Informed Consent Form

Validation Study of a Digital Measurement Device for Central Hand Representation in Children with Neonatal Brachial Plexus Palsy (NBPP)

NCT Number
NCT06950879

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Date: December 16, 2024
Version: 1.4

Informed consent for Parents/Guardians of Minor Participants in an Experiment

Study Title: Assessing Implicit Hand Size Representation In Children With Neonatal Brachial Plexus Palsy: Validation Study Of The Handuz Device

Dear Sir/Madam,

Your child is invited to participate in a clinical study. Before deciding whether to allow your child to participate, please take sufficient time to read this information sheet carefully and discuss it with the medical investigator or their representative, or with others of your choice. Feel free to ask questions if anything is unclear or if you or your child wish to receive more information. This process is known as "informed consent" for participation in a study. Once you decide to let your child participate, you will be asked to sign the consent form on the last page.

1 WHAT IS THE AIM OF THIS STUDY?

We invite your child to participate in a clinical study aimed at validating a new digital measurement device to map how the brain represents our hands. We know that the brain's image of the hand differs from reality. Without visual control, the brain tends to underestimate finger length and overestimate hand width. We designed a device to map these distortions. We've already tested this device on children and adolescents, and now we want to verify if the digital version works just as well.

We know that in Neonatal Brachial Plexus Palsy (NBPP), hand representation is altered but can also be trained.

The sponsor of this study is Ghent University Hospital (UZ Gent). Students from the Department of Rehabilitation Sciences will be part of the research team..

2 WHAT DOES PARTICIPATION IN THE STUDY MEAN FOR YOUR CHILD?

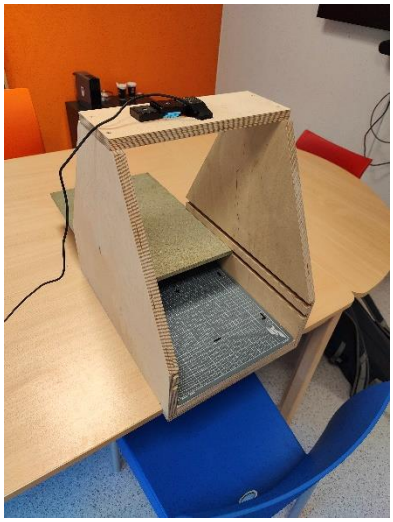
Participation means your child will be invited for testing at the Pediatric Rehabilitation Center of UZ Gent. Two different doctors will conduct the measurements independently.

Your child will be asked to place their hand on a measuring mat, after which a wooden board will slide over the hand to prevent visual feedback.

Then, your child will be instructed (in random order) to indicate the fingertips, knuckles, and wrist. The system will automatically register these points and calculate the difference between actual hand size and the indicated hand size.

One test takes 5–10 minutes. This will be done twice by the first physician.

After a short break, the same test will be repeated twice by a second physician, after which the first physician repeats his measurements. In total, your child will undergo six measurements for each hand.



2.1 Inclusion Criteria:

- Aged between 8 and 18 years
- Presence of a Neonatal Brachial Plexus Palsy

2.2 Exclusion Criteria:

- Other significant physical, neurological, or psychiatric disorders

3 HOW MANY PARTICIPANTS WILL BE INVOLVED IN THIS STUDY?

A total of 20 children/adolescents will take part in this study.

4 HOW LONG WILL THE STUDY TAKE?

The total expected duration for your child is **a maximum of 60 minutes**.

5 WHAT IS EXPECTED OF THE PARTICIPANT?

For the success of this study, it is very important that you and your child cooperate fully with the medical investigator and follow the instructions carefully when indicating reference points on the hand.

6 WHAT ARE YOUR CHILD'S RIGHTS WHEN PARTICIPATING IN THIS STUDY?

6.1 Rights during participation

Participation is entirely voluntary. You or your child may refuse to participate or withdraw at any time, without having to give a reason. This will not affect the treatment or relationship with the researcher or physician. The quality of care and follow-up will not be impacted.
Participation will end if the physician believes it is in your child's best interest. The researcher may also withdraw your child if the procedures are not followed properly.
If withdrawn, collected data will be retained in pseudonymized form for analysis, but no new data will be added.

The study has been approved by an independent Medical Ethics Committee of Ghent University Hospital and Ghent University. It is conducted in line with Good Clinical Practice (ICH/GCP) and the Declaration of Helsinki.

6.2 Rights regarding data protection

In line with the Belgian Patient Rights Law (22 Aug 2002), the EU General Data Protection Regulation (GDPR), and Belgian law (30 July 2018), your child's privacy will be protected. Your child has the right to access their data, request corrections, or exercise other rights (e.g., restriction, deletion, objection, or filing a complaint).

More information is available on the UZ Gent website:
https://www.uzgent.be/patient/gegevensbescherming/u-neemt-deel-aan-wetenschappelijk-onderzoek

By participating, your child agrees to the processing of their data for scientific purposes under GDPR Article 6(1)(e) and Article 9(2)(j).

All collected data will be pseudonymized. Only the research/treating physician or their delegate can trace the data back to your child.

Pseudonymized data may be shared with future researchers for academic studies in similar fields, pending ethics committee approval. If you don't want your child's data reused, contact the DPO (see section 7).

Only pseudonymized data will be used in reports or publications, and confidentiality will be ensured.

Personal and health-related data will be stored for at least **10 years** after the study ends, for safety and follow-up purposes.

Data controller: Institution of lead investigator Prof. Dr. R. Van der Looven (UZ Gent)

Representatives of the sponsor, auditors, the Ethics Committee, and authorities (bound by professional secrecy) may access medical records for study control purposes. Signing the consent form means you agree to this access.

For more information or to exercise your rights, contact the study team or:

DPO contact:
Katya Van Driessche – dpo@uzgent.be

Belgian Data Protection Authority:
Drukpersstraat 35, 1000 Brussels
Tel: +32 2 274 48 00
Email: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

7 INSURANCE

The sponsor provides compensation and/or medical care in the event of injury or harm caused by participation. This is covered by insurance in accordance with Belgian law (Allianz Global Corporate & Specialty – UZ Gent policy number BEL001889 – UGent policy number BEL000862).
If the investigator considers the injury related to the study, the insurance procedure will be initiated. In that case, your child's data may be shared with the insurer.
In case of dispute, you or your child's legal heirs may take legal action directly in Belgium.

8 WHAT ARE THE RISKS AND EXPECTED BENEFITS OF PARTICIPATION?

Participation in this study brings no therapeutic benefit to your child. However, your child's participation in the study may help to better help patients in the future.

There are also no risks to be expected from participating in the study.

It is also possible that other risks and discomforts may occur that are unknown at this time. Therefore, it is very important to report any new health complaint in your child to the physician-investigator as soon as possible, whether or not you or your child believe the complaint is related to the study.

You and your child have the right to ask questions about the potential and/or known risks of this study at any time. If any information comes to light during the course of the study that could affect your willingness to allow your child to continue participating in this study, you will be informed. If your child does experience any harm as a result of his/her participation in the study, your child will receive appropriate treatment.

9 ARE THERE ANY COSTS ASSOCIATED WITH PARTICIPATING IN THIS STUDY?

Your child's participation in this study does not involve any additional cost to you or your child.

10 IS COMPENSATION PROVIDED WHEN PARTICIPATING IN THIS STUDY?

You will not receive financial compensation or reimbursement of travel expenses for your child's participation in this clinical study.
A free parking ticket will be provided.

11 TO WHOM CAN YOU/YOUR CHILD TURN IN CASE OF PROBLEMS OR IF YOU/YOUR CHILD HAS QUESTIONS?

If an injury occurs as a result of the study, or if you or your child require additional information about the study or about your child's rights and obligations, you and your child may contact the physician-investigator or a member of his/her team at any time during the course of the study:

Physician-Investigator: Vanhoorebeeck Lothar
Principal Investigator: Ruth Van der Looven
Phone number: 09 332 42 37 (secretariat)

PARTICIPATION FORM FOR PARENTS/GUARDIANS OF MINOR PARTICIPANTS

Reference number of the participant	

I have read and understood the document "Information letter for parents/guardians of minor participants to a clinical study" page 1 to 4 and I have received a copy. I have been informed about the nature of the study, its purpose, duration, the foreseeable effects of the study and what is expected of me and my child. I have been informed about the possible risks and benefits of the study. I have had the opportunity and sufficient time to ask questions about the study and I have had all my questions answered, including medical questions.
I understand that my child's participation in the study is voluntary and that I can withdraw my child from the study at any time without giving a reason for this decision and without this having any influence on his/her further treatment or relationship with the investigator.
I understand that representatives of the sponsor, auditors, the Medical Ethics Committee and the competent authorities may want to inspect my child's data in order to check the collected information. These parties will not violate confidentiality.
I am aware that this study has been approved by an independent Medical Ethics Committee affiliated with Ghent University Hospital and Ghent University and that this study will be conducted in accordance with the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki, established to protect people participating in studies. This approval should under no circumstances be taken as an incentive to let my child participate in this study.
I have been informed that personal data, including health data, of my child will be processed and kept for at least 10 years after the end of the study. I am informed that I have the right to access and correct this data. Since this data is processed for medical scientific purposes, I understand that access to my child's data may be delayed until after the study ends. If I want access to my child's data, I will contact the investigator who is responsible for the processing of the data.
I am aware that my child's pseudonymised data will be used for the current study.
I am aware that my child's pseudonymised data may be used for future academic scientific research compatible with the current study. Such new study should always be submitted and approved by an ethics committee or Data Access Committee. If I wish my child's data not to be used for future research, I will contact the investigator.

	Tick by the participant's parents/guardian if agreed
I agree to let my child participate in this study consisting of the following mandatory items: - This study requires a data transfer to a country outside the EEA. By checking this box, I give my consent for this. If I do not give permission for this transfer, my child cannot participate in the study.	

Name and first name of the parent/guardian of the participant	Handtekening	Datum
Name and first name of the second parent/guardian of the participant	Handtekening	Datum
Name and first name of the investigator*	Handtekening	Datum

2 copies should be completed. The investigator should keep an original for at least 10 years; the parents/guardians of the participant will also receive a copy.

*By signing the participation form as investigator

- I certify that I have verbally given the necessary information about the study (its nature, purpose and foreseeable effects) and that the parents/guardians of the minor participant have received a copy of the information letter and participation form.

- I confirm that no pressure has been put on the parents/guardians of the minor participant to let his/her child participate in the study and show my willingness to answer any additional questions.

* Tick by the investigator if agreed

By signing the participation form as a witness/interpreter, I certify that I was present during the entire information process and confirm that the information about the goals and interventions of the study was given appropriately, that the parents/guardians of the minor participant understood the study, and that consent for the child's participation in the study was given voluntarily.	
Name, first name and qualification of the witness/interpreter	Signature