UNIVERSITY OF CANBERRA

Human Research Ethics Application

Notes for applicants

Notes for Applicants

Please consult the National Statement on Ethical Conduct in Human Research and all information available on the Research Ethics & Integrity website before preparing your application. The documents and guidelines contain very useful information that will help you to prepare a sound application. Templates and annual review forms can be downloaded from the "Templates" section in the Help menu.

If your application is written in poor English with typographical and grammatical errors, and thus difficult to understand, the Committee is likely to seek clarification.

The Committee meets once a month, with applications due two weeks prior to the meeting. You can find the meeting dates here: http://www.canberra.edu.au/research/ucresearch/integrityandethics/human-ethics/meeting-dates. Please note that your faculty/research institute may have an internal deadline well before the Committee's deadline. Please check with your faculty. Also, please be aware that the process of getting ethics clearance can take considerable time. You should, therefore, plan ahead and submit your application well before the commencement of your research.

Please note: You are the person with the detailed knowledge of your research and the Committee and/or Research Ethics & Integrity team cannot tell you how to answer questions. The Committee's job is to evaluate whether you have considered and ensured the rights and welfare of participants. The Committee also assesses compliance with the National Statement to ensure that both the university and the researcher are protected.

For technical support, please consult the "FAQ" section in the Help menu.

Research Integrity

As part of its commitment to supporting high standards of research integrity, all members of the UC community are able to access discipline specific training modules that provide guidance on principles of robust research practices and advice on solving complex ethical and integrity issues that they may encounter. In addition, they are designed to ensure researchers fully understand their professional responsibilities. Completion of the discipline-specific training modules is mandatory for all HDR students prior to confirmation of candidature as well as new, incoming academic staff. The training modules can be found here: https://uclearn.canberra.edu.au/courses/1945. To enrol, please go to https://uclearn.canberra.edu.au/enroll/NPDKRB. Alternatively, training may be undertaken by means of a face-to-face workshop offered by the Research Ethics & Integrity team on a regular basis as part of the UCRed programme. Following the online or face-to-face training, participants must complete a short online test and achieve a score of 80% or more to be deemed to have successfully completed the course.

1. Information about the research project

1.1. Short Project Title

The GTPS shoe insert study

1.2. Full Project Title

Do Shoe Inserts (Orthosis) Affect Walking and Provide Pain Relief in Individuals with Greater Trochanteric Pain Syndrome Syndrome?

1.3. Type of Project

- ○ Research involving Human Participants
- ◉ Clinical Trial involving Human Participants
- ○ Research not involving Human Participants

1.4. Is this research project related to a previous application?

- ○ Yes
- ◉ No

1.5. Will this research project repeat a previous study?

- ○ Yes
- ◉ No

1.6. Has this research project already been approved by another NHMRC registered Human Research Ethics Committee?

- ○ Yes
- ◉ No

1.7. Anticipated Start Date

07/06/2018

1.8. Anticipated Completion Date

01/05/2019

1.9. Would you like to add your project to the Research Ethics & Integrity team's research study register?

- ◉ Yes
- ○ No

2. Information about the research sites

2.1. Will this research study be conducted in Australia and/or overseas?

- ☑ Australia
- ☐ Overseas

2.1.1.a Please provide the sites where the research will be conducted.

University of Canberra biomechanics laboratory and clinical research rooms. (Buildings 12 and 29)

2.2. Will the research be undertaken in schools and/or child care centres?

- ○ Yes
- ◉ No

3. About the Chief Investigator

3.1. Are you a student or a staff member?

- ○ Student
- ◉ Staff

3.2. Chief Investigator (Staff)

Title	First Name	Surname
Asst/Prof	Angela	Fearon

Staff ID	s621863
Phone	6206 8717
Email	angie.fearon@canberra.edu.au

3.2.1. Please provide your qualifications and detailed information about your research experience.

PhD (Medical Science)
Masters (Physiotherapy)
B(App)Sc (Physiotherapy)
31 years of clinical practice
Registered Physiotherapist with AHPRA
Advanced clinical practitioner - Clinical assistance to Professor Paul Smith (Professor of orthopedic surgery, ANU)
Visiting clinician - Australian Institute of Sport

3.3. Please select your Faculty or Research Centre.

Research Institute for Sport and Exercise

3.4. Have you undertaken the University's integrity training?

- ○ Yes
- ◉ No

4. About the Co-Investigators

4.1. Are there any co-investigators?

- (•) Yes
- ( ) No

4.1.1. Please provide the details of your co-investigators.

Title	First Name	Surname
Dr	Jaquelin	Bousie

Qualifications: PhD (Physiotherapy), B Phty (Hons), BE

Phone: 6201 2035

Email: jaquelin.bousie@canberra.edu.au

Please select the Faculty or Research Centre.

Faculty of Health

If "External Organisation" or "Other Research Centre", please provide details.

Title	First Name	Surname

Qualifications:

Phone:

Email:

Please select the Faculty or Research Centre.

Please Select...

If "External Organisation" or "Other Research Centre", please provide details.

5. Details of any others involved in the research.

5.1. Are there other persons involved in the research project?

- (•) Yes
- ( ) No

5.1.1. Please provide the details of other persons involved in the research project.

Title	First Name	Surname
Ms	Bhavleen	Smoot

Qualifications	Bachelor of Psychobiology (Wheaton College), Visiting Fellow (Harvard GSAS), (Student) Bachelor of Physiotherapy (University of Canberra)
Role	Research Assistant
Email	u3180869@uni.canberra.edu.au

Title	First Name	Surname
Mrs	Lisa	Rich

Qualifications	Honours student - Bachelor of Physiotherapy (University of Canberra)
Role	Honours student
Email	

Title	First Name	Surname
Mr	Jayden	Hunter

Qualifications	Honours student - Bachelor of Physiotherapy (University of Canberra)
Role	Honours student
Email	

6. Funding

6.1. Will your research project be funded externally or internally?

- (•) Internal Funding
- ( ) External Funding
- ( ) Self-funded

6.1.1. Please advise the source of funds and the amount of funding received.

Pitch for Funds $3000. There is no requirement for funding body to review this application

6.2. Will the funding and/or commercial and intellectual property arrangements place you in a conflict of interest as a researcher?

- ( ) Yes
- (•) No

7. Review

7.1. Has your research project been reviewed?

- ☐ Supervisor/s
- ☐ Colleague/s
- ☐ Confirmation Seminar
- ☐ Funding Body
- ☑ Research Team
- ☐ Other
- ☐ No peer review

7.2. Will there be any constraints on publication?

- ○ Yes
- ◉ No

8. Rationale and Literature Review

8.1. Please provide a short summary of the research / coursework in plain English.

People with greater trochanteric pain syndrome experience severe hip pain, for which they seek relief. We will be testing if the use of shoe inserts correct the known walking related changes, and b) reduce pain in this group.

8.2. Please provide a justification for your research based on a literature review (including references for citations).

Gluteal tendinopathy is believed to the primary source of pain on the side of the hip. It plays a significant role in negatively affecting an individual's quality of life, earning potential and affects their ability to experience an active lifestyle.(1-8) A common cause of hip pain is related to the thickening and thinning of the gluteus medius and gluteus minimus tendons, along with "bursitis", which has been coined greater trochanteric pain syndrome (GTPS). (3, 5, 9-11)

The cause of gluteal tendinopathy has yet to be fully established. However, there is growing evidence that an increase in work-load (overload)(13, 14), a detrimental change in lontitutidal load along the gluteal tendon)(15, 16), and increased compression of the gluteal tendons onto the bony part of the top of the thigh (the greater trochanter) are likely to contribute to the problem.(13, 15, 17). This amount of compression is increased when the leg moves across the midline, or if the femoral neck-shaft angle is more acute than normal. These circumstances lead to a long band of tissue that runs down the side of the leg (the iliotibial band) compressing the gluteal tendons onto the greater trochanter.(18)

People with gluteal tendinopathy walk with increased hip adduction and forces encouraging this movement (this may present as a limp).(19) These changes in gait lead to higher levels of likely lead to the development and persistence of GTPS.(5, 18)

Shoe inserts (orthoses) are often prescribed to people with musculoskeletal pain and dysfunction. For example, people with low back pain, feet or knee problems; to enhance foot stability.(22,23) The use of shoe inserts (orthoses) has been shown to play a role in the recruitment patterns of spinal muscles and to improve back pain.(2, 23) Specially shaped shoe inserts (orthoses) have demonstrated to reduce pain in patients with knee osteoarthritis. (24-27)

The use of shoe inserts may play an important role in improving alignment at the hip, but preventing the leg from moving towards the mid line during walking (excessive adduction) and overall reducing the pain present in people with GTPS. To our knowledge, the usage of shoe inserts (orthoses) for the relief of pain or for correction gait changes has not been reported for people with GTPS. Therefore, the current study is designed to evaluate if the use of shoe inserts (orthoses) can control the abnormal hip function (thereby decreasing the damaging longitudinal and

compressive load on the gluteal tendons) and thus potentially reduce the pain and disfunction associated with GTPS.

SIGNIFICANCE OF PROJECT

People with GTPS frequently seek treatment to reduce their hip pain. The most commonly reported treatment is a corticosteroid injection. However, corticosteroid injections provide short-term relief only, and do not address the underlying biomechanical problem.(28, 29) Cortisone is also known to have negative biochemical effects on the structure of the tendon, which could aggravate the tendinopathy.(30) While exercise is thought to correct the gait changes seen in this population, this has not been established, if found to be an effective treatment, exercise is likely to a long-term strategy for the gait changes, and possibly secondary pain reduction. Hence, alternative pain relief strategies should be identified for the management of individuals with GTPS. The use of orthoses could play a role in improving the gait of individuals with GTPS and thereby reducing pain. To our knowledge no-one has investigated the use of orthoses in this population.

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9. Research Approach, Methods and Instruments

9.1. Which of the following instruments will be used in your research project?

- ☐ Hard copy questionnaire
- ☑ Electronic questionnaire
- ☐ Focus Groups
- ☐ Interviews
- ☑ Observations
- ☐ Ethnography
- ☐ Photographs
- ☑ Video recordings
- ☐ Audio recordings
- ☐ Creative, artistic or design process
- ☑ Performance tests
- ☐ Other

9.2. Will your research project include the following types of research?

- ☐ Collection of human samples
- ☐ Genetic testing
- ☐ Cellular therapy
- ☐ Ionising and non-ionising radiation
- ☑ None of the above

9.3. Please describe the research approach and methods in more detail.

This will be a randomised controlled, double-blind trial of the use of orthoses in people with greater trochanteric pain syndrome. Following initial telephone screening, likely participants will have a clinical screening (inclusion and exclusion criteria) assessment. Those that fit the inclusion criteria, and not the exclusion criteria, will be invited to join the study. At this time participants will undertake a number of clinical outcome tests (see below). At the end of the appointment the participant will be asked to wear an accelerometer for one week - to measure their activity level. The clinical screening and outcomes assessments will be undertaken by a registered physiotherapist (AF or JB). Following the one week of accelerometer data collection, the participants will be invited to undertake a gait assessment (via VICON Motion Capture system and force place).

Participants will undertake three walking based assessments: baseline gait (self-selected "fast" walking speed), first orthosis, washout period, second orthosis (orthosis order will be randomised) - described below. Between the clinical and VICON assessment participants will be asked to wear an accelerometer for a week - to assess their activity level.

Below is a timeline of events:

Initial Telephone Screening (No appointment necessary)

Appointment 1, time 0:
The trail will ask people to insert the orthosis into their shoe during the clinical trial. They will use two orthoses during the testing period: Orthosis A (active) and orthosis B (sham). The order of use (A or B) will be randomised to first or second, and the researchers and participants will be blinded to the type of orthosis. The participant will be asked to continue to use the second orthosis for a period of 4 weeks.

During the study period they will have four appointments:

Appointment 1, time 0/52, duration: 1 hour
Clinical screening (see below)
Patient-reported outcome measures (see below, and attached)
Clinical outcome measures (see below, and attached)
Participant provided with an accelerometer to wear for one week.

Appointment 2, time +1/52 (approximately), duration: 1 hour.
Baseline VICON assessment & verbal rating of pain (VRP)

Orthosis 1 VICON assessment & VRP
Wash out period of 15-25 minutes
Orthosis 2 VICON assessment & VRP
Participants are sent home with the second orthosis (Orthosis A or Orthosis B) and they will be asked to use these for four weeks

Appointment 3, time +4/52, duration: 1/4 hours
Provide participant with accelerometer

Appointment 4, time +5/52, duration: 1.5 hours
Baseline VICON assessment & verbal rating of pain (VRP)
Orthosis 2 VICON assessment & VRP
Success of blinding assessed: Ask participants if they are still using their orthosis and if they could guess if they had Orthosis A/B (Active/Sham)

VICOM testing:
Participants will then be asked to walk approximately 100m on three occasions. This is expected to take 1.5 hours. Their motion will be captured via the VICON motion analysis system. In order to capture their motion, participants will be required to have reflective markers at on their trunk, legs, and feet. One on the first and fifth metatarsal (middle of the foot), one on the calcaneum (heel), the medial and lateral malleolli (inside and outside of the ankle); clusters of 3 on the lateral lower and upper leg and on the femoral condyles (knee); one on the anterior superior iliac spine (front of the hip), the posterior iliac spine (back of the hip), L1, L5, (lower back),C7 (back of the neck); the sternum and the sternal notch (chest). Participants will be asked to wear loose clothing (shorts/skins and shirt) to ensure that the participants modesty can be preserved. The participant will then walk between 12 cameras that pick up the reflection from the markers. The walking will be done in a protected environment.

Patient-reported outcomes measurements (see attached documents):
The Global rating of change (GRoC)
VISA-G
HHS
Assessment of Quality of Life (AQoL)
OARSI ICOAP score
Functional co-morbidity index (this asks participants about their medical history. This will only be collected once).

Clinical screening tests:
Timed single leg stance
FABER
FADDIR
Physical palpation of the greater trochanter and surrounding area.

Clinical measures: (see attached documents)
Foot posture and mobility assessment (first assessment only, not attached)
The 30s Chair stand test
40m fast paced walk test
stair climb test (timed up and go)
6 minute walk test

Wash out period:
These assessments will be repeated twice: once post Orthosis 1 (A or B) and once post Orthosis 2 (A or B). The order of the orthosis applications will be randomized via a random order generator. Participants will be given a “wash out” period between orthosis applications where they are placed back into their own shoes and instructed to climb a flight of stairs and have a cup of tea for a period of 15-25 mins between the first and second application of orthosis study is conducted.

There are no requirements for the participants to change their overall level of activity, diet or drugs during the study. However, participants will be requested to keep a measure of activity diary during and after the study. They will be asked to wear their orthosis post gait assessment for a period of 4 weeks, this is not expected to impact on their activity level. It is anticipated that the active orthosis may provide pain relief.

9.4. Please outline how the data will be collected, processed and analysed.

Data will be collected over three occasions (as outlined above).

Appointment 1: Clinical data will be collected by the registered physiotherapists (Dr Fearon and Dr Bousie) included in this proposal. Prior to appointment 1 the patient-reported outcome measures will be uploaded on to Qualtrics. At appointment 1 data will be collected via Qualtrics as this reduced double handling of data and transcription errors. This will be undertaken in building 12 of the University of Canberra and online.

Appointment 2: Dr. Spratford and two others of the research team will undertake the VICON data collection, in the gait laboratory in building 29 of Canberra University.

Appointment 4: VICON assessment and the clinical outcomes and patient-reported outcomes will be recollected.

Data processing
Clinical and patient-reported outcome data will be collected on paper (clinical tests) and online (patient-reported outcome measures) via Qualtrics - a secure, university-based survey program.

Data analysis will be undertaken using SPSS.
Demographic data will be analyzed using descriptive statistics.
Clinical data, VICOM data, and patient-reported data will be analyzed using linear mixed models.

10. Aims and Benefits of the Research

10.1. What are the aims of the research project?

The primary aim of this project is to determine if the use of orthoses causes a change in adductor moment and movement, so as to control of the pelvis on the femur during walking in individuals with symptomatic GTPS. The secondary aim is to determine if using orthoses reduces the discomfort or pain reported by people with GTPS during and following walking.

10.2. What are the benefits and other impacts of the research project?

If orthoses are found to provide pain relief, this may provide an alternative treatment to the use of corticosteroid injections for people with GTPS. This is likely to provide a more long-term come without the iatrogenic effects of cortisone on tendons. Should we find that there is no effect on pain or hip adduction movement or moment, then this will provide a financial benefit to patients, as there should be a reduction in the use of orthoses.

10.3. What research products will be created by this research project?

- ☐ Book(s)
- ☐ Commercial Product(s)
- ☑ Conference Paper(s)
- ☐ Exhibition(s)
- ☑ Journal Article(s)
- ☐ Performance(s)
- ☑ Report(s)
- ☐ Therapeutic Product(s)
- ☐ Thesis
- ☐ Other

11. Participants

11.1. Will you target participants for whom there are specific ethical considerations?

- ☐ Children and young people
- ☐ People in dependent and unequal relationships
- ☐ People unable to give consent for health or other reasons
- ☐ People with a cognitive impairment, intellectual disability or mental illness
- ☐ Women who are pregnant and the human foetus
- ☐ Aboriginal and Torres Strait Islanders
- ☐ People who are homeless
- ☐ People who are incarcerated
- ☐ People who may be involved in illegal activities
- ☐ Victims of crime
- ☐ People in other countries
- ☐ People for whom English is a second language
- ☐ Migrants, refugees and asylum seekers
- ☑ None of the above

11.2. Will you exclude any participant categories?

- ○ Yes
- ◉ No

11.3. How will you select, recruit and contact participants?

Participants will be recruited via online and word of mouth. They will be invited to contact Ms Smoot, or one of the honours students, in the first instance who will undertake an initial verbal consent, and administer initial screening questions (provided by Dr Fearon). Where appropriate they will then arrange a screening appointment.

We have a list of potential participants from a previous study who have asked to be contacted for future studies. We are seeking planning to contact these people.

Inclusion criteria

Participants will be invited into the study if they have a minimum three month history of GTPS; an average pain score of greater than 3 on an 11-point verbal rating scale (VRS) on most days in the preceding week (3). They will undergo a clinical assessment to confirm the diagnosis. The clinical examination will be undertaken by the honours students under the direct supervision of either Dr Fearon or Dr Bousie. The clinical diagnosis of GTPS will be defined as reported pain over the greater trochanter, pain on palpation of the greater trochanter, and a positive result to two or more of the the following specific tests: FABER (flexion, Abduction, External Rotation), Single Leg Stance (SLS) test or the resisted FADDIR (Flexion, Adduction, Internal Rotation) test. Assuming a pre-test probability 50%, this testing algorithm is likely to provide a diagnostic accuracy of better than 95%

Exclusion criteria

Participants with current low back pain for more than 2/10 on a VRS, lumbar radiculopathy, or low back pain that extends below the buttock, will be excluded. Participants with a systemic inflammatory disease (e.g. Rheumatoid arthritis), neurological disease (e.g. Parkinson's disease) or bone cancer (e.g. breast cancer metastases or Paget's disease) will be excluded. Participants who are unable to provide informed consent in English will be excluded.

Participants will be excluded if the participant is not tender to palpation over the greater trochanter, if they have a history of groin pain or if groin pain is reproduced with medial rotation or FABER test.

11.4. How many participants will you recruit and what is the rationale for this number?

The primary research question is "Do orthoses affect hip adduction moment and movement in people with GTPS?". Adduction moment has been used as a surrogate for gait dysfunction in people with GTPS (Allison, et al 2016). The minimal clinical significant reduction of the adductor moment is not known. Sample size calculation based on Allison et al. (2016), using 0.5% significance level and an 80% power of identifying a difference, we estimate that we will need 44 to 50 participants.

11.5. Will you need to obtain approval to access participants?

- (•) Yes
- ( ) No

11.5.1. Please outline how approval will be obtained to access participants.

We plan to invite participants from a previous study (2 years ago), and also potential participants who contacted us for the previous study after recruitment had finished. We plan to write to them, or call them directly - having previously asked them for permission to do so.

11.6. Do you and/or your co-investigators have any pre-existing relationship with participants?

- (•) Yes
- ( ) No

11.6.1. Please describe any pre-existing relationship with participants and any ethical considerations that need to be addressed as a result of this relationship.

Some participants from previous studies have asked, or have consented to be approached for further studies. In approaching this possible participant's additional care will be taken to ensure that they feel no obligation to take part in the research.

11.7. Will you provide any payment or compensation to participants?

- ( ) Yes
- (•) No

11.8. How will you provide feedback to participants?

Participants will be invited to leave their contact details with the research team. Participants will be invited to the Honours seminar and will be sent a summary of the findings.

12. Risks

12.1. What will participants be required to do or agree to have done to them?

The trail will ask people to use a shoe insert (orthosis) during the clinical trial. They will use two orthoses during the 3 dimensional biomechanical (VICON) testing period: Orthosis A (active) and orthosis S (sham). The order of use (A or B) will be randomised to first or second, with the researchers and participants blinded to the type of orthosis. The participant will be asked to continue to use the second orthosis for a period of 4 weeks.

During the study period the participants will have three appointments:

Appointment 1, time 0/52, duration: 1 hour
Clinical screening (see below)
Patient-reported outcome measures (see below, and attached)
Clinical outcome measures (see below, and attached)

Appointment 2, time +1/52 (approximately), duration: 1 hour.
Baseline VICON assessment & verbal rating of pain (VRP)
Orthosis 1 VICON assessment & VRP
Wash out period of 15-25 minutes during which the participant will be asked to ascend and descend a flight of stairs, and will be offered a cup of tea and a biscuit.
Orthosis 2 VICON assessment & VRP
Participants are sent home with the second orthosis (orthosis A or orthosis S). The participant will be asked to use the second orthosis for four weeks

Appointment 3, time +5/52, duration: 1.5 hours
Baseline VICON assessment & verbal rating of pain (VRP)
Orthosis 2 VICON assessment & VRP
Clinical measures
The success of blinding will be assessed by asking the participants if they are still using their orthosis and if they could guess if they had Orthosis A/S (Active/Sham)

All participants will undertake a battery of clinical screening tests:
The honours students following the appropriate training and under the direct supervision of Dr Fearon or Dr Bousie (both registered with APRHA) will undertake the following the screening tests:
Timed single leg stance
FABER
FADDIR
Physical palpation of the greater trochanter and surrounding area.
Screening of the lumber spine for possible pain referral

VICON testing:
This will be completed under the supervision of Dr Wayne Spratford.
VICON Motion Capture system and force place. The participant will wear reflective markers placed on the neck, chest, pelvis, leg, and foot. (See participant information sheet). The participant will then walk between 12 cameras that pick up the reflection from the markers. They will undertake six "walking" and "sit to stand", and "step up" assessments. This will be repeated three times:

1: baseline
2: orthosis trial 1, washout period
3: orthosis trial 2 (orthosis order will be randomised)

Patient-reported outcomes measurements (see attached documents):
The Global rating of change (GRoC)
VISA-G
HHS
Assessment of Quality of Life (AQoL)
OARSI ICOAP score
Functional co-morbidity index (this asks participants about their medical history). This will only be collected once.

Clinical measures: (see attached documents)
Foot posture and mobility assessment (first assessment only)
The 30s chair stand test
40m fast paced walk test
stair climb test (timed up and go)
6-minute walk test

Wash out period:
The assessment above will be repeated twice: once post orthosis 1 trial (A or S) and once post orthosis 2 (A or S). The order of the orthosis applications will be randomised via a random number generator. Participants will have a “wash out” period between orthosis trials 1 and 2 so as to reduce any crossover effect. This will involve the

participants being placed back into their own shoes without any orthosis in situ. Participants will be asked to ascend and descend a flight of stairs, and invited to have a cup of tea for a period of 15-25 mins before the second orthosis trial is conducted.

12.2. What are the risks for participants and your strategies for minimising this risk?

There are no large movement or movements related to a risk of falling required of participants in this study. There is a small risk of a small, short-term increase in discomfort following the clinical tests, however, we do not anticipate any significant increase in the participants' discomfort. We have used a similar VICON protocol previously will no adverse events related to the biomechanical (VICON) protocol. Participants will be provided with advice as to how to mitigate this should it occur, and will be provided with Dr Fearon and Dr Bousie's (both registered physiotherapists) contact details should they be concerned about ongoing discomfort.

The AQoL questionnaire as questions related to mental health issues. Dr Fearon has Mental Health first aid training and will be available should this questionnaire raise issues for people. The participant information sheet has been amended to include a warning to this effect and includes contact details for Lifeline and Beyond Blue.

Participants will be instructed to remove the orthosis from their shoe if they encounter any discomfort or excessive pain.

Participants will have the process of the VICON assessment clearly explained to them, including the need to wear reflective markers, and to wear tight-fitting clothes - so as to minimize any unexpected embarrassment. We have access to some "Skins" that participants may borrow if they don't own something similar.

Should an adverse event occur, such as a fall, the participant will be provided with first aid (Dr Spratford is a qualified first-aider) and either taken to Accident and Emergency or asked to see their own GP if appropriate.

It is anticipated that the active orthosis will provide pain relief, while the sham orthotic will make no difference.

12.3. Is there any possible risk to you as the researcher and if so, what are your strategies for minimising this risk?

No risk to the researchers from this research project.

12.4. Is there any possible risk to others arising from this research project?

No risk to others arises from this research project.

13. Consent

13.1. How will participants consent to the research and how will you ensure that participation is voluntary?

Participants will be initially screened via a telephone call. During this call the purpose of the study, the methods and any associated risks and benefits will be explained. Verbal consent will be gained at this time. At the time of the clinical screening, the purpose of the study and any associated risks and benefits will be explained again and the participant invited to ask for clarification. Following the screening appointment, where the participant meets the inclusion criteria, they will be provided with an opportunity to ask further questions about the study, invited to join the study and invited to provide written, informed consent. Participants will be clearly informed that they may withdraw at any stage without consequence.

13.2. How will participants be able to withdraw from the research project without penalty and without feeling discomfort?

Participants will be informed that they may withdraw at any time during the study, without having to supply an explanation and without risk of affecting any medical care or future participation in a study. Should a participant withdraw they will be treated respectfully. Any data collected up to the point of withdrawal will be maintained.

13.3. Do you intend to withhold or disguise the purpose of the research in any way?

- ○ Yes
- ◉ No

14. Data, Access and Storage

14.1. What type of data will be collected?

- ☐ Non-personal information
- ☑ Personal information
- ☐ Sensitive Information
- ☑ Health Information
- ☐ Information about the health of Aboriginal people

14.1.1. Please outline in more detail what type of sensitive and/or health information will be collected.

We will be collection health information in the form of the Functional Comorbidity Index (see attached). This will be collected by a honours student under the direct supervision of a registered physiotherapist (Dr Fearon or Dr Bousie). The Functional Comorbidity Index is a widely used, reliable and valid tool for assessing co-morbidities that may impact on musculoskeletal conditions.

14.2. Will the data be individually identifiable, re-identifiable or non-identifiable?

- ☐ Individually identifiable
- ☑ Re-identifiable
- ☐ Non-identifiable

14.2.1. Please outline in detail how re-identifiable data will be coded.

A table will be developed that lists the participants' name and code (numeric). This will be kept separately to the data on the secure computer, and later UC server.

14.3. Will other persons be able to identify research participants from published data or other sources?

- ○ Yes, but only with the participants' consent
- ◉ No

14.4. Who will have access to the data?

- ☑ Only personnel listed in this application
- ☐ Researchers other than those listed in this application
- ☐ Transcription and/or translation services

14.5. What source(s) of information will be used in this research project?

- ☑ Individual participants
- ☐ Relatives or associates of participants
- ☐ Medical/health/mental health records
- ☐ Electoral roll
- ☐ Law enforcement agency
- ☐ Publicly available database
- ☐ Privately available database
- ☐ Internet

14.6. Where will the data be stored?

- ☐ Electronic data will be stored for at least five years after publication at UC
- ☑ Clinical Trial data will be stored for at least 15 years after publication at UC
- ☐ Data in paper format will be stored for at least five years in a secure cabinet and office at UC
- ☑ Clinical Trial data in paper format will be stored for at least 15 years in a secure cabinet and office at UC
- ☑ The data will be archived at UC (longer than the required period)
- ☐ A copy of the dataset will be stored on my password protected private computer/laptop
- ☐ Data will be stored in the cloud or other devises throughout the project but transferred to UC at the conclusion of the project

14.7. Do you intend to use the data in future research projects?

- ○ Yes
- ◉ No

15. Clinical Trial Description

15.1. Please provide a short trial description in plain English.

This is a prospective randomised controlled trial that will examine the effect of using shoe inserts (orthotic) on pain and walking dysfunction in people with hip pain.

15.2. Please advise whether the investigators have sufficient experience and provide details of previous trials conducted by the investigators.

The research team has extensive research experience in this field.
Dr. Fearon's Ph.D. was specifically on GTPS. She has 15 peer-reviewed papers examining various aspects of the pathology and function of people with tendinopathy, 9 of them specific to GTPS, and one specific to VICON related testing. She was the primary supervisor of an honours student in 2017 who undertook a similar protocol - the paper is currently under review. She was a co-supervisor (along with Dr. Spratford) for a visiting Ph.D. student who used the VICON to assess athletes jumping off a box and the force through the patella tendon. In addition, Dr. Fearon has 32 years of relevant clinical experience and currently works with Prof. Paul Smith as a clinical consultant, and is a visiting physiotherapist at the AIS.

Dr. Spratford has over 15 years of experience in conducting scientific research studies using motion analysis equipment both here at UC and the Australian Institute of Sport.

Dr. Bousie's research area is on the use of orthoses in clinical conditions. Further, due to her dual professional backgrounds as both an engineer and physiotherapist, her skills have enabled her to conduct research within the biomechanic domain. Dr. Bousie also has 15 years of clinical experience as a practicing physiotherapist.

Dr. Welvaert received extensive training on the ethical conduct and data requirements of clinical trials during her Master in Statistical Data Analysis and PhD in Applied Statistics. She has 3 years of post-doctoral experience in supporting clinical researchers with their experimental design, data management and analysis.

15.3. Please provide the name(s) and contact details of the trial sponsors.

Funding was won during the University of Canberra "Pitch for funds"

15.4. Please provide indemnity information.

The study will fall under the University of Canberra's insurance. Please see attached certificate.

15.5. Please provide the name and contact details of the granting body.

Funding was won during the University of Canberra "Pitch for funds". Contact is the Research Office at UC.

15.6. Please provide the target participant numbers.

The sample size was calculated for the primary outcome of hip adduction moment. Allison et al, (2016). Using 80% power, an alpha of 0.05, and assuming a conservative mean difference (SD) of 0.4 Nm/BW.Ht (1.0) we calculated 50 participants would be required to detect a difference. Calculations were carried out using STATA 12.1 (STATA Corp, Texas, USA).

15.7. Please provide the target participant numbers for the whole trial period.

50

15.8. Does the trial involve the following:

- ☐ The administration of drugs (including complementary and alternative medicine)
- ☐ The use of a medical device
- ☐ The administration of human somatic cell gene therapy
- ☐ The use of xenotransplants
- ☐ The use of stem cells (adult or embryonic) as therapy
- ☑ Other

15.8.1.f If "Other", please provide more information.

We will be asking participants to place shoe inserts, "orthotics", into their shoes, and to use these for four weeks.

15.9. Please provide detailed information on any expected adverse events for this trial and how these events will be mitigated.

The most likely adverse event is a mild discomfort associated with having the shoe insert in the shoe. The participants will be advised to take the orthotic out of their shoe in the first instance and directed how to wean into using the shoe insert.
A second possible adverse event is that participants may notice increase anxiety following undertaking the AQOL. Participants will be advised of this slight risk, and first invited not to continue with the questionnaire should this be an issue. Secondly, the lead investigator has Mental Health first aid training, and she will be available should this issue arise. Participants who report high levels of anxiety, or measure the same on the AQoL will be followed up and invited to make an appointment with their GP (or A&E if the event is acute and there is a concern for the participants' safety.

15.10. Will the project be conducted under the Clinical Trial Notification Scheme (CTN)?

- ○ Yes
- ◉ No

15.11. Will the project be conducted under the Clinical Trial Exemption Scheme (CTX)?

- ○ Yes
- ◉ No

15.12. Will this be a multi-centre trial?

- ○ Yes
- ◉ No

15.13. Where will the trial be held?

- ☐ Public Hospital
- ☐ Private Hospital
- ☐ Community Health Centre
- ☑ UC Campus
- ☐ Other University / Research Centre
- ☑ Other

15.13.1. If 'Other' or 'Other University / Research Centre', please provide more information.

Participants will be using the orthotics for four weeks during their everyday activities.

15.14. Are the premises suitable for the proposed trial?

- (•) Yes
- ( ) No

15.15. Will trials be conducted in the USA or Canada?

- ( ) Yes
- (•) No

15.16. Will the trial be registered with the ANZCTR database?

- (•) Yes
- ( ) No

Upload relevant attachments

Please upload all relevant documents supporting your application.

Type	Name	File Name	Date	Version	Size
Default	4. Outcome measure AQoL-6D	4. Outcome measure AQoL-6D.pdf	11/04/2018 00:00:00	1	94.9 KB
Default	4. Outcome measure Functional co-morbidity index	4. Outcome measure Functional co-morbidity index.doc	11/04/2018 00:00:00	1	44.5 KB
Default	4. Outcome measure_Harris Hip Score	4. Outcome measure_Harris Hip Score.pdf	11/04/2018 00:00:00	1	123.1 KB
Default	4. Outcome measure_OARSI ICOAP_ hip_pain	4. Outcome measure_OARSI ICOAP_ hip_pain.pdf	11/04/2018 00:00:00	1	39.5 KB
Default	4. Outcome measure_VISA-G	4. Outcome measure_VISA-G.pdf	11/04/2018 00:00:00	1	360.8 KB
Default	4. Outcome measures_clinical	OARSI manual.pdf	13/04/2018 00:00:00	1	1.3 MB
Default	4. Outcome measure_Global Rating Of Change	4. Outcome measure_Global Rating Of Change.pdf	13/04/2018 00:00:00	1	54.2 KB
Default	4. Participant Information and Consent Form	Participant Information and Consent Form AF20180802.docx	02/08/2018 00:00:00	2	551.9 KB
Default	CAN - GPL $20m CoP 17-18	CAN - GPL $20m CoP 17-18.pdf	07/08/2018 00:00:00	1	113.4 KB
Default	CAN - PL $30m CoP 17-18	CAN - PL $30m CoP 17-18.pdf	07/08/2018 00:00:00	1	119.8 KB

Declarations and Signatures

Declaration

I certify that:

1. All information is truthful and as complete as possible.
2. I have had access to and read the National Statement on Ethical Conduct in Human Research, and that the research will be conducted in accordance with the National Statement and in accordance with the ethical arrangements of the organisations involved.
3. I have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
4. I have, if applicable, discussed this application with any collaborators and other persons involved in this research project, they are aware of the requirements and conditions and will conduct the research in accordance with these.
5. I will immediately report to Research Ethics & Integrity anything which might warrant review of the ethical approval of the proposal.
6. I will inform Research Ethics & Integrity, giving reasons, if the research project is discontinued before the expected date of completion.
7. I will adhere to the conditions of approval stipulated by the Committee and will cooperate with the Committee's monitoring requirements, including the provision of annual progress reports and final reports as required.

Signature of Chief Investigator

Signed: This form was signed by Angie Fearon (Angie.Fearon@canberra.edu.au) on 18/08/2018 13:03