Centre intégré
universitaire de santé
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de la Capitale-Nationale
Québec

Predictors of Response to an Intensive Bimanual Intervention in Children Living with Cerebral Palsy

Numéro de projet : 2020-1961

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☐ CER-S Troubled Youth and Their Family
☒ CER-S Rehabilitation and Social Integration
☐ CER-S Population Health and FrontLine
☐ CER-S Neuroscience and Mental Health

I. Project title:

Predictors of Response to an Intensive Bimanual Intervention in Children with Cerebral Palsy.

II. Responsible and collaborators (with *professional affiliation and* identify *clinicians, coordinators, students, trainees, etc., if necessary):*

Catherine Mercier erg., Ph.D., Researcher at CIRRIS and Full professor at Université Laval
Alexandre Campeau-Lecours, Ph.D., Researcher at CIRRIS and Assistant professor at Université Laval
Véronique Flamand erg., Ph. D., Researcher at CIRRIS and Assistant professor at Laval University
Maxime Robert Ph.D., Researcher at CIRRIS and Assistant professor at Laval University
Dr. Émilie Croteau MD, Physiatrist at CIUSSS de la Capitale-Nationale
Floriane Bretheau, Ph. D, Research professional, CIRRIS

III. Grant agency:

Université Laval Cerebral Palsy Research Chair.

IV. Introduction:

We ask for your participation in a research project. However, before agreeing to participate in this project, please take the time to read, understand and carefully consider the following information.

This information and consent form explains the purpose of this research project, the procedures, benefits, risks and disadvantages, as well as the relevant contact information.

The information and consent form may contain words you don't understand. We invite you to ask any questions that you deem useful to the researcher in charge of the project and other staff assigned to the project and ask them to explain any words or information that are not clear.

V. Nature and project objective:

Activities of daily living (ADL) require the use of both hands in a coordinated manner. Impairments affecting the movement and sensations of the arms therefore have a significant impact on the daily activities of children living with cerebral palsy. It has already been demonstrated that an intensive bimanual intervention can improve arm movement, but its impact on the spontaneous use of the most affected arm in everyday life remains to be established.

This project aims to understand the impacts of an intensive bimanual therapy on the motor functions of both arms (working together or in isolation) as well as on the spontaneous use of the most affected limb.

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The intervention consists of a day camp, where a small group of participants will be stimulated (one therapy worker per child) to do activities using both hands 6 hours a day for 10 days. The use of more precise measurements of arm movement and sensation using robotic systems will help clarify the relationship between measures of brain function and clinical improvements, and thereby better understand the significant variability observed in response to interventions.

VI. Project process:

The intervention consists of an intensive bimanual therapy lasting a total of 60 hours over a period of two weeks. Evaluations will be carried out before, immediately after and 6 months after the intervention.

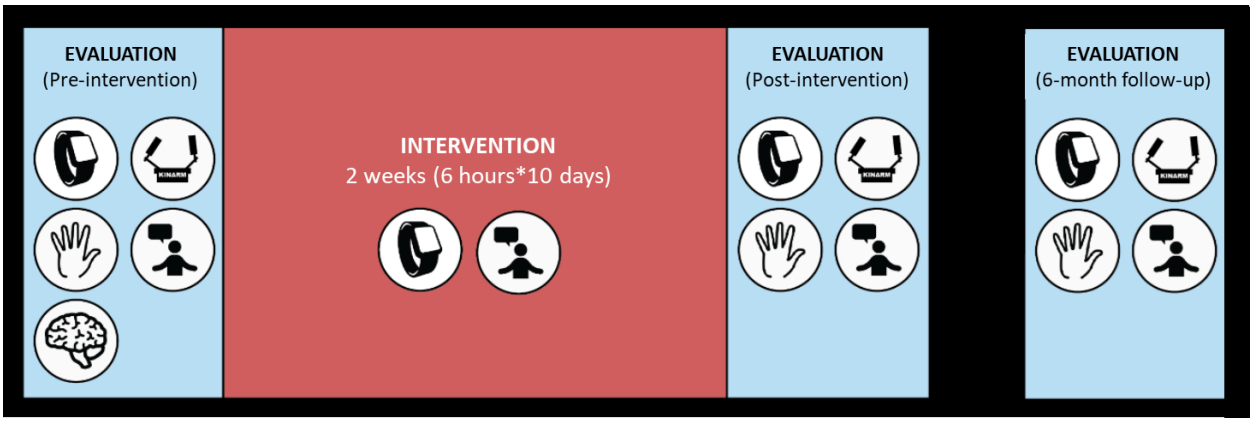

Figure 1. Course of the intensive bimanual therapy camp

Overall, your child's participation in the project component involves **four** evaluation sessions (see Table 1 below), two before the camp, one after the camp and a final six months later. The evaluations will be carried out at the Center for Interdisciplinary Research in Rehabilitation and Social Integration (Cirris).

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Table 1. Assessments carried out

	What is assessed	When	Location (duration)
Magnetic Resonance imaging (MRI)	Brain structure	• Before the camp	Clinique IRM Québec Synase (35 min)
Robotic assessment (KINARM)	Motor function of both arms and the sensation of their position in space	• Before the camp • After the camp • Followed by 6-months	Laboratory at the Cirris (45 min)
Accelerometry	Measurement of the spontaneous use of each arm during daily activities	Weekends • Before camp • During camp • After camp • 6-month follow-up	At camp and at home (during awakening)
2-point discrimination test	Evaluation clinic to determine touch sensitivity	• Before camp • After camp • 6-month follow-up	At camp (5 min) or at the Cirris
Jebsen Taylor Test of Hand Function (JTTHF)	Clinical assessment of one-handed motor function	• Before camp • After camp • 6-month follow-up	At camp (15 min) or at the Cirris
Box and Block Test (BBT)	Clinical evaluation of one-handed dexterity	• Before camp • After camp • 6-month follow-up	At the camp (5 min) or at the Cirris
Assisting Hand Assessment (AHA)	Rating c bimanual motor function	• Before camp • After camp • 6-month follow-up	At the Cirris (20 min)
Two-Arm Coordination Test (TACT)	Assessment of bilateral arm use	• Before camp • After camp • 6-month follow-up	At the Cirris (15-20 min)
Motor-Free Visual Perception Test– Revised (MVPT-R)	Virtual perception assessment	• Before camp • After camp • 6-month follow-up	At the Cirris (15-20 min)
Children's Hand-use Experience Questionnaire (CHEQ)	Questionnaire on the use of hands in activities of daily living	• Before camp • After camp • 6-month follow-up	At camp (10 min) or at the Cirris
Canadian Occupational Performance Measure (COPM)	Interview in connection with daily life	• Before camp • After camp • 6-month follow-up	At camp (15 min) or at the Cirris
Pediatric Motivation Scale Motivation	Questionnaire	• 2 times during camp	At camp (10 min)

The magnetic resonance exam will be conducted at the Clinique IRM Québec Synase, a private clinic (you will be accompanied by a member of the research team). This exam consists of taking a three-dimensional image of the child's brain (in a scanner, approximately 15 minutes). For the exam, the child will be lying on a mattress that will be slid into a large tube opened at both ends. An intercom system will allow the child to communicate with the technician as required. It is generally requested that the parent remains in the adjacent room. However, if your child is anxious about the exam

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and the accompanying parent has no contraindications to enter the exam room (*e.g.*, metallic, or electronic implants), they may be allowed to enter the room. In all cases, the parent will be able to see and hear their child during the examination (glass room and intercom). We also ask that you have access to your child's medical record in order to assess any medical condition that could lead to a contraindication to magnetic stimulation or magnetic resonance examinations. If your child has a contraindication to this test, they will still be eligible to participate in the other parts of the study.

Clinical and robotic assessment sessions will take place at the CIRRIS laboratory. In the laboratory, the child will be asked to perform 4 activities with the arms using the KINARM robotic system which includes a video interface. Before starting this evaluation, a period of familiarization and discovery of the robotic system will be carried out using a short video presented to the child.

After the first assessment your child may not be able to participate in the project due to the study inclusion and exclusion criteria. However, this probability is low since an interview will be done by telephone before the first evaluation.

Figure 2. Illustration of a child installed in the KINARM system (left). The child is installed in the exoskeleton which can both measure the movements made by the child or slowly move her/his arms (to assess the sensation of the movement). During the experiment, the subject is placed in front of a screen showing, for example, targets to be reached (illustration on the right).

In our study, motion sensors (accelerometers) resembling a watch (see below) will be worn on both wrists for the 4 weekends and 2 weeks of camp.

Figure 3. Illustration of an accelerometer.

Kathleen Friel / Burke Research Institute

At the beginning and the end of the camp, the clinical measurements and the administration of the questionnaires will be carried out. These same measurements will be carried out at CIRRIS for the 6-month post-intervention follow-up. In the 2-Point Discrimination Test, the child must detect (without seeing their hand) whether there are one or two points touching

the tip of their finger, starting with the less affected hand. Tips with different gaps between them are used. In the JTTHF clinical assessment, the child will be asked to perform six manual tasks (*e.g.,* turning cards, picking up small objects one at a time and putting them in a container) with one hand at a time. The BBT is a test where the child will have to move wooden blocks one at a time as quickly as possible. The AHA assesses the effectiveness with which the more affected hand assists the dominant hand in performing bimanual activities with toys during a semi-structured play session. The game session is filmed, and the video is analyzed and scored later. Thus, this implies that you accept that your child be filmed during the assessment. Finally, two questionnaires (CHEQ and MCRO) will be used to measure your child's perception of the ease with which they use their hands daily to perform different activities. In addition, the *Pediatric Motivation Scale* will be completed at the end of the day on the two Wednesdays of the intervention to understand your child's level of motivation during a camp day.

Your consent for your child to participate in this study implies that you consent to us consulting the following information in your child's clinical record: type of cerebral palsy, type of brain injury, prematurity and birth weight , classification in the "Manual ability classification system" and the "Gross motor function classification system", medical and surgical history, medication, level of spasticity (result of the Ashworth scale), presence or not of intellectual and/or visual deficits as well as the presence of comorbidities such as epilepsy for example. This will make it possible to verify that your child meets the inclusion criteria for the study and to describe the overall sample that participated in the study when the results are published scientifically.

VII. Potential risks and personal inconveniences:

You will have to travel several times to accompany your child to the evaluations (four sessions) and to bring him back to camp (10 days). However, financial compensation will be offered to cover your travel for the three evaluation sessions. You will also be asked to provide lunch and snacks for day camp days, to ensure that your child's preferences and possible dietary restrictions are respected.

Magnetic resonance imaging provides images of the shape and structure of the brain, as well as images of its activity at rest or during a task. This is considered as a safe technique, but because strong magnetic fields are used to generate images, you must complete the security questionnaire that will be provided to you by the researcher. No sedative will be given to your child. If necessary, a simulator will be used to familiarize your child with the environment and the noise emitted by the device (like alarms or the sounds of power tools). Ear plugs will be provided for extra comfort. A technician will be able to see and hear your child at any time. In case of discomfort, your child can communicate verbally, waving or pressing the emergency switch. The MR exam performed as part of this research is not performed for diagnostic purposes as the type of images acquired is not the type used for medical examinations. Thus, anomalies may not be detected. However, it may happen that the study suggests the presence of a previously ignored anomaly (incidental discovery). If the researchers feel that this finding is important, that is, it could have a significant impact on the child's well-being, your child's doctor will be informed. The latter may then order additional examinations if they consider it necessary. If your child does not have a doctor, we can help you obtain contact information for a health service. It will be your responsibility to make an appointment.

Other inconveniences could be anxiety or fatigue experienced by your child. Your child may feel anxious about being tested in the lab. However, the research team will make sure to explain procedures before the evaluation and to answer all their questions. Also, many of the assessments are in the form of games, and the robotic system with virtual reality appeals to children. We believe that this playful approach will encourage the collaboration of children and the establishment of a climate of trust. In order to minimize the risk of fatigue during the assessments, several breaks may

be taken according to your child's needs. It is also recommended that you bring a snack for your child to ensure their good disposition and optimal energy level.

VIII. Possible benefits:

The main benefit of your child's participation in this project is that they will receive 60 hours of intervention based on scientific evidence for free, while having the opportunity to interact with other children living with cerebral palsy. They will also have access to state-of-the-art assessments that are typically not available in regular clinical services. If your child is currently undergoing rehabilitation, we can, with your agreement, transmit the results of her/his evaluations to their treating team.

Your child's participation in this research project will allow us to deepen scientific knowledge on the factors explaining the response to rehabilitation interventions in children living with cerebral palsy. This information is important for the development of more effective and better targeted rehabilitation approaches according to the individual needs of each child. If you show interest, we will send you a summary of the results at the end of the research project.

IX. Voluntary participation and withdrawal of participation:

Your child's participation in this research project is voluntary. You are therefore free to refuse to allow them to participate. You can also withdraw it from this project at any time, without having to give any reasons, by making your decision known to the researcher in charge of the project or to one of the staff members assigned to the project. You can also request the removal of data collected as part of the project. Your decision not to participate in this research project or to withdraw will have no impact on the quality of care and services to which you are entitled or on your relationship with the researcher in charge of the project and the other stakeholders.

We would like to thank you for your valuable collaboration in carrying out this research. We appreciate the time and attention you devote to it.

X. Responsibility clause:

By agreeing to participate in this research project, you are not waiving any of your rights or releasing the researchers, sponsor or institutions involved from their legal and professional obligations.

XI. Indemnity compensatory:

No compensation is attached to your participation. However, the costs incurred for your travels to go to CIRRIS and Synase private clinic will be reimbursed to you. If you live in the Quebec region, a lump sum of $20 per visit will be paid to you for each evaluation session carried out before or after the camp. If you come from outside the Quebec region, the actual travel costs (including meal and accommodation costs if necessary) will be fully reimbursed for these same evaluation sessions. However, no compensatory indemnity will be paid for the costs incurred for participation in the day camp. However, the therapy will be offered free of charge. Your child will be invited to choose a small gift after each evaluation session to thank them for their participation.

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XII. Confidentiality, storage, and use of results:

For monitoring and control purposes, your research file may be consulted by a person appointed by the Sectoral Research Ethics Committee in Rehabilitation and Social Integration of the CIUSSS de la Capitale-Nationale, or by any other duly authorized person.

In addition, for purposes of inspection or constitution of a register, the responsible researcher will keep the name, the date of birth and the telephone number of the participant for the duration of the research project.

All information collected will remain strictly confidential within the limits provided by law. In order to preserve your identity and the confidentiality of information, you will be identified by a code. The list of codes linking your name to your research file will be kept **in the office of the responsible researcher, in a locked filing cabinet**. The video of the AHA clinical evaluation will be recorded on a hard drive which will be stored in a locked file cabinet after each evaluation session and accessible only by team members directly involved in the project.

The data will be kept for 7 years following the end of the project, then destroyed.

Any scientific publication that will result from this research project will present statistical data only and that in no case will the names of the participants be published or disclosed to anyone.

XIII. Questions on the projects and contacts:

During the study, there will be a responsible person you can speak to if you have any concerns or questions about the study or your participation. You can contact Catherine Mercier by phone at 529-9141 ext. 6701 or by email (catherine.mercier@rea.ulaval.ca)
For any additional information you may need, if an unusual change in your condition (health, etc.) occurs during the study, or to comment on this research, please contact

For questions about your rights and remedies or any ethical questions, you can join the coordinator of the Ethics Committee for Sector Research in Rehabilitation and Social Integration at 418-821-0835(lyne.martel2.ciussscn@ssss.gouv.qc.ca).

For any complaints, you can contact the National Capital Capital's CIUSSS Complaints and Quality Of Services Commissioner at 418-691-0762, commissaire.plainte.ciussscn@ssss.gouv.qc.ca

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Project title: Predictors of Response to an Intensive Bimanual Intervention in Children with Cerebral Palsy.

Project responsible researcher: Catherine Mercier, erg. Ph.D.

1) The manager informed me of the nature and purposes of this research project and how it unfolds;
2) The manager informed me of the risks and inconveniences associated with my participation;
3) My participation in this study is voluntary and I can withdraw at any time without prejudice;
4) The data in this study will be treated confidentially and will only be used for scientific purposes and by the partners identified on the information form;
5) I was able to ask all my questions about this project and got satisfactory answers;
6) My decision to participate in this study does not release the researchers or the host institution from their obligations to me;
7) I know that there is no remuneration attached to my participation;
8) The person in charge gave me a copy of the information and consent form;
9) I have read this form and I voluntarily agree to participate in this study;
10) I would like to receive a copy of the results of the study yes ❑ no ❑
11) I agree to be contacted again for other projects carried out by the researchers of this project yes ❑ no ❑
12) I agree to have my clinical record reviewed yes ❑ no ❑
13) I agree to have data collected in my clinical record yes ❑ no ❑
14) I agree to be filmed as part of this project yes ❑ no ❑
15) I undertake to keep confidential the names of individuals and discussion groups

In the case of minors, it is the responsibility of the parent who signs this consent form to inform the other parent of the participation of the child in the research and to provide the researcher's contact

*Information For incapacitated adults, replace the participant's signature with that of the mandatary or the person consenting to the care

Participant's name	**Date of birth**	**Telephone number**
Participant's signature *	Date	
Name of the researcher or of the person witnessing the participant's consent	Date	Signature
Assent of the minor (if required in this case)	Date	Signature

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Researcher's commitment:

I have explained the purpose, nature, advantages, risks and disadvantages of the research project to the participant. I answered their questions to the best of my knowledge and checked the participant's understanding. I will give them a dated and signed copy of this document.

_____	_____	_____
Name of person who obtained consent	Signature	Date (DMY)