PARTICIPANT INFORMATION SHEET
For parents/guardians of children with cerebral palsy

Project title: Smart Splint: Generate patient-specific musculoskeletal gait models of children with cerebral palsy.

Researchers

Julie Choisne (Principal Investigator, Research Fellow)
Thor Besier (Co-investigator, Associate Professor)
Susan Stott (Co-investigator, Professor and Paediatric Orthopaedic Surgeon)
Laura Carman (Co-investigator, PhD student)
Geoffrey Handsfield (Co-investigator, Research Fellow)
Salim Bin Ghouth (Co-investigator, PhD student)

Invitation

You and your child are invited to take part in a study to validate a patient-specific musculoskeletal gait model which require partial MRI images around the hip and knee of the patient. Patient’s full leg bones 3 dimensional geometry will be estimated from partial MRI volume which will make our model more accurate and reliable for clinician to use. This research project is jointly undertaken by the researchers at the Auckland Bioengineering Institute (ABI) and Starship Children’s Hospital for a period of 36 months. The study will be overseen by Dr Julie Choisne, a research fellow and primary investigator in the ABI musculoskeletal modelling group, Prof. Thor Besier, a specialist in musculoskeletal systems and orthopaedics; Prof. Susan Stott, a consultant Paediatric Orthopaedic Surgeon at Starship Children’s hospital and Professor of Paediatric Orthopaedic Surgery at the University of Auckland; Dr Geoffrey Handsfield, a research fellow in the ABI and Ms Laura Carman and Mr Salim Bin Ghouth, PhD students at the ABI.

This Parent/Guardian Information Sheet will help you decide if you and your child would like to take part. It sets out why we are doing the study, what is involved, what the benefits and risks to you might be, and what would happen after the study ends. There is also a separate information sheet for your child. We will go through this information with you and answer any questions you both may have. You may also want to talk about the study with other people, such as family/whānau, friends, or healthcare providers. Feel free to do this. Whether or not you take part in this study is your choice.
If you do not want your child to take part, you do not have to give a reason, and it won’t affect the care they receive. If you do want your child to take part now, but change your mind later, you can pull out of the study at any time without giving a reason.

Your child has the right to consent to participate in research when they are capable of understanding what the study involves and the risks. If your child is unable to fully understand, their assent must be obtained unless your child is unable to communicate.

If you agree for your child to take part in this study, you will be asked to complete and sign a Consent Form. You will be given a copy of both the Parent/Guardian Information Sheet and the Consent Form to keep.

This document is 5 pages long, please make sure you have all the pages.

**Why are we doing the study?**

3-D gait analysis (3-DGA) is a key assessment for ambulatory children with cerebral palsy to determine if interventions can improve walking ability. Biomechanical analysis of gait relies on the use of lower-limb musculoskeletal models. These computational models have provided new ways to study muscle and joint function during motion and elucidate effects of musculoskeletal deformities on gait dynamics. However, these models are based on a generic model which takes into account the subject's bone dimensions by rescaling. We know that “children are not small adults” and differ significantly with respect to skeletal anatomy and physiology which makes generic models not adapted for paediatric population. We created a new tool to generate patient-specific bone shape from partial MRI data from children with CP. We want to validate this tool by comparing pelvis, femur, tibia and fibula bone shape from 1) manually reconstructed bone from full MRI and 2) bone estimated from partial MRI volumes at the hip and knee.

**What would your child’s participation involve?**

Your child participation consist of 2 visits.

- The first consist of imaging your child with a MRI scan from pelvis to toes at the Centre for Advanced MRI (CAMRI, FHMS, Grafton campus, University of Auckland). To minimize inconvenience to you and your child, you may choose to undertake imaging immediately following a regularly scheduled visit to your orthopaedic clinic. Your child will be accompanied into the scanner and set up in position on the bed of the MRI scanner with a foam block comfortably supporting your child’s foot and ankle in a slightly plantarflexed (~15°) position. A flex coil will be placed around your child’s leg. His/Her comfort will be ensured and verbally confirmed. Your child will be asked to remain motionless during MRI scans and scans will be initiated. Your child can talk
during the scan and give us verbal statements of discomfort at any moment. This will result in a scanning until reasonable comfort can be re-acquired. You can request to terminate the scan at any moment without giving a reason. This experiment will not take more than an hour.

- The second visit will consist of performing a gait analysis as your child might have done in the past at the Auckland gait clinic. We will place small wearable sensors; inertial measurement units (Figure 1) and Electromyography (Figure 2) onto the skin of your child’s foot, shank, thigh and trunk. The Inertial Measurement unit will be strapped with Velcro and will measure your child’s movement. Electromyography sensors will be used to record your child’s muscle activity and therefore needs a little bit more preparation. First we will wipe your child’s skin with alcohol prep pads where we want to place the electrode, then we will put a drop of gel on the area for the electrode to stick on the skin. These sensors will be used to measure your child’s lower limb movement and muscle activity. We will also place small reflective markers onto your child’s skin (little grey balls of 6.35 mm diameter), which will be tracked by several infrared cameras. The sensors and markers placed on the skin will be attached using double-sided hypoallergenic tape. We might have to remove hair from your child’s skin to ensure that the sensor is adequately attached and does not fall off during the experiment. Your child might experience some mild discomfort when removing the tape at the end of the experiment. In order to attach markers on your child’s skin we will ask your child to bring some tight above the knee short and a t-shirt. During the experiment, we will ask your child to walk several times as for his/her usual gait analysis at the Auckland gait clinic. The entire experiment will last no longer than two (2) hours.

What are the possible benefits and risks to your child of participating?

The first session does not involve any risk. A technical radiologist assistant will be present for the entire session.

The second session should not differ from the traditional gait analysis provided at the Auckland gait clinic except that we will place additional sensors on your child.

Every session is closely monitored and safety precautions will be in place.
There may be no direct benefit to you or your child from being part of the study. However, the information gained in the study will help validating our new model which will give more accurate information to your treating physician about how you walk.

**What are the rights of participants in the study?**

Participation is completely voluntary. Individuals are free to decline to participate, or to withdraw from the research at any time, without experiencing any disadvantage and without giving a reason.

All participants have the right to access information about them collected as part of the study. Participants will be told of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on their health.

All information collected will be kept strictly confidential. Privacy will be ensured in the collection, storage and publication of this research material. Data generated by the study will become property of the University of Auckland. Data that is created in the course of the research will be kept securely for a period of 10 years after the completion of this research project.

**What will happen after the study ends, or if your child pulls out?**

Participants are allowed to pull out of the study at any time without giving a reason and to withdraw any data traceable to them up to 13 months after signing the consent form.

**Where can you go for more information about the study, or to raise concerns or complaints?**

If you have any questions, concerns or complaints about the study at any stage, you can contact:

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For any queries regarding ethical concerns you may contact: The Chair, The University of Auckland Human Participants Ethics Committee, Office of the Vice Chancellor, Level 10, 49 Symonds Street, Auckland 1142. Telephone: 3737599 ext 83711. Email address: ro-ethics@auckland.ac.nz

Statement of Approval

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 27/07/18 FOR THREE YEARS. REFERENCE NUMBER 021615