

Participant Information Sheet

for young people 16-18 years

Study Title: Rehabilitation following Selective Dorsal Rhizotomy in New Zealand

Locality: Auckland, New Zealand

Ethics Committee ref.: 000114

Lead Investigator: Dr Nichola Wilson

Starship Child Health, Paediatric Orthopaedics, Level 4 Starship Children's Health Park Road
Grafton Auckland, Phone: (09) 307 4949

The University of Auckland, Department of Surgery, Level 12, Auckland City Hospital
Support Building, 2 Park Road, Grafton, Auckland, Phone: (09) 923 9820

SDR may be an important treatment option for children and young adults who have cerebral palsy and has generated much interest for individuals and their families. There has not been much research done about this topic in our country and we want to get a much better understanding of it. That is why we are inviting you to take part in our study that will document the delivery of healthcare for children and young adults in New Zealand who have had SDR performed.



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. You may contact us (see contact details below) if you would like us to 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.

Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

NZ children and young adults have been accessing the SDR procedure for a number of years to improve the spasticity associated with their cerebral palsy. We know very little about who they are, and the number, type and frequency of rehabilitation services they have required to support the success of their SDR procedure.

We would like to document the healthcare of children and young adults in New Zealand that have had SDR, with the long-term aim to improve access for all families to a co-ordinated and effective set of rehabilitation therapies following SDR.

Why me? You have been invited to be part of this study since you had an SDR procedure for cerebral palsy when you were a child or a young person, you are aged 2-18 years old, and are within the NZ hospital system. Families and individuals are being recruited to be part of this study in a variety of ways:

- The Cerebral Palsy Society NZ is aware of families and individuals in New Zealand who have had SDR and have offered to assist our study with contacting them to see if they would like to be involved.
- A clinician who was or is involved in your care may have mentioned the study to you and provided a participant information sheet or advertisement for you to consider.
- You may have noticed an advertisement in a newsletter from the New Zealand Cerebral Palsy Register or on a social media site, or seen a study poster displayed in a hospital or health service provider clinic, and requested we send this information to you.

This study has been approved by the Auckland Health Research Ethics Committee.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

There is no time required from you aside from reviewing the participant information sheet and signing the consent form. You have already done your part, and all the information we need to do this research is already recorded in your medical notes. If you agree to participate in this study no specific follow up will be involved.

The way that we will gather information for this study is to conduct what is known as a 'retrospective case note review'. A researcher will review your medical records to collect information. With your permission, the researcher may also need to contact any private rehabilitation providers that you may have engaged with to ask for information about the services they provided. Please list these providers on the attached consent form. Since your SDR procedure may have been done some years ago when you were a child, you may need to ask a parent, guardian or caregiver to confirm these details.

The information extracted from the case note review will include details about: demographics, past medical history, previous interventions, the SDR procedure (e.g. date and location, other surgery, rehabilitation protocol), radiological investigations and service delivery (e.g. type and number of hospital visits and therapy appointments before and after SDR).

The study will run for 2 years and during that time we will recruit participants, conduct case note reviews, and systematically record and summarise the findings.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The study will not immediately benefit you. If you decide not to participate your clinical care will not change. However, the information gained in the study will give families, individuals, clinicians and policy makers an understanding of rehabilitation for SDR in New Zealand. The findings will help us make comparisons with international practice and identify areas where access to services might vary according to differences in ethnicity or region.

There are no specific risks involved in taking part, as this study involves collecting information only. Whether you choose to take part or not, or if you wish to withdraw at any time, you will still be treated at the hospital as usual.

WHO PAYS FOR THE STUDY?

This study is funded by a research grant awarded by the Starship Foundation. There is no financial cost relating to your participation and you will not receive any payment for your participation.

WHAT ARE MY RIGHTS?

Participation in this research is completely voluntary and you are free to decline to participate, or to withdraw from the research at any time, without experiencing any disadvantage or judgment. If you decide to withdraw from the study, the information collected about you up to the point when you withdraw may continue to be processed.

Your privacy will be protected and identity kept confidential. You have the right to access information that was collected about you as part of the study. This information can be obtained by contacting the Principal Investigator.

HOW WILL THIS INFORMATION BE USED?

All patient details will be collected and kept in a confidential manner. Electronic data is stored in a password-protected computer network environment, and paper based data will be stored in a locked cabinet at Starship Child Health. Study data on participants will be retained by the researchers for 10 years after the youngest participant has reached 16 years of age. The Lead Investigator will be responsible for the secure storage and confidential destruction of all data. Participants will not be identified in published articles, presentations or training materials based on this study, but due to the small number of children who have undergone SDR may be potentially identifiable. Researchers will endeavour to present material to minimize this risk



We are happy to send you a lay summary of the results upon its completion. The results of this research may be published in a report for the Cerebral Palsy Society, scientific journals and/or presented at conference proceedings. We may also use the information from this study to compare with future research, and to direct future planning of health service delivery in New Zealand. Please note that a significant delay may occur between data collection and publication of results.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, please feel free to contact the research team:

Ms Jessica Broadbent,

Study Coordinator, Starship Child Health

Phone: (09) 307 4949 extension 21898 (Mon/Wed/Fri)

Email: broadbentj@adhb.govt.nz



Dr Nichola Wilson,

Lead Investigator, Paediatric Orthopaedic Rehabilitation, Starship Child Health

Phone: 021 144 1162

Email: nicholaw@adhb.govt.nz

Co-investigators:

Dr Ewei Lim, Wilson Centre

Phone: (09) 488 4688 extension 45813, Email: elim@adhb.govt.nz

Dr Kathryn Edward, Wilson Centre

Phone: (09) 488 4688 extension 45813, Email: kathryne@adhb.govt.nz

Prof Susan Stott, The University of Auckland

Phone: (09) 923 2858, Email: s.stott@auckland.ac.nz

Dr Anna Mackey, Starship Child Health

Phone: (09) 307 4949, Email: amackey@adhb.govt.nz

Dr Sian Williams, The University of Auckland

Phone: (09) 923 9820, Email: sian.williams@auckland.ac.nz

Department of Surgery:

Prof Richard Douglas, Head. Phone: (09) 923 9820, Email: Richard.douglas@auckland.ac.nz

If you require Māori cultural support talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning (09) 486 8324 extension 42324. If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by phoning (09) 486 8920 extension 43204.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at (09) 373 7599 extension 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

Thank you for your consideration in participating in this important study.

Approved by the Auckland Health Research Ethics Committee on 7/8/2019 for three years. Reference No. 000114.