

Participant Information Sheet – Parent/ Guardian

Helping kids with cerebral palsy to be more physically active through doing sports and leisure

Formal Study title: Optimising participation in physically active leisure for children with cerebral palsy: A randomised controlled trial

Sponsor: University of Queensland, National Health and Medical Research Council (NHMRC) APP1140756.

Lead Researcher: Associate Professor Leanne Sakzewski, University of Queensland

New Zealand coordinator: Dr Sian Williams, University of Auckland

Contact phone number: +64 9 923 6929

Ethics committee ref.: Northern B Health and Disability Ethics Committee 2022 FULL 11876

You are invited to take part in a study on participation in physical activities in children with cerebral palsy. 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, and 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 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

You and your child's participation in this research is voluntary, it is you and your child's choice whether or not you both can take part. You are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage to any future participation in research or to any treatment or care your child may receive.

WHAT IS THE PURPOSE OF THE STUDY?

Kids with cerebral palsy (CP) do not participate in as many physical activities as kids without CP. They are also less physically active, which means they do not move their body as much. Health professionals are worried about this because we know that being physically active is so important for healthy development.

There are lots of reasons why kids with CP participate less. Some of the “barriers” (things that make it harder) include:

- Negative attitudes of people in the community, like coaches
- Not having the equipment needed because it's expensive or hard to get
- Not knowing about what inclusive activities are available locally
- Child does not yet have the skills to do the activity
- Being worried about what others might think or say
- Lots of extra things to work around, like physical access or medical worries that other parents don't have to think about
- Lack of time

Doing physical activities is a good way to have lots of fun, keep fit, and make friends. All kids, including kids with cerebral palsy, have the right to participate in physical activities. However, coming up with solutions to the above barriers can be challenging.

Most therapy (Physio, OT or exercise physiology) for children with CP is focused on trying to improve strength or walking ability. We now know that this type of therapy does NOT help to improve participation in physical activities.

We are testing a new type of therapy to see if it CAN improve participation in physical activities. Some differences between standard therapy and this new type are:

- More focus on the child's strengths, preferences, uniqueness and capabilities
- Takes place in your home and community, rather than the therapy clinic
- Uses goal-setting and discussion a lot more
- Allows for the therapist to work on things that might have been 'out of your control' before

We have done a small trial of this type of therapy with 37 families with promising results. Kids who got the therapy did better in achieving their physical activity goals. Families were more satisfied with how they did on their goals.

We need to test this type of therapy on a larger group of kids from different areas across Australia and New Zealand. This will help us be sure that this type of therapy works and can be done in normal clinical practice.

HOW IS THE STUDY DESIGNED?

This is an Intervention study, where the intervention is a 10 week community based program (i.e. taking place in the community where sports happen in your area, like the pool or basketball courts) where our study therapist will come to you to work with your child (once per week for approximately 1 hour).

Because we need to compare the new therapy to something else, we have 2 groups. One group gets the therapy right away (NOW), and one group gets put on a wait-list (WAIT). There is a 50% chance of getting in each group. It is totally random, so it is FAIR for everyone. It is not possible to know which group you will be in until after the first assessment. Families who are on the wait-list will still get to have the therapy at the end of 6 months of waiting. Most of the assessments that we complete to learn about the effect of the therapy will be questionnaires

(some for the child, and some for the parent to complete), as well as an activity tracker to track how active your child is.

This study is being conducted in Australia (across five sites) and is anticipated to take place across two sites in New Zealand, and we are aiming to recruit 100 children into the study.

WHO CAN TAKE PART IN THE STUDY?

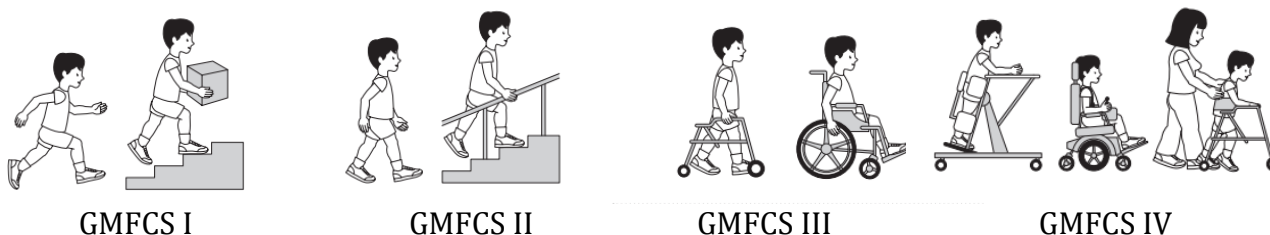
You and your child are being invited to participate because your child has cerebral palsy, and you want to set goals about (your child) participating more often, or being more involved in physical activities.

You also meet the following criteria:

- Your child is 8-14 years old
- Your child is GMFCS level I, II, III, or IV (see pictures below)
- Your child can communicate their wants, needs, thoughts and preferences by spoken English or using an Augmentative and Alternative Communication (AAC) system

Children who have the following characteristics are unfortunately not eligible:

- Moderate-severe intellectual disability
- Unstable medical conditions that make exercise unsafe (like severe epilepsy or severe asthma)
- Orthopaedic and/or neurological surgery less than 6 months ago or definitely planned within the next 12 months



WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you provide your consent, you have the right for your information to be treated confidentially. You also have a responsibility to *do your best* to meet the commitments of the study.

The main things involved are:

- Being in the study for between 6 and 9 months
- Having our study therapist come to your house 3 or 4 times for assessment sessions and for 10 therapy sessions (1 hour, once per week, for 10 weeks) (therapy sessions can also happen in places where sports happen in your area, like the pool or basketball courts)

Because it is for research, we ask you and your child to do *more* things than you would do if you were getting this therapy in a normal way. These extra things include:

- Filling out surveys at the beginning, middle (12 weeks) and end (26 weeks) of the study. These surveys can take between 30 and 90 minutes to complete each time
- Your child wearing an activity tracker around their waist and/or wrist at the beginning, middle (12 weeks) and end (26 weeks) of the study. They must wear it for 7 days straight each time
- Committing to being available for as many of the 13/14 appointments as possible (but we will work around your availability and make it as easy as we can for you)

A summary of the research activity is outlined below.

	Assessment / activity
First visit: phone screening for study (30 minutes)	<ul style="list-style-type: none"> - Obtain consent to be involved in study - Background questions about your child's cerebral palsy - Questionnaire on use of health services
First assessment (~30-90minutes)	<ul style="list-style-type: none"> - 7 days of wearing an activity tracker - Goal setting - Questionnaires on quality of life - Questionnaires on participation - Questionnaires on physical activity and health
NOW group: 10 weeks of Therapy, ~1 hour per week WAIT group: 10 weeks of normal activities	
Second Assessment (~30-90minutes)	<ul style="list-style-type: none"> - 7 days of wearing an activity tracker - Review of goals - Questionnaires on quality of life - Questionnaires on participation - Questionnaires on physical activity and health
All: 12 weeks of normal activity	
Third assessment (~30-90minutes)	<ul style="list-style-type: none"> - 7 days of wearing an activity tracker - Review of goals - Questionnaires on quality of life - Questionnaires on participation - Questionnaires on physical activity and health
WAIT group only: 10 weeks of therapy, ~1 hour per week	
WAIT group only Fourth assessment (~30-90minutes)	<ul style="list-style-type: none"> • 7 days of wearing an activity tracker • Review of goals • Questionnaires on quality of life • Questionnaires on participation • Questionnaires on physical activity and health

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

For your child, the risks of doing this study are the same as any regular sport or physical activity. These include the risks of:

- Falling over
- Getting minor injuries
- Sore muscles from exercise
- Being upset if something goes wrong

For you, the risks of doing this study are the same as when you are helping your child with something physical. You also might sometimes talk about difficult or upsetting topics. Therefore, the risks for you may be:

- Sore muscles or minor injuries (if you hurt yourself while helping your child)
- Feeling upset, worried or guilty about something.

If you feel upset after talking about any difficult or upsetting topics, we would be happy to talk to you about it, or link you in to professional services that can help you.

- New Zealand Research Coordinator: Dr Sian Williams: 09 923 6929
- *New Zealand: Lifeline:* 0800 543 354 *Healthline:* 0800 611 116 *Your local GP*

Our study therapist treating your child has been given training about how to minimise risks. Together with you, they will assess the risk of harm and make decisions to minimise that risk. All therapists will have a current first aid and CPR certificate. Therapists will carry basic first aid kits.

If you have any concerns about the risks involved, please contact one of the people listed on page 7 so we can talk to you about your concerns.

PROTECTION AGAINST COVID-19

Because of the COVID-19 pandemic, we have safety measures in place to ensure the safety of the research team, participants, and members of the community. All staff members and students involved in the study have already been fully vaccinated against SARS-CoV-2 (the COVID-19 virus), and will be following a number of safety protocols during their visits to participants, including, where indicated, the provision of Rapid Antigen Tests (RATs).

If you or your child do have any symptoms, we will reschedule your child's participation to a later date.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

Participation in this study may not have any benefits for you or your child, but based on what we have learnt from other studies like this, your child could achieve their goals of doing more physical activity. They might learn something new, like how to ride a bike or use a racing wheelchair. They might also feel better about themselves, their body, and their relationships with people. They could be more motivated to be physically active because they feel confident they can do it. You might find out about lots of inclusive activities in your local area. You could also learn how to solve future problems about your child's participation, so you would not be as reliant on therapists to help you.

In the future, your participation could help other kids with CP be more active and do the things they want. We will learn a lot about how this therapy works and whether it will be worth making it available to other kids with CP. If the therapy works, we will use the results of this trial to inform future clinical practice.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

Alternative treatment includes the normal therapy that your child would have from their regular providers (hospital, private, non-government, and/or school therapists). Your child can still continue to have all their normal therapy appointments if you decide to participate in the study.

WILL ANY COSTS BE REIMBURSED?

You get all the therapy in this study for FREE. You do not have to pay anything. However, you will not get any money or gift cards for being in the study. Your child will get a certificate at the end to say thank you.

WHAT IF SOMETHING 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 you were injured in an accident at work 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.

WHAT WILL HAPPEN TO MY/MY CHILD'S INFORMATION?

We assign you a secret participant number that only the researchers know. This participant number is used to label all of you and your child's data (instead of their name). That way, your data is not joined to your identity. The type of data we collect includes:

- Demographic and personal information about you, your child and your family (electronic)
- Answers to research surveys and outcome measures (electronic and paper)
- Data from the activity tracker (electronic)

If you are happy for us to do so, we would like to take photos, videos and audio recordings of all the treatment and assessment sessions. This will help us to test how well we can measure changes in your child's physical skills even with different people scoring the skills. We will ask you to sign a separate consent form for this, so you can still do the study even if you do not want photos/videos/audio recordings of yourself or your child.

All electronic data and paper data will be stored securely at the University of Auckland during the study. All videos and photos are stored on a double authentication password encrypted university server, and which can only be viewed by study authorised researchers and therapists. Each file is identified via the participants' study ID number. Coded (de-identified) information will then be transferred to Australian-based servers that only the approved research team have access to. Electronic files are sent between sites using secure file-transfer platforms. Paper files are stored in locked filing cabinets at each site. Paper files are sent to the main site (Queensland Cerebral Palsy and Rehabilitation Research Centre using registered secure post and courier (after being coded (de-identified))). **This means that you and your child's information collected for this study will be sent and stored securely in Australia.**

We understand that many Māori consider health information taonga. Use of information for research, and sending information overseas, may require careful consideration. There are a range of views held by Māori around these issues; however, it is acknowledged that individuals have the right to choose. It may be appropriate to discuss this with your whanau. Alternatively, you may wish to contact He Kamaka Waiora Māori Health Team whose details are listed below.

It is possible that an ethics committee, funding body, or external researcher may ask for the study data. This is important for future research and discoveries, and to check the validity of the research. If this happens, we send them data that is completely de-identified and there is no way to connect you with the information. We use group-level data when we report the study to others, such as at conferences, research papers, newsletters and media releases.

Data from the study will not be destroyed. Once the data has been collected and analysed at the group level, it is not possible to ask for it to be deleted.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed.

Even with coded information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Our study therapist will conduct assessments (and if suitable, also the therapy) at your home or in the community nearby your home, which may introduce a potential for stigma or concerns for your privacy. Your home/community location will not be recorded or reported with the information collected for this study, nor will your personal living situation be discussed.

This research includes basic information such as your ethnic group, geographic region, age range, sex, and type of cerebral palsy. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

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 Dr Sian Williams.

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

After the study is over, you and your child can still choose to continue with any activities taken up as part of the study, but any arrangements and associated costs will be at your own discretion.

Your decision whether or not your child participates will not prejudice their future relations with the researchers. 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 people treating them.

If you withdraw your consent, your child's study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

CAN I FIND OUT THE RESULTS OF THE STUDY?

At the completion of the study, participants will be provided with a plain English summary of study results, if requested.

WHO IS FUNDING THE STUDY?

This study being is funded by a project grant from the Australian National Health and Medical Research Council (NHMRC) APP1140756.

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 [insert Committee name] has approved this study.

This study has also been approved by The Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/17/QRCH/283) and the University of Queensland Human Research Ethics Committee (HREC number: 2018000019).

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:

Dr Sian Williams, New Zealand Participate-CP Research Coordinator

Telephone number: +64 9 923 6929

Email: sian.williams@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/>

For Māori health support please contact:

For support, talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora Māori Health Team on 09 486 8324 ext 2324.

If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards' Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC

Email: hdecs@health.govt.nz

Or the HREC Coordinator in Queensland, Australia on:

+61 3069 7002 or email CHQETHICS@health.qld.gov.au

Consent Form

Helping kids with cerebral palsy to be more physically active through doing sports and leisure

If you need an INTERPRETER, please tell us.

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.

I have been given sufficient time to consider whether or not to participate in this study.

I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.

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.

I understand that mine and my child's participation in this study is voluntary (our choice) and that we may withdraw from the study at any time without this affecting my child's medical care.

I understand that the study therapist will visit my home, or a location near my home to complete the assessments and intervention.

I consent to the research staff collecting and processing my child's information, including information about my child's health.

I consent to supplying information about my child in the study questionnaires.

I consent to my information being sent to the research team in Australia leading this work, and will be stored securely in Australia.

If I decide to withdraw myself and my child from the study, I agree that the information collected about them up to the point when I withdraw may continue to be processed.

I understand that mine and my child's participation in this study is confidential and that no material, which could identify us personally, will be used in any reports on this study.

I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant.

I wish to receive a summary of the results from the study. Yes No

Declaration by participant (parent/guardian): I have read the above information. I have asked all of my questions and received answers. I hereby consent for me and my child to take part in this study.

Parent/Guardian 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: _____