Study Protocol

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

NCT Number

NCT06950879

Researchers:
L. Vanhoorebeeck, N. Vermassen, E. Staelens, Prof. Dr. R. Van Der Looven
Date: November 19, 2024
Version: 1.2

1. Introduction

Hand function is one of the most complex sensorimotor skills, requiring both motor output and multisensory input. The brain forms a complex representation of the hand using visual, proprioceptive, and anthropometric information.

This study focuses on **implicit hand representation**, which is influenced by non-visual afferent signals. In children with Neonatal Brachial Plexus Palsy (NBPP), this implicit hand representation appears to be disrupted, leading to altered hand function.

Previous research by Van Der Looven et al. showed that the reproducibility of existing test methods is good but that the procedures are cumbersome. This led to the development of the **HANDUZ prototype**, a digitized device that can automatically capture and process hand representation.

This validation study aims to evaluate the **reproducibility** of this prototype in children with NBPP. Reproducibility is measured both **intra-observer** and **inter-observer**.

---

2. Study Design

Type of study:
Validation study with reproducibility analysis

Design:
This is a single-center, observational reliability study involving children with a confirmed diagnosis of NBPP. Each participant completes six localization trials per hand using the HandUZ device. Two trained raters alternate administration to assess interrater and intrarater reliability. The study is conducted at the Child Rehabilitation Centre of Ghent University Hospital.

Population:
Participants: 18 children aged 8–18 years diagnosed with NBPP.

Inclusion and Exclusion Criteria:

- **Inclusion:** Children with a confirmed diagnosis of NBPP
- **Exclusion:** Children with other neurological, psychiatric, or physical disorders that could affect hand function

Measurement method:
Participants are seated comfortably in front of a custom-built HandUZ setup, which consists of a three-layered vertical structure: a bottom plate with a measuring mat for hand positioning, a middle plate for visual occlusion, and a top plate holding an overhead webcam. The camera captures an image of the participant's hand for landmark annotation. The tested hand is placed palm-down on the measuring mat, and vision is occluded using the middle plate during the perceptual task.

Each hand is assessed six times in an alternating sequence by two trained raters, following a standardized protocol. The examiner verbally names specific anatomical landmarks—including the centers of the metacarpophalangeal (MCP) joints, fingertips, and wrist styloid processes—and the child uses the index finger of the contralateral (non-tested) hand to localize the

corresponding point on the occluded test hand. The examiner then digitally records the judged location on the computer interface.

The estimated finger length (FL) is calculated using the Euclidean distance between each fingertip and the corresponding MCP joint, as identified during the perceptual task. These values are averaged across two trials to obtain a representative estimated FL for each finger.

Separately, the actual FL is calculated from the image of the participant's hand (taken before the task), using the same anatomical landmarks. For each finger, the percentage overestimation (OE) is calculated using the following formula:

OE (%) = 100 × [(Estimated FL – Actual FL) / Actual FL]

Negative values indicate underestimation while positive values indicate overestimation.

To account for potential learning effects, non-consecutive trials are averaged (e.g., trials 1 and 5; 2 and 6). These averaged values are then used for reliability analyses.

---

3. Statistical methods

A detailed SAP is included in a separate section and outlines the statistical procedures for assessing reliability, learning effects, and assumption checks. All analyses were conducted using IBM SPSS Statistics (Version 29.0.2.0). A significance level of $\alpha = 0.05$ was applied. ICC(3,1) was used for reliability analysis, and repeated-measures ANOVA assessed learning effects. Assumption checks included Shapiro-Wilk tests and Mauchly's test for sphericity.

---

4. Reporting of Results

- **Tables:** ICC values for intra- and inter-observer reproducibility with 95% confidence intervals
- **Graphs:** Bland-Altman plots to visualize measurement differences and detect systematic bias
- **Conclusions:** Whether the HANDUZ system provides reproducible measurements for clinical use. High reproducibility would support its further clinical implementation.

---

5. Ethical Considerations

The study protocol was approved by the Ethics Committee of Ghent University Hospital (reference B6702024000525) and conducted in accordance with the Declaration of Helsinki. All participants and/or their legal guardians provided written informed consent.

---

6. Potential Limitations

- **Small sample size** (17 children) may limit generalizability
- **Accuracy of reference point indication** by participants may vary, introducing minor measurement errors

---

7. Study Timeline

- **Participant recruitment:** 2 months
- **Data collection:** 2 months
- **Data analysis and reporting:** 1 month
- **Total study duration:** ~5 months