

## Parent / Guardian Information Sheet

<b>Scientific Title</b>	Optimising participation in physically active leisure for children with cerebral palsy: A randomised controlled trial		
<b>Title</b>	<b>Helping kids with cerebral palsy to be more physically active through doing sports and leisure</b>		
<b>HREC Number</b>	HREC/17/QRCH/283		
<b>Investigators</b>	Dr Leanne Sakzewski, Professor Catherine Elliott, Professor Roslyn Boyd, Professor Jenny Ziviani, Professor Iona Novak, Professor Stewart Trost, Professor Annette Majnemer		
<b>Version Number:</b>	<b>3.0</b>	<b>Version Date:</b>	<b>05/02/2019</b>

**Thank you for taking the time to read this Parent/Guardian Information Statement and Consent Form. We would like to ask your child to participate in a research project that is explained below.**

**It is ok to say no**

### What is an Information Statement?

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether or not you would like your child to take part in the research. Please read this Information Statement carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

### Important things to know

- It is your choice whether or not your child can take part in the research. You do not have to agree if you do not want to.
- If you decide you do not want your child to take part, it will not affect the treatment and care your child receives through Children's Health Queensland

If you would like your child to take part in the research project, please sign the consent form provided by the Researcher. By signing the consent form you are telling us that you:

- understand what you have read
- had a chance to ask questions and receive satisfactory answers
- consent to your child taking part in the project

We will give you a copy of this information and consent form to keep.

**There are 5 pages of this information sheet. Please check to see if you have all the pages.**

## **Body of Information Sheet:**

### **1. What is the research project about?**

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 (including regional areas). This will help us be sure that this type of therapy works and can be done in normal clinical practice. We will be doing this trial in two sites in Queensland (metro and regional), two sites in New South Wales (metro and regional) and one site in Western Australia (metro).

### **2. Who is funding the research project?**

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

### **3. Why is my child being asked to take part?**

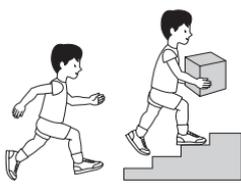
You and your child are being invited to participate because your child has cerebral palsy, and you want to set goals about (your child) participating more often, or being more involved in physical activities.

You also meet the following criteria:

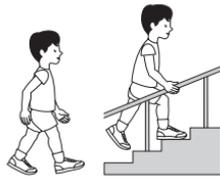
- Your child is 8-14 years old
- You live within 150km of one of the trial sites
- Your child is GMFCS level I, II, III, or IV (see pictures below)
- Your child can communicate their wants, needs, thoughts and preferences by spoken English or using an Augmentative and Alternative Communication (AAC) 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



GMFCS I



GMFCS II



GMFCS III



GMFCS IV

#### 4. What is involved in the study?

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.

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, like flipping a coin, 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.

The main things involved are:

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

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 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 attend 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)

There is also part of the research that might involve using an app on your smartphone or tablet device. This app, called *Jooy*, is a map-based program that helps you locate activities in your community. You will be able to use this on your own device for free or on the therapists' device if you do not have one of your own. This app can be used together with the therapist or in your own time. You are not obligated to use it.

## 5. Does it cost anything?

You get all the therapy in this study for FREE. You do not have to pay anything. If you have to pay money for parking or transport to a research centre, we will reimburse you. You will not get any money or gift cards however for being in the study. Your child will get a certificate at the end to say thank you.

## 6. Compensation

This trial is covered by standard clinical trials insurance. That means you may be entitled to make a claim if you believe your child suffers an injury as a result of their participation in the study. You may request a copy of the terms of this insurance.

## 7. What if I wish to withdraw from the research project?

Your decision whether or not your child participates will not prejudice their future relations with Children's Health Queensland. 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.

## 8. What are the possible benefits for my child and other people in the future?

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.

## 9. Alternative Treatment

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 have all their normal therapy appointments even if you also decide to participate in the study.

## 10. What are the possible risks, side-effects, discomforts and/or inconveniences?

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

The therapist treating your child has been given training about how to minimize risks. Together with you, they will assess the risk of harm and make decisions to minimize 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 5 so we can talk to you about your concerns.

## 11. What will be done to make sure my child's information is confidential?

We assign you a secret participant number that only the researchers know. This participant number is used to label all of your data (instead of your 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 is important for the research. 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 is stored on secure, Australian-based servers that only the researchers 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 de-identified).

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.

## 12. Who should I contact for more information?

If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact:

**Name:** Dr Leanne Sakzewski  
**Contact telephone:** 07 3069 7345  
**Email:** l.sakzewski1@uq.edu.au

The Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC) has approved this study. If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact the HREC Coordinator on: 3069 7002 or email [CHQETHICS@health.qld.gov.au](mailto:CHQETHICS@health.qld.gov.au)

# Children’s Health Queensland Hospital and Health Service Participant Consent Form

**Parent/Guardian**

I have read the above information. I have asked all of my questions and received answers. I agree to enroll my child in this study.

\_\_\_\_\_  
Signature of Parent/Guardian

\_\_\_\_\_  
Date

**CHIEF INVESTIGATOR**

I have fully explained to the parent/guardian ..... the nature and purpose of the program and the procedures to be employed as described above and such risks as are involved in their performance, and I have provided the parent/guardian with a copy of the Patient Information Sheet.

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Position

**INDEPENDENT WITNESS**

I have witnessed the receipt of a Patient Information Sheet by the parent/guardian and exchanging of information between the investigator and the parent/guardian about the study.

*An auditor witness would optimally discuss the study with the subject and witness the subject signature*

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Position

IF DEEMED APPROPRIATE:

**PARTICIPANT**

I have read the above information. I have asked all of my questions and received answers. I agree to take part in this study.

\_\_\_\_\_  
Signature of Child/Adolescent

\_\_\_\_\_  
Date

**Documentation of consent conversation**

**Who was there:** \_\_\_\_\_

**Any relevant information:**