Participant Information Sheet

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Project title: **Insole testing (biomechanics and pain rating)**

Research Team

Professor Patria Hume, Aaron Jackson, Scott Crawford, Juno Collins, Libby Anderson, Greta Gottschick, Sara Bartolo, Nikki Reynolds, Dr Doug King, Dr Dion Enari

Sponsor: AUT and AUT Ventures

Funder: Implus, LLC (An American company that distributes insoles).

Study Site: Auckland University of Technology (AUT Millennium campus in Rosedale)

Contact phone numbers:

1. Clinical Evaluator (CE) Libby Anderson (**022 308 7780**)
2. Research Officer Juno Barnett Collins (**021 028 43954**)

Ethics committee ref.: HDEC #2024 FULL 21021

AN INVITATION

Tēnā koe (greetings to you). My name is Professor Patria Hume and on behalf of the research team, you are invited to participate in this research study that aims to assess how insoles affect lower limb biomechanics, foot pressure, and self-reported pain and comfort.

You are invited to participate in this research study that includes two laboratory testing sessions of one hour each plus wearing an insole for 5 weeks and reporting each of those weeks for 5 minutes.

Participation is voluntary. If you agree to participate you will be assessed at AUT Millennium. We will collect some basic information about you, such as your age, height, weight, any clinical conditions you have, and your level of physical activity. During the lab visits, you will undergo several tests, including walking for 10 steps, foot pressure measurement, pain assessment, your standing posture, a scan of your feet, and a comfort evaluation. You can also participate in an additional 3D biomechanics test, which involves walking with markers on the shoes and your lower limbs. Initially, you will complete a set of tests (S1), then you will wear an insole for five weeks, followed by a second set of tests (S2). Throughout the five weeks, you will self-report your pain levels and physical activity each week. This process helps us understand how the insole affects your movement and comfort over time.

The data collected within this research will be analysed only by the research team and will be presented as deidentified group data before being published.

Please ensure you read the information below and understand this prior to partaking in the study. If you have further questions or concerns, you can contact the research team using the details at the bottom of this document.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 9 pages long. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Insoles are commonly used to improve foot function, alleviate pain, and enhance comfort. Understanding their impact on lower limb biomechanics, foot pressure distribution, and self-reported pain and comfort is crucial for optimizing their design and application. Therefore, the aim of the study is to assess how the insoles affect lower limb biomechanics, foot pressure, and self-reported pain and comfort.

The findings of this research may be used for academic publications and presentations and future research grant applications.

HOW WAS I IDENTIFIED TO PARTICIPATE IN THIS SURVEY?

To identify potential participants for our study, we have used a multi-faceted recruitment strategy involving posters and social media. Posters have been placed in podiatry clinics, gymnasiums, and medical clinics to target individuals who are likely experiencing musculoskeletal issues. Additionally, social media platforms have been utilized to reach a broader audience through targeted ads, community groups, and collaborations with local influencers and healthcare professionals. Interested individuals will contact the research team via insole@aut.ac.nz and the researchers contact phone number, undergo an initial screening to ensure they meet the inclusion criteria, and then provide informed consent before being enrolled in the study. This approach ensures a diverse and relevant participant pool, enhancing the study's effectiveness and reach.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

If you are 18 years of age or over you express interest in the study via the researcher at insole@aut.ac.nz. After reading the participant information sheet, you can sign the consent form if you are happy to proceed. This can then be emailed back to our team or brought with you to your session. If you have questions we are happy to answer these via email or in person at your session. If it is easier for you, the consent form can be completed upon arrival at our testing site.
If you choose to not participate this will not affect you negatively and you can decide not to participate at any time during the data collection and analysis and you do not need to provide a reason.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

As a study participant you will be given the option of being assessed at AUT Millennium. We will collect some basic information about you, such as your age, height, weight, any clinical conditions you have, and your level of physical activity.

During the lab visits (session-1 and five weeks later session-2), you will undergo several assessments, including pain and comfort assessment, a foot posture index assessment, and a scan of your feet. You will perform four walks for 8-10 steps each for four conditions with and without insoles and with and without an in-shoe pressure system. Two will examine the way you move and the other will look at pressure under feet. We will insert a thin measurement insole on top of the shoe insole. We record your movements with high-speed cameras.

You will complete the assessments in session-1 (S1), then you will wear an insole for five weeks, followed by a second set of assessments (S2). Throughout the five weeks, you will self-report your pain and comfort levels and physical activity each week. This process helps us understand how the insole affects your movement and comfort over time.

After the initial S1 session you will be sent a new weblink every seven days via email. This link will provide access to self-reporting of pain level and physical activity set up on REDCap, which is a secure online research database. The self-reporting will take a maximum of five minutes to complete each week. You will use your unique identifier number when you answer the questions.

Assessment	S1	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	S2
1. Demographics	X						X
2. Clinical condition	X						X
3. Pain-comfort	X	X	X	X	X	X	X
4. Foot pain	X	X	X	X	X	X	X
5. Physical activity	X	X	X	X	X	X	X
6. Injuries	X	X	X	X	X	X	X
7. Foot posture index	X						X
8. Foot scan	X						X
9. Plantar pressure	X						X
10. 3D biomechanics	X						X

You are asked to bring close-fitting shorts and a T-shirt. Close-fitting clothing such as shorts, and a T-shirt ensures the markers can be placed accurately on the body for the movement analysis. Shoes will be provided for the lab testing sessions. Please also bring a pair of walking shoes that you would like to wear your new insole in for five weeks.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You can withdraw from the study at any time. If you choose to

withdraw from the study, you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. Your data will be de-identified in all analysis, reports and publications. Once the data has been analysed and findings have been produced, removal of your data may not be possible.

You need to decide given your foot, knee or back discomfort if you want to participate in this study; but you can opt out at anytime.

Whilst this project does not target any specific cohort, given the large percentage of Māori and Pacific peoples who have diabetes it does acknowledge the potential to involve participants from these populations. The research team are aware of the need to observe tikanga and have taken steps to seek guidance prior to implementation of the study protocol. Formal Māori consultation has been undertaken in preparing for the study and ethics applications via Dr Doug King who is the co-investigator and Māori liaison for the project.

HOW IS THE STUDY DESIGNED?

The study is a pre-post study where participants are measured before (pre) and after (post) the intervention of wearing insoles for five weeks. This design helps to evaluate the effectiveness of the intervention by comparing the outcomes before and after it is applied. There are ten insoles to be assessed for different clinical conditions – except plantar fasciitis where there are three insoles and so participants will try all three and give pain and comfort scores, and take the one they self-select for the five weeks intervention.

WHO CAN TAKE PART IN THE STUDY?

You have been invited to take part in this study because you are between 18-65 years old and have heel pain, sore knees or back, or diabetes, are able to complete a 2-minute walk, and are willing to wear the provided insoles for five weeks and participate in two testing sessions that will last one hour each.

You will be able to start the study if you meet the inclusion criteria outlined below.

Inclusion Criteria
- Age: Participants aged 18-65 years.
- Ethnicity: Any
- Individuals with specific health conditions relevant to the study (i.e. heel pain, knee or back pain).
- Residents of the Auckland region to facilitate follow-up and community engagement.

Willingness to Participate:
- Participants must be willing to attend the two data collection sessions and wear the insole over five weeks.

Exclusion Criteria
- Individuals with severe comorbidities that could interfere with the study outcomes (e.g., severe cardiovascular disease).
- Individuals who are unable to provide informed consent due to cognitive impairments or language barriers.
- Participants who are physically unable to complete a 2-minute walk.
- Individuals who currently wear foot orthoses, or non-standard insoles

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There are no risks to participating in this study other than what is normal for walking activity. There is no direct cost to you for participating in this study. To protect your comfort and privacy your data collection sessions will be conducted according to standard sport and exercise science and clinical protocols.

Individual information will not be shared or discussed. Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small but may increase in the future as people find new ways of tracing information.

This research includes basic information such as your ethnic group, age range, and gender. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

WHAT ARE THE BENEFITS?

The benefit of participating in this study is you are helping the researchers to evaluate the efficacy of readily accessible, over the counter insoles which are commonly used to address foot pain and discomfort. There is a benefit to the funder as they will receive a report on the study.

HOW WILL MY PRIVACY BE PROTECTED?

Results will be provided as de-identified group data. All data collected during the study will be in storage at the AUT SPRINZ ethics storage room. All data will be stored under the AUTEC policy, which secures this data for six years.

WHAT IF SOMETHING GOES WRONG?

As this research study is for the principal benefit of its commercial sponsor (Implus), if you are injured as a result of taking part in this study you won't be eligible for compensation from ACC.

However, AUT has satisfied the Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study. If you sustain an injury during the course of the study you are required to report this to the research team who will contact insurance to help you.

New Zealand ethical standards require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand's ACC scheme.

WHAT WILL HAPPEN TO MY INFORMATION?

When you consent to take part in this study, you will be assigned a unique identifier number (e.g. CH001) so that your information can be de-identified for analysis. This number will be noted on your consent form. During this study the trained research officers will record information about you and your study participation. This includes your consent form.

The self-reported pain and physical activity ratings will be collected online and you will use your unique identifier number when you complete this questionnaire. You cannot take part in this study if you do not consent to the collection of this information.

All of the research data collected in this study will be stored on a secure computer and password protected at AUT Millennium. Aaron Jackson, Juno Collins and Professor Patria Hume will have access to your identifiable research data. HDEC and AUT may have access to identifiable data for audit purposes.

For research purposes, a master spreadsheet will be created with all information that could identify you removed, your unique identifier number will be used to record data in this spreadsheet. Only this second de-identified spreadsheet will be shared with the rest of the research team and used for analysis and in publications/presentations.

If you choose to withdraw from the study, you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. Your data will be de-identified in all analysis, reports and publications. Once the data have been analysed and findings have been produced, removal of your data may not be possible.

IDENTIFIABLE INFORMATION

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only Professor Patria Hume will have access to your identifiable information.

DE-IDENTIFIED (CODED) INFORMATION

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by Professor Patria Hume. Instead, you will be identified by a code. Juno Collins will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following people may have access to your de-identified (coded) information:

- Biostatistician assisting in final data analysis.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

SECURITY AND STORAGE OF YOUR INFORMATION

All of your personal information will be stored on a secure computer and password protected at SPRINZ. Only named members of the research team will have access to this information.

For research purposes, you will be assigned a unique identifier code so that your data can be de-identified. A second master spreadsheet will be created with all information that could identify you removed. Only this second de-identified spreadsheet will be shared with the rest of the research team and used for analysis and used in publications/presentations. Analysis and reporting of data will be de-identified and at the group level. All reporting of data in reports and publications will be de-identified and at the group level.

RIGHTS TO ACCESS YOUR INFORMATION

You have the right to request access to your information held by the research team in the SPRINZ ethics storage room. You also have the right to request that any information you disagree with is corrected.
Please ask if you would like to access the results of your tests during the study.
If you have any questions about the collection and use of information about you, you should ask Juno Collins.

RIGHTS TO WITHDRAW YOUR INFORMATION

You may withdraw your consent for the collection and use of your information at any time, by informing Juno Collins or Professor Patria Hume. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you wish to withdraw from the study at any point you can contact either Juno Collins or Professor Patria Hume. If you do withdraw from the study, you can choose to either, allow the information collected up until your withdrawal to continue to be used or you may ask for it to be deleted when you withdraw. If you withdraw after the study analyses have been undertaken it may not be possible to remove your data/information.

WILL I RECEIVE FEEDBACK ON THE RESULTS OF THIS RESEARCH?

The overall study results will be published on the AUT SPRINZ SKIPP website Sports Kinesiology Injury Prevention and Performance - SPRINZ - AUT.

Within 120 days of the study finishing a 1-2 page summary of the research findings will be available. If you would like to receive your individual results, please indicate on the consent form, and provide a contact email address.

WHO IS FUNDING THE STUDY?

There are no direct financial costs to you as a participant in this study. This research is part funded by Implus (An American company that distributes insoles).

Each participant will receive $20 voucher for each of the pre and post in clinic tests (i.e., $40 for the study). In addition there is a prize draw for 20 pairs of Asics shoes for those that complete the 5-week intervention and post-testing session. Each participant gets to keep the pair of insoles from the intervention and the socks used in lab testing.

WHAT DO I DO IF I HAVE CONCERNS OR FURTHER QUESTIONS ABOUT THIS RESEARCH?

If you have any concerns regarding this project, please contact the lead investigator – Professor Patria Hume, patria.hume@aut.ac.nz mobile 021 805 591.

For Māori cultural support contact please contact Dr Doug King, doug.king@aut.ac.nz; and for Pacific cultural support please contact Dr Dion Enari, dion.enari@aut.ac.nz.

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@advocacy.org.nz
Website:	https://www.advocacy.org.nz/

You can contact the health and disability ethics committee (HDEC) that approved this study on:

Phone:	0800 4 ETHIC
Email:	hdecs@health.govt.nz

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The HDEC Northern Committee has approved this study.

Approved by

Health and Disability Ethics Committee September 2024; HDEC Reference number HDEC #2024 FULL 21021

Note: The Participant should retain a copy of this form.