Children’s Health Queensland

Parent / Guardian Information Sheet

**Project Title HABIT-ILE: A RANDOMISED TRIAL OF HAND ARM BIMANUAL INTENSIVE TRAINING INCLUDING LOWER EXTREMITY TRAINING FOR CHILDREN WITH BILATERAL CEREBRAL PALSY**

**HREC Number HREC/17/QRCH/282**

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**Research Staff** There will be other experienced occupational therapists and physiotherapists in each state who will be trained to provide the intervention. University therapy students will also be involved and supervised by senior therapists at each site.

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#### 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 received 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.

#### Body of Information Sheet:

#### What is the research project about?

This project is for children and teenagers with cerebral palsy (CP) aged between 6 and 16 years who have difficulties with movement on both sides of their body (bilateral CP). We are trying to see if a particular intensive therapy called Hand Arm Bimanual Intensive Training Including Lower Extremity Training (HABIT-ILE) can help to improve hand and gross motor skills.

Intensive therapies such as HABIT-ILE have mainly been used for children with CP who have difficulties moving one side of their body. There has only been one small study of HABIT-ILE with children and teenagers with bilateral CP and results were promising. There are no other intensive movement training therapies for children with bilateral CP. This project will see whether HABIT-ILE can help children and teenagers with bilateral CP improve their hand and gross motor function.

1. **Who is funding the research project?**

The National Health and Medical Research Council of Australia (1144846).

1. **Compensation**

**This project has two parts. 1. The therapy. 2. Neuroscience**

**Why is my child being asked to take part?**

We are asking your child to take part because he/she:

* Is 6-16 years of age
* Has a diagnosis of CP and experiences difficulties with movement of both legs and one or both arms
* Is classified using the Gross Motor Function Classification System II, III or IV
* Is able to grasp light objects and lift their most impaired arm 15 cm above a table surface
* Is able to understand instructions and complete all the tests
* Does not have epilepsy uncontrolled by medication
* Has not had any orthopaedic surgery in the six months prior to the study period
* Has difficulties with vision that interfere with treatment and tests
* Is able to undertake standing transfers (with at most the help from one adult) and/or walks a few steps (with a walker)

**What does my child need to do in this research project?**

Part 1. The therapy

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

1. 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 meets the above inclusion criteria of the study.
2. If we are not sure if your child meets these criteria we will organize an appointment to see you and your child to see whether he/she would benefit from HABIT-ILE.
3. Then your child will be randomly assigned to a group as by the flip of a coin, completely by chance, to either HABIT-ILE (NOW) or a waitlist HABIT-ILE group (WAIT) who will receive the therapy after waiting 6 months. 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.
4. HABIT-ILE runs over 2 weeks of the school holidays like a “day camp”. Your child will come to a group every day from Monday to Friday between 9 and 3.30. There will be about 10 to 12 children in each group. There will be at a minimum one therapist working with each child. If your child needs more help because of balance difficulties, one therapist will work with your child and one will be a “spotter”. We will have therapy students helping with the camps and they will be closely supervised by our senior occupational therapist and physiotherapist. Each day will involve:
5. practice of daily life goals that are important to you and your child,
6. Table-top games, craft, cooking and other activities to encourage the use of both hands together
7. Activities of daily living while standing/walking
8. Gross motor play and physical activities

We will video record each day so we can review the content of the program and see whether it is being done in the same way across each State. You will be able to stay and participate in the program, or you can drop your child off. We ask all parents to join us each day during the camps for at least the last hour of the day so you can see what your child is working on and talk with your child’s therapists about things you can work on at home with your child.

1. To help us work out if HABIT-ILE helps improve hand and gross motor skills in children and teenagers with bilateral CP, your child will complete a number of tests and we will get you to do some questionnaires. This will happen in the week before your child’s school holiday camp, the week after the camp, and then 6 months later. The tests your child will do will be:
2. **Gross Motor Function Measure:** This measures how your child does different motor skills like sitting, walking, and running. The test takes about 30 minutes to do.
3. **Both Hands Assessment:** This measures how your child uses two hands together during a play session. The session is video-taped and is later scored by an occupational therapist who has been trained to use it.
4. **Six Minute Walk Test:** This short 6 minute test measures walking endurance. Your child will walk as far as possible in six minutes around a 10 meter track.
5. **Canadian Occupational Performance Measure:** asks your child to identify areas of difficulty in everyday activities and rate how they feel they are doing that activity and how satisfied they are with how they do it. This helps to identify goals to work on in therapy and see if their goals are met as a result of the therapy. This takes about 15-20 minutes.

We will ask you to do one questionnaire at the first assessment only and two questionnaires at each appointment:

1. **Study Baseline Questionnaire**: This questionnaire will be completed at the first assessment time only. We will ask questions about your child and family. We will also ask about medications your child might be using, any food allergies or intolerances and any other information we need to know for your child to attend the HABIT-ILE camp.
2. **Pediatric Evaluation of Inventory Computer Adapted Test.**  You can do this questionnaire electronically on a laptop or tablet. There are two areas: The questionnaire gets you to rate how your child does a range of daily activities and also about their mobility. This will take you up to 15 minutes to do.
3. **Child Health Utility (CHU-9D)** is a relatively new measure which is designed to measure health related QOL in children and those affected by a disability from a young age. The CHU-9D will be completed by both you and your child.

**Part 2. Neuroimaging**

In Part 2, we want to find out how your child controls his/her hand and foot movements by performing Magnetic Resonance Imaging (MRI) before and after the treatment. The MRI will include taking pictures of your child’s brain while he/she is resting, and while he/she is moving his/her hand and foot (functional MRI). We hope to find out if HABIT-ILE has a greater effect on brain function than usual care. MRI is safe, there is no ionizing radiation, it has no known dangerous or harmful effects, causes no pain, and no sedation or any drugs are given.

We will ask your child to lie on a table inside the MRI scanner. Some people feel uncomfortable in the MRI scanner because of the tight space. To help make your child feel comfortable he/she will be offered to watch an age-appropriate movie. Your child can withdraw from the MRI scan at any time, before and also during the scan. A member of the research team can stay with your child at all times. We are also in continuous communication with your child via a two-way intercom system. The test should take approximately 1-1.5 hours to complete, but only 30-45 minutes of this time will be spent inside the scanner.

The scanner will record information about your child’s brain. It is very important that your child keeps very still during the scanning. When your child lies on the table we will make sure that they are in a comfortable position so that they can keep still. The scanner can be very noisy and we will give your child some earphones to reduce the noise. During the fMRI scan we will ask your child to do some movement tasks with their hand and some with their foot. It is very important that they lie completely still as even one millimetre of head movement causes blurring of the scans. To help keep your child’s head still we will place a vacuum beanbag under their head with a Velcro strap across their forehead.

**Your child can still be involved in Part 1, the therapy even if you do not want them to participate in the Neuroimaging part of the study.**

1. **What if I wish to withdraw from the research project?**

My decision whether or not my child participates will not prejudice their future relations with Children’s Health Queensland. If I decide for my child to participate, I am free to withdraw my consent and to discontinue participation at any time. The decision to withdraw from the study will not affect their routine medical treatment or their relationship with the people treating them.

1. **What are the possible benefits for my child and other people in the future?**

Regardless of the group your child is in, they will receive HABIT-ILE that may help improve his/her hand gross motor skills. If we show HABIT-ILE is helpful, then occupational therapists and physiotherapists working with other children with bilateral CP to improve their hand and gross motor skills can use it.

1. **Alternative Treatment**

At the moment, there are no other intensive group therapies for children with bilateral CP aimed to improve hand and gross motor skills.

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

The assessments will happen at the Centre for Children’s Health Research (QLD), Cerebral Palsy Alliance (NSW) or Princess Margaret Hospital for Children (WA) however these appointments will be planned to minimize any inconvenience to you. The only inconvenience to you and your child is the time that the assessment and training will take – The assessments will take approximately 1-1/2 hours in total for the clinical assessments, and 1-1/2 hours for the neurological assessments. If your child is in the immediate HABIT-ILE group, this will mean assessments on 3 occasions. If your child is in the waitlist HABIT-ILE group, it will mean 4 assessment occasions. The groups will be run during one week of school holidays and one week in school term. This means your child will miss one week of school. Doing the camps can be tiring, so it is important your child has some school holiday time so they are not tired before they go back to school. The camps run for 6.5 hours/day, so if your child is younger they might find it a bit tiring.

Neuroimaging tests:

* The noise during fMRI test can be loud but we use high-quality headphones to reduce the noise to safe levels. Keeping still during the fMRI is important, so we will use velcro strapping to keep your child’s head still - this can be a little uncomfortable after 30-45 minutes of scanning. Your child will receive a practice session in a mock scanner to prepare them for the real fMRI. At this time your child can try lying in a mock scanner and ask questions of the researchers. The research team is experienced at supporting children having fMRI. Professor Boyd has performed functional MRI on 80 children on 3 occasions in a randomised control trial (with a 90% success rate).

If you/your family refuse to participate in neuroimaging at any stage of the project, you will be able to remain in the study and complete the clinical tests without the neuroimaging component. You will still be able to participate in HABIT-ILE.

The scans taken are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at the MRI scans for features relevant to the research project. On rare occasions, the specialist may find an unusual feature that could have a significant risk to a participant’s health. If this happens, we will contact participants and their families to talk about the findings. In the unlikely event that we find an unusual feature, it could have consequences for a participant. It may affect their ability to work in certain professions, or get life or health insurance. However, if we do find an unusual feature, a participant may be able to get treatment that might be of benefit. We cannot guarantee that we will find any/all unusual features. Participants will be notified of these issues when they are considering being in the study.

1. **What will be done to make sure my child’s information is confidential?**

#### Confidentiality

* All results of assessments/questionnaires will be stored without your child’s name on them.
* A number is used to identify the assessments. This number is linked to your child’s name but the linking file will be kept confidential and only made available to the researchers.
* We will use electronic forms and all information will be kept on a database at the Queensland Cerebral Palsy and Rehabilitation Research Centre, South Brisbane Queensland. Any paper forms that we use to record the assessments and questionnaires will be stored in a secure filing cabinet and only the researchers will have access to this information. The paper forms containing assessment or questionnaire results will be kept at the Queensland Cerebral Palsy and Rehabilitation Research Centre in Brisbane in a locked filing cabinet until your child is 21 years old, and then destroyed.
* Videos of the therapy sessions and assessments will be kept at the Queensland Cerebral Palsy and Rehabilitation Centre on a secure University of Queensland server.
* If we give talks or write about the results of this project, we will not use any names or identifying details.
1. **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:

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| **Name:** | Dr Leanne Sakzewski |
| **Contact telephone:** | 07 30697345 |
| **Email:** | l.sakzewski1@uq.edu.au  |

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| 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 |