




BMJ Open Prefabricated contoured foot orthoses to reduce pain and increase physical activity in people with hip osteoarthritis: protocol for a randomised feasibility trial

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ABSTRACT

Introduction The aim of this randomised feasibility trial is to determine the feasibility of conducting an adequately powered randomised controlled trial (RCT) investigating the efficacy of prefabricated contoured foot orthoses in people with hip osteoarthritis (OA). The secondary aims of the trial are to compare the effect of prefabricated contoured foot orthoses to a flat shoe insert comparator on outcomes of hip-related pain, physical activity and quality of life. We hypothesise that the demand, implementation, acceptability and practicality of foot orthoses as a treatment option for people with hip OA will be deemed feasible, informing the development of an adequately powered RCT to evaluate the efficacy and long term outcomes.

Methods and analysis We will recruit 28 people with hip OA who will be randomised to receive either prefabricated contoured foot orthoses or flat shoe inserts to use for a 6-week period. Both groups will receive standardised education on hip OA and physical activity. The study's primary outcome is the feasibility domains of demand, implementation, acceptability and practicality. The secondary outcomes include the change in Hip Osteoarthritis Outcome Score-12, Patient Health Questionnaire-9, Brief Fear of Movement Scale for OA, Physical activity accelerometry and the Physical Activity Questionnaire-short form. Descriptive statistics will be used to describe feasibility outcomes with limited efficacy analysis used for the secondary outcomes. Linear mixed models will be used to analyse between-group differences at 6 weeks, with baseline values used as covariates, treatment allocation as a fixed factor and participant as a random factor.

Ethics and dissemination This trial has been approved by the La Trobe University Human Research Ethics Committee (HEC20427), St. Vincent's Hospital Melbourne, Human Research Ethics Committee (HREC 266/20) and Northern Health Research Governance (NH-2021-292862). The results will be disseminated via a peer-reviewed journal and presented at international conferences.

Trial registration number NCT05138380.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study's design will adequately assess feasibility outcomes to inform design of a fully powered randomised controlled trial.
- ⇒ The study is underpowered to determine the efficacy of prefabricated contoured foot orthoses for the management of hip osteoarthritis.
- ⇒ The outcomes assessed are clinically relevant, valid and time-efficient to administer, allowing for the assessment of real-world outcomes important to patients.
- ⇒ Participants and the treating clinician are unable to be blinded to group allocation.

INTRODUCTION

Hip osteoarthritis (OA) is a burdensome condition, with pain typically affecting an individual's participation in physical activity and ultimately contributing to poorer health-related quality of life (QOL).¹ Approximately 40%–70% of people with hip OA do not meet the WHO physical activity guidelines.² Insufficient physical activity contributes to elevated body mass index (BMI),³ muscle weakness,³ psychological distress and social disengagement and can increase the risk of chronic diseases, including heart disease and diabetes.⁴ Ultimately, this lack of physical activity increases the personal and societal burden of hip OA.⁴

The healthcare costs associated with OA are expected to increase by 38% by 2030.⁵ Therapeutic exercise therapy (defined as exercises specifically prescribed to correct impairments and improve musculoskeletal function)⁶ are recommended by clinical guidelines as first-line management⁷; however, current evidence indicates the presence of suboptimal outcomes for patients at times.⁸ Non-adherence and poor compliance to therapeutic exercise therapy is a continual

barrier to its efficacy,⁹ ultimately contributing to suboptimal long-term outcomes.

General physical activity (defined as any movement raising energy expenditure,^{10 11} such as walking frequently) mediates the relationship between symptomatic OA and mortality.¹² This is likely due to the positive effects of general physical activity on chronic conditions such as heart disease and diabetes. Providing general advice and support to promote regular physical activity such as walking may be an alternative strategy offered by physiotherapists or other health professionals. Since walking may be limited in people with hip OA due to symptoms, additional tools or devices may be needed to alleviate symptoms while walking.

Prefabricated contoured foot orthoses are inserts worn in everyday shoes, are inexpensive and readily worn by patients with few complications. They are currently prescribed for people with hip pain by more than one-third of podiatrists in Australia, New Zealand and the UK.¹³ Rigorous randomised controlled trials (RCTs) have found that foot orthoses effectively reduce pain and symptoms associated with heel pain¹⁴ and knee pain¹⁵ but have not been rigorously studied as an option to treat hip OA pain.¹⁶ This suggests that foot orthoses for hip pain already have clinical utility, but currently, there is no evidence base to support this practice. We theorise a biologically plausible mechanism for foot orthoses to reduce pain and increase physical activity in people with hip OA. The small hip muscles^{3 17} of people with hip OA generate high and inefficient muscle activity^{18 19} when walking. This inefficient muscle activity may contribute to hip pain and difficulty with walking.²⁰ Walking with prefabricated contoured foot orthoses can lower hip muscle activity by up to 30%.²¹ Thus, foot orthoses could be a simple strategy to reduce the demand on overworked hip muscles of people with hip OA and hence, reduce pain and improve capacity for physical activity. Prior to committing the resources required to conduct an adequately powered RCT, it is necessary to determine if such a trial is feasible. Bowen *et al*²² provides a framework for determining feasibility addressing eight areas of focus. Therefore, the primary aim of this randomised feasibility trial is to determine the feasibility of conducting an adequately powered RCT that investigates the efficacy of foot orthoses in people with hip OA. The secondary aim of the trial is to compare the effect of prefabricated contoured foot orthoses to a flat shoe insert comparator on outcomes of hip-related pain, hip-related physical function, hip-related QOL, fear of movement, depressive symptoms and physical activity over a 6-week period. We hypothesise that the demand, implementation, acceptability and practicality of prefabricated foot orthoses as a treatment option for people with hip OA will be deemed feasible, informing the development of an adequately powered RCT to evaluate the efficacy and long-term outcomes.

METHODS

Trial design

This 6-week participant-blinded, two-arm parallel-group feasibility RCT was designed in accordance with the Consolidated Standards of Reporting Trials 2010 statement: extension for pilot/feasibility studies²³ and the Standard Protocol Items: Recommendations for Interventional Trials statement²⁴ (where appropriate).²⁵ The trial proposal has been peer-reviewed and endorsed by the Australia and New Zealand Musculoskeletal Clinical Trials Network (ANZMUSC; NHMRC Centre of Research Excellence). The trial will conform to ANZMUSC governance and publication policies. The trial has also been prospectively registered with the National Institute of Health Trial Registry (NCT05138380).

Ethical approval and consent

Ethical approval for this study has been obtained from the La Trobe University Human Ethics Committee (HEC 20427) and Saint Vincent's Hospital Melbourne Human Ethics Committee under the National Health and Medical Research Council of Australia, National Mutual Acceptance Scheme (HREC 266/20). The study was also approved by Northern Health Research Governance (NH-2021-292862). All participants will provide informed, written consent before commencing the study.

Participants

Eligibility

The inclusion criteria are as follows: mild to moderate idiopathic (primary) hip OA in accordance with the American College of Rheumatology²⁶ as defined by:

- Age >45 years.
- Pain in the hip or groin for more than 3 months.
- Average pain intensity over the last week of >3 or higher on a 0–10 Numerical Rating Scale during functional tasks such as walking, climbing stairs or climbing in/out of a car.
- Radiographic confirmation of hip OA with a Kellgren-Lawrence score ≥ 2 ²⁷ within the last 12 months.
- Mild to moderate disability indicated by the ability to^{28 29}
 - Reciprocally ascend and descend ten stairs unaided.²⁸
 - Safely walk one city block,.
 - Jog five metres if required.

Individuals will be excluded if they meet any of the following criteria:

- Other musculoskeletal lower limb or back conditions requiring assessment or treatment by a health professional (medical practitioner, physiotherapist, podiatrist, etc) in the last 6 months.
- Have received active treatment for their hip pain by a health professional (eg, physiotherapist) in the last 3 months.
- Use of foot orthoses or therapeutic shoe inserts in the last 12 months.
- History of hip trauma or surgery on the affected side.

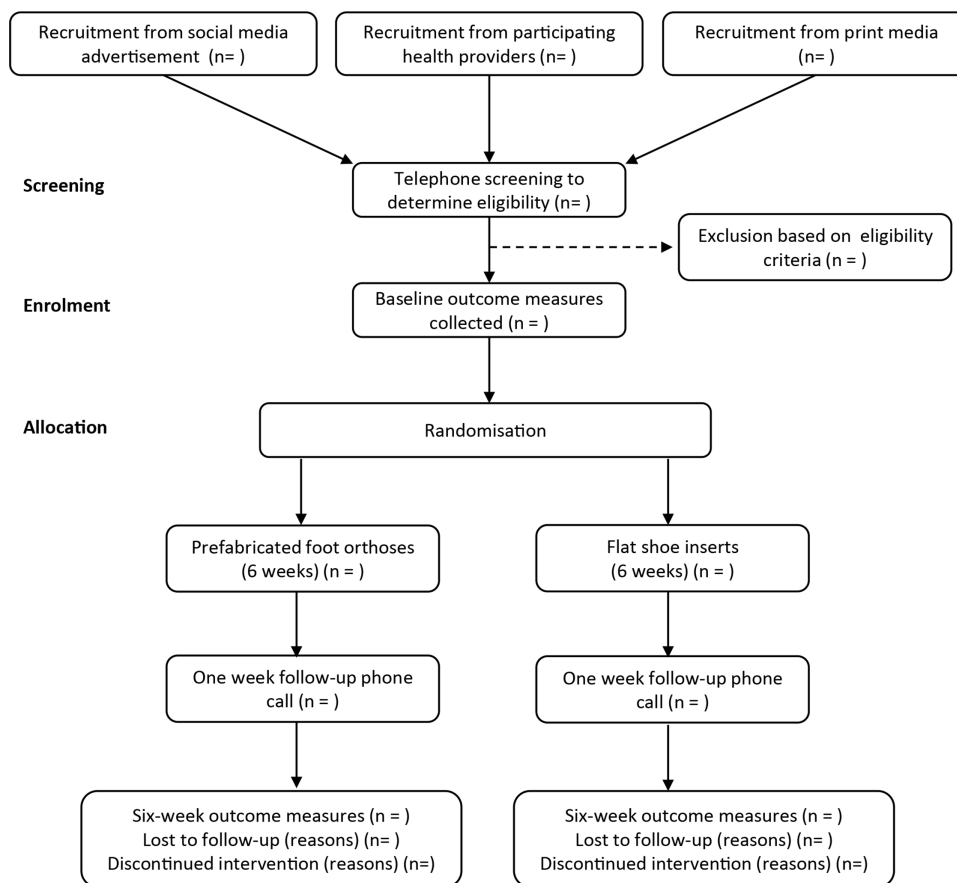


Figure 1 Participant flow through the trial.

- v. Corticosteroid use (oral or intra-articular) in the past 3 months.
- vi. Neurological impairment or condition affecting lower limb function.
- vii. Conditions or factors affecting the ability to take part in the intervention, for example, unavailable for a 6-week intervention period, routine use of gait aids, uncontrolled hypertension, or morbid obesity (BMI >40).
- viii. Systemic inflammatory disease (eg, rheumatoid arthritis).
- ix. Unable to write, read or comprehend English.

Study procedure including participant identification, location and consent

Participant flow through the trial is outlined in [figure 1](#). Potential participants with hip OA will be recruited via social media, local print media and advertising information distributed through participating health providers and community notice boards. Interested volunteers will contact the research team via email and will be provided with a patient information sheet. Potential participants will be screened by telephone for eligibility. There will be no physical assessment or screening to accommodate potential COVID-19-related interruptions. After completing phone screening to determine eligibility, participants will be invited to provide informed consent via Research Electronic Data Capture (REDCap)³⁰ platform.

On entering the study, participants will be given a physical activity monitor (accelerometer) to wear for 7 days and complete baseline outcome measures (online data capture tool; REDCap)³⁰ at the conclusion of the 7-day wear period. The randomisation schedule will then be revealed to a trial investigator, not involved in data collection or analysis, in random permuted blocks, who will schedule an initial appointment with a study practitioner within 1 week of the conclusion of their baseline assessment.

All initial consultations with study practitioners will be delivered online via Zoom over 1 hour. These consultations will include administering the educational material (OA, physical activity, caring for their shoe inserts, and progressively increasing their wear time) as well as the prescription of the prefabricated contoured foot orthoses or flat shoe inserts. A follow-up appointment with the study practitioner (in week 1 or 2), will be optional and provided on request from the participant. Those who do and do not request an additional appointment will be recorded.

Prior to their telehealth consultation, the prefabricated contoured foot orthoses or flat shoe inserts will be delivered to participants via registered post. The selection of orthoses length will be based on participants' reported shoe size. The prefabricated contoured foot orthoses will be constructed with high grade thermoformable

closed-cell polyolefin foam (medium density), to match the density of the flat shoe inserts (sham). Participants will be provided with one pair, and instructed by the trial physiotherapist to use their existing shoe liner to trim the orthoses (if required) during their initial consultation. Using a hairdryer, heat moulding may adjust comfort and better fit to the participants' shoes.

All outcome measures will be collected at 6-week postrandomisation (primary end-point). The outcome of pain is self-reported; therefore, participants are considered assessors. To ensure participant and thus assessor blinding, consent will involve limited disclosure. Participants will be informed that they will receive a shoe insert treatment but will not be informed of the difference between the treatment conditions nor the hypothesis. Study practitioners will be trained not to disclose information that might unblind participants.

Interventions

Standardised education

Standardised education and advice on hip OA and physical activity will be delivered to all participants during their

consultation via an educational video. The multimedia education content will be used to ensure participants in both groups receive identical advice. Participants will have the opportunity to ask questions or clarify content during their consultation. Participants will be provided with hard copy fact sheets on OA (https://arthritisaustralia.com.au/wordpress/wp-content/uploads/2018/02/Osteoarthritis_New-updated.pdf) and physical activity (https://arthritisaustralia.com.au/wordpress/wp-content/uploads/2018/01/ArthAus_PhysicalActivity_1805.pdf) that are openly available (Arthritis Australia). Participants will also receive standardised education and information sheets on caring for their shoe inserts and progressively increasing their wear time.

Prefabricated contoured foot orthosis and flat shoe inserts

Participants will be randomly allocated to receive one of either (1) prefabricated contoured foot orthoses or (2) flat shoe inserts (table 1). These devices will be prescribed during a telehealth-delivered consultation with a registered physiotherapist (minimum 2 years experience). A follow-up consultation will be offered if required. The use

Table 1 Outline of prefabricated contoured foot orthoses and flat shoe inserts administered

	Prefabricated contoured foot orthoses	Flat shoe inserts
What?	Manufacturer: Foot Science International. Material: High grade thermoformable closed-cell polyolefin foam (medium density) Arch support: inbuilt. Covering: fabric Commercially available: Yes Brand name: Formthotics Product name: Original Single Medium Product Webpage: https://www.formthotics.com/products/original-single-medium/	Manufacturer: Foot Science International. Material: High grade thermoformable closed-cell polyolefin foam (medium density) Arch support: no. Covering: fabric Commercially available: No (custom made sham comparator for this study) Brand Name: NA Product Name: NA Product Webpage: NA
Who Provides?	Study Practitioner: Registered physiotherapist or podiatrist >2 years musculoskeletal experience will be trained to prescribe the insert according to the prescription algorithm and standard formthotic protocols (https://www.youtube.com/watch?v=X7kc7jak21o).	
Where?	Administered via telehealth with orthoses posted to study participants	
When and how much?	Week 0–1: one telehealth session with study practitioner to fit one pair of prefabricated orthoses Week 1–2: Follow-up session for questions if required (either via telephone call or telehealth consult)	Week 0–1: one telehealth session with study practitioner to fit one pair of flat shoe inserts Week 1–2: Follow-up session for questions regarding use if required (either via telephone call or telehealth consult)
Tailoring?	Orthoses are fit to comfort according to the prescription algorithm below. Lengths (S, S, M, L, XL, XXL) (dependent on participant's shoe size). Hardness=Medium density. Modifications: can be cut to size to assist in fit using the shoes original sock liner as a guide, by participants using standard scissors. Heat moulding: optional	Flat shoe inserts are fit to comfort according to the prescription algorithm below. Lengths (S, S, M, L, XL, XXL) (dependent on participant's shoe size). Hardness=Medium density. Modifications: can be cut to size to assist fit using the shoes original sock liner as a guide, by participants using standard scissors. Heat moulding: optional
How well?	Adherence recorded with diary/log book (insert wear time)	
NA, not applicable.		

Table 2 Outline of outcome measures administered during the trial

	Study period									
	Enrolment	Allocation	Postallocation				Close-out			
	$-t_1$		t_1	t_2	t_3	t_4	T_5	T_6	T_x	
Time point		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6			
Enrolment:										
Eligibility screen	X									
Informed consent	X									
Allocation		X								
Interventions:										
Prefabricated contoured foot orthoses			←————→							
Flat shoe inserts			←————→							
Assessment:										
Demographic questionnaire	X									
HOOS-12 questionnaire	X								X	
TSK6-BFM questionnaire	X								X	
PHQ-9 questionnaire	X								X	
IPAQ	X								X	
Practicality and Acceptability Q	X								X	
GROC									X	
7 day wear of accelerometer	X							X		
Daily Diary and Logbook			X	X	X	X	X	X		

GROC, global rating of change; HOOS-12, Hip Osteoarthritis Outcome Score; IPAQ, International physical activity questionnaire; PHQ-9, Patient health questionnaire-9; TSK-6BFM, Tampa scale of Kinesiophobia-6 brief fear of movement.

of additional physiotherapy or podiatry services for their hip pain and injections will be discouraged. Participants can use other interventions such as analgesics, heat/cold and general exercise. All cointerventions and use and insert wear time will be recorded daily via a daily diary and log-book.

Outcomes

Demographic details, including age, gender, height, mass, employment status and symptom history, will be recorded.

Primary outcome: feasibility

The following parameters have been set a priori to determine feasibility: one participant recruited per week, 20% (35 hours/week) adherence to the intervention, 50% log-book completion rate, and less than 20% drop-out rate.

Feasibility will also be described using the Bowen framework domains²² of:

Demand

As indicated by the rate of participant recruitment in the study (number of participants randomised per month). Such data assist in the time component for recruitment in a fully powered RCT.

Implementation (extent of use)

Recorded via participant's daily diary and log-book and assessed at the end of the 6-week intervention period. These data will be reported descriptively and qualitatively analysed along with medication use and cointerventions

Acceptability

Participant acceptability of the intervention will be assessed via the Credibility and Expectancy Questionnaire.³¹ This

questionnaire reviews the participants' perception and credibility of the intervention and perceived improvements in their function. These data will be reported descriptively in the analysis.

Practicality

The trial physiotherapist and participants will monitor and record adverse events via direct participant reports to the trial physiotherapist or daily diary and log-book during the 6-week intervention period. Data such as adverse event type, location, severity and duration will be reported descriptively. Adverse events will be monitored and recorded by the physiotherapist and participant.

Secondary outcome measures: proof of concept

Hip related QOL and pain

Hip Osteoarthritis Outcome Score 12

The Hip Osteoarthritis Outcome Score 12 (HOOS-12) is a short form 12 questions edition of the original 40-item HOOS.^{32–34} The HOOS-12 consists of 12 questions across three subscales, including (1) pain, (2) activities of daily living and (3) QOL. Participants respond to each question on a 5-point Likert scale with each individual subscale score converted to a 101-point scale, with 100 indicating the best possible score and 0 indicating the worst possible score. The HOOS-12 questionnaire is considered a valid, discriminative, and reliable outcome measure across the three subscales measured with substantially reduced participant burden.³²

Depressive symptoms and pain thoughts

The Patient Health Questionnaire-9 (PHQ-9)³⁵ will be used to measure depression severity. The PHQ-9 is a valid and reliable nine-item scale used to measure the severity of depression. Resultant scores range from 0 to 27 and can classify depression symptom severity from mild (≥ 5), moderate (≥ 10), moderately severe (≥ 15) and severe (≥ 20).³⁵ The Brief Fear of Movement Scale for OA³⁶ (adapted from the Tampa Scale of Kinesiophobia)³⁷ will evaluate participants' feeling that physical movement will cause pain, injury or reinjury.³⁶ The six-item scale is scored from 0 to 24, with a higher score indicating lower fear of movement (better score).

Global Rating of Change : overall change in hip OA symptoms

A seven-point global rating of change (GROC) will be used to assess the participant's perceived overall change in their condition at the conclusion of the intervention period.³⁸ A version of the GROC from previous hip pain trials has been adapted for this trial.^{29 39} Participants initially indicate if they feel 'better', 'no change' or 'worse'. If better or worse is selected, they are then given the opportunity to indicate if they are 'a little better/worse', 'better/worse' or 'much better/worse' with scores ranging from +1 to +3 for the 'better' categories and -1 to -3 for the 'worse' categories. Scores will be further dichotomised to define 'success' as a score of 'better' or 'much better' (ie, $\geq +2$).

Physical activity accelerometry

Objective and reliable physical activity data will be collected using a tri-axial accelerometer (activPAL). The activPAL is a valid and reliable measure of physical activity in community-dwelling older adults.⁴⁰ The device is worn on the participant's thigh (pain-free or least symptomatic side) affixed with a waterproof dressing. Participants will be instructed to wear the device continuously for a 7-day period, removing it only for extended water-based activities such as swimming. Researchers will collect the device after the baseline assessment (allowing the baseline data to be downloaded and batteries to be recharged). It will then be returned to the participant for the same process to occur at week 6. The monitor will record daily steps, time spent performing moderate and vigorous physical activity (using a threshold of a cadence of 100 steps/min to denote moderate-intensity physical activity⁴¹ as well as sedentary behaviour expressed as daily time lying down or sitting.

Self-reported physical activity

Self-reported physical activity will be collected using an overall change in physical activity GROC³⁸ and the International Physical Activity Questionnaire-short form.⁴² This patient-reported outcome assesses health-related physical activity over the preceding 7 days across vigorous and moderate activity, walking and sitting.⁴²

The timeline of outcome measure collection is outlined in table 2. All patient-reported outcome measures will be collected using REDCap³⁰ except for the daily diary and log-book, which will be collected via a paperback version and posted back to the researcher team at the conclusion of the 6-week intervention period.

Data safety monitoring committee

A formal data safety monitoring committee will not be implemented for the feasibility trial due to its low-risk nature, short duration of intervention, and since the intervention is widely administered in the healthcare setting and adverse events are rare. Any adverse events or outcomes will be reviewed by the study authors and reported to the approving HRECs as required.

Sample size

The recommended sample size for feasibility and pilot studies is 12 people per group.⁴³ Allowing for a 20% drop-out rate per group, a total of 28 participants (14 per group) will be recruited for this study. No interim analysis will be conducted as a component of this study.

Randomisation and blinding

A randomisation schedule will be generated by a research team member not involved in data collection or analysis. The R statistical software package (R, R Foundation for Statistical Computing) will be used to generate a sex-stratified (male/female) randomisation schedule of a 1:1 ratio in random blocks of 4 and 6.

Group allocation will be concealed in serially numbered, opaque, sealed envelopes. A research team member not

involved with recruitment, screening or intervention will open the envelopes sequentially according to participant number to determine the participant's group allocation prior to their first appointment (after eligibility screening and enrolment have been completed). They will inform the trial physiotherapist of treatment allocation for the relevant participant and mail the appropriate shoe inserts (flat or contoured) to the participant prior to their initial telehealth appointment.

Participants and assessors will be blinded. Participants will be advised that they have an equal chance of being allocated to either shoe insert, thus are blind to allocation. Participants will also be blind to the study hypothesis, so they are unaware which of the interventions is 'active'. However, participants will complete their own patient-reported outcome measures (questionnaires) online and are thus not blinded to their own outcome assessment.

Accelerometer data will remain assessor-blinded, with all other patient-reported outcomes assessed by a research team member who will be blind to participant group allocation. Participants will be instructed not to divulge any aspect of their intervention to the research team member conducting follow-up assessments.

It is not possible to blind the trial physiotherapist to the group allocation. However, they will not be involved in the assessment of outcome measures.

Statistical analysis

Descriptive statistics will be used to describe feasibility outcomes of demand, implementation, acceptability and practicality (primary outcome). These will include recruitment rate and participants willing to enrol (n), eligible participants randomised, adherence, log-book completion, adverse events, drop-out rates, lost to follow-up, as well as the practicality and acceptability questionnaire.³¹

For the secondary outcomes of hip-related QOL and pain as well as physical activity, limited efficacy analysis will be used to assess the effect of the interventions and inform potential sample size calculations for a fully powered RCT. Linear mixed models will be used to analyse between-group differences at 6 weeks, with baseline values used as covariates, treatment allocation as a fixed factor and participant as a random factor. Adjustments will be made for differences between groups in potential confounders such as age, sex, BMI. Statistical significance will be determined at the level of $\alpha=0.05$. Data will be presented as means (SD) at baseline and 6 weeks; mean change (95% CI) within each group over 6 weeks and adjusted mean differences (95% CI) between groups at 6 weeks. For the GROG scores, data will be dichotomised to define 'success' as those with a score of 'better' or 'much better'. A generalised mixed model (adjusted for baseline differences and covariates) will be used to assess differences in the proportion of 'successes' between groups at 6 weeks. Missing data will be recorded and the assumption of missing at random evaluated to help inform design of a larger trial. For this pilot feasibility trial, no imputation methods will be used. However,

consistent with intention to treat principles all available data will be included in analysis according to allocation, regardless of adherence.

DISCUSSION

The global prevalence of hip OA is estimated at 0.85%⁴⁴ and in combination with knee OA is the 11th highest contributor to global disability.⁴⁴ In Australia alone, the personal and societal financial costs of total hip replacements is projected to reach US\$2 billion by 2030.⁴⁵ Thus, there is a need to develop, test and if efficacious, implement cost-effective and accessible treatment strategies for people with hip OA.

This study aims to determine the feasibility of conducting a RCT on the efficacy of prefabricated contoured foot orthoses in the treatment of people with hip OA, a potentially innovative and cost-effective solution to a burdensome condition. Adherence to wearing orthoses is high in other lower limb musculoskeletal conditions,⁴⁶⁻⁴⁸ with wear times of approximately 40 hours a week,⁴⁶ allowing for the potential to provide a therapeutic effect during family, recreational and social settings. High adherence rates and wear time also enhance the opportunity to receive a therapeutic benefit and demonstrate a clinical meaningful effect at minimal cost, and negligible adverse events. However, in order to establish such information specific to hip OA, the feasibility of assessing the potential benefit is required.

The design and outcomes of this feasibility trial will adequately inform the decision-making process in the potential development of a fully powered RCT. The defined feasibility cut-off values of one participant recruited per week, 20% (35 hours/week) adherence to the intervention, 50% log-book completion rate, and less than 20% drop-out rate provide pragmatic, real-world outcomes to inform RCT design. Secondary outcomes are valid, and reliable^{32 35 36 38} for use in this clinical population investigated, with the variability in the data collected used to inform a sample size calculation for the RCT.

In designing the study, it was important to consider its implementation within the unprecedented demands placed on the healthcare system due to the global pandemic. Therefore, the study will use telehealth and standardised multimedia education resources in its delivery. These methods will allow for greater access to services and aid in the potential feasibility of the future design.

Trial status

Recruitment commenced in March 2022 and is projected to be completed by November 2022.

Data access

On completion and publication of the feasibility of the trial, deidentified data can be accessed via appropriate written request to the corresponding author.

ETHICS AND DISSEMINATION

This trial complied with the Declaration of Helsinki and has been approved by the La Trobe University Human Research Ethics Committee, St. Vincents Hospital Melbourne Human Research Ethics Committee and Northern Health Research Governance. Participant information and consent form is provided in online supplemental file 1. The study outcomes will be disseminated via submission to a high impact peer-reviewed publication in the area of OA. The findings of the study will also be presented at international scientific conferences.

Patient and public involvement

- ▶ Patients and clinicians were involved in the initial planning stage of the feasibility trial via the use of questionnaires and pilot testing.
- ▶ Patients and clinicians were involved in designing and developing educational material on hip OA and physical education.
- ▶ Patients will not be involved in the recruitment or completion of the study.
- ▶ Patients and clinicians will provide input into the dissemination strategy for the study, including the type of information to share and the format it is delivered in.

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Contributors AIS, JLK and HM conceived the study design, MGK and AIS prepared the manuscript. JLK, RH, TP, JW, HM, NFT, AH and JAM all contributed to the drafting of the manuscript and approved the final version.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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