HABIT-ILE@home for children with cerebral palsy: protocol of 2 randomised controlled trials

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Cerebral Palsy (CP) is the most common cause of motor disability in children with a major impact on daily life autonomy.

As a goal-oriented therapy based on motor skill learning principles, **H**and-Arm **B**imanual **I**ntensive **T**herapy **I**ncluding **L**ower **E**xtremities (**HABIT-ILE**) have shown large improvements in children with CP.

Nonetheless, HABIT-ILE therapy could be hard to set up : need of numerous trained therapists over 2 weeks, therapy only available in some specific places. It could be difficult for patients to access the therapy.

1st RCT : What is the efficiency of **2 weeks of HABIT-ILE@home** with telerehabilitation compared to a usual HABIT-ILE camp ?

2nd RCT: Could a **HABIT-ILE follow-up** at home show a better improvement after camp than usual therapy ?

Method

Participants: n = 48, from 6 to 18y with bilateral CP

HABIT-ILE :
2 weeks on site, 6h30/day, 5 days/week.
One therapist per child and supervision on site.

Figure 1. HABIT-ILE on site

HABIT-ILE@home :
2 weeks at home, 6h30/day, 5 days/week.
One caregiver at home and supervision via telerehabilitation.

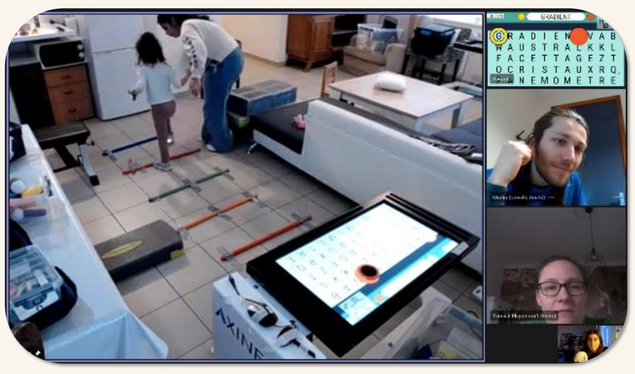


Figure 2. HABIT-ILE@home

Follow-up HABIT-ILE@home :
9 weeks, 1h/day, 5 days/week.
One caregiver one site and supervision via telerehabilitation

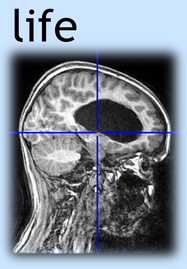
Non specific follow-up :
9 weeks, 1h/day, 5 days/week.
One caregiver on site, no supervision.

Design

3 assessment times : before therapy (T0), after therapy (T1), and 3 months after the beginning of the therapy (T2) (fig. 3).

The main outcome will be the change observed in the Gross Motor Function Measure (GMFM-66).

Secondary outcomes will be :
- Upper and lower limbs abilities in daily life activities
- Social participation and quality of life
- Self-esteem
- Quantity and type of movement
- Neuroplastic changes (MRI).



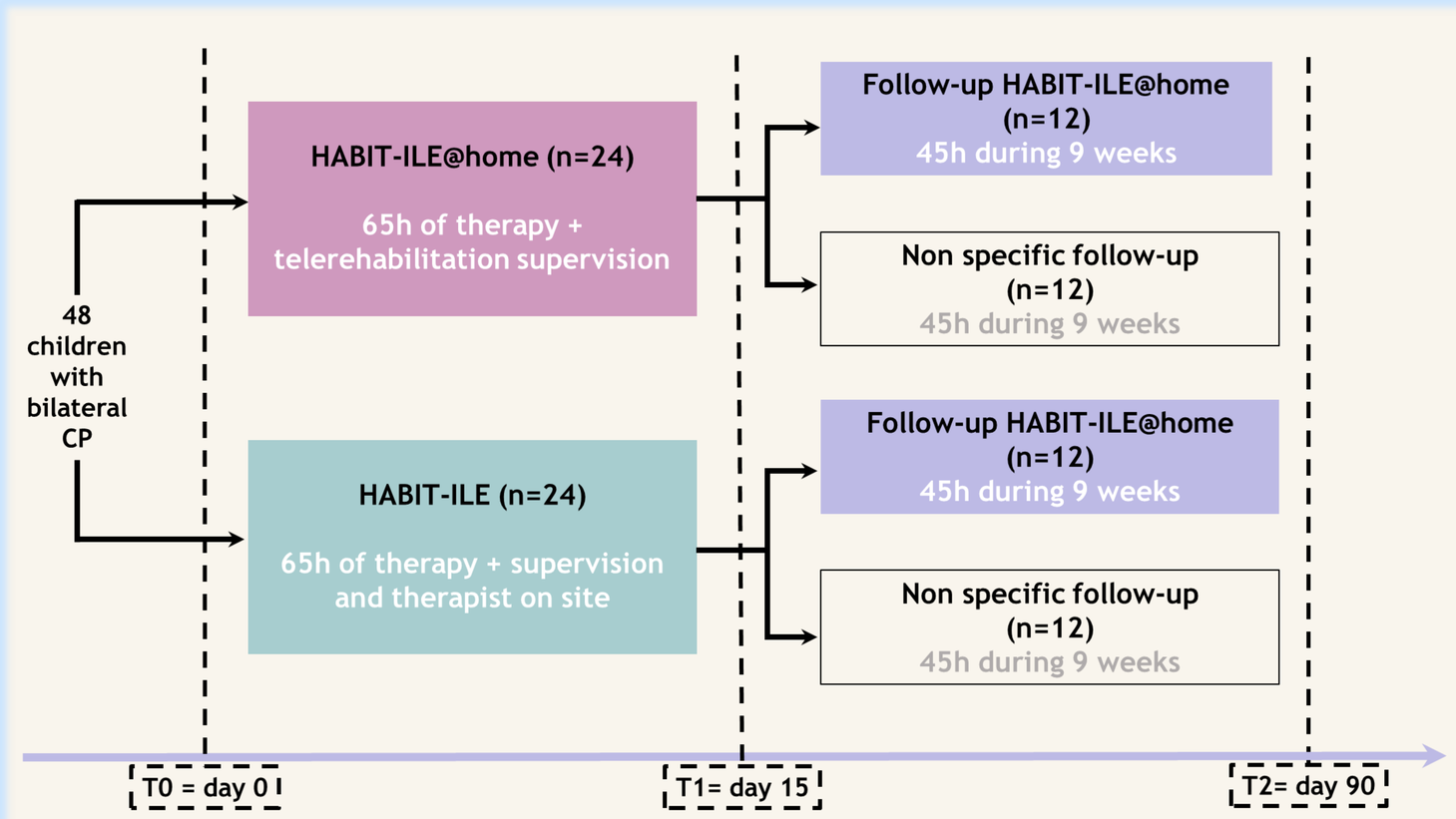


Figure 3. Clinical study design

Hypothesis

1st RCT : We expect **a similarity between HABIT-ILE and HABIT-ILE@home** at functional, biomechanical and neuroplastic levels. This may allow more children to benefit from efficient therapies.

2nd RCT : the changes induced by both therapies could be **improved by the HABIT-ILE follow up**.