Parent or Guardian of a Child with Cerebral Palsy
Participant Information and Consent Form

The Australasian Cerebral Palsy Musculoskeletal Health Network

Lead: Professor Ngaire Susan Stott and Professor Paul Hoffman
Study Site: Starship Children's Hospital; Liggins Institute University of Auckland
Contact phone number: 0212242298
Contact email: Msk.study@auckland.ac.nz
Ethics committee reference: 2025 FULL 21456

You are invited to take part in a study that looks at muscle and bone health in children living with cerebral palsy (CP). 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.

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
- 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 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 11 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Participation in this study is voluntary. You are free to decline to participate.

Participation, non-participation, or withdrawal will not affect your relationship with the University of Auckland or any hospital and healthcare services you receive.

You can withdraw from the research at any time without experiencing any disadvantage, and your data will be removed from the study unless it has been de-identified.

WHAT IS THE PURPOSE OF THE STUDY?

This project is for children with CP who have difficulties with movement and posture that could lead to progressive musculoskeletal (muscle and bone) complications. Children with moderate to severe CP are at risk of hip displacement, developing scoliosis (a curve) of their spine and/or sustaining a bone fracture. Hip displacement occurs when the femoral head ("ball") moves out of the acetabulum ("hip socket"). Scoliosis is when the spine curves increase.

Some children may experience discomfort, muscle tightness, pain and other symptoms when they have severe hip displacement and /or their spine starts to develop scoliosis. Some children with cerebral palsy have fractures of the arms or legs following very little trauma. This may cause a lot of pain and sometimes the child needs to have surgery to help the fracture heal. Our project aims to collect health information about your child to find out whether identifying musculoskeletal problems earlier can lead to more timely treatments and reduce the chance of these problems getting worse. This information may benefit future children with CP.

HOW IS THE STUDY DESIGNED?

We are looking for up to **sixty children between the ages of 4- 12 years living with CP** classified as Gross Motor Function Classification System (GMFCS) III, IV or V (please ask one of the research team members if you are unsure of your child's GMFCS level). This study is part of a multi-center study with Australia, other sites involve include Children's Health Queensland, Sydney Children's Hospital Network and Royal Children's Hospital Melbourne.

This study will be run over 4 years, one-time point per year, with assessments taking place at the Liggins Institute based at the University of Auckland. We will try to coincide these visits with other appointments your child has at Starship Hospital (which is based next door to the Liggins Institute) or we will arrange for travel and accommodation if you live in Northland or Waikato region and you do not normally come to Starship for your child's appointments.

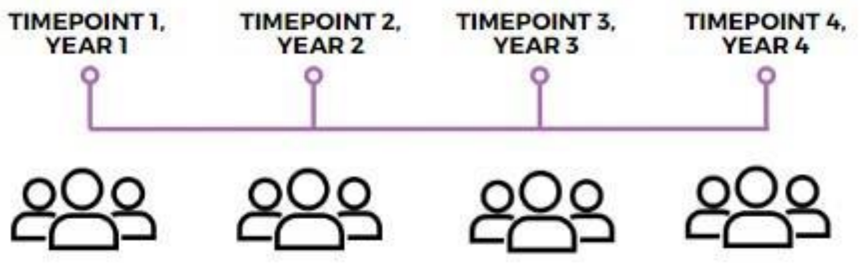
WHO CAN TAKE PART IN THE STUDY?

You and your child are asked to participate in this study because:

- your child is between the ages of 4 to 12 years' old
- they have a confirmed diagnosis of cerebral palsy, and
- their sitting and walking abilities match GMFCS level III, IV or V. This means that they require assistance to stand, sit or walk

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you and your child are enrolled in the study, you and your child will be required to complete four (4) assessments: 1) at the beginning of the study; 2) 1 year after the study began; 3) 2 years after the study began; and 4) 3 years after the study began. This includes 4 visits in total over 4 years.



If you agree to participate in the study, there are a number of steps:

We will contact you with a 10–15-minute telephone call to talk about the project and ask you some questions to help us see whether your child is a good fit for the study.

You and your child will be invited to attend the Liggins Institute based in Auckland next to Starship Hospital for your study visits. Whenever possible, information for this study will be collected during your child’s regular clinic appointments. All staff undertaking the assessments are registered health practitioners and trained in looking after children with CP.

A) Your child’s early medical history:

We will ask you about information on your child’s early medical and birth history. If your child has been in other clinical trials and you agree, we can find out the information from these studies and/or your child’s hospital discharge summaries and medical records.

B) Previous brain MRIs and cranial ultrasound scans: We will ask your permission to get copies of your child’s previous brain MRI and/or ultrasounds.

C) Investigations and assessments that your child will undertake at each study visit:

1. Growth: Your child’s body weight will be measured using chair scales. We will measure their height using a measuring device called a stadiometer. If they cannot stand by themselves, their length will be measured lying down. Their knee height will also be measured to predict height in children where standing height or supine length may be difficult or impossible to acquire.

2. X-rays of their hip and spine: Your child’s hip and spine X-rays will be reviewed and collected with all identifying information removed so that we can take measurements of any hip displacement and scoliosis they may have. The child’s hip X-rays will be part of routine screening. Depending on whether your child already has a scoliosis, the spine X-rays may be in addition to what they would normally have done.

3. Physical exam and range of motion evaluation: At each visit, a physiotherapist will take measurements of the amount of movement in your child’s hips, knees, feet and spine. These measurements take about 10-15 minutes to do.

4. Bone health: Bone Mineral Density (BMD) and body composition: A bone mineral density scan will be done in the 1st, 3rd and potentially the 4th years of the study using Dual-energy X-ray Absorptiometry (DXA, often pronounced ‘dexa’). The scan will take images of your child’s whole body, lower back, left and right hips, and thighs. For this scan, your child will be laying down and will need to lay reasonably still. To help with this we may ask to loosely wrap your child in a sheet. The bone mineral density and body composition testing will take approximately 45-60 minutes to do.

5. Gross Motor Function Measure (GMFM): measures how your child does different physical activities like lying, rolling, sitting, standing, and walking. The test will be recorded by video to allow the physiotherapist to accurately score the GMFM. The GMFM takes about 20 minutes to do and will be completed each year.

6. Classification of function: the following classifications will be assessed at each visit. These classifications are very quick to do and are often done as part of the physical exam or GMFM.

6.i. Gross Motor Function Classification System (GMFCS): The GMFCS records your child’s self-initiated movements such as sitting, walking and the use of mobility devices in everyday life.

6.ii. Manual Ability Classification System (MACS): The MACS records how your child uses their hands in everyday life.

6.iii. Communication Function Classification System (CFCS): The CFCS records how your child communicates.

7. Blood tests: A blood test will be collected by an expert blood collector or under general anaesthetic (if your child is having a procedure under anaesthesia). The blood tests will measure hormones involved in growth, vitamin D, calcium and phosphate levels. These can be altered in children with CP. The blood test will take about 5-10 minutes to do and will be completed each year.

8. Brain structure: If your child has previously had an MRI of their brain taken, the MRI images will be assessed. If they have not had an MRI done before, they will not need to have one done especially for this study.

D) Questionnaires about your child: We will ask you to complete the following questionnaires. If you would like, some of these questionnaires can be sent out for you to complete 2 weeks prior to any of your child's study visits to minimise the time spent with the study team on the day. Study staff will be available to assist you with any questionnaires or answer any questions you may have.

1. Demographic questionnaire: We will ask questions about your child and family. We will also ask for your permission to access your child's previous medical history and tests. We are interested in whether your child has had an MRI scan of their brain, or if they have had any previous medical interventions. This questionnaire is completed once, at the first study visit.

2. Perinatal and birth history questionnaire: We will ask about your child's genetic history and information regarding your pregnancy and the birth of your child. This questionnaire is completed once, at the first study visit.

3. Clinical History questionnaire: We will ask about your child's previous medical history and information, including clinical treatments, age and severity of CP, early intensive therapy interventions, and any investigations they may have had.

4. Paediatric Evaluation of Disability Inventory (PEDI-CAT): The questionnaire asks you to rate how your child does a range of daily activities. It asks about their mobility, cognitive and social abilities, and how much assistance you give your child to do everyday activities. You can do this questionnaire on a laptop or tablet. It will take you 15-20 minutes to complete each year.

5. Fracture questionnaire: Once a year you will fill in a fracture questionnaire. If your child has a fracture, you will be asked to let us know about it within 24 hours, including information on if/where an X-ray has been completed and what the management details are.

6. Health resource usage questionnaire: This questionnaire asks about the types of health care and equipment that your child uses. It will help us to record any costs of health resource use associated with your child's care and musculoskeletal outcomes. This will be completed each year.

7. Child Health Utility (CHU9D): We will ask you to complete a very short questionnaire called the Child Health Utility which asks you to rate 9 short items about your child's health. The CHU will take about 2 minutes to do each year and will give us more of an understanding about the costs and benefits of health care.

8. Pain experience: Episodes of pain and any treatments, including the need to see a doctor or use of medications, will be assessed using a survey and scoring tool called the Paediatric Pain Profile. If possible, your child will be asked to rate their pain on a series of smiling faces called the Wong Baker Faces Pain Scale. This will be completed each year.

9. Pubertal development: You or your child will be shown a diagram each year called the Tanner Stage of Puberty and you or your child will be asked to circle which diagram best represents your child's pubertal stage. Depending on the age and ability of your child, this may be something they can complete by themselves or with the researcher.

10. Nutrition: We will ask you about your child's diet, feeding and frequency of certain foods over the last 6 months through our parent reported Feeding and Food Frequency Questionnaire. This will help us to work out the vitamin D and calcium your child gets from the food they eat. It includes any gastrostomy feeds for children who have a PEG. This takes about 15 minutes to complete. If your child eats some foods orally, you will also be asked to complete the Australia Recommended Feeding Score (AFRS). This takes about 10 minutes to do. The nutrition questionnaire is completed each year.

11. Sun exposure: For the 7 days after each assessment visit, you will be asked to complete a Sun Diary to record the time your child spends in the sun. This will help us to assess the natural vitamin D they receive. The diary will take about 5-10 minutes to do each day.

12. The Caregiver Priorities & Child Health Index of Life with Disabilities (CPCHILD©) Questionnaire: the CPCHILD is a questionnaire that asks you to rate how easy or difficult many activities are across a number of areas in your child's daily life including personal care, positioning, transferring and mobility; their comfort and emotions; and their communication and social interactions. This takes about 15 minutes to do, each year.

The total time for assessments with your child is approximately 4 hours at each study visit, and approximately 2.5 hours for you to complete the parent questionnaires. Please note that this time may fluctuate depending on wait-times at departments (i.e. X-rays, blood test). You will be given the opportunity to complete some of the questionnaires at home prior to assessment visits if you choose. The first time point will typically be the longest, though we will make every effort to minimise the time spent on study assessments at each time point.

Schedule of Activities				
Study Period	**T1**	**T2**	**T3**	**T4**
General Procedures				
Informed Consent	X			
Inclusion/Exclusion criteria review	X			
Retrospective Data				
Perinatal and Birth History	X			
Clinical History	X			
Assessments				
Anthropometry (height, weight)	X	X	X	X
X-rays – hip and PA/AP lateral spine	X	X	X	X
Musculoskeletal Range of Movement Assessment	X	X	X	X
Spinal Range of Movement Assessment	X	X	X	X

Densitometry – DXA	X		X	X
Blood test	X	X	X	X
GMFM 88	X	X	X	X
PEDI-CAT	X	X	X	X
Maturation	X	X	X	X
Classifications	X			
Sun Diary	X	X	X	X
Parent-Reported Outcome Assessments				
Demographics Questionnaire	X			
Health Resource Use Questionnaire	X	X	X	X
Fracture Questionnaire	X	X	X	X
Feeding Questionnaire	X	X	X	X
Paediatric Pain Profile	X	X	X	X
Child Health Utility 9D (CHU-9)	X	X	X	X
CP-CHILD	X	X	X	X

E) We will capture data on medical and pharmacy services your child uses. As part of the consent form, you will be asked if we can link your child's National Health Identifier (NHI) to any hospital admissions, outpatient appointments and medications dispensed from a community pharmacy over the study timeframe.

WHAT WILL HAPPEN TO MY CHILD'S INFORMATION?

- All results and information from the tests, scans, assessments and questionnaires will be stored without your child's name on them.
- A number is used to identify the information. This number is linked to your child's name but the linking file will be kept confidential and only made available to the NZ researchers.
- Any paper forms that we use to record the assessments and questionnaires will be stored in a secure filing cabinet in the research team's office and only the New Zealand researchers will have access to this. Electronic and paper forms will be kept for 10 years from the time the child turn 16 years of age.
- De-identified results of some of the assessments will be electronically entered into the cloud based University of Queensland (UQ) Research Electronic Data Capture (REDCap) platform, which is protected by 2-factor authentication. Access to REDCap will be controlled by UQ. We will not enter any information such as your child's name, date of birth or ethnicity onto this database. Video recordings, digital copies of questionnaires and physiotherapy assessments will be transferred to the password protected cloud based UQ Research Data Manager (RDA).
- The assessments downloaded from the RDA will be kept at the Queensland Cerebral Palsy and Rehabilitation Centre on a secure password protected University of Queensland server.
- MRI scans will be shared with a member of the research team who works at the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and with other research team members.

  The CSIRO adheres to strict privacy policies that can be found at https://www.csiro.au/en/about/policies/privacy. Because MRIs are images, they could be potentially re-identifiable. When they are shared, any of your child's personal information on the image will be removed and a code number will be added instead.

- If we give talks or write about the results of this project, we will not use any names or identifying details.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There are no potential harms associated with this study. Any risk involved in this study is no greater than your child's usual clinical care.
The possible inconvenience to you and your child is the time that the assessments will take, which is approximately 4-6 hours for each visit, 4 visits over 4 years. The assessments might be a bit tiring, so there will be scheduled breaks during the assessment. You will also be able to complete some of the questionnaires in your own time, before or after the assessment visit if you choose. You are also welcome to involve other family members who care for your child when answering the questionnaires.
Your child may experience slight discomfort during the physical exam or X-rays. The X-rays of the hips will be performed as part of your child's usual clinical care. Depending on your child's clinical status, the spine X-rays and DXA may be additional to X-rays they currently have.

This research study involves exposure to an amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.2 mSv. The benefits from the study should be weighed against the possible detrimental effects of the additional radiation exposures, including an increased risk of cancer induction. In this particular study, the risk is minimal, and the estimated risk of such harm is up to about 1 in 10,000. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You and your child will not benefit directly from participating in this study. What we find out from this study may help to guide future treatment for your child and others. We will share the results of the study with you when it is finished.

The information from this study may help select the best treatments for preventing hip dislocation, scoliosis and low trauma fracture, relieving pain, help caregiving and improving the quality of life of children with moderate to severe CP and their parents/caregivers. The findings will have applications for the care of children with moderate to severe CP across Australia and New Zealand.

WILL ANY COSTS BE REIMBURSED?

There will be no cost to you to participate in this study.

A $50 koha (thank you) grocery gift card will be offered to all participants who attend each assessment (maximum four in total). All travel and accommodation costs will be covered if you live outside Auckland and do not attend Starship for appointments.

WHAT IF SOEMTHING GOES WRONG?

If your child is injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if they were injured in an accident at school or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

If you find any of the questions very upsetting or distressing, we will immediately inform your GP by telephone or letter.

WHAT WILL HAPPEN TO MY INFORMATION?

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and de-identified information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information is very low.

Sharing your results with you and your relevant health professional/s

Your GP will be informed that your child is enrolled in the study.

Following your child's assessment, we will provide you and your child's hospital specialist/s and/or GP with a summary of the results in the form of a letter.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, you should ask the research team.

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

Your decision about whether or not your child participates will not change their future relationship with Health Care Professionals at the Liggins Institute, Starship Children's Hospital or your local hospital if you are outside of Auckland.

If you decide for your child to participate, you are free to withdraw your consent and to discontinue participation at any time. The decision to withdraw from the study will not affect your child's routine medical treatment or their relationship with the person treating them.

You can withdraw your child from the study at any time by letting the research team know in person or by email or phone. You will be able to choose whether the study will destroy or continue to use the information that has been collected about your child.

CAN I FIND OUT THE RESULTS OF THE STUDY?

The results of the study will be published in a scientific journal once the study has been completed. You may request to receive a lay summary of the results of the research.

Please indicate on the consent form if you wish to receive a summary of the study findings. Any publications related to this study can be found at on the UQ Child Health Research Center Page (https://child-health-research.centre.uq.edu.au/research/med-kids)

WHO IS FUNDING THE STUDY?

The study is funded by the Australian Government Medical Research Futures Fund. The Starship Foundation has provided extra funding for travel expenses for those living in the Waikato and Northland region who would like to be a part of the study.

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 Central Health and Disability Ethics Committee has approved this study (Ref: 2025 FULL 21456)

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, you can contact:

Janene McMillan (Liggins Senior Research Nurse) by email:

Msk.study@auckland.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 also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 400 569 (Ministry of Health general enquiries)
Email: hdecs@health.govt.nz

Māori Support
If you require Māori cultural support, contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 307 4949 ext 29200.

Consent Form

The Australasian Cerebral Palsy Musculoskeletal Health Network

Please tick to indicate you consent to the following

I have read or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes ☐	
I have been given sufficient time to consider whether or not my child can participate in this study.	Yes ☐	
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐	
I understand that my child taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	Yes ☐	
I consent to the research staff collecting and processing my child's information, including information about my child's health.	Yes ☐	No ☐
I consent to the research staff using my child's NHI to link to information about hospital admissions, specialist hospital appointment and medicines that were dispensed over the time my child is enrolled in the study (page 7)	Yes ☐	No ☐
I understand that the name of our family GP and/or hospital specialist will be collected in order to allow direct sharing of information regarding study results for your child	Yes ☐	
I understand de-identified results of my child's assessments, video, results and questionnaires with be entered into cloud based databases held at the University of Queensland, Australia	Yes ☐	
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed unless you let the research team know that you would like all of your data removed from the study	Yes ☐	
I understand that my child's participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes ☐	
I know who to contact if I have any questions about the study in general.	Yes ☐	
I understand my responsibilities as a study participant.	Yes ☐	
I wish to receive a summary of the results from the study. Email address (if yes)	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant’s name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher’s name:

Signature: Date:

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