime [38]; establishing a trusting relationship by providing education and rationale for treatments [39]; catering for different learning styles [40]; and implementing simple behavioural intervention [34]. Adherence will be measured by a daily patient log – recording splint wearing time in the intervention group and recording uptake of standardized usual care in both the intervention and the control group. The clinical research administrator will telephone or text reminders (as preferred) on a weekly basis to remind the participant to complete the daily log.

Clinical assessments

The clinical assessments (secondary outcomes) are a combination of self-reported and performance measures. Assessments are collected at baseline, then at 4 weeks and 6 months (Table 3). Patient characteristic variables will be collected at baseline (Table 4). Grip strength will be measured using the same dynamometer for all assessments for each participant (i.e. one dynamometer in Dunedin and one in Invercargill).

Imaging

X-ray imaging will occur for each participant to characterise radiological involvement of the CMC joint at baseline, unless a recent (< 6 months) X-ray of good quality is available. X-rays will be interpreted by a consultant orthopaedic surgeon according to the OARSI-atlas grade for individual features (osteophytes and joint space narrowing) [41] and modified Eaton-Littler grade [42], with a second independent interpretation by a Professor of Radiology. X-rays may help to identify potential factors that predict treatment response. A random selection of X-rays will be repeat read by a consultant radiologist.

Similarly, ultrasound imaging will be performed in a convenience sample of eight participants at the Dunedin site. Ultrasound imaging will be undertaken and interpreted independently by two consultant rheumatologists (SS) with experience and training in musculoskeletal ultrasound, according to a recommended scanning protocol [43], each patient being scanned blind by both clinicians.

Clinicians involved in acquisition and/or reading of X-rays or ultrasound images will be blinded to group allocation.

Quality audit

Quality of intervention delivery and outcome assessment will be audited using a pre-defined quality audit tool based on that used in the OTTER trial [2019 email from fourth author (JA) to first author (MB)].

Training of independent assessors

Three independent health research assistants (two in Dunedin and one in Invercargill) will be trained to conduct baseline and follow-up outcome assessment according to assessor manual (Supplementary 8). Each participant will be assessed by the same assessor at each of the three assessment timepoints.

Statistical analysis

Data analysis

Data analysis will comprise descriptive analysis of the feasibility outcomes and appraisal against feasibility criteria. Baseline participant characteristics will be presented using descriptive statistics (mean, standard deviation and 95% confidence interval). Differences between the groups at different time points will be described but formal statistical analysis will not be undertaken due to the small sample size.

Ethics

This study will be conducted according to good clinical practice guidelines and in compliance with the Declaration of Helsinki. Investigators who are also clinician employees of the Southern District Health Board (MB, SS and DGJ) will not be involved in gaining consent from potential participants to avoid any potential perception of coercion. A $20 petrol voucher along with other benefits of involvement in the study including education and advice about thumb base OA, will reimburse participants for their costs incurred in attending each of the three assessments. The

study has ethical approval from the New Zealand Northern B Health and Disability Ethics Committee Ref 18/NTB/240.

Notification of adverse events

Participants will be asked to notify the research administrator of any adverse events. These will be forwarded to the study treating therapist who will address concerns with the patient by telephone in the first instance and in person if necessary and/or refer on for further care. All adverse events will be recorded and brought to the study monitoring committee. Splinting is a low risk intervention and few adverse events are anticipated.

Discussion:

This study will contribute to a broader programme of OA research that aims to enable equitable access to low cost non-surgical, non-pharmacological treatments to improve daily life and maintain healthy ageing for people with OA in New Zealand and internationally. The current study will provide essential information about the feasibility of conducting a future full-sized trial. If shown to be feasible, a subsequent RCT investigating the effectiveness of a soft off-the shelf splint as first-line option for managing thumb CMC OA will be undertaken using the current protocol with any adaptations resulting from analysis of the feasibility data. The contribution of expert clinicians in the study development will enhance relevance and uptake of the study findings to the real-world clinical setting. This project embeds methodology that aims to ensure participants of Māori descent are included in the generation of new health knowledge, a key step in addressing the poor health care utilisation for osteoarthritis by Māori (19). Further, the inclusion of participants who have not sought care for their thumb CMC OA will help to ensure that findings from the current study are relevant for equitable health outcomes across the spectrum irrespective of barriers to accessing health care. Ultimately, findings can inform health

funding policy on provision of orthotic devices for people with thumb CMC OA, and clinicians will be better informed and more likely to nominate an appropriate intervention for their patients.

Acknowledgments

An industry partner (At Therapy, Auckland, New Zealand) will supply the splints and loan of a pinch grip assessment equipment at no cost, with no influence on study design, data analysis or reporting. Ms Buhler's work is supported by a University of Otago Doctoral Scholarship and the Centre for Health, Activity and Rehabilitation Research, School of Physiotherapy, University of Otago. The authors thank the Hand Therapy New Zealand-registered hand therapists who participated in the stakeholder focus groups and interview for the development of the standardized usual care and splint intervention: Amy Wang, Kirsty Clunie, Julie Collis, Diana Edwards, Shirley Collocott, Elaine Duguid, Evangeline Leys, Helen Hills, and Jane Sweeney.

Funding

This study is funded by the Otago Medical Research Fund Jack Thomson Arthritis Fund (Award No. OMRF-JT381).

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Figure captions

Figure 1. Participant flow diagram

Table 1 Feasibility trial objectives and primary outcomes

Study objectives	**Primary outcomes**	**Feasibility criteria**
1. Recruitment and retention: to be able to determine the number of potential participants needed to be screened across two centres to meet sample size requirements in given timeframe	Number screened, number eligible and number allocated, over 4-month period or until 30 participants are allocated, whichever is earlier. • *Proportion of population coming forward* • *Proportion of screened eligible* • *Proportion of eligible allocated* • *Proportion of allocated assessed at 4 weeks, 6 months* • *No. of days to allocate 30 participants.*	Recruit 30 participants in 4-month period. Retain >85% of participants at 6 months
2. To determine acceptability of splint intervention	Exit interview with participants (qualitative data).	≥90% of participants find intervention acceptable.
3. Determine rate of adverse events	Number of major adverse events; rate of minor adverse events (type and number of events).	Consideration by trial monitoring committee (Co-investigators and Advisors).

Table 2 Table of inclusion and exclusion

Inclusion criteria	Exclusion criteria
• Aged 40+ years • Physician diagnosis of thumb base OA OR answer "yes" to the question, "Have you experienced aching, discomfort, pain and/or stiffness in or around the joint at the base of either thumb on most days for at least 1 month (15 or more days of the month) during the past year?" and have no other specific diagnosis[31]. • Minimum severity pain VAS 4/10[44] • Minimum score FIHOA 6/30[44] • One or more clinical sign(s) of 1st CMC joint involvement*. • Give written informed consent	• Thumb non-symptomatic for the past month • Previous surgery of the symptomatic joint • Steroid injection in the past 6 months • Previous splint intervention prescribed by health professional • Concurrent rheumatoid arthritis or any other significant musculoskeletal, inflammatory or autoimmune conditions affecting the hand such as scleroderma, systemic lupus erythematosus and psoriatic arthritis, or another kind of chronic pain syndrome or metabolic disorder, such as fibromyalgia, diabetic neuropathy, or gout. • Injury to thumb/wrist in past 6 months • Unable to comprehend instructions and outcome measure instruments in English.

* See clinical tests outlined in Table 4 Baseline characteristics

Table 3 Secondary outcome measures

Assessment – secondary outcomes:	**Measurement scale:**	**Time*:**
Pain numeric rating scale (NRS) for pain at base of thumb, on average in past week	0-10	0, 4, 26
Pain at base of thumb interfering with sleep (NRS), on average in past week, and dichotomous	0-10 Yes / No	0, 4, 26
Functional Index of Hand Osteoarthritis (FIHOA) (10 questions relating to function, rated 0-3; low score is better) [45]	0-30	0, 4, 26
Additional functional and participation questions (from qualitative study [6])	0-3	0, 4, 26
Quick Disability of the Arm, Hand and Shoulder (QuickDASH) (11-item questionnaire, rated 0-4; low score is better)	0-100	0, 4, 26
GROC (Global Rating of Change)	-5 to +5	4, 26
Patient-reported health status (EQ5D)	0.0 – 1.0	0, 4, 26
NSAID Equivalent score (+/- other medications)		0, 4, 26
Other interventions sought (including surgery)		4, 26
Power grip strength, dynamometer (best of three)	Kilogram	0, 4, 26
Pinch grip strength, dynamometer (best of three)	Kilogram	0, 4, 26
Inter-digit distance (length of 1st webspace, ruler)	mm	0, 4, 26
CMC joint palmar abduction (Pollexograph – purpose-built box with protractor printed on top) [46]	Degrees	0, 4, 26
Grip Ability Test (GAT) (test of functional performance, timed)	Seconds	0, 4, 26
OMERACT-OARSI responder [47]	Yes / No	4, 26

*0 = baseline, 4 = 4 weeks, 26 = 26 weeks (6 months)

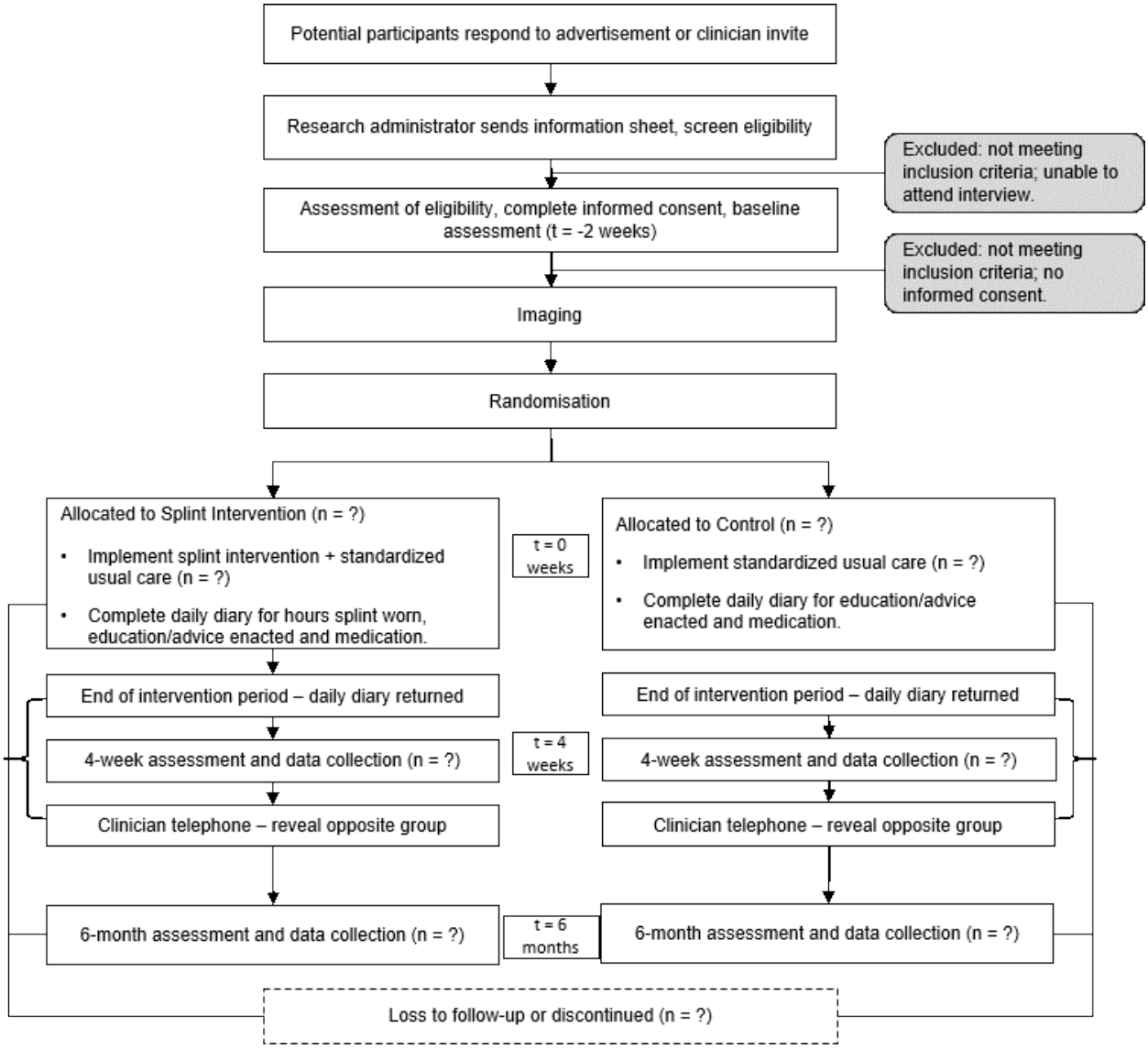
Table 4 Participant baseline characteristics

Participant characteristic variable:	**Measurement scale:**
Age	years
Gender	male / female / gender diverse
Ethnicity	
Descent	
Work status	Full time / part time / not working / student / in the home / unemployed or seeking work / age retired / disability pension / sick leave
Dominant hand	Left / Right / Ambidextrous
Hand with thumb CMC OA	Left / Right / Both
Thumb osteoarthritis diagnosed by health care provider?	Yes / No
If yes, which health care provider?	GP, physio/hand therapy, rheumatologist, surgeon
How long have you had your thumb CMC problem(s)?	years
Other joints with osteoarthritis (besides your hands):	
Other medical conditions	(e.g. rheumatoid arthritis, other arthritis, gout, diabetes, heart problems)
Current medications	
Current and previous treatments for thumb CMC problem	
Thumb MCP hyperextension at rest	degrees
Joint tenderness on palpation*	Present / absent
Grind test* [48]	Positive / negative
Pressure-shear test* [49]	Positive / negative
“Step-off” sign* [32]	Present / absent
BMI	

X-ray: standard PA view, OARSI-atlas grade for individual features (osteophytes, JSN) [41]; Eaton-Littler grade [42]	0-3 0-4
Ultrasound: grade for synovitis and osteophytes ;	0-3 semi-quantitative scale, and dichotomous “Present / Not present”

* Clinical tests for 1st CMC joint involvement – one or more are positive for inclusion (see Table 2)

Figures


Potential participants respond to advertisement or clinician invite
Research administrator sends information sheet, screen eligibility
Excluded: not meeting inclusion criteria; unable to attend interview.
Assessment of eligibility, complete informed consent, baseline assessment (t = -2 weeks)
Excluded: not meeting inclusion criteria; no informed consent.
Imaging
Randomisation
Allocated to Splint Intervention (n = ?)
• Implement splint intervention + standardized usual care (n = ?)
• Complete daily diary for hours splint worn, education/advice enacted and medication.
t = 0 weeks
Allocated to Control (n = ?)
• Implement standardized usual care (n = ?)
• Complete daily diary for education/advice enacted and medication.
End of intervention period – daily diary returned
End of intervention period – daily diary returned
t = 4 weeks
4-week assessment and data collection (n = ?)
4-week assessment and data collection (n = ?)
Clinician telephone – reveal opposite group
Clinician telephone – reveal opposite group
t = 6 months
6-month assessment and data collection (n = ?)
6-month assessment and data collection (n = ?)
Loss to follow-up or discontinued (n = ?)