Baby HABIT-ILE: study protocol of a randomized controlled trial of intensive rehabilitation in infants aged 6-18 months with unilateral cerebral palsy

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Introduction

Recent research using animal models suggests that intensive motor skill training in infants with cerebral palsy may significantly reduce or even prevent maladaptive neuroplastic changes consecutive to the brain lesion. The aim of this randomized controlled trial is therefore to determine the effect of Hand and Arm Bimanual Intensive Therapy Including Lower Extremities (HABIT-ILE) in infants with cerebral palsy compared to a control group, in order to optimize clinical management.

Materials and methods

48 infants aged from 6 to 18 months with unilateral cerebral palsy will be recruited. They will then be paired according to age (+/-3 to 4 months), etiology of the cerebral palsy (brain malformations, periventricular white matter lesions and cortico-subcortical lesions) and, as far as possible, according to the affected side.

Inclusion criteria	Exclusion criteria
• Corrected age of 6-18 months at first assessment • Diagnosed with hemiplegia (paresis) as a result of cerebral palsy, or with asymmetry as determined by a health professional, or at risk of developing unilateral cerebral palsy • Able to complete testing according to age	• Uncontrolled epileptic seizures • Botulinum toxin injections or orthopedic surgery in the 6 months previous the intervention, during the intervention or 6 months after the intervention • Any of the usual contraindications to MRI such as metal implants • Severe visual (ophthalmological examination) or cognitive impairments preventing the child from being interested in simple games

Intervention

Each pair will be randomly assigned to the HABIT-ILE treatment group (n=24; "immediate treatment") or to the control group (n=24; "delayed treatment"). The treatment group will receive 50 hours of HABIT-ILE treatment over 2 weeks (5h/day, 5 days/week) whereas the control group will follow their usual activities for 2 weeks.

48 infants

Randomization

« treatment » (n=24)

« control » (n=24)

Baseline

Baseline + 30j

Baseline + 90j

HABIT-ILE (50 hours over 2 weeks)

2 weeks of standard motor activities + conventional treatment

Conventional treatment

Conventional treatment

HABIT-ILE (50 hours over 2 weels)

Evaluation 1

Evaluation 2

Evaluation 3

Measures and evaluation

Assessments will be performed at 3 intervals: at baseline, 1 month after baseline and 3 months after baseline. The control group will still receive HABIT-ILE therapy after the 3rd assessment.
The primary outcome will be the Mini-Assisting Hand Assessment.
Secondary outcomes will include:

- GMFM-66;
- Bayley Scales of Infant and Toddler Development-III (cognitive, motor and language domains);
- Pediatric Evaluation of Disability Inventory -CAT;
- Canadian Occupational Performance Measure;
- Young Children's Participation and Environment Measure;
- Visual-Spatial Attention Test “Batterie d’évaluation du jeune enfant";
- Magnetic Resonance Imaging (DTI);
- Upper limb kinematics and accelerometers in daily wear.

Perspectives

We assume that the baby HABIT-ILE intervention will induce greater improvements in the different tests and questionnaires than in the control group and that these results will be correlated with neuroplastic changes. In conclusion, if such therapy is shown to be effective in babies from 6 to 18 months of age, we hope that this will influence the type of practical recommendations for the follow-up of these children from the age of 6 months.

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