Toe Walking

Participant Information and Consent Form

Short Name of Project	Do textured insoles reduce the amount of toe walking in children or alter function?
Full Name of Project	Can textured insoles reduce the amount of toe walking in children with sensory needs? A randomised controlled feasibility trial.
Principal Investigator	Nicole Marshall
Project Sponsor	Southern Adelaide Local Health Network with contributions from the Flinders Foundation and The Hospital Research Foundation
Site Name	Flinders Medical Centre

What am I being invited to do?

Your child is being invited to participate in a project that investigates if we can improve the amount or height of toe walking, balance or walking speed with the use of supportive sneakers (ASICS contend) with or without Naboso textured insoles. We are also determining the feasibility of the study design and whether it can be conducted on a larger group of children. Before you decide it is important for you to understand why the research is being done and what it will involve

Please take the time to read this information carefully and feel free to ask any questions. You can take some time to make up your mind and decide if this project is right for you. You can also talk to someone you trust, like a family member, friend, or your local doctor.

What is the purpose of this project?

Toe walking occurs in 5% of all children, more in children with Autism Spectrum Disorder. Toe-walking can result in pain, changes in foot bone development, more trips or falls and even bullying. Good shoes are known to improve the way our feet move. Textured insoles have shown to improve balance in children and adults. We do not know, however, if either shoes or shoes plus a textured insole will work for children who toe-walk.

In this project, we are recruiting children aged between 4 to14 years who walk on their tip toes. Children will be eligible if we are not sure why they toe walk or they have been diagnosed with Autism Spectrum Disorder or Sensory Processing Disorder. We want to see if using an insole with textures can change their toe walking.

We also want to find out if it improves ankle movement, helps with their balance or makes them less tired when they are walking. The usual ways for treating toe walking don't always work well and take time, can be uncomfortable, and expensive. We know that shoes and insoles have helped adults and kids with movement problems and we want to see if it will help toe walkers too. Before we start a larger study, we're checking if the way we're doing this study works well for parents, kids and the researchers involved.

Who can take part?

Children aged 4 to14 years who are seeking treatment for toe-walking. The child/ren will also need to:

1. be able to communicate with researchers,
2. participate in simple balance tests that are modified depending on the age of your child (e.g. attempt to walk along a line on their tip toes and on their heels, standing on one leg for short periods of time and hopping or jumping on mats). They will also be asked to stand still on a force platform in relaxed standing for up to 30 seconds and this will be repeated 5 times with their eyes open and with their eyes closed.
3. complete 2 walking tests (one where they walk for 2 minutes around a dedicated circuit, and another where they walk along a 10 meter walkway with 3 markers placed on their shoes and we measure the height of their toe walking). Children will be able to rest as many times as they need during the walking assessments.
4. not have had treatment for toe-walking in the last 3 months, including surgical, casting of their feet and/or legs or Botox, and,
5. be able to stand with their heels touching the ground.

If you are not sure whether your child is eligible for this study, a researcher can contact you to discuss any medical or health related issues. All children will be required to have a parent/caregiver attend with them.

Do I have to take part and can I change my mind?

Taking part is up to you

You get to decide whether you take part in this project. You can say yes or no.
Your decision won't affect your relationship with your podiatrist, health professionals or the hospital. If you don't take part, your health professional will discuss other options with you.

You can change your mind at any time

If you do take part, you can stop at any time. If you want to stop, please tell someone in the project team. You do not have to tell us the reason. You can keep the shoes (and insole if relevant)

Once you stop taking part, we will not collect any more information about you. We will keep the information we have already collected to make sure the results of the project can be measured properly.

The project might stop for other reasons

We might need to stop the project while you are taking part. If this happens, we will explain the reasons to you.

We may also ask you to stop taking part in the project if it is no longer in your best interest. If this happens, we will discuss this with you.

What do I have to do if I take part?

Children and their caregivers will need to be willing and able to attend Flinders Medical Centre three times over 4-6 months, for around 1 and a half hours each time. During the 3 sessions we ask that your child wears comfortable clothing such as shorts or pants which will not interfere with their ability to jump or hop and brings their shoes along. All of the assessments will take part within the Flinders Medical Centre Gait Laboratory or an adjacent clinical consultation room.

This table below outlines what you need to do in this project. For more information, please ask Nicole Marshall (Chief Investigator).

What part of the project?	What do I have to do?
Consenting to take part in this project	If you are happy to take part in this project, you will be asked to sign a consent form.
When you start	At the first visit we will measure your child's height, weight and ask you questions about their medical and toe walking history. We will assess their ankle movement using a simple standing calf stretch (modified for younger children). Children will be asked to complete a series of simple balance and walking tests as described above in their own shoes. At the end of the first appointment children will be fitted with Asics ® Contend sneakers, and randomised to receive the shoes alone, or to also be fitted for a textured insole to be worn inside the shoes. Children will be asked to wear the footwear (including insoles where relevant) over 8 weeks and then return for follow up testing. During this time children and parents/caregivers will be asked to keep a daily diary (on a sheet of paper supplied) on how often they wore the footwear and how they felt in terms of comfort and performance. An occupational therapist will contact parents/caregivers over the phone (at a mutually acceptable time) to ask a range of questions about your child's sensory profile. This assessment is called The Sensory Profile 2 and will take approximately 45 minutes to complete.

At your second appointment (8 weeks after receiving footwear)	At the second visit, the child will complete the same balance and walking tasks in the shoes (plus insole where relevant) we have supplied. Some photos of the child's feet and legs may be taken whilst completing these tasks.
At your third appointment (final follow up 16 weeks after receiving footwear)	At the third visit, children will complete the same balance and walking tasks in the shoes (plus insole where relevant) we have supplied. Some photos of the child's feet and legs may be taken whilst completing these tasks.
At the end of the project	Parents/caregivers will also be asked to partake in a 10-minute telephone interview with a researcher (at a mutually acceptable time) within a couple of weeks of completing the study. This interview will be audio-recorded for transcription (note-taking) purposes. We will also ask for your diary that has been filled out over the course of the project.

Payment for your time and expenses

You will be asked to spend 6 hours in total over 3 visits. There will be 3 visits to Flinders Medical Centre and 1.5 hours should be allocated to each visit. You will receive 2 phone calls, the Sensory Profile will take 45 minutes with an occupational therapist, the second will be a 15 minute phone call with a research assistant at the end of the project. To recognise your time, we will offer you a $25 gift voucher at the midpoint follow up and a $25 gift voucher will be posted to your nominated address at the end of the project. Your child will receive a free pair of ASICS Contend footwear and some children will receive a textured insole. The shoes and insole (where given) will be yours to keep at the end of the trial.

What are the benefits of taking part?

We cannot guarantee your child will receive any benefits from taking part in this research (other than the supply of ASICS Contend shoes free of charge and 2 x $25 gift certificates for those who complete the study). However, it is possible that your child's toe walking may improve from taking part in this project but this remains unknown. You will receive a summary of your child's sensory report and of the balance/gait assessments conducted. These will be available once the study has been completed and submitted for publication. Broader benefits of taking part may include a broader understanding of how footwear, and footwear and insoles may impact on balance, endurance and toe walking in children. It will also indicate the feasibility of running the study for a larger group of children.

What are the risks and discomforts of taking part?

As your child will be completing motor skill assessment protocols and being asked to wear new footwear, there is the potential risk of injury as your child may be unfamiliar with the movements and there can be some discomfort in phasing in new shoes. Possible injuries may include a fall resulting in a soft tissue injury or a bruise. Wearing new shoes may result in a pressure area or a blister. However, the tasks will be undertaken in line with standardised protocol that is expected of gross motor skill assessment and injuries during these assessments are rare. If the child expresses that the shoes are causing discomfort, general fitting checks can be completed and mild modifications to footwear conducted (e.g. looser lacing or the addition of 'bandaids' to friction areas). If your child experiences any adverse events as a result of participating in the tasks associated with this research, a first aid protocol will be followed. If the child is feeling more than general discomfort at any time, the session can be stopped, rescheduled, or ceased depending on child's wishes.

Your child will be asked for some sensitive and personal information such as their height and weight which will be kept private and confidential.

All researchers hold a National Police Clearance and the appropriate clearances to work with children.

If I take part, what will happen to my information and samples?

Collecting your information

By signing the consent form you consent to the research team collecting and using information about/from you and your child for the research project. Any information obtained in connection with this research project that can identify your child will remain confidential. Information collected or used will be stored as re-identifiable during the course of the study (so we can check your results from visit 1 compared to visit 2/3 and be able to cross-check this with the footwear diary and survey) and then non-identifiable once your participation is complete. Non-identifiable data may be made publicly available in a data repository as required by the journal of publication and can be shared with participants on request.

All paper copies (e.g. of the diary) will be transposed into an electronic version and the hard copies securely destroyed. All balance and walk test outcomes will be stored electronically on an excel file. All 3D gait analysis and GaitRite measures will be stored on password protected systems within SA Health. This de-identified data will be kept on a secure server, password protected, within SA Health.

Your information will be used for the purpose of this research project and, if a larger study using the same insoles and measures is conducted later, your non-identifiable data will be included in that study outcomes. Data will only be disclosed with your written consent, except as required by law.

Keeping your information safe

To keep your information safe, we will:

- follow all relevant privacy requirements
- keep it securely on an electronic excel file which is password protected and stored a password protected PC on SA Health's password protected database.
- take steps to prevent anyone from accessing information that identifies you unless they need to, for example, to check it in an audit
- give it a code and keep it separate from anything that could easily identify you, like your name or contact information.

You can ask us to tell you what information we have collected about you as part of this project. If your information is not correct, you can also ask us to change it. We will keep your and your child's information for 33 years. After this, it will be deleted from our system.

Getting more information

If you would like to know more about how we will collect, store, and share your information as part of this project, see SA Health's Data Quality Management Policy and Privacy Policy. A copy of the results of the study will be available by request once analysis and publication has been achieved. To receive a copy, please email nicole.marshall@sa.gov.au. We will also ask you if you want a copy of the results at the follow up telephone interview.

Who is running and paying for this project?

This project is being run by the Southern Adelaide Local Health Network (SA Health).

This project is being funded by the SALHN enquiry grant with funding sources from The Hospital Research Foundation and The Flinders Foundation. ASICS, Naboso and the sponsors do not have a financial interest in the outcome of the research and have no input into the design, conduct, interpretation and analysis of the results.

Who has approved this project?

The WCHN HREC has approved this project. This committee ensures that this project meets Australian ethical standards for research that involves people.

If you have any complaints about how this project is being run, please contact:

Reviewing HREC Name	Women's and Children's Health Network Human Research Ethics Committee
HREC Executive Officer Telephone and email details	Telephone: (08) 8161 6521 Email: HealthWCHNResearch@sa.gov.au

Where can I find more information?

Thank you for taking the time to read this information about our project. You can contact a member of the project team at any time to ask questions.

Name	Role (and organisation)	Phone	Email
Nicole Marshall	Podiatrist and lead investigator (Flinders Medical Centre)	0447 396 955 (08) 8384 9233	nicole.marshall@sa.gov.au
Dr Helen Banwell PhD	Podiatrist and associate investigator (University of South Australia)	(08) 8302 1256	helen.banwell@unisa.edu.au
Dr Ben Patritti PhD	Gait Laboratory Manager and associate investigator (Flinders Medical Centre)	(08) 8404 2661	ben.patritti@sa.gov.au
Kerrie Anderson	Physiotherapist and associate investigator (Flinders Medical Centre)	(08) 8302 2571	kerrie.anderson@sa.gov.au
Melanie Tripptree	Occupational Therapist and associate investigator (Flinders Medical Centre)	(08) 8204 6228	melanie.tripptree@sa.gov.au
Kelly Donnellan	Head of Unit, Orthopaedic Physiotherapy and associate investigator (Women's and Children's Hospital)	(08) 8161 7381	kelly.donnellan@sa.gov.au
Dr. Felix Tan	Senior Staff Paediatrician, Clinical Academic and associate investigator (Flinders Medical Centre)	(08) 8204 4459	Felix.tan@sa.gov.au

Signature page

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By signing this consent form, I acknowledge that:

- I freely agree to take part in this project
- I understand that I can stop taking part in the project at any time
- I have read, or have had read to me, the information provided about this project and understand what is involved
- I have had the opportunity to consider the information, ask questions, and am satisfied with the answers I received
- I give permission for my medical records to be access for the purposes of this project

Consent to optional parts of the project	Yes	No
I consent to my information being collected, stored and shared for any future research		

Person taking part in the project

Signature: _____ Date: _____

Name: _____

Person conducting the informed consent discussion

I have explained the research project, its procedures and risks to the participant and I believe they have understood that explanation.

Signature: _____ Date: _____

Name: _____

Witness

Signature: _____ Date: _____

Name: _____ *Each person must sign and personally date this consent form