



PLAIN LANGUAGE STATEMENT - parents

Project Title: Characteristics of mobility in children with Hereditary Spastic Paraplegia

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Your child is invited to participate in a research study designed to investigate walking patterns in children with Hereditary Spastic Paraplegia (HSP). This Plain Language Statement contains detailed information regarding this study. The aim of the statement is to clearly and openly explain all the procedures involved in the study. Feel free to ask questions about any information in the statement. Once you understand the information and if you agree to have your child to take part in the study, you will be asked to sign the two accompanying Consent Forms (one for your child to be involved in the study the other for consent to collect video footage).

Participation in this study is voluntary. If you agree to have your child take part, but later change your mind, you are free to withdraw consent for your child's participation at any time as well as withdraw any un-processed data previously supplied. Involvement in this project will not change the relationship with healthcare providers or researchers from the University of Melbourne, and will not influence the healthcare provided to your child. This project has received clearance from the Human Research Ethics Committee at The University of Melbourne.

What is the purpose of the study?

The aim of this study is to investigate whether children with HSP show particular patterns of movement in their legs and trunk when they walk. HSP can affect how people to walk, however not much is known about walking patterns in children with this condition. Walking patterns can be measured using a technique called three-dimensional gait analysis (3DGA). This picks up movements that cannot be seen by the eye and therefore can give a more complete picture of how the joints of the body move when someone walks. A better understanding of the common walking patterns of children with HSP may assist clinicians with diagnosis and treatment.

What will my child have to do?

You and your child will be asked to attend the Physiotherapy Department human movement laboratory at the University of Melbourne for a single assessment. The test will take approximately 2 hours to complete. You will be asked to bring a pair of shorts and a singlet for your child to wear during the assessment. During the first part of the assessment you and your child will be asked several questions relating to your child's age and date of birth, the history of HSP or walking difficulties in your family, your child's surgical history, the splints your child uses and the physiotherapy or exercise program that your child undertakes. You will also be asked to rate your child's general walking habits. You will be asked to bring copies of your child's medical reports or test results to help confirm your child's diagnosis.

During the next part of the assessment your child will be asked to change into their shorts and singlet and some measurements of their legs will be taken. These measurements help the computer to collect the information during the assessment and may include measures such as height, weight and leg length. We will also take other measures of your child's legs, including measures of how strong their muscles are and how tight their joints are. This part of the assessment will involve the researcher bending and straightening your child's legs and asking them to perform particular

movements. Following these measurements we will stick small shiny markers to different spots on your child's legs and back. These markers will be attached to the skin using double-sided sticky tape. Your child will then be asked to walk back and forth along a 10 metre level walkway approximately 10-14 times. During the walking assessment we will ask your child to walk barefoot and if possible without walking aids, such as crutches. When your child walks, the reflective markers move with your child's legs and the movement is recorded by 12 special cameras. The data from the cameras is sent to the computer. The computer will then turn the information from the cameras into information of how your child's body moves when walking. To help with our assessment of how your child walks, we will also take a video of your child walking during the assessment. The video footage will be used to confirm the data from the computer. Once the walking test has been completed the small markers will be removed.

Are there any potential adverse effects or risks?

Your child may experience fatigue from walking back and forth along the walkway. If your child does experience fatigue they can rest at any point during the testing session. They may also feel a stretch when we assess the muscles of their legs. If your child is sore during the assessment they should let us know and we can stop. The sticky tape that we use during the assessment is hypo-allergenic (non-itchy). We will ask before the test if your child has any allergies to latex or tape. There is a small chance that the tape will cause some skin irritation. If this does occur we ask that you tell the research staff as soon as possible. Sometimes there is some discomfort when the tape is removed, as it pulls on the small hairs on the skin. To help prevent this, the tape will be removed as gently as possible.

Will my child's details be kept confidential?

Any information collected during this study that can identify you or your child will remain confidential. It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Forms, we plan to publish the results of this study in scientific journals, as part of one of the researcher's doctoral thesis (Brooke Adair) and to present the results at scientific meetings.

In any publication, information will be provided in such a way that your child cannot be identified. For the purpose of the study, your child will be identified by a code number and not their name. Access to individual results is restricted to the named investigators of the study. According to the University regulations, coded data will be stored securely for 5 years following the publication of the results. All data and results will be handled in a strictly confidential manner, and the Principal Investigator is personally responsible for maintaining this confidentiality. These projects are subject to the requirements of the Human Research Ethics Committee of The University of Melbourne and the records may be inspected for the purposes of data audit by authorised representatives of this committee.

Despite the best efforts of the researchers to maintain your child's confidentiality, the relatively low incidence of HSP and the small number of children in this study may impact on the de-identification of your child.

Further information and problems

If you would like any further information regarding this study please contact Ms Brooke Adair, Department of Physiotherapy, the University of Melbourne, VIC 3010. Brooke can also be contacted via email b.adair@student.unimelb.edu.au or via telephone (03) 8344 0486. You may also contact the Principal Investigator of this project, Prof. Meg Morris on (03) 9035 3771.

If there is any matter about the study that concerns you, either now or in the future, you should contact the Executive Officer, Human Research Ethics, the University of Melbourne VIC 3010, Ph: (03) 8344 2073, fax: (03) 9347 6739.