Parent/Guardian Information Sheet

Interventional Study - Parent/Guardian consenting on behalf of participant

Title	*iWHOTrial*: A multicentre randomised controlled trial of rigid wrist hand orthoses for young children with cerebral palsy
Short Title	*iWHOTrial*: Infant Wrist Hand Orthoses Trial
Protocol Number	Version 12.0 22/06/2020
Project Sponsor	Murdoch Children's Research Institute
Principal Investigator	Prof Christine Imms, Murdoch Children's Research Institute
Site Investigator:	Dr Brian Hoare
Location	Monash Children's Hospital

SHF00057

Part 1 What does the child's participation involve?

Introduction

This is an invitation for the child in your care to take part in this research project because your child is receiving early childhood intervention services. The research project is aiming to evaluate the use of rigid wrist hand orthoses for children who are at risk of having difficulties using their hands. Sometimes orthoses are called splints.

This Parent/Guardian Information Sheet/Consent Form tells you about the research project. It explains the assessments and research involved. Knowing what is involved will help you decide if you want your child to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether your child can take part, you might want to talk about it with a relative, friend or local doctor.

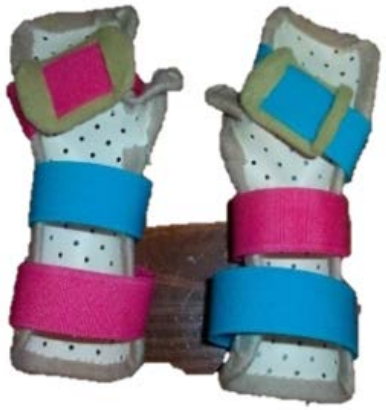
Participation in this research is voluntary. If you do not wish for your child to take part, he or she does not have to do so. If you decide to take part and later change your mind, you are free to withdraw at any point in the study. Your child will receive the best possible care whether or not they take part.

If you decide you want your child to take part in the research project, you will be asked to sign the consent section. By signing the consent form, you are telling us that you:

- Understand what you have read
- Consent to your child taking part in the research project
- Consent to your child having the assessments and interventions described
- Consent to the use of your child's personal and health information as described.

You will be given a copy of this Parent/Guardian Information and Consent Form to keep.

What is the purpose of this research?



Children who have difficulties using their hands may find it difficult to do day-to-day tasks as they get older, such as buttoning a shirt or playing with toys. These difficulties may be due to a variety of reasons, such as tightness or weakness in the muscles of the arm and hand. These changes in the structure of the hand (deformities), can lead to long-term changes in how a child is able to use their hands.

There are a number of treatment options recommended by Occupational Therapists to help children improve the use of their hands. One of these options which is **current standard practice** is for children to wear a night orthosis (also called a splint) to help maintain muscle length and prevent hand deformities. An orthosis is a special support worn on the hands to hold them in a particular position. They are usually made from materials such as special plastics (thermoplastic).

Even though wearing an orthosis is currently standard practice there is no real research proving that orthoses work. We use orthoses because we *think* they work. In this study, we will be comparing results from two groups of children, those who wear an orthosis each night for 3 years and a group of children who do not wear a night orthosis. We will follow children over a 3-year period to learn if wearing a night orthosis, in conjunction with children's usual therapy, can prevent the development of tight or stiff muscles and improve hand function.

Who can take part in the study?

Children are able to be included in this study if they have cerebral palsy, or are at risk of cerebral palsy, are aged less than three years and have stiffness in the muscles surrounding their hand. For some very young children it is not known if they have cerebral palsy, or not, as it can take some time to make a definite diagnosis. If your child has stiffness in their arm and hand muscles, but you are not sure if they have cerebral palsy, we would still like your child to participate in this study. If you are informed during the study, that your child has a diagnosis other than cerebral palsy please let your therapist or the study staff know. If your child does not have cerebral palsy, she/he will no longer be eligible to take part in the study but may still receive a night orthosis if it is required.

Children also need an occupational therapist who is available to fabricate the orthosis. If you do not have an occupational therapist who is able to fabricate the orthosis, we will try to find one for you.

Study staff will assess your child to work out with you if your child is eligible.

Who is carrying out the study?

The study is a collaboration between the Murdoch Children's Research Institute, Monash Children's Hospital, the Royal Children's Hospital, the Australian Catholic University and Deakin University in Victoria; Perth Children's Hospital, the Ability Centre and Curtin University in Western Australia; the Cerebral Palsy Alliance in New South Wales, CPL in Queensland, and Novita in South Australia.

Who are the Researchers participating in this study?

Christine Imms, Murdoch Children's Research Institute, Parkville, VIC, Australia
Margaret Wallen, Australian Catholic University, North Sydney, NSW, Australia
Catherine Elliott, Telethon Kids Institute - Perth Children's Hospital, Nedlands, WA, Australia
Brian Hoare, Monash Children's Hospital, Clayton, VIC, Australia
Susan Greaves, The Royal Children's Hospital, Parkville, VIC, Australia
Melinda Randall, The Royal Children's Hospital, Parkville, VIC, Australia
Brooke Adair, Murdoch Children's Research Institute, Parkville, VIC, Australia
Dinah Reddihough, Murdoch Children's Research Institute, Parkville, VIC, Australia
Rob Carter, Deakin University, Burwood, VIC, Australia
Katherine Lee, Murdoch Children's Research Institute, Parkville, VIC, Australia
Francesca Orsini, Murdoch Children's Research Institute, Parkville, VIC, Australia
Leanne Johnson, University of Queensland, St Lucia, QLD, Australia
Michelle Hollier, CPL, Brisbane, QLD, Australia
Megan Auld, CPL, Brisbane, QLD, Australia
Anna Klemm, Novita, St Marys, SA, Australia
Utsana Tonmukayakul (UT), Deakin University, Burwood, Australia

Who initiated the research project?

This research has been initiated by Professor Christine Imms, Murdoch Children's Research Institute, Parkville, VIC, Australia.

Who is conducting this research at Monash Children's Hospital?

This research is being conducted by Dr Brian Hoare and has been reviewed and approved by the Human Research Ethic Committee of Monash Health.

The research grants associated with this study:

This research has been funded by the Australian Catholic University, a grant from the National Health and Medical Research Council, Centre for Research Excellence in Cerebral Palsy (CRE-CP), in which Professor Reddihough, Professor Imms and Professor Carter are chief investigators, and the Percy and Ruby Haddy Foundation managed by Equity Trustees.

What will the study tell us?

The study will give us important information about the long-term effects of upper limb orthoses on children who have early difficulties using one or both hands. We want to know if we can prevent young children from developing hand and wrist problems by wearing an orthosis.

Does my child have to take part?

Participation in this study is voluntary. You do not have to participate if you do not want to. If you and your child choose to start out in the study but change your minds you are free to withdraw at any time without impact to your current or future care. You are not required to provide a reason for this decision.

What will you be asked to do if you decide to take part in this study?

Once you are accepted into this study, you and your child will come to one of the local sites associated with this study or your local therapy centre for 7 assessment sessions over 3 years. The first assessment will take place at the start of the study. You will then be asked to come back every 6 months for a follow-up assessment. Most assessment sessions will last approximately 60 minutes. The assessment tasks may vary between assessment sessions, as your child grows older. During all assessment sessions, measurements will be taken of your child's arm and hand movements. We will also ask you to complete some questionnaires.

After the first assessment session your child will be allocated to one of two groups – the treatment group or the control group. This will be done by chance, similar to the toss of a coin. Neither you nor the researcher can decide which study group your child is in. If you agree that your child can participate in this study, you should understand that your child may be allocated to the control group of children who do not receive a night orthosis.

<u>The Treatment Group</u>

If your child is allocated to the treatment group, your child will attend an appointment to be fitted with a thermoplastic orthosis. There will be no cost to you for the orthosis. The therapist who fits the orthosis will follow a special protocol to make sure your child's fingers and wrist are well positioned. The fitting of each orthosis usually takes about 45-60 minutes. Your child will be asked to wear the orthosis for a minimum of 6 hours each night for the 3-year study period.

You will be provided with monthly paper calendars to record how long each night the orthosis was worn. The Research Assistant will request that you return a calendar at the end of each month either via message, email or post. The calendar also contains the contact details of the Research Assistant should your child experience any problems with wearing the night orthosis.

Your child will attend their regular therapy appointments, with your usual Occupational Therapist. This may involve extra sessions to monitor the orthosis is fitting well and is comfortable.

The Control Group

If your child is allocated to the control group, they will not be fitted with a night orthosis. Your child will be asked to stop wearing any night orthosis they may be already wearing. Your child will attend their regular therapy appointments with their usual occupational therapist, as normal. There will be no change to their therapy schedule.

Children in Both Groups

Children allocated to either group will be free to continue with existing treatments or to participate in any new therapies or interventions that you choose during the study period, including Botulinum toxin-A (Botox) injections and other upper limb interventions. The exceptions are night-time wrist/hand orthoses and casting of the wrist and fingers/thumbs, which we ask that your child avoid during the study period except when implemented through the study. Your child will also be able to wear orthoses during the day if the orthosis helps your child to perform activities. Your child will not able to use a rigid wrist hand orthosis during the day that prevents him/her from using his or her hand for activities.

The movement and hand function of children in both groups will be monitored at the assessment sessions every 6 months. It is possible that your child, in either group of the study, may lose movement in his/her wrists and fingers. During the first 12 months of the study we will ask your child to keep doing what she/he is doing. This means that,

- if your child is allocated to the *treatment group*, she/he will keep wearing the night orthosis, but we will carefully monitor that it fits properly.
- If your child is allocated to the *control group* and does not wear a night orthosis, then she/he will continue to avoid wearing a night orthosis.

After the first 12 months, and if the amount of loss of movement is greater than 30^{o}, we will discuss with you the options for ensuring that no further loss of movement occurs.

What does my child need to do to be in the study?

Your child needs to be identified as having difficulty using one or both hands. If over the course of the study, it becomes evident that your child does not meet the criteria of this study, this will be discussed with you. In this instance, you will be supported to access appropriate therapy services.

Is there likely to be a benefit to my child?

- You will receive regular monitoring of your child's arm and hand function.
- The data recorded from the assessment sessions will be shared with your therapy team with your consent.

Is there likely to be a benefit to other people in the future?

We hope that the results of this project will help other children who might be at risk of developing difficulties using their hands.

What are the possible risks and/or side effects?

Risks associated with wearing the orthosis

If your child is in the treatment group, she/he may experience side effects because of wearing the orthosis. Possible, but unlikely reactions include pressure on the skin, pain, disturbed sleep, and skin allergies.

Your child's reaction to the orthosis will be closely monitored throughout the study. If you notice any skin allergies or other difficulties, please contact your local Research Assistant so they can coordinate modifications to the orthosis.

Risks associated with not wearing an orthosis

Currently, night orthoses are used to try and prevent muscle stiffness in young children with cerebral palsy, however, we do not have any evidence that this works. It is possible that children in either group of the study may lose movement at their wrists and fingers. If the amount of loss of movement is greater than 30^{o} we will discuss options with you for ensuring that no further loss of movement occurs.

What are the possible discomforts and/or inconveniences?

The assessments are additional visits to the local, state-based therapy site or your local therapy centre. However, these appointments will be planned to minimise any inconvenience to you. Assessment sessions will be conducted with breaks as required, to maintain your child's comfort, interest and motivation.

Part 2 How is the research project being conducted?

By signing the consent form, you consent to the researcher and relevant research staff collecting and using personal information about your child for the research project. Any information obtained in connection with this research project that can identify your child will remain confidential.

Where is your information kept and for how long?

All information for this trial will be stored in a locked cabinet in a locked room, or electronically on a password-protected database, and only accessed by this research team. Once the study is completed videorecords will be archived in a secure storage facility along with all other study data. De-identified data may be accessed for future ethically approved studies.

The length of time data will be kept after a study is completed varies between Australian states. Data collected in Victoria, South Australia, New South Wales and Queensland will be kept until the youngest participant turns 25 years of age at which time digital, electronic and paper data will be securely destroyed. Data collected in Western Australia will be securely archived and stored indefinitely.

What about my privacy?

Your child's privacy is of utmost importance and will be maintained throughout the implementation of this study. Where possible your child's data will be de-identified. Any videos recorded for assessment purposes will be stored securely at the study site and be only accessible by this research team. The results of this trial may be published but none of your child's personal information or identifiable data will be included.

Can I access my child's information/data?

In accordance with relevant Australian laws, you have the right to request access to the information collected about your child and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your child's information.

Who has approved the study?

This study has been granted approval by the Human Research Ethics Committees from Monash Health (VIC) for Monash Children's Hospital, The Royal Children's Hospital and Novita; the Child and Adolescent Health Service for Perth Children's Hospital (WA); the Cerebral Palsy Alliance (NSW); CPL (QLD) and the Australian Catholic University.

Who can I contact for more information about this study?

If you would like any more information about this study, please do not hesitate to contact Dr Brian Hoare or one of the research team listed below. They are very happy to answer your questions.

What to do next if you would like your child to take part in this research:

If you would like to take part in this research study, please contact Dr Brian Hoare to clarify any questions you may have and establish your child's eligibility to participate.

Who to contact if you have any concerns about the organisation or running of the study?

If you have any concerns or complaints regarding this study, you can contact Deborah Dell, Manager Human Research Ethics Committee & Research Support Services at Monash Health on (03) 9594 4611 or via email at research@monashhealth.org. Your concerns will be drawn to the attention of the Ethics Committee monitoring the study.

Names of relevant people:

Principal Investigator	Professor Christine Imms Murdoch Children's Research Institute	(03) 9345 4953
Site Investigator	Dr Brian Hoare Monash Children's Hospital	0435 615 187

THANK YOU FOR YOUR TIME

Parent/Guardian Consent Form

Interventional Study - Parent/Guardian consenting on behalf of participant

Title	*iWHOTrial*: A multicentre randomised controlled trial of rigid wrist hand orthoses for young children with cerebral palsy
Short Title	*iWHOTrial*: Infant Wrist Hand Orthoses Trial
Protocol Number	Version 12.0 22/06/2020
Project Sponsor	Murdoch Children's Research Institute
Principal Investigator	Prof Christine Imms, Murdoch Children's Research Institute
Site Investigator:	Dr Brian Hoare
Location	Monash Children's Hospital

SHF00057

Declaration by Parent/Guardian

- I have read the Parent/Guardian Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I give permission for my child's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Monash Children's Hospital concerning my child's diagnosis and treatment for the purposes of this project. I understand that such information will remain confidential.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to my child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.
- I understand that, if my child is already wearing a night-time orthosis and is randomised to the control group, my child will be required to stop wearing the existing orthosis for the 3-year study period.
- I understand videorecords will be taken of my child and will be viewed by the research team
- I understand that my child's de-identified data may be accessed for future ethically approved studies.
- I understand that, if I decide to discontinue my child's participation in this study a request may be made for him/her to attend follow-up visits to allow collection of information regarding his/her arm and hand movements. Alternatively, a member of the research team may request my permission to obtain access to my child's medical records for collection of follow-up information for the purposes of research and analysis.
- I understand that I will be given a signed copy of this document to keep.

Name of Child (please print) Name of Parent/Guardian (please print) Signature of Parent/Guardian Date

Name of Witness* to Parent/Guardian's Signature (please print) _____ Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent/guardian has understood that explanation.

Name of Senior Researcher† (please print) _____ Signature _____ Date _____

† A senior member of the research team or their delegate must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.