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Foot orthoses to reduce pain and increase physical activity in people with hip osteoarthritis: protocol for a randomised feasibility trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-062954
Article Type:	Protocol
Date Submitted by the Author:	16-Mar-2022
Complete List of Authors:	King, Matthew; La Trobe University Kemp, Joanne; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Hon, Ryan; Northern Health Pizzari, Tania; La Trobe University, Rehabilitation, Nutrition and Sport Wong, Justin; Northern Health Menz, Hylton; LaTrobe University Taylor, Nicholas ; La Trobe University, College of Science Health and Engineering; Eastern Health, Allied Health Clinical Research Office Harms, Anton; Northern Health McClelland, Jodie A.; La Trobe Univ, Rehabilitation, Nutrition and Science Semciw, Adam Ivan; La Trobe University; Northern Health
Keywords:	Hip < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE, Clinical trials < THERAPEUTICS

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Title Page

Foot orthoses to reduce pain and increase physical activity in people with hip osteoarthritis: protocol for a randomised feasibility trial.

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Word count: 290 Abstract, 3766 Manuscript (excluding reference, tables, and figures)

Tables: 2

Figures: 1

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Abstract

Introduction: This randomised feasibility trial aims to determine the feasibility of conducting an adequately powered RCT investigating the efficacy of foot orthoses in people with hip osteoarthritis (OA). The secondary aims of the trial are to compare the effect of contoured, prefabricated foot orthoses to a flat insole 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 randomised controlled trial 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 six 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 Osteoarthritis, 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: NCT05138380

Keywords

Hip Osteoarthritis, Orthotic inserts, Feasibility, Clinical Trial, Rehabilitation.

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Article Summary

Strengths and Limitations for the study

- This randomised trial is the first to evaluate the feasibility of conducting an adequately powered trial on the effect of foot orthoses to reduce pain and increase physical activity in people with 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.

- This trial can inform future research directions in evaluating cost-effective treatment strategies for people with hip osteoarthritis.

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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]. Many people with hip OA (40% to 70%) do not meet the current walking and 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 projected healthcare costs associated with OA are expected to increase by 38% by 2030 [5]. Non-surgical, non-drug treatments, such as exercise therapy, are recommended by clinical guidelines as first-line management[6]; however, current evidence fails to demonstrate convincing outcomes for patients [7]. Non-adherence to exercise therapy is well known[8], ultimately contributing to poor long term outcomes.

General physical activity, such as walking frequency, mediates the relationship between symptomatic OA and mortality [9]. 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 a self-limiting activity in people with hip OA, additional tools or devices may be needed to alleviate symptoms while walking.

Foot orthoses are contoured inserts worn in everyday shoes, are inexpensive and readily worn by patients with few complications. Prefabricated contoured foot orthoses are currently prescribed for people with hip pain by more than one-third of podiatrists in Australia, New Zealand and the United Kingdom[10]. Rigorous randomised controlled trials (RCT)s have found that foot orthoses effectively reduce pain and symptoms associated with heel pain [11] and knee pain [12] but have not been rigorously studied as an option to treat hip OA pain[13]. 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 14] of people with hip OA generate high and inefficient muscle activity [15 16] when walking. This inefficient muscle activity may contribute to hip pain and difficulty with walking [17]. Walking with foot orthoses can lower hip muscle activity by up to 30% [18].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-powred RCT, it is necessary to

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determine if such a trial is feasible. Bowen et al. [19] 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 investigating the efficacy of foot orthoses in people with hip OA. The secondary aim of the trial is to compare the effect of contoured, prefabricated foot orthoses to a flat insole comparator on outcomes of hip-related pain, hip-related physical function, hip-related quality of life, fear of movement, depressive symptoms, and physical activity over a 6-week period.

Methods

Trial design

This six-week participant-blinded, two-arm parallel-group feasibility RCT aligns with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement: extension for pilot/feasibility studies [20]. 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 (NIH) 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 Rheumatology [21] as defined by:

(i) age > 45 years;

(ii) pain in the hip or groin for more than three months;

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(iii) average pain intensity over the last week of ≥ 3 or higher on a 0 to 10 numerical rating scale (NRS) during functional tasks such as walking, climbing stairs or climbing in/out of a car;

(iv) radiographic confirmation of hip OA with a Kellgren-Lawrence score ≥ 2 [22] within the last 12 months;

(v) mild to moderate disability indicated by the ability to [23 24];

a. reciprocally ascend and descend ten stairs unaided, [23]

b. safely walk one city block, and

c. jog five metres if required

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

(i) other musculoskeletal lower limb or back conditions requiring assessment or treatment by a health professional (medical practitioner, physiotherapist, podiatrist etc) in the last six months;

(ii) have recived active treatment for their hip pain by a health professional (eg physiotherapist) in the last 3 months;

(iii) use of foot orthoses or therapeutic shoe inserts in the last 12 months;

(iv) history of hip trauma or surgery on the affected side;

(v) corticosteroid use (oral or intra-articular) in the past three months;

(vi) neurological impairment or condition affecting lower limb function;

(vii) conditions or factors affecting the ability to take part in the intervention, e.g., unavailable for a six-week intervention period, routine use of gait aids, uncontrolled hypertension, or morbid obesity (body mass index > 40);

(viii) systemic inflammatory disease (e.g. 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)[25] platform.

Insert Figure 1

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On entering the study, participants will be given a physical activity monitor (accelerometer) to wear for seven days and complete baseline outcome measures (online data capture tool; REDCap)[25] 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 one 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 foot orthoses. 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 foot orthoses or inserts will be delivered to participants via registered post. The selection of orthoses length will be based on participants' reported shoe size. All orthoses will be constructed with high grade thermoformable closed-cell polyolefin foam (medium density), to match the density of the flat 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 consolation. Using a hairdryer, heat moulding may adjust comfort and better fit to the participants' shoes.

All outcome measures will be collected at 6-weeks post-randomisation (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-

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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 (i) contoured, prefabricated foot orthoses, or (ii) flat insert (**Table 1**). These devices will be prescribed during a 1 hour; telehealth delivered consultation with a registered physiotherapist (minimum two years experience). A follow-up consultation will be offered if required. The use 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.

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	***Manufacturer***: Foot Science International. ***Material:*** *High grade thermoformable closed-cell polyolefin foam (medium density)* ***Arch support***: no. ***Covering***: fabric, identical to the contoured device.
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 to 1: one telehealth session with study practitioner to fit one pair of prefabricated orthoses Week 1 to 2: Follow-up session for questions if required (either via telephone call or telehealth consult)	Week 0 to 1: one telehealth session with study practitioner to fit one pair of prefabricated orthoses Week 1 to 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	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 fit using the shoes original sock liner as a guide, by participants using standard scissors. Heat moulding: optional

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How well?	Adherence recorded with diary/ log book (insert wear time)

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 h/week) adherence to the intervention, 50% log-book completion rate, and less than 20% dropout rate.

Feasibility will also be described using the Bowen framework domains [19]:

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: 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 [26]. 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 quality of life and pain

Hip Osteoarthritis outcome score 12 (HOOS-12)[27]: The HOOS-12 is a short form 12 question edition of the original 40 item HOOS. [27-29] The HOOS-12 consists of 12 questions across three subscales, including (i) pain, (ii) activities of daily living, and (iii) quality of life. Participants respond

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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[27].

Depressive symptoms and pain thoughts: The Patient Health Questionnaire-9 (PHQ-9)[30] 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 0-27 and can classify depression symptom severity from mild (≥ 5), moderate (≥ 10), moderately severe (≥ 15) and severe (≥ 20)[30]. The Brief Fear of Movement Scale for Osteoarthritis (BFOM)[31] (adapted from the Tampa Scale of Kinesiophobia[32]) will evaluate participants' feeling that physical movement will cause pain, injury, or re-injury[31]. 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 (GROC) – overall change in hip OA symptoms: A seven-point GROC will be used to assess the participant's perceived overall change in their condition at the conclusion of the intervention period [33]. A version of the GROC from previous hip pain trials has been adapted for this trial [24 34]. 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" (i.e. ≥ +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. [35] 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 seven-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 activity [36] 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 GROC[33] and the International Physical Activity Questionnaire –

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short form[37]. This patient-reported outcome assesses health-related physical activity over the preceding seven days across vigorous and moderate activity, walking, and sitting[37].

The timeline of outcome measure collection is outlined in **TABLE 2**. All patient-reported outcome measures will be collected using REDCap[25] 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.

TABLE 2: Outline of outcome measures administered during the trial.

		STUDY PERIOD						
	Enrolment	Allocation	Post-allocation						Close-out
TIMEPOINT**	$-t_1$	0	t_1 Wk 1	t_2 Wk 2	t_3 Wk 3	t_4 Wk 4	T_5 Wk 5	T6 Wk 6	T_x
ENROLMENT:									
Eligibility screen	X								
Informed consent	X								
Allocation		X							
INTERVENTIONS:									
Contoured foot orthoses			←	—	—	—	—	→	
Flat insert			←	—	—	—	—	→	
ASSESSMENTS:									
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

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GROC									X
7-day wear of accelerometer	X							X	
Daily Diary and Logbook			X	X	X	X	X	X	

HOOS-12 - Hip osteoarthritis outcome score; TSK-6BFM - Tampa scale ofkKinesiophobia-6 brief fear of movement; PHQ-9 – Patient health questionnaire-9; IPAQ – International physical activity questionnaire; GROC – global rating of change.

Sample size

The recommended sample size for feasibility and pilot studies is 12 people per group[38]. 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

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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, dropout rates, loss to follow-up, as well as the practicality and acceptability questionnaire[26].

For the secondary outcomes of hip-related quality of life 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 six 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 α=0.05. Data will be presented as means (SD) at baseline and six weeks; mean change (95% CI) within each group over six weeks and adjusted mean differences (95% CI) between groups at 6 weeks. For the GROC 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. All data will be analysed as randomised consistent with intention to treat principals.

Discussion and conclusion

The global prevalence of hip OA is estimated at 0.85% [39] and, in conjunction with knee OA, is the 11th highest contributor to global disability and rising [39]. In Australia alone, the personal and societal financial costs of total hip replacements is projected to reach $2 billion by 2030 [40]. 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 randomised controlled trial on the efficacy of foot orthoses in the treatment of people with hip OA, a potentially innovative and cost-effective solution to a burdensome condition. Adherence to wearing othoses is high in other lower limb musculoskeletal conditions [41-43], with wear times of approximately 40 hours a week[41], allowing

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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.

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 utilise 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 August 2022. +

Data Access

On completion and publication of the feasibility of the trial, de-identified 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 supplementary file 1. The study outcomes will be disseminated via submission to a high impact peer-reviewed publication in the area of osteoarthritis. 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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353

354

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Additional Information:

Registration:

The trial will be prospectively registered to the National Institute of Health Trial Registry (NCT05138380)

Funding

- This project was supported by a La Trobe University Research Focus Area for Sport, Exercise and Rehabilitation Grant Ready Scheme (reference number 2000004276).
- The development of multimedia education material for the project was supported by a La Trobe University Social Research Platform Grant.
- The contour foot orthoses and the comparator were provided at no cost from the manufacturer (Foot Science International – Formthotics).

Funding bodies were not involved in the design, collection, analysis and interpretation of data; in the writing of the manuscript; or in the decision to submit the manuscript for publication.

Ethical Approval

- La Trobe University Human Ethics Committee (HEC 20427)
- 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).
- Northern Health Research Governance (NH-2021-292862).

Competing Interests

The authors declare they have no competing interests

Author contributions

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

Acknowledgements

We acknowledge Juliette Gentle from Northern Health and Marcella Ferraz Pazzinatto from the La Trobe Sport and Exercise Medicine Research Centre for their assistance on the development of the multimedia educational resources.

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383

384

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Figure Legends

Figure 1: Participant flow through the trial

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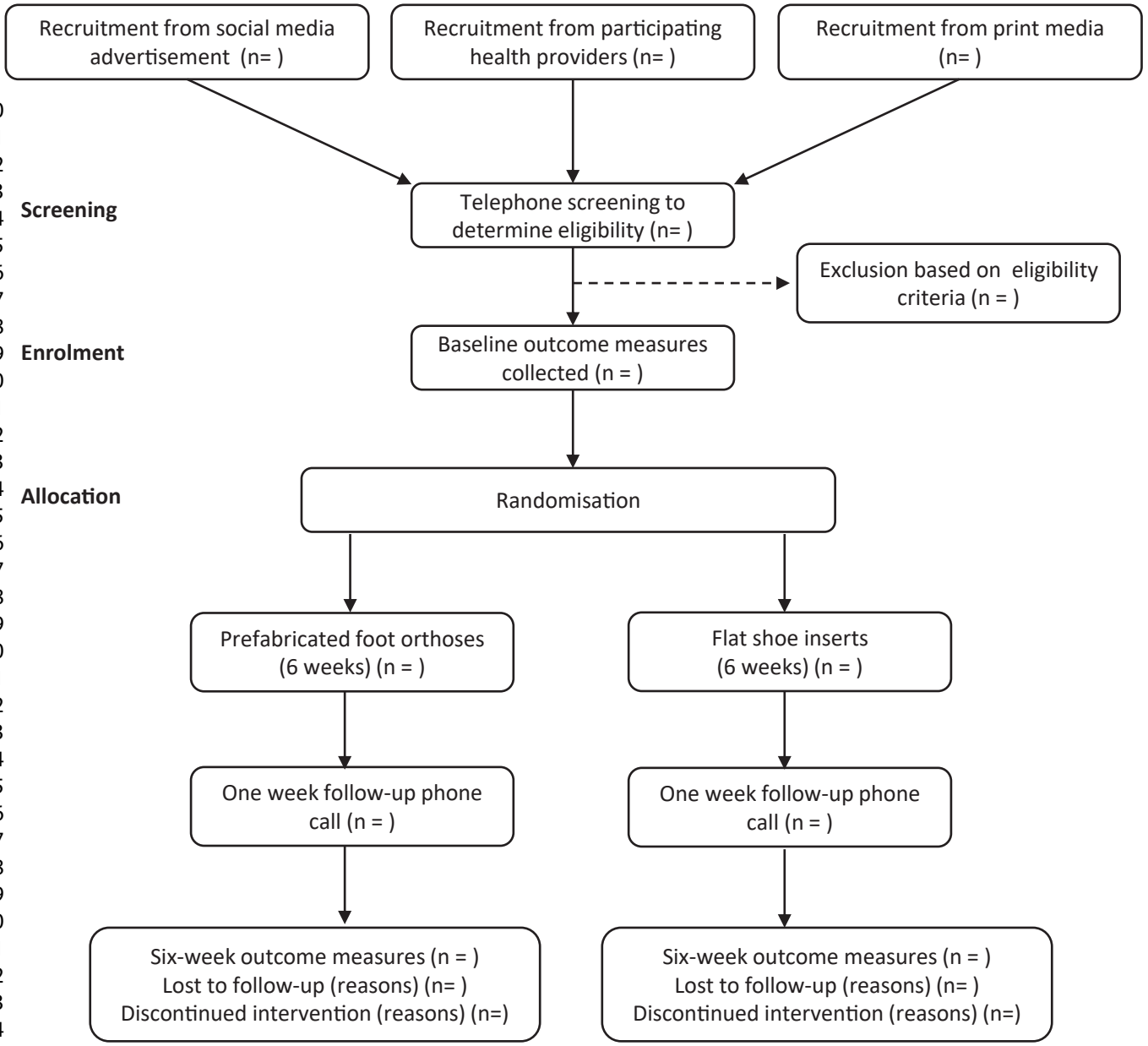
Recruitment from social media advertisement (n=)
Recruitment from participating health providers (n=)
Recruitment from print media (n=)
Screening
Telephone screening to determine eligibility (n=)
Exclusion based on eligibility criteria (n =)
Enrolment
Baseline outcome measures collected (n =)
Allocation
Randomisation
Prefabricated foot orthoses (6 weeks) (n =)
Flat shoe inserts (6 weeks) (n =)
One week follow-up phone call (n =)
One week follow-up phone call (n =)
Six-week outcome measures (n =)
Lost to follow-up (reasons) (n=)
Discontinued intervention (reasons) (n=)
Six-week outcome measures (n =)
Lost to follow-up (reasons) (n=)
Discontinued intervention (reasons) (n=)

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Northern Health

RESEARCH PARTICIPANT INFORMATION CONSENT

AFFIX PATIENT IDENTIFICATION LABEL HERE

U.R. NUMBER: _____

SURNAME: _____

GIVEN NAME: _____

DATE OF BIRTH: _____/_____/_____ SEX: _____

PARTICIPANT INFORMATION SHEET/CONSENT FORM

Title	Hip Osteoarthritis and foot Orthoses Trial (HOOT): A randomised feasibility trial
HREC No.	*266.20* (ERM 69224)
Coordinating Principal Investigator	*Associate Professor Adam Semciw*
Associate Investigators	Prof Hylton Menz Prof Nick Taylor Prof Kay Crossley Dr Joanne Kemp Dr Matthew King Dr Tania Pizzari Prof Emmanuel Stamatakis Dr Andrew Bouldt Dr Jade Tan Assoc Prof Michelle Dowsey Mr Justin Wong Mr Ryan Hon Mr Anton Harms
Location	*Northern Health*

Participant Involvement In Research Project:

Start Date: 1st February 2022 Finish Date: 30th November 2022

1 Introduction

You are invited to take part in this research project. This is because you have Hip Osteoarthritis (OA). Hip osteoarthritis (OA) is a painful condition of the hip, that may affect the ability to exercise. We wish to determine if two types of shoe inserts can reduce the pain associated with hip osteoarthritis and improve the ability to exercise.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it, you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described

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RESEARCH – PARTICIPANT INFORMATION CONSENT

FNH010610

Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Hip osteoarthritis (OA) is a painful condition of the hip, that may affect the ability to exercise. We wish to determine if two types of shoe inserts can reduce the pain associated with hip osteoarthritis and improve the ability to exercise.

You have invited to participate because you have hip pain and satisfy the following criteria:

- You are aged > 45 years, have had hip pain for more than three months, and have had an x-ray confirming hip osteoarthritis within the last 12 months.
- You are able to walk up and down 10 stairs unaided
- You are able to safely walk one city block
- You are able to jog 5 metres if required

You may not be able to participate if

- You have had any other leg or back complaints that required assessment or treatment in the last six-months
- You have previously had surgery on your hip
- You have been prescribed corticosteroid (oral or injection) in the past 3 months
- You have a neurological impairment or condition affecting lower limb function

The shoe inserts have been approved for use by the Australian Federal Government to treat lower limb problems, but have never been tested in individuals with hip OA. As a result, the aims of this study are:

- To evaluate if the use of shoe inserts are able to change hip pain and quality of life, as well as physical activity levels, in adults with hip osteoarthritis over a six-week period
- To examine how acceptable and how consistently the shoe inserts are used by adults with hip osteoarthritis over a six-week period
- To determine if conducting a full-scale trial is a feasible and viable option in testing shoe inserts for hip osteoarthritis

This research has been initiated by the research team, lead by Associate Professor Adam Semciw, and is supported by a $20,000 research grant from the La Trobe University Sport, Exercise, and Rehabilitation Research Focus Area. This research is being conducted at La Trobe University in conjunction with Northern Health and Saint Vincent's Hospital, Melbourne.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All appointments and the shoe inserts required as part of the research project will be provided to you free of charge.

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4 What do I have to do?

If you want to take part in this study, we ask that you contact Dr. Matthew King via email on m.king@latrobe.edu.au

We will ask you to partake in the following steps to ensure your eligibility:

Initial Phone Screening: We will first conduct a telephone screening with you to confirm your eligibility to participate in the study. This will take approximately 5 to 10 minutes and also provides an opportunity for you to ask any questions about the study.

Once we have confirmed your eligibility and you consent to participate in the study, we will invite you to complete the following tasks

Baseline questionnaires and data collection: This is to obtain information about you prior to using the shoe inserts, so we have something to compare too. This step involves:

- *Online questionnaires*: These questionnaires will provide us with information about your hip pain and symptoms, your activities of daily living, your physical activity, and your quality of life. These questionnaires will be sent to you via an email web-link and will take approximately 20 minutes to complete.

- *Physical activity monitor*: We will supply you with a activity monitor (called an accelerometer). We will ask you to wear this small device (approximately the same size as a 50-cent coin) at all times for a continuous seven-day period to measure your physical activity throughout the day. The device is battery-operated and is stuck to your thigh using a 10cm x 10cm waterproof dressing. The battery inside the sensor lasts for longer than the seven days you will wear it for, so there is no need for you to charge it. The device can be worn in the shower with the waterproof dressing; however, not during a bath or in a pool. If you prefer to have baths, or attend a pool regularly (i.e. swimming laps or attend a hydrotherapy class) we ask that you please inform the researchers so we can provide you will additional dressings for the device to be taken on and off. At the end of the seven days, we will collect the monitor and download the activity data from it

Six-week period using the shoe inserts:

- *You will receive a pair of shoe inserts in the mail*: As one of the objectives of this trial is to compare the effects of the shoe inserts in people with hip osteoarthritis, you will only receive one of the two types of shoe inserts to use. Which type of insert you receive is randomly allocated and you will receive your inserts in the mail. You are asked not to use them until your appointment with the physiotherapist.

- *Appointment with trial physio*: You will be asked to attend up to two telehealth appointments with the trial physiotherapist. The initial appointment will aim to provide you with education about your hip pain, and then guide you with fitting your shoe insert. You will have the opportunity to participate in a follow-up consultation one week later if you wish. These appointments will be conducted using telehealth (online weblink video chat); thus, you can attend them from home. There will be no cost for you to attend these appointments.

- *Wearing your inserts:* The trial physiotherapist will guide you through using the shoe inserts for the six-week period. During the first week, we ask that you gradually increase the time you wear the shoe inserts (starting with one hour and increasing by one hour a day over the first week), until they can be tolerated all day. You will be encouraged to use them as much as possible (e.g. around 8 hours per day), whenever you are moving around (e.g. daily tasks such as cleaning, or exercise such as walking).

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

- *Daily diary:* So we can record how often you are wearing your inserts and whether you experience and adverse events from wearing them, we will provide you with a diary/logbook where you can record this information. Each day of the six-week trial period, you are asked to record:
  - How many hours you used the inserts for?
  - If you used any additional interventions for your hip pain that day (i.e. medications such as pain killers, hot/cold packs, exercises)?
  - If you experienced any issues or adverse events in wearing the inserts (i.e. blisters)?

- *Additional interventions for your hip OA:* During the six weeks of wearing your shoe inserts, we ask that you refrain from additional podiatry or physiotherapy interventions. However, you are allowed to continue to take any medication (over the counter or prescription), do any rehabilitation exercises you may have, or use heat or ice packs. We ask that, if you do, please record this in your trial diary.

Final questionnaires and data collection:

- *Physical activity monitor*: In the sixth week of using your shoe inserts, you will be asked to wear the activity monitor again, following the same instructions outlined earlier in this section. This will allow us to see if there have been any changes in your physical activity over the six-week period.

- *Online questionnaires*: At the end of the six-week period, we will resend the questionnaires to you via an email web link for completion. These questionnaires will be the same as the ones you completed six weeks prior, along with some additional questions about whether you feel your pain, function and physical activity changed during the trial.

What happens after the final questionnaires and data collection are completed: Once you reach the six-week time-point and the final questionnaires and data collection are completed (online questionnaires and physical activity monitoring) your involvement in the study is over. There are no longer-term follow-ups in this study, so we will not be asking you to complete any more tasks, nor will we collect any further data about you. At the completion of the study, you can elect to continue to wear the inserts if you feel they were of benefit to you, or you can elect to discard them.

At the conclusion of your involvement in the study, we will send you an information pack with your results from the study. This information pack will include a summary of your online questionnaires from your baseline (initial assessment) and six-week follow-up time points, as well as a summary of your insert wear time, co-interventions and adverse events from your daily diary. If you would like a summary of the physical activity monitor information, you will be able to request this from the researchers during, or at the end of the trial.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with La Trobe University, Northern Health or St Vincent's Hospital.

6 What are the possible benefits of taking part?

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We cannot guarantee or promise that you will receive any benefits from this research. You will be provided with a free telehealth consult with a registered physiotherapist to provide you with education about your hip pain, and guide you with fitting your shoe insert. You will also be provided with a free pair of shoe inserts.

7 What are the possible risks and disadvantages of taking part?

Medical devices, like shoe inserts, may cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study physiotherapist. Your study physiotherapist will also be looking out for side effects.

You may feel some discomfort in your feet or knees when starting to wear the foot orthoses. Occasionally, orthoses can cause some skin irritation, pressure points under the feet, or an increase in joint pain. If you experience any continued pain or discomfort in your hip or leg muscles, please contact the researchers. These problems are usually quickly and easily resolved with modifications to the footwear interventions and/or wearing time

8 Can I have other treatments during this research project?

Whilst you are participating in this research project, we ask that you do not undergo additional physiotherapy or podiatry appointments for your hip OA. However, you are able to continue any exercises that you have been previously prescribed by these individuals. You are able to continue to take any prescribed over the counter medication as directed by your doctor. You should also tell your study physiotherapist about any changes to these during your participation in the research project.

9 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study physiotherapist and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

10 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The shoe inserts being shown not to be effective
- The shoe inserts being shown to work and not need further testing
- Decisions made by local regulatory/health authorities.

11 What will happen to information about me?

By signing the consent form, you consent to the study physiotherapist and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

We will **collect** information about you in ways that will reveal who you are.

We will **store** information about you in ways that will reveal who you are.

We will **publish** information about you in ways that will not be identified in any type of publication from this study.

We will **keep** your information for 7 years after the project is completed. After this time we will destroy all of your data.

The storage, transfer and destruction of your data will be undertaken in accordance with the Research Data Management Policy https://policies.latrobe.edu.au/document/view.php?id=106/.

The personal information you provide will be handled in accordance with applicable privacy laws, any health information collected will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your personal information by contacting the research team.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

12 Who is organising and funding the research?

This research project is being conducted by the researchers named at the start of this document, and is supported by a $20,000 research grant from the La Trobe University Sport, Exercise, and Rehabilitation Research Focus Area.

You will not benefit financially from your involvement in this research project. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the study researchers or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

13 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of

La Trobe University – HEC 20427
St Vincent's Hospital (under the National Mutual Acceptance Scheme) – HREC266/20
Northern Health Governance – SSA/69224/NH-2021-292862

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies**.**

14 Further information, complaints, and who to contact

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the chief Investigator Associate Professor Adam Semciw on (03) 9479 6452, a.semciw@latrobe.edu.au or any of the following people:

Clinical contact person and Expression of interest to participate

Name	Dr Matthew King
Position	Post-Doctoral Research Fellow – La Trobe University
Email	m.king@latrobe.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Jingfei Wu
Position	Research Governance Officer
Telephone	8405 2918
Email	ethics@nh.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*St Vincent's Hospital Melbourne*
HREC Executive Officer	*The Executive Officer of Research*
Telephone	*03 9231 2394*
Email	*Research.Ethics@svhm.org.au*

Local HREC Office contact

Name	Jingfei Wu
Position	Research Governance Officer
Telephone	8405 2918
Email	ethics@nh.org.au

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FNH010610

Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

Consent Form

Title	Hip Osteoarthritis and foot Orthoses Trial (HOOT): A randomised feasibility trial
HREC No.	*266.20*
Coordinating Principal Investigator	*Associate Professor Adam Semciw*
Associate Investigators	Prof Hylton Menz Prof Nick Taylor Prof Kay Crossley Dr Joanne Kemp Dr Matthew King Dr Tania Pizzari Prof Emmanuel Stamatakis Dr Andrew Bouldt Dr Jade Tan Assoc Prof Michelle Dowsey Mr Justin Wong Mr Ryan Hon Mr Anton Harms
Location	*Northern Health*

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Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Declaration by Participant:

Name of Participant (please print) _____

☐ I have been given a verbal explanation of the research project, its procedures and risks, and have read the participant information sheet. I agree to participate in the research study

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FNH010610

Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

❒ Discussed with _____via telephone on_____ and received completed consent form on _____

Signed by _____

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Northern Health

RESEARCH PARTICIPANT INFORMATION CONSENT

AFFIX PATIENT IDENTIFICATION LABEL HERE

U.R. NUMBER: _____

SURNAME: _____

GIVEN NAME: _____

DATE OF BIRTH: _____/_____/_____ SEX: _____

Form for Withdrawal of Participation

Title	Hip Osteoarthritis and foot Orthoses Trial (HOOT): A randomised feasibility trial
HREC No.	*266.20*
Coordinating Principal Investigator	*Associate Professor Adam Semciw*
Associate Investigators	Prof Hylton Menz Prof Nick Taylor Prof Kay Crossley Dr Joanne Kemp Dr Matthew King Dr Tania Pizzari Prof Emmanuel Stamatakis Dr Andrew Bouldt Dr Jade Tan Assoc Prof Michelle Dowsey Mr Justin Wong Mr Ryan Hon Mr Anton Harms
Location	*Northern Health*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with La Trobe University, Northern Health or St Vincent's Health

Name of Participant (please print) _____

☐ I wish to withdraw from the study

Signed:_____ Date:_____

Verbal request to withdraw: Notes section (to be completed by the researcher)

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

Declaration by Study Senior Researcher

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Researcher _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	NA - Nill
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	15
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	15
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4 and 3

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Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	1, 4 and 12
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5 and 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7 and 8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9, 10, 11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11 and 12
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12

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Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9, 10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10, 11
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13

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Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA – Feasibility trial
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2 and 15
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA

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Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supp File
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-062954.R1
Article Type:	Protocol
Date Submitted by the Author:	18-Jul-2022
Complete List of Authors:	King, Matthew; La Trobe University Kemp, Joanne; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Hon, Ryan; Northern Health Pizzari, Tania; La Trobe University, Rehabilitation, Nutrition and Sport Wong, Justin; Northern Health Menz, Hylton; LaTrobe University Taylor, Nicholas ; La Trobe University, College of Science Health and Engineering; Eastern Health, Allied Health Clinical Research Office Harms, Anton; Northern Health McClelland, Jodie A.; La Trobe Univ, Rehabilitation, Nutrition and Science Semciw, Adam Ivan; La Trobe University; Northern Health
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Sports and exercise medicine
Keywords:	Hip < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE, Clinical trials < THERAPEUTICS

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Manuscripts

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Title Page

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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Word count: 300 Abstract, 3721 Manuscript (excluding reference, tables, and figures)

Tables: 2

Figures: 1

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Abstract

Introduction: The aim of this randomised feasibility trial is to determine the feasibility of conducting an adequately powered 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 randomised controlled trial 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 six 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 Osteoarthritis, 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: NCT05138380

Keywords

Hip Osteoarthritis, Hip, Orthotic inserts, Feasibility, Clinical Trial, Rehabilitation.

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Article Summary

Strengths and Limitations for the 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.

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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 to 70% of people with hip OA do not meet the World Health Organization 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 management [7]; however, current evidence indicates the presence of sub-optimal 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 sub-optimal 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 United Kingdom[13]. Rigorous randomised controlled trials (RCT)s have found that foot orthoses effectively reduce pain and symptoms associated with heel pain [14] and knee pain [15] 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

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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 quality of life, 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 randomised controlled trial to evaluate the efficacy and long-term outcomes.

Methods

Trial design

This six-week participant-blinded, two-arm parallel-group feasibility RCT was designed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement: extension for pilot/feasibility studies [23] and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [24] (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 (NIH) 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.

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Participants

Eligibility

The inclusion criteria are as follows: mild to moderate idiopathic (primary) hip OA in accordance with the American College of Rheumatology [26] as defined by:

(i) age > 45 years;
(ii) pain in the hip or groin for more than three months;
(iii) average pain intensity over the last week of ≥ 3 or higher on a 0 to 10 numerical rating scale (NRS) during functional tasks such as walking, climbing stairs or climbing in/out of a car;
(iv) radiographic confirmation of hip OA with a Kellgren-Lawrence score ≥ 2 [27] within the last 12 months;
(v) mild to moderate disability indicated by the ability to [28 29];
    a. reciprocally ascend and descend ten stairs unaided, [28]
    b. safely walk one city block, and
    c. jog five metres if required

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

(i) other musculoskeletal lower limb or back conditions requiring assessment or treatment by a health professional (medical practitioner, physiotherapist, podiatrist etc) in the last six months;
(ii) have received active treatment for their hip pain by a health professional (eg physiotherapist) in the last 3 months;
(iii) use of foot orthoses or therapeutic shoe inserts in the last 12 months;
(iv) history of hip trauma or surgery on the affected side;
(v) corticosteroid use (oral or intra-articular) in the past three months;
(vi) neurological impairment or condition affecting lower limb function;
(vii) conditions or factors affecting the ability to take part in the intervention, e.g., unavailable for a six-week intervention period, routine use of gait aids, uncontrolled hypertension, or morbid obesity (body mass index > 40);
(viii) systemic inflammatory disease (e.g. 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

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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.

Insert Figure 1

On entering the study, participants will be given a physical activity monitor (accelerometer) to wear for seven 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 one 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 consultaion. Using a hairdryer, heat moulding may adjust comfort and better fit to the participants' shoes.

All outcome measures will be collected at 6-weeks post-randomisation (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.

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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 (i) prefabricated contoured foot orthoses, or (ii) flat shoe inserts (**Table 1**). These devices will be prescribed during a telehealth-delivered consultation with a registered physiotherapist (minimum two years experience). A follow-up consultation will be offered if required. The use 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.

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	

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	(https://www.youtube.com/watch?v=X7kc7jak21o).	
Where?	Administered via telehealth with orthoses posted to study participants	
When and how much?	Week 0 to 1: one telehealth session with study practitioner to fit one pair of prefabricated orthoses Week 1 to 2: Follow-up session for questions if required (either via telephone call or telehealth consult)	Week 0 to 1: one telehealth session with study practitioner to fit one pair of flat shoe inserts Week 1 to 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 insertsare 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

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 h/week) adherence to the intervention, 50% log-book completion rate, and less than 20% dropout rate.

Feasibility will also be described using the Bowen framework domains [22] 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.

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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 quality of life and pain

Hip Osteoarthritis outcome score 12 (HOOS-12) [32]: The HOOS-12 is a short form 12 question edition of the original 40 item HOOS. [32-34] The HOOS-12 consists of 12 questions across three subscales, including (i) pain, (ii) activities of daily living, and (iii) quality of life. 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 0-27 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 Osteoarthritis (BFOM) [36] (adapted from the Tampa Scale of Kinesiophobia [37]) will evaluate participants' feeling that physical movement will cause pain, injury, or re-injury [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 (GROC) – overall change in hip OA symptoms: A seven-point 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" (i.e. ≥ +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

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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 seven-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 activity [41] 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 GROC [38] and the International Physical Activity Questionnaire – short form [42]. This patient-reported outcome assesses health-related physical activity over the preceding seven 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 REDCap [30] 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.

TABLE 2: Outline of outcome measures administered during the trial.

		STUDY PERIOD							
	Enrolment	**Allocation**	**Post-allocation**						**Close-out**
TIMEPOINT**	$-t_1$	0	t_1 Wk 1	t_2 Wk 2	t_3 Wk 3	t_4 Wk 4	T_5 Wk 5	T6 Wk 6	T_x
ENROLMENT:									
Eligibility screen	X								
Informed consent	X								
Allocation		X							
INTERVENTIONS:									
Prefabricated contoured foot orthoses			♦—	—	—	—	—	—♦	
Flat shoe inserts			♦—	—	—	—	—	—♦	

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ASSESSMENTS:									
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	

HOOS-12 - Hip osteoarthritis outcome score; TSK-6BFM - Tampa scale ofkKinesiophobia-6 brief fear of movement; PHQ-9 – Patient health questionnaire-9; IPAQ – International physical activity questionnaire; GROC – global rating of change.

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 health care 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)

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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, dropout rates, loss to follow-up, as well as the practicality and acceptability questionnaire [31].

For the secondary outcomes of hip-related quality of life 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 six 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 six weeks; mean change

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(95% CI) within each group over six weeks and adjusted mean differences (95% CI) between groups at 6 weeks. For the GROC 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 and conclusion

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 $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 randomised controlled trial 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 othoses 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 feasility 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 h/week) adherence to the intervention, 50% log-book completion rate, and less than 20% dropout 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

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utilise 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, de-identified 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 supplementary file 1. The study outcomes will be disseminated via submission to a high impact peer-reviewed publication in the area of osteoarthritis. 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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Additional Information:

Registration:

The trial will be prospectively registered to the National Institute of Health Trial Registry (NCT05138380)

Funding

- This project was supported by a La Trobe University Research Focus Area for Sport, Exercise and Rehabilitation Grant Ready Scheme (reference number 2000004276).
- The development of multimedia education material for the project was supported by a La Trobe University Social Research Platform Grant.
- The contour foot orthoses and the comparator were provided at no cost from the manufacturer (Foot Science International – Formthotics).

Funding bodies were not involved in the design, collection, analysis and interpretation of data; in the writing of the manuscript; or in the decision to submit the manuscript for publication.

Ethical Approval

- La Trobe University Human Ethics Committee (HEC 20427)
- 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).
- Northern Health Research Governance (NH-2021-292862).

Competing Interests

The authors declare they have no competing interests

Author contributions

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

Acknowledgements

We acknowledge Juliette Gentle from Northern Health and Marcella Ferraz Pazzinatto from the La Trobe Sport and Exercise Medicine Research Centre for their assistance on the development of the multimedia educational resources.

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406

407

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Figure Legends

Figure 1: Participant flow through the trial

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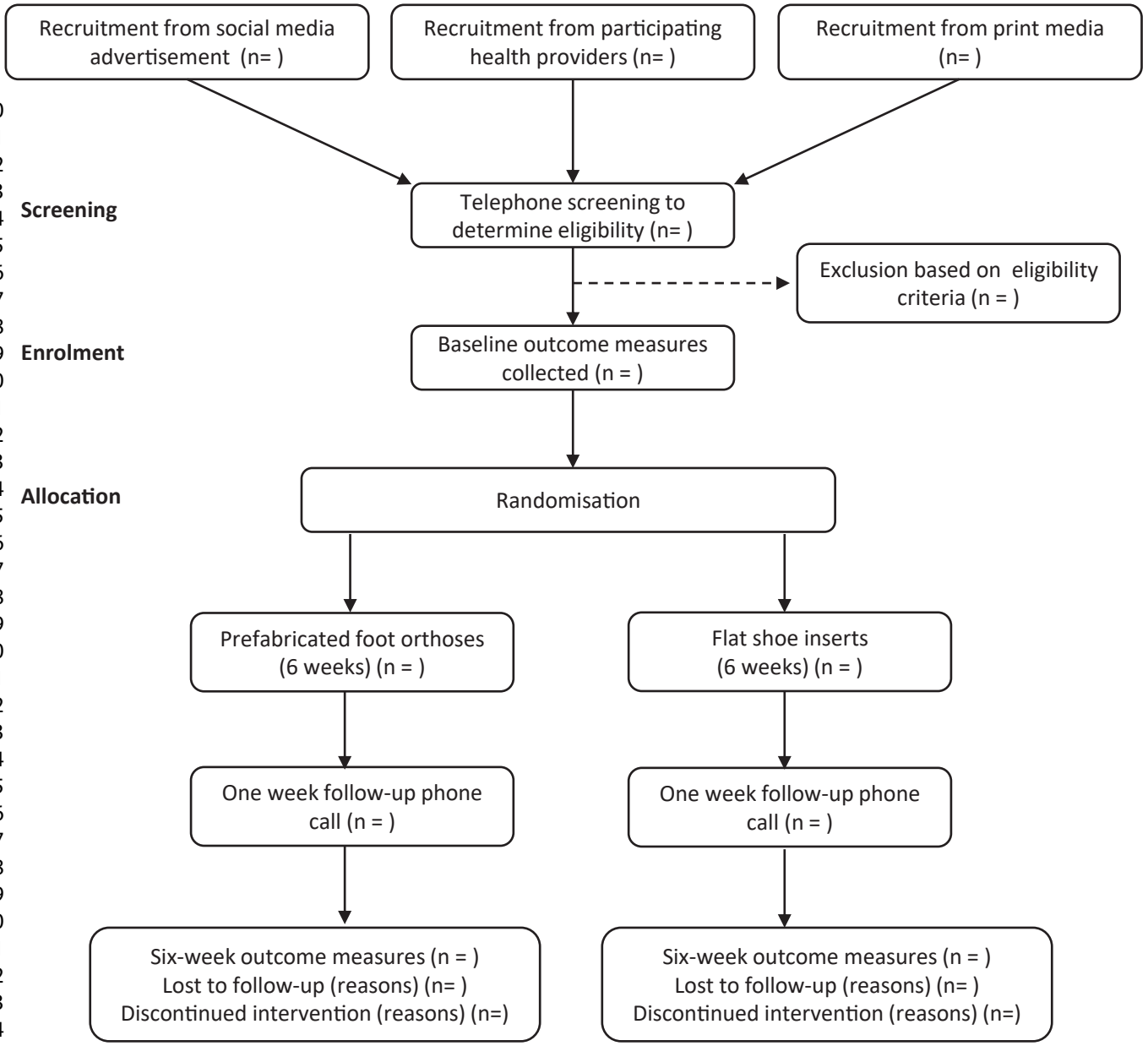
Recruitment from social media advertisement (n=)
Recruitment from participating health providers (n=)
Recruitment from print media (n=)
Screening
Telephone screening to determine eligibility (n=)
Exclusion based on eligibility criteria (n =)
Enrolment
Baseline outcome measures collected (n =)
Allocation
Randomisation
Prefabricated foot orthoses (6 weeks) (n =)
Flat shoe inserts (6 weeks) (n =)
One week follow-up phone call (n =)
One week follow-up phone call (n =)
Six-week outcome measures (n =)
Lost to follow-up (reasons) (n=)
Discontinued intervention (reasons) (n=)
Six-week outcome measures (n =)
Lost to follow-up (reasons) (n=)
Discontinued intervention (reasons) (n=)

FNH010610

Northern Health

RESEARCH PARTICIPANT INFORMATION CONSENT

AFFIX PATIENT IDENTIFICATION LABEL HERE

U.R. NUMBER: _____

SURNAME: _____

GIVEN NAME: _____

DATE OF BIRTH: _____/_____/_____ SEX: _____

PARTICIPANT INFORMATION SHEET/CONSENT FORM

Title	Hip Osteoarthritis and foot Orthoses Trial (HOOT): A randomised feasibility trial
HREC No.	*266.20* (ERM 69224)
Coordinating Principal Investigator	*Associate Professor Adam Semciw*
Associate Investigators	Prof Hylton Menz Prof Nick Taylor Prof Kay Crossley Dr Joanne Kemp Dr Matthew King Dr Tania Pizzari Prof Emmanuel Stamatakis Dr Andrew Bouldt Dr Jade Tan Assoc Prof Michelle Dowsey Mr Justin Wong Mr Ryan Hon Mr Anton Harms
Location	*Northern Health*

Participant Involvement In Research Project:

Start Date: 1st February 2022 Finish Date: 30th November 2022

1 Introduction

You are invited to take part in this research project. This is because you have Hip Osteoarthritis (OA). Hip osteoarthritis (OA) is a painful condition of the hip, that may affect the ability to exercise. We wish to determine if two types of shoe inserts can reduce the pain associated with hip osteoarthritis and improve the ability to exercise.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it, you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described

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RESEARCH – PARTICIPANT INFORMATION CONSENT

FNH010610

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• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Hip osteoarthritis (OA) is a painful condition of the hip, that may affect the ability to exercise. We wish to determine if two types of shoe inserts can reduce the pain associated with hip osteoarthritis and improve the ability to exercise.

You have invited to participate because you have hip pain and satisfy the following criteria:

- You are aged > 45 years, have had hip pain for more than three months, and have had an x-ray confirming hip osteoarthritis within the last 12 months.
- You are able to walk up and down 10 stairs unaided
- You are able to safely walk one city block
- You are able to jog 5 metres if required

You may not be able to participate if

- You have had any other leg or back complaints that required assessment or treatment in the last six-months
- You have previously had surgery on your hip
- You have been prescribed corticosteroid (oral or injection) in the past 3 months
- You have a neurological impairment or condition affecting lower limb function

The shoe inserts have been approved for use by the Australian Federal Government to treat lower limb problems, but have never been tested in individuals with hip OA. As a result, the aims of this study are:

- To evaluate if the use of shoe inserts are able to change hip pain and quality of life, as well as physical activity levels, in adults with hip osteoarthritis over a six-week period
- To examine how acceptable and how consistently the shoe inserts are used by adults with hip osteoarthritis over a six-week period
- To determine if conducting a full-scale trial is a feasible and viable option in testing shoe inserts for hip osteoarthritis

This research has been initiated by the research team, lead by Associate Professor Adam Semciw, and is supported by a $20,000 research grant from the La Trobe University Sport, Exercise, and Rehabilitation Research Focus Area. This research is being conducted at La Trobe University in conjunction with Northern Health and Saint Vincent's Hospital, Melbourne.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All appointments and the shoe inserts required as part of the research project will be provided to you free of charge.

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4 What do I have to do?

If you want to take part in this study, we ask that you contact Dr. Matthew King via email on m.king@latrobe.edu.au

We will ask you to partake in the following steps to ensure your eligibility:

Initial Phone Screening: We will first conduct a telephone screening with you to confirm your eligibility to participate in the study. This will take approximately 5 to 10 minutes and also provides an opportunity for you to ask any questions about the study.

Once we have confirmed your eligibility and you consent to participate in the study, we will invite you to complete the following tasks

Baseline questionnaires and data collection: This is to obtain information about you prior to using the shoe inserts, so we have something to compare too. This step involves:

- *Online questionnaires*: These questionnaires will provide us with information about your hip pain and symptoms, your activities of daily living, your physical activity, and your quality of life. These questionnaires will be sent to you via an email web-link and will take approximately 20 minutes to complete.

- *Physical activity monitor*: We will supply you with a activity monitor (called an accelerometer). We will ask you to wear this small device (approximately the same size as a 50-cent coin) at all times for a continuous seven-day period to measure your physical activity throughout the day. The device is battery-operated and is stuck to your thigh using a 10cm x 10cm waterproof dressing. The battery inside the sensor lasts for longer than the seven days you will wear it for, so there is no need for you to charge it. The device can be worn in the shower with the waterproof dressing; however, not during a bath or in a pool. If you prefer to have baths, or attend a pool regularly (i.e. swimming laps or attend a hydrotherapy class) we ask that you please inform the researchers so we can provide you will additional dressings for the device to be taken on and off. At the end of the seven days, we will collect the monitor and download the activity data from it

Six-week period using the shoe inserts:

- *You will receive a pair of shoe inserts in the mail*: As one of the objectives of this trial is to compare the effects of the shoe inserts in people with hip osteoarthritis, you will only receive one of the two types of shoe inserts to use. Which type of insert you receive is randomly allocated and you will receive your inserts in the mail. You are asked not to use them until your appointment with the physiotherapist.

- *Appointment with trial physio*: You will be asked to attend up to two telehealth appointments with the trial physiotherapist. The initial appointment will aim to provide you with education about your hip pain, and then guide you with fitting your shoe insert. You will have the opportunity to participate in a follow-up consultation one week later if you wish. These appointments will be conducted using telehealth (online weblink video chat); thus, you can attend them from home. There will be no cost for you to attend these appointments.

- *Wearing your inserts:* The trial physiotherapist will guide you through using the shoe inserts for the six-week period. During the first week, we ask that you gradually increase the time you wear the shoe inserts (starting with one hour and increasing by one hour a day over the first week), until they can be tolerated all day. You will be encouraged to use them as much as possible (e.g. around 8 hours per day), whenever you are moving around (e.g. daily tasks such as cleaning, or exercise such as walking).

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- *Daily diary:* So we can record how often you are wearing your inserts and whether you experience and adverse events from wearing them, we will provide you with a diary/logbook where you can record this information. Each day of the six-week trial period, you are asked to record:
  - How many hours you used the inserts for?
  - If you used any additional interventions for your hip pain that day (i.e. medications such as pain killers, hot/cold packs, exercises)?
  - If you experienced any issues or adverse events in wearing the inserts (i.e. blisters)?

- *Additional interventions for your hip OA:* During the six weeks of wearing your shoe inserts, we ask that you refrain from additional podiatry or physiotherapy interventions. However, you are allowed to continue to take any medication (over the counter or prescription), do any rehabilitation exercises you may have, or use heat or ice packs. We ask that, if you do, please record this in your trial diary.

Final questionnaires and data collection:

- *Physical activity monitor*: In the sixth week of using your shoe inserts, you will be asked to wear the activity monitor again, following the same instructions outlined earlier in this section. This will allow us to see if there have been any changes in your physical activity over the six-week period.

- *Online questionnaires*: At the end of the six-week period, we will resend the questionnaires to you via an email web link for completion. These questionnaires will be the same as the ones you completed six weeks prior, along with some additional questions about whether you feel your pain, function and physical activity changed during the trial.

What happens after the final questionnaires and data collection are completed: Once you reach the six-week time-point and the final questionnaires and data collection are completed (online questionnaires and physical activity monitoring) your involvement in the study is over. There are no longer-term follow-ups in this study, so we will not be asking you to complete any more tasks, nor will we collect any further data about you. At the completion of the study, you can elect to continue to wear the inserts if you feel they were of benefit to you, or you can elect to discard them.

At the conclusion of your involvement in the study, we will send you an information pack with your results from the study. This information pack will include a summary of your online questionnaires from your baseline (initial assessment) and six-week follow-up time points, as well as a summary of your insert wear time, co-interventions and adverse events from your daily diary. If you would like a summary of the physical activity monitor information, you will be able to request this from the researchers during, or at the end of the trial.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with La Trobe University, Northern Health or St Vincent's Hospital.

6 What are the possible benefits of taking part?

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We cannot guarantee or promise that you will receive any benefits from this research. You will be provided with a free telehealth consult with a registered physiotherapist to provide you with education about your hip pain, and guide you with fitting your shoe insert. You will also be provided with a free pair of shoe inserts.

7 What are the possible risks and disadvantages of taking part?

Medical devices, like shoe inserts, may cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study physiotherapist. Your study physiotherapist will also be looking out for side effects.

You may feel some discomfort in your feet or knees when starting to wear the foot orthoses. Occasionally, orthoses can cause some skin irritation, pressure points under the feet, or an increase in joint pain. If you experience any continued pain or discomfort in your hip or leg muscles, please contact the researchers. These problems are usually quickly and easily resolved with modifications to the footwear interventions and/or wearing time

8 Can I have other treatments during this research project?

Whilst you are participating in this research project, we ask that you do not undergo additional physiotherapy or podiatry appointments for your hip OA. However, you are able to continue any exercises that you have been previously prescribed by these individuals. You are able to continue to take any prescribed over the counter medication as directed by your doctor. You should also tell your study physiotherapist about any changes to these during your participation in the research project.

9 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study physiotherapist and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

10 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The shoe inserts being shown not to be effective
- The shoe inserts being shown to work and not need further testing
- Decisions made by local regulatory/health authorities.

11 What will happen to information about me?

By signing the consent form, you consent to the study physiotherapist and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

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We will **collect** information about you in ways that will reveal who you are.

We will **store** information about you in ways that will reveal who you are.

We will **publish** information about you in ways that will not be identified in any type of publication from this study.

We will **keep** your information for 7 years after the project is completed. After this time we will destroy all of your data.

The storage, transfer and destruction of your data will be undertaken in accordance with the Research Data Management Policy https://policies.latrobe.edu.au/document/view.php?id=106/.

The personal information you provide will be handled in accordance with applicable privacy laws, any health information collected will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your personal information by contacting the research team.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

12 Who is organising and funding the research?

This research project is being conducted by the researchers named at the start of this document, and is supported by a $20,000 research grant from the La Trobe University Sport, Exercise, and Rehabilitation Research Focus Area.

You will not benefit financially from your involvement in this research project. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the study researchers or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

13 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of

La Trobe University – HEC 20427
St Vincent's Hospital (under the National Mutual Acceptance Scheme) – HREC266/20
Northern Health Governance – SSA/69224/NH-2021-292862

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies**.**

14 Further information, complaints, and who to contact

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The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the chief Investigator Associate Professor Adam Semciw on (03) 9479 6452, a.semciw@latrobe.edu.au or any of the following people:

Clinical contact person and Expression of interest to participate

Name	Dr Matthew King
Position	Post-Doctoral Research Fellow – La Trobe University
Email	m.king@latrobe.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Jingfei Wu
Position	Research Governance Officer
Telephone	8405 2918
Email	ethics@nh.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*St Vincent's Hospital Melbourne*
HREC Executive Officer	*The Executive Officer of Research*
Telephone	*03 9231 2394*
Email	*Research.Ethics@svhm.org.au*

Local HREC Office contact

Name	Jingfei Wu
Position	Research Governance Officer
Telephone	8405 2918
Email	ethics@nh.org.au

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

Consent Form

Title	Hip Osteoarthritis and foot Orthoses Trial (HOOT): A randomised feasibility trial
HREC No.	*266.20*
Coordinating Principal Investigator	*Associate Professor Adam Semciw*
Associate Investigators	Prof Hylton Menz Prof Nick Taylor Prof Kay Crossley Dr Joanne Kemp Dr Matthew King Dr Tania Pizzari Prof Emmanuel Stamatakis Dr Andrew Bouldt Dr Jade Tan Assoc Prof Michelle Dowsey Mr Justin Wong Mr Ryan Hon Mr Anton Harms
Location	*Northern Health*

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Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Declaration by Participant:

Name of Participant (please print) _____

☐ I have been given a verbal explanation of the research project, its procedures and risks, and have read the participant information sheet. I agree to participate in the research study

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Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

❒ Discussed with _____via telephone on_____ and received completed consent form on _____

Signed by _____

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RESEARCH PARTICIPANT INFORMATION CONSENT

AFFIX PATIENT IDENTIFICATION LABEL HERE

U.R. NUMBER: _____

SURNAME: _____

GIVEN NAME: _____

DATE OF BIRTH: _____/_____/_____ SEX: _____

Form for Withdrawal of Participation

Title	Hip Osteoarthritis and foot Orthoses Trial (HOOT): A randomised feasibility trial
HREC No.	*266.20*
Coordinating Principal Investigator	*Associate Professor Adam Semciw*
Associate Investigators	Prof Hylton Menz Prof Nick Taylor Prof Kay Crossley Dr Joanne Kemp Dr Matthew King Dr Tania Pizzari Prof Emmanuel Stamatakis Dr Andrew Bouldt Dr Jade Tan Assoc Prof Michelle Dowsey Mr Justin Wong Mr Ryan Hon Mr Anton Harms
Location	*Northern Health*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with La Trobe University, Northern Health or St Vincent's Health

Name of Participant (please print) _____

☐ I wish to withdraw from the study

Signed:_____ Date:_____

Verbal request to withdraw: Notes section (to be completed by the researcher)

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Declaration by Study Senior Researcher

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Researcher _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	NA - Nill
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	15
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	15
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4 and 3

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Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	1, 4 and 12
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5 and 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7 and 8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9, 10, 11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11 and 12
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12

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Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9, 10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10, 11
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13

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Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA – Feasibility trial
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2 and 15
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA

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Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supp File
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-062954.R2
Article Type:	Protocol
Date Submitted by the Author:	08-Aug-2022
Complete List of Authors:	King, Matthew; La Trobe University Kemp, Joanne; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Hon, Ryan; Northern Health Pizzari, Tania; La Trobe University, Rehabilitation, Nutrition and Sport Wong, Justin; Northern Health Menz, Hylton; LaTrobe University Taylor, Nicholas ; La Trobe University, College of Science Health and Engineering; Eastern Health, Allied Health Clinical Research Office Harms, Anton; Northern Health McClelland, Jodie A.; La Trobe Univ, Rehabilitation, Nutrition and Science Semciw, Adam Ivan; La Trobe University; Northern Health
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Sports and exercise medicine
Keywords:	Hip < ORTHOPAEDIC & TRAUMA SURGERY, REHABILITATION MEDICINE, Clinical trials < THERAPEUTICS

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Manuscripts

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Title Page

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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Word count: 300 Abstract, 3721 Manuscript (excluding reference, tables, and figures)

Tables: 2

Figures: 1

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Abstract

Introduction: The aim of this randomised feasibility trial is to determine the feasibility of conducting an adequately powered 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 randomised controlled trial 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 six 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 Osteoarthritis, 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: NCT05138380

Keywords

Hip Osteoarthritis, Hip, Orthotic inserts, Feasibility, Clinical Trial, Rehabilitation.

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Article Summary

Strengths and Limitations for the 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.

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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 to 70% of people with hip OA do not meet the World Health Organization 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 management [7]; however, current evidence indicates the presence of sub-optimal 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 sub-optimal 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 United Kingdom[13]. Rigorous randomised controlled trials (RCT)s have found that foot orthoses effectively reduce pain and symptoms associated with heel pain [14] and knee pain [15] 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

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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 quality of life, 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 randomised controlled trial to evaluate the efficacy and long-term outcomes.

Methods

Trial design

This six-week participant-blinded, two-arm parallel-group feasibility RCT was designed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement: extension for pilot/feasibility studies [23] and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [24] (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 (NIH) 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.

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Participants

Eligibility

The inclusion criteria are as follows: mild to moderate idiopathic (primary) hip OA in accordance with the American College of Rheumatology [26] as defined by:

(i) age > 45 years;
(ii) pain in the hip or groin for more than three months;
(iii) average pain intensity over the last week of ≥ 3 or higher on a 0 to 10 numerical rating scale (NRS) during functional tasks such as walking, climbing stairs or climbing in/out of a car;
(iv) radiographic confirmation of hip OA with a Kellgren-Lawrence score ≥ 2 [27] within the last 12 months;
(v) mild to moderate disability indicated by the ability to [28 29];
    a. reciprocally ascend and descend ten stairs unaided, [28]
    b. safely walk one city block, and
    c. jog five metres if required

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

(i) other musculoskeletal lower limb or back conditions requiring assessment or treatment by a health professional (medical practitioner, physiotherapist, podiatrist etc) in the last six months;
(ii) have received active treatment for their hip pain by a health professional (eg physiotherapist) in the last 3 months;
(iii) use of foot orthoses or therapeutic shoe inserts in the last 12 months;
(iv) history of hip trauma or surgery on the affected side;
(v) corticosteroid use (oral or intra-articular) in the past three months;
(vi) neurological impairment or condition affecting lower limb function;
(vii) conditions or factors affecting the ability to take part in the intervention, e.g., unavailable for a six-week intervention period, routine use of gait aids, uncontrolled hypertension, or morbid obesity (body mass index > 40);
(viii) systemic inflammatory disease (e.g. 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

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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.

Insert Figure 1

On entering the study, participants will be given a physical activity monitor (accelerometer) to wear for seven 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 one 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 consultaion. Using a hairdryer, heat moulding may adjust comfort and better fit to the participants' shoes.

All outcome measures will be collected at 6-weeks post-randomisation (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.

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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 (i) prefabricated contoured foot orthoses, or (ii) flat shoe inserts (**Table 1**). These devices will be prescribed during a telehealth-delivered consultation with a registered physiotherapist (minimum two years experience). A follow-up consultation will be offered if required. The use 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.

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	

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	(https://www.youtube.com/watch?v=X7kc7jak21o).	
Where?	Administered via telehealth with orthoses posted to study participants	
When and how much?	Week 0 to 1: one telehealth session with study practitioner to fit one pair of prefabricated orthoses Week 1 to 2: Follow-up session for questions if required (either via telephone call or telehealth consult)	Week 0 to 1: one telehealth session with study practitioner to fit one pair of flat shoe inserts Week 1 to 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 insertsare 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

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 h/week) adherence to the intervention, 50% log-book completion rate, and less than 20% dropout rate.

Feasibility will also be described using the Bowen framework domains [22] 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.

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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 quality of life and pain

Hip Osteoarthritis outcome score 12 (HOOS-12) [32]: The HOOS-12 is a short form 12 question edition of the original 40 item HOOS. [32-34] The HOOS-12 consists of 12 questions across three subscales, including (i) pain, (ii) activities of daily living, and (iii) quality of life. 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 0-27 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 Osteoarthritis (BFOM) [36] (adapted from the Tampa Scale of Kinesiophobia [37]) will evaluate participants' feeling that physical movement will cause pain, injury, or re-injury [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 (GROC) – overall change in hip OA symptoms: A seven-point 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" (i.e. ≥ +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

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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 seven-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 activity [41] 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 GROC [38] and the International Physical Activity Questionnaire – short form [42]. This patient-reported outcome assesses health-related physical activity over the preceding seven 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 REDCap [30] 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.

TABLE 2: Outline of outcome measures administered during the trial.

		STUDY PERIOD							
	Enrolment	**Allocation**	**Post-allocation**						**Close-out**
TIMEPOINT**	$-t_1$	0	t_1 Wk 1	t_2 Wk 2	t_3 Wk 3	t_4 Wk 4	T_5 Wk 5	T6 Wk 6	T_x
ENROLMENT:									
Eligibility screen	X								
Informed consent	X								
Allocation		X							
INTERVENTIONS:									
Prefabricated contoured foot orthoses			♦—	—	—	—	—	—♦	
Flat shoe inserts			♦—	—	—	—	—	—♦	

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ASSESSMENTS:									
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	

HOOS-12 - Hip osteoarthritis outcome score; TSK-6BFM - Tampa scale ofkKinesiophobia-6 brief fear of movement; PHQ-9 – Patient health questionnaire-9; IPAQ – International physical activity questionnaire; GROC – global rating of change.

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 health care 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)

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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, dropout rates, loss to follow-up, as well as the practicality and acceptability questionnaire [31].

For the secondary outcomes of hip-related quality of life 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 six 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 six weeks; mean change

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(95% CI) within each group over six weeks and adjusted mean differences (95% CI) between groups at 6 weeks. For the GROC 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 $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 randomised controlled trial 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 othoses 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 feasility 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 h/week) adherence to the intervention, 50% log-book completion rate, and less than 20% dropout 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

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utilise 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, de-identified 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 supplementary file 1. The study outcomes will be disseminated via submission to a high impact peer-reviewed publication in the area of osteoarthritis. 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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Additional Information:

Registration:

The trial will be prospectively registered to the National Institute of Health Trial Registry (NCT05138380)

Funding

- This project was supported by a La Trobe University Research Focus Area for Sport, Exercise and Rehabilitation Grant Ready Scheme (reference number 2000004276).
- The development of multimedia education material for the project was supported by a La Trobe University Social Research Platform Grant.
- The contour foot orthoses and the comparator were provided at no cost from the manufacturer (Foot Science International – Formthotics).

Funding bodies were not involved in the design, collection, analysis and interpretation of data; in the writing of the manuscript; or in the decision to submit the manuscript for publication.

Ethical Approval

- La Trobe University Human Ethics Committee (HEC 20427)
- 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).
- Northern Health Research Governance (NH-2021-292862).

Competing Interests

The authors declare they have no competing interests

Author contributions

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

Acknowledgements

We acknowledge Juliette Gentle from Northern Health and Marcella Ferraz Pazzinatto from the La Trobe Sport and Exercise Medicine Research Centre for their assistance on the development of the multimedia educational resources.

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406

407

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Figure Legends

Figure 1: Participant flow through the trial

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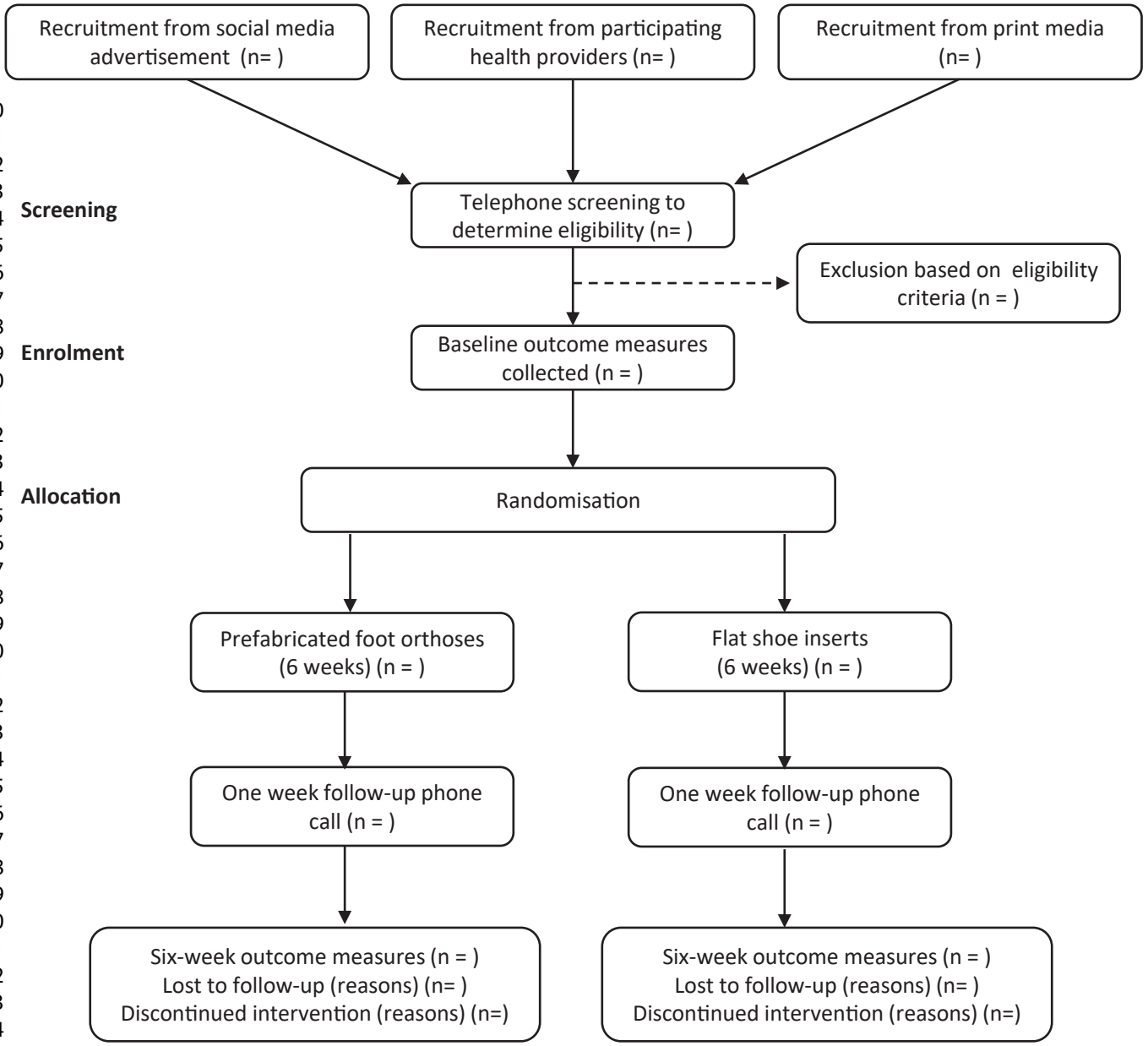
Recruitment from social media advertisement (n=)
Recruitment from participating health providers (n=)
Recruitment from print media (n=)
Screening
Telephone screening to determine eligibility (n=)
Exclusion based on eligibility criteria (n =)
Enrolment
Baseline outcome measures collected (n =)
Allocation
Randomisation
Prefabricated foot orthoses (6 weeks) (n =)
Flat shoe inserts (6 weeks) (n =)
One week follow-up phone call (n =)
One week follow-up phone call (n =)
Six-week outcome measures (n =)
Lost to follow-up (reasons) (n=)
Discontinued intervention (reasons) (n=)
Six-week outcome measures (n =)
Lost to follow-up (reasons) (n=)
Discontinued intervention (reasons) (n=)

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Northern Health

RESEARCH PARTICIPANT INFORMATION CONSENT

AFFIX PATIENT IDENTIFICATION LABEL HERE

U.R. NUMBER: _____

SURNAME: _____

GIVEN NAME: _____

DATE OF BIRTH: _____/_____/_____ SEX: _____

PARTICIPANT INFORMATION SHEET/CONSENT FORM

Title	Hip Osteoarthritis and foot Orthoses Trial (HOOT): A randomised feasibility trial
HREC No.	*266.20* (ERM 69224)
Coordinating Principal Investigator	*Associate Professor Adam Semciw*
Associate Investigators	Prof Hylton Menz Prof Nick Taylor Prof Kay Crossley Dr Joanne Kemp Dr Matthew King Dr Tania Pizzari Prof Emmanuel Stamatakis Dr Andrew Bouldt Dr Jade Tan Assoc Prof Michelle Dowsey Mr Justin Wong Mr Ryan Hon Mr Anton Harms
Location	*Northern Health*

Participant Involvement In Research Project:

Start Date: 1st February 2022 Finish Date: 30th November 2022

1 Introduction

You are invited to take part in this research project. This is because you have Hip Osteoarthritis (OA). Hip osteoarthritis (OA) is a painful condition of the hip, that may affect the ability to exercise. We wish to determine if two types of shoe inserts can reduce the pain associated with hip osteoarthritis and improve the ability to exercise.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it, you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described

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RESEARCH – PARTICIPANT INFORMATION CONSENT

FNH010610

Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Hip osteoarthritis (OA) is a painful condition of the hip, that may affect the ability to exercise. We wish to determine if two types of shoe inserts can reduce the pain associated with hip osteoarthritis and improve the ability to exercise.

You have invited to participate because you have hip pain and satisfy the following criteria:

- You are aged > 45 years, have had hip pain for more than three months, and have had an x-ray confirming hip osteoarthritis within the last 12 months.
- You are able to walk up and down 10 stairs unaided
- You are able to safely walk one city block
- You are able to jog 5 metres if required

You may not be able to participate if

- You have had any other leg or back complaints that required assessment or treatment in the last six-months
- You have previously had surgery on your hip
- You have been prescribed corticosteroid (oral or injection) in the past 3 months
- You have a neurological impairment or condition affecting lower limb function

The shoe inserts have been approved for use by the Australian Federal Government to treat lower limb problems, but have never been tested in individuals with hip OA. As a result, the aims of this study are:

- To evaluate if the use of shoe inserts are able to change hip pain and quality of life, as well as physical activity levels, in adults with hip osteoarthritis over a six-week period
- To examine how acceptable and how consistently the shoe inserts are used by adults with hip osteoarthritis over a six-week period
- To determine if conducting a full-scale trial is a feasible and viable option in testing shoe inserts for hip osteoarthritis

This research has been initiated by the research team, lead by Associate Professor Adam Semciw, and is supported by a $20,000 research grant from the La Trobe University Sport, Exercise, and Rehabilitation Research Focus Area. This research is being conducted at La Trobe University in conjunction with Northern Health and Saint Vincent's Hospital, Melbourne.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out, we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All appointments and the shoe inserts required as part of the research project will be provided to you free of charge.

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

4 What do I have to do?

If you want to take part in this study, we ask that you contact Dr. Matthew King via email on m.king@latrobe.edu.au

We will ask you to partake in the following steps to ensure your eligibility:

Initial Phone Screening: We will first conduct a telephone screening with you to confirm your eligibility to participate in the study. This will take approximately 5 to 10 minutes and also provides an opportunity for you to ask any questions about the study.

Once we have confirmed your eligibility and you consent to participate in the study, we will invite you to complete the following tasks

Baseline questionnaires and data collection: This is to obtain information about you prior to using the shoe inserts, so we have something to compare too. This step involves:

- *Online questionnaires*: These questionnaires will provide us with information about your hip pain and symptoms, your activities of daily living, your physical activity, and your quality of life. These questionnaires will be sent to you via an email web-link and will take approximately 20 minutes to complete.

- *Physical activity monitor*: We will supply you with a activity monitor (called an accelerometer). We will ask you to wear this small device (approximately the same size as a 50-cent coin) at all times for a continuous seven-day period to measure your physical activity throughout the day. The device is battery-operated and is stuck to your thigh using a 10cm x 10cm waterproof dressing. The battery inside the sensor lasts for longer than the seven days you will wear it for, so there is no need for you to charge it. The device can be worn in the shower with the waterproof dressing; however, not during a bath or in a pool. If you prefer to have baths, or attend a pool regularly (i.e. swimming laps or attend a hydrotherapy class) we ask that you please inform the researchers so we can provide you will additional dressings for the device to be taken on and off. At the end of the seven days, we will collect the monitor and download the activity data from it

Six-week period using the shoe inserts:

- *You will receive a pair of shoe inserts in the mail*: As one of the objectives of this trial is to compare the effects of the shoe inserts in people with hip osteoarthritis, you will only receive one of the two types of shoe inserts to use. Which type of insert you receive is randomly allocated and you will receive your inserts in the mail. You are asked not to use them until your appointment with the physiotherapist.

- *Appointment with trial physio*: You will be asked to attend up to two telehealth appointments with the trial physiotherapist. The initial appointment will aim to provide you with education about your hip pain, and then guide you with fitting your shoe insert. You will have the opportunity to participate in a follow-up consultation one week later if you wish. These appointments will be conducted using telehealth (online weblink video chat); thus, you can attend them from home. There will be no cost for you to attend these appointments.

- *Wearing your inserts:* The trial physiotherapist will guide you through using the shoe inserts for the six-week period. During the first week, we ask that you gradually increase the time you wear the shoe inserts (starting with one hour and increasing by one hour a day over the first week), until they can be tolerated all day. You will be encouraged to use them as much as possible (e.g. around 8 hours per day), whenever you are moving around (e.g. daily tasks such as cleaning, or exercise such as walking).

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

- *Daily diary:* So we can record how often you are wearing your inserts and whether you experience and adverse events from wearing them, we will provide you with a diary/logbook where you can record this information. Each day of the six-week trial period, you are asked to record:
  - How many hours you used the inserts for?
  - If you used any additional interventions for your hip pain that day (i.e. medications such as pain killers, hot/cold packs, exercises)?
  - If you experienced any issues or adverse events in wearing the inserts (i.e. blisters)?

- *Additional interventions for your hip OA:* During the six weeks of wearing your shoe inserts, we ask that you refrain from additional podiatry or physiotherapy interventions. However, you are allowed to continue to take any medication (over the counter or prescription), do any rehabilitation exercises you may have, or use heat or ice packs. We ask that, if you do, please record this in your trial diary.

Final questionnaires and data collection:

- *Physical activity monitor*: In the sixth week of using your shoe inserts, you will be asked to wear the activity monitor again, following the same instructions outlined earlier in this section. This will allow us to see if there have been any changes in your physical activity over the six-week period.

- *Online questionnaires*: At the end of the six-week period, we will resend the questionnaires to you via an email web link for completion. These questionnaires will be the same as the ones you completed six weeks prior, along with some additional questions about whether you feel your pain, function and physical activity changed during the trial.

What happens after the final questionnaires and data collection are completed: Once you reach the six-week time-point and the final questionnaires and data collection are completed (online questionnaires and physical activity monitoring) your involvement in the study is over. There are no longer-term follow-ups in this study, so we will not be asking you to complete any more tasks, nor will we collect any further data about you. At the completion of the study, you can elect to continue to wear the inserts if you feel they were of benefit to you, or you can elect to discard them.

At the conclusion of your involvement in the study, we will send you an information pack with your results from the study. This information pack will include a summary of your online questionnaires from your baseline (initial assessment) and six-week follow-up time points, as well as a summary of your insert wear time, co-interventions and adverse events from your daily diary. If you would like a summary of the physical activity monitor information, you will be able to request this from the researchers during, or at the end of the trial.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with La Trobe University, Northern Health or St Vincent's Hospital.

6 What are the possible benefits of taking part?

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

We cannot guarantee or promise that you will receive any benefits from this research. You will be provided with a free telehealth consult with a registered physiotherapist to provide you with education about your hip pain, and guide you with fitting your shoe insert. You will also be provided with a free pair of shoe inserts.

7 What are the possible risks and disadvantages of taking part?

Medical devices, like shoe inserts, may cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study physiotherapist. Your study physiotherapist will also be looking out for side effects.

You may feel some discomfort in your feet or knees when starting to wear the foot orthoses. Occasionally, orthoses can cause some skin irritation, pressure points under the feet, or an increase in joint pain. If you experience any continued pain or discomfort in your hip or leg muscles, please contact the researchers. These problems are usually quickly and easily resolved with modifications to the footwear interventions and/or wearing time

8 Can I have other treatments during this research project?

Whilst you are participating in this research project, we ask that you do not undergo additional physiotherapy or podiatry appointments for your hip OA. However, you are able to continue any exercises that you have been previously prescribed by these individuals. You are able to continue to take any prescribed over the counter medication as directed by your doctor. You should also tell your study physiotherapist about any changes to these during your participation in the research project.

9 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study physiotherapist and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

10 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The shoe inserts being shown not to be effective
- The shoe inserts being shown to work and not need further testing
- Decisions made by local regulatory/health authorities.

11 What will happen to information about me?

By signing the consent form, you consent to the study physiotherapist and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

We will **collect** information about you in ways that will reveal who you are.

We will **store** information about you in ways that will reveal who you are.

We will **publish** information about you in ways that will not be identified in any type of publication from this study.

We will **keep** your information for 7 years after the project is completed. After this time we will destroy all of your data.

The storage, transfer and destruction of your data will be undertaken in accordance with the Research Data Management Policy https://policies.latrobe.edu.au/document/view.php?id=106/.

The personal information you provide will be handled in accordance with applicable privacy laws, any health information collected will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your personal information by contacting the research team.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

12 Who is organising and funding the research?

This research project is being conducted by the researchers named at the start of this document, and is supported by a $20,000 research grant from the La Trobe University Sport, Exercise, and Rehabilitation Research Focus Area.

You will not benefit financially from your involvement in this research project. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the study researchers or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

13 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of

La Trobe University – HEC 20427
St Vincent's Hospital (under the National Mutual Acceptance Scheme) – HREC266/20
Northern Health Governance – SSA/69224/NH-2021-292862

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies**.**

14 Further information, complaints, and who to contact

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the chief Investigator Associate Professor Adam Semciw on (03) 9479 6452, a.semciw@latrobe.edu.au or any of the following people:

Clinical contact person and Expression of interest to participate

Name	Dr Matthew King
Position	Post-Doctoral Research Fellow – La Trobe University
Email	m.king@latrobe.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Jingfei Wu
Position	Research Governance Officer
Telephone	8405 2918
Email	ethics@nh.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*St Vincent's Hospital Melbourne*
HREC Executive Officer	*The Executive Officer of Research*
Telephone	*03 9231 2394*
Email	*Research.Ethics@svhm.org.au*

Local HREC Office contact

Name	Jingfei Wu
Position	Research Governance Officer
Telephone	8405 2918
Email	ethics@nh.org.au

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

Consent Form

Title	Hip Osteoarthritis and foot Orthoses Trial (HOOT): A randomised feasibility trial
HREC No.	*266.20*
Coordinating Principal Investigator	*Associate Professor Adam Semciw*
Associate Investigators	Prof Hylton Menz Prof Nick Taylor Prof Kay Crossley Dr Joanne Kemp Dr Matthew King Dr Tania Pizzari Prof Emmanuel Stamatakis Dr Andrew Bouldt Dr Jade Tan Assoc Prof Michelle Dowsey Mr Justin Wong Mr Ryan Hon Mr Anton Harms
Location	*Northern Health*

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Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Declaration by Participant:

Name of Participant (please print) _____

☐ I have been given a verbal explanation of the research project, its procedures and risks, and have read the participant information sheet. I agree to participate in the research study

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

❒ Discussed with _____via telephone on_____ and received completed consent form on _____

Signed by _____

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Northern Health

RESEARCH PARTICIPANT INFORMATION CONSENT

AFFIX PATIENT IDENTIFICATION LABEL HERE

U.R. NUMBER: _____

SURNAME: _____

GIVEN NAME: _____

DATE OF BIRTH: _____/_____/_____ SEX: _____

Form for Withdrawal of Participation

Title	Hip Osteoarthritis and foot Orthoses Trial (HOOT): A randomised feasibility trial
HREC No.	*266.20*
Coordinating Principal Investigator	*Associate Professor Adam Semciw*
Associate Investigators	Prof Hylton Menz Prof Nick Taylor Prof Kay Crossley Dr Joanne Kemp Dr Matthew King Dr Tania Pizzari Prof Emmanuel Stamatakis Dr Andrew Bouldt Dr Jade Tan Assoc Prof Michelle Dowsey Mr Justin Wong Mr Ryan Hon Mr Anton Harms
Location	*Northern Health*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with La Trobe University, Northern Health or St Vincent's Health

Name of Participant (please print) _____

☐ I wish to withdraw from the study

Signed:_____ Date:_____

Verbal request to withdraw: Notes section (to be completed by the researcher)

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Northern Health **RESEARCH PARTICIPANT INFORMATION CONSENT**	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER: _____ SURNAME: _____ GIVEN NAME: _____ DATE OF BIRTH: _____/_____/_____ SEX: _____

Declaration by Study Senior Researcher

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Researcher _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	NA - Nill
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	15
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	15
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4 and 3

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Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	1, 4 and 12
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5 and 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7 and 8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9, 10, 11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11 and 12
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12

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Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9, 10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10, 11
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13

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Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA – Feasibility trial
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	9
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2 and 15
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA

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Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supp File
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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