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EUROPEAN PAEDIATRIC TRANSLATIONAL RESEARCH INFRASTRUCTURE

PhiCube: Bilateral upper-limb robotic device for neuromotor recovery

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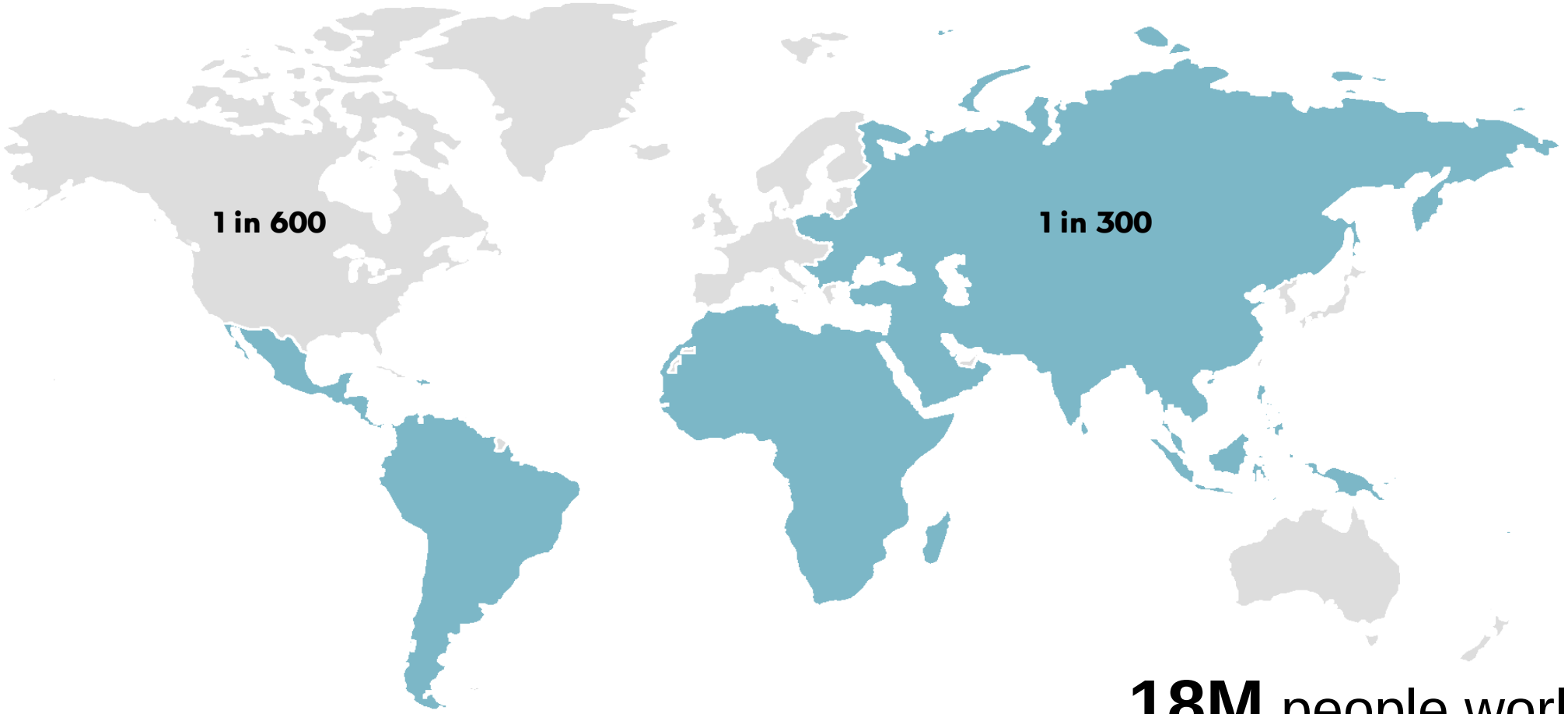
EPTRI – BARI – 19/07/2024

Mario - A sweet beginning

Photo credits: FightTheStroke Foundation
Posted with parental consent.

Infantile Cerebral Palsy



18M people worldwide

Higher incidence in developing countries

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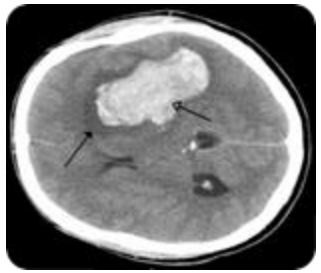
Infantile Cerebral Palsy

Cerebral palsy (CPI) is a group of neurological disorders resulting from a permanent, non-progressive lesion of the developing brain that occurs before, during, or after birth. This injury variably affects the child's motor function and overall development, primarily affecting posture and movement. Sensory, intellectual, communication, swallowing and emotional problems can also be associated with relational difficulties. Although brain damage is not reversible, its consequences can vary and change over time, making them sensitive to early and targeted interventions.



The most frequent causes include:

- **pre-natal causes**, genetically based brain malformations, maternal infections that affect the developing fetus such as, for example, toxoplasmosis, syphilis, rubella, cytomegalovirus, herpes simplex (these infections are collectively called the TORCH complex), reduction the blood supply or oxygen supply to the developing brain; genetic, chromosomal or toxic factors
- **peri-natal causes**, reduced blood and oxygen supply to the brain (hypoxic-ischemic encephalopathy), cerebral hemorrhage
- **post-natal causes**, meningo-encephalitis, severe head trauma, reduced blood supply to the brain causing brain damage (cardiocirculatory diseases and respiratory arrest for various causes)

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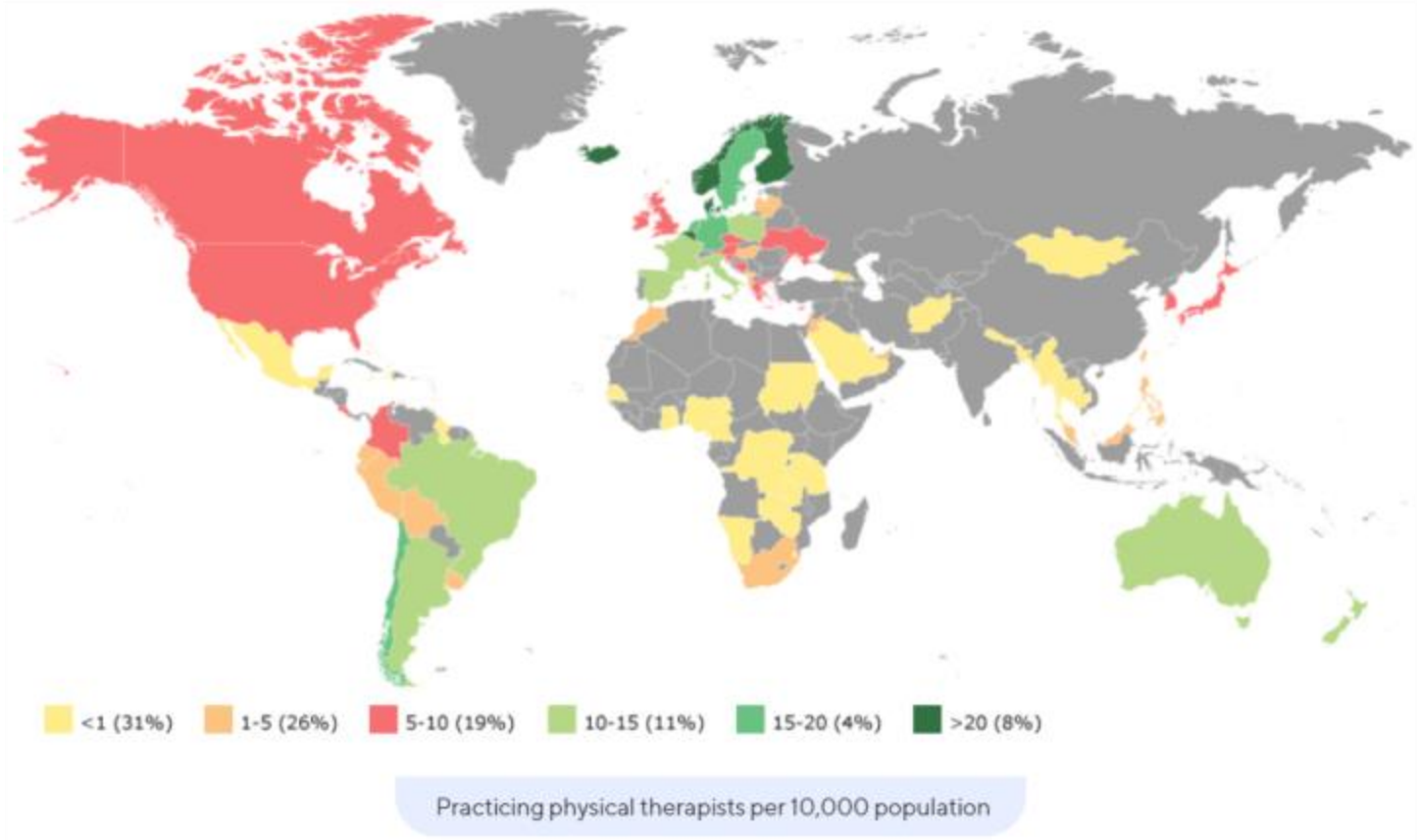
Infantile Cerebral Palsy

patient NEED

- Early Medical and Therapeutic intervention
- Personalized and Person-centered therapy
- **Intensity** of the treatment
- Assiduous Occupational Therapy
- Physical Therapy
- Parental Support
- Emotional and Psychological Support
- Adaptive Equipment

A growing problem

The distribution and density of therapists are uneven and the healthcare system cannot keep up with the demand.



The promise of rehabilitation robots

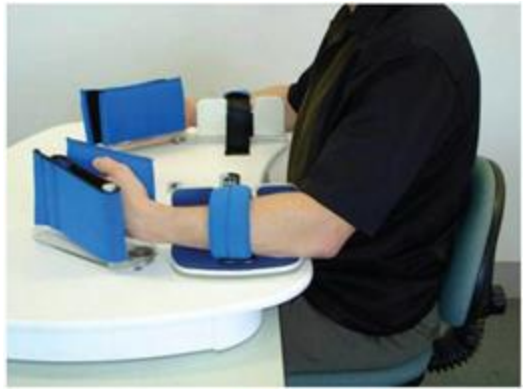
Braccio di Ferro.

Reha-Slide Duo.

EXO-UL7

BFIAMT

Bi-Manu Track.



Rocker (APBT).

Tailwind.

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Drawbacks

- Bulky
- Expensive
- Invasive
- Hostile

How to design for neuromotor impairments?

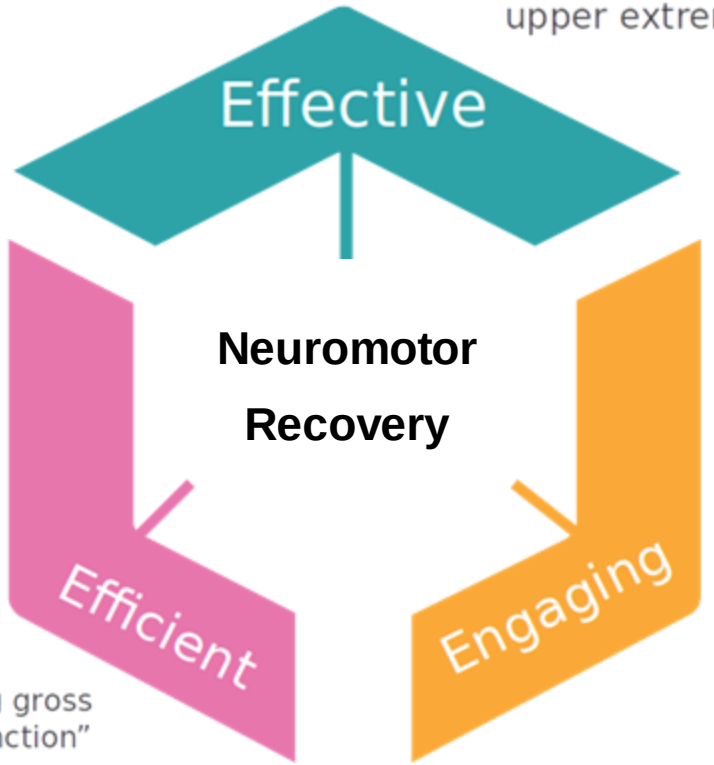
ANYONE

ANYWHERE

ANYTIME

Bilateral Training

"can improve unilateral paretic limb functions of the upper extremity"



Treatment Frequency

"plays a crucial role in improving gross motor function"

PLAY

"provides context for learning and adaptation"

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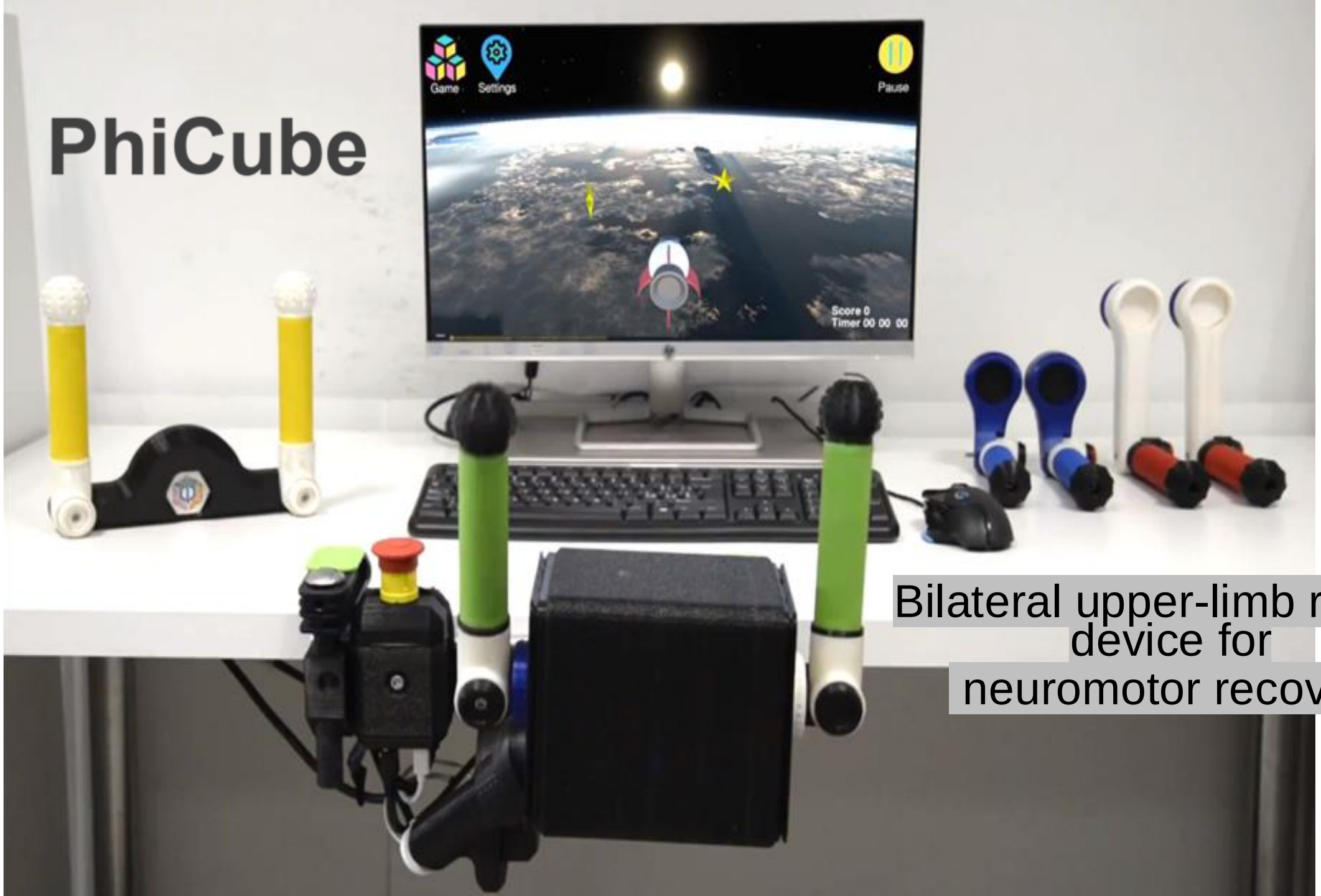

Bilateral upper-limb robotic device for neuromotor recovery

Effective

Bilateral treatment

Rehabilitation approach leveraging cerebral neuroplasticity to maximize motor recovery.

Ouyang R.G., et al. (2020), Effectiveness of hand-arm bimanual intensive training on upper extremity function in children with cerebral palsy: A systematic review, EJPN, 25, 17-28
McCombe Waller, S., & Whitall, J. (2008). Bilateral arm training: why and who benefits?. NeuroRehabilitation, 23(1), 29–41.

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Flexible and personalized upper-limb involvement

More than 30
configurations

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Efficient

High treatment intensity

Of utmost importance to guarantee the improvement of motor functionality, especially during the acute phase.

Hsu C.W., et al. (2020), Effects of Therapeutic Exercise Intensity on Cerebral Palsy Outcomes: A Systematic Review With Meta-Regression of Randomized Clinical Trials., Front Neurol., 2019 Jun 21;10:657.

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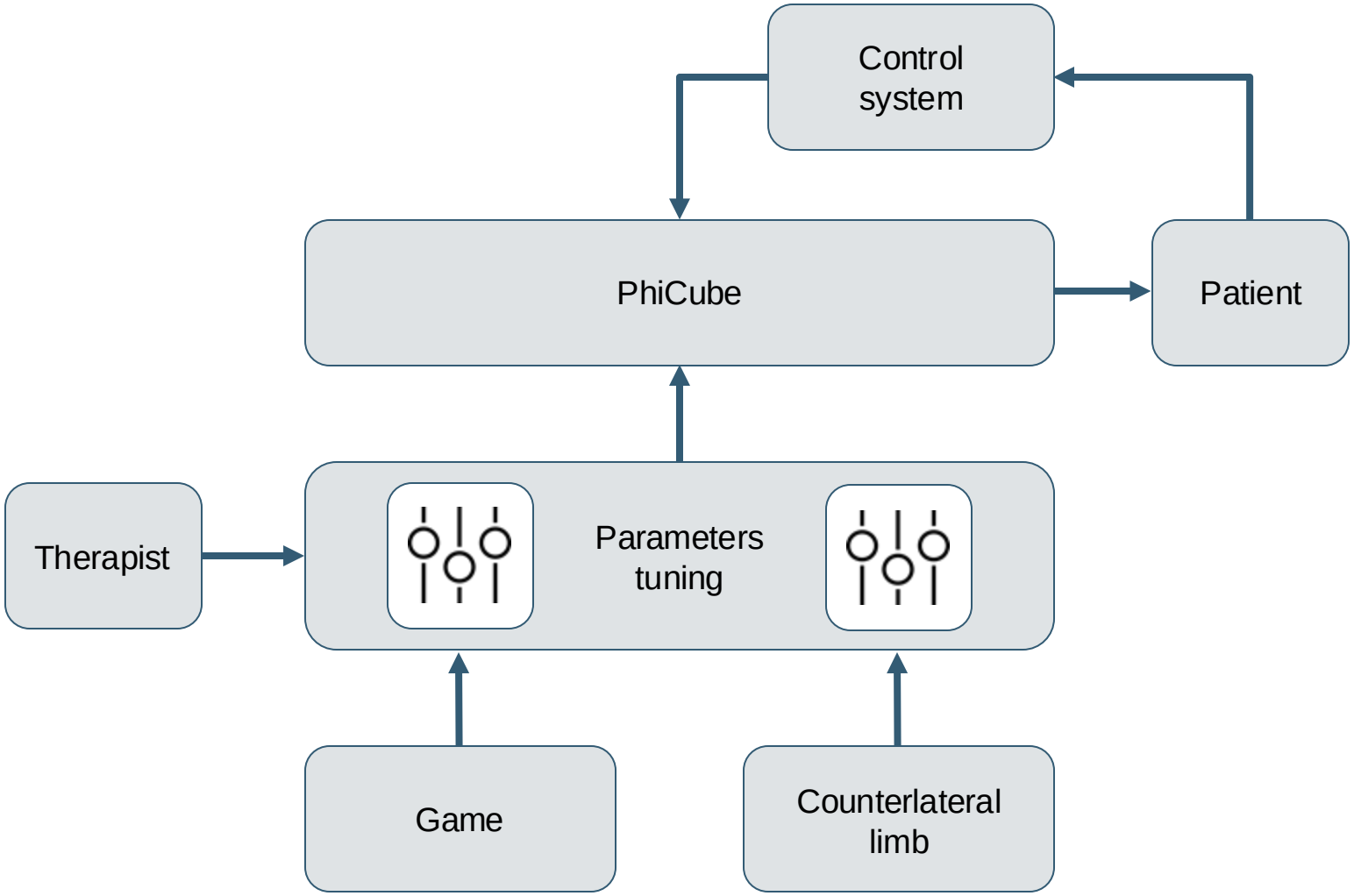
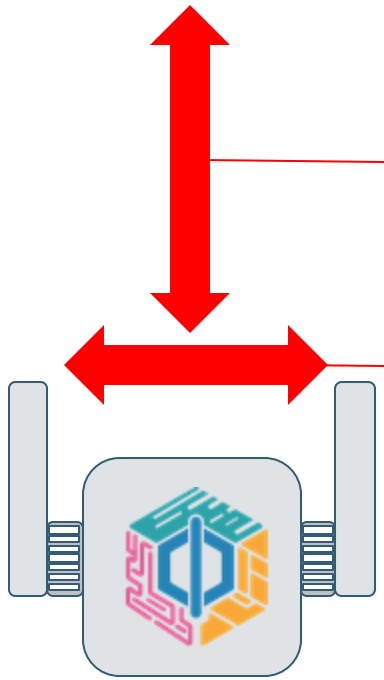
Patient in the loop - The *assist-as-needed* paradigm





Task-based assistance

Patient-based assistance

Patient in the loop - The *assist-as-needed* paradigm

	Bilateral movement (Phase)	Bilateral movement (Counter-phase)	Monolateral movement
PATIENT-BASED ASSISTANCE			**N/A**
TASK-BASED ASSISTANCE			

Engaging

Gamification

Helps increasing treatment adherence providing a context for learning that aims to maximize relearning and neuroplasticity.

Blanche, E. I. (2008). Play in Children with Cerebral Palsy: Doing With – Not Doing To. In Parham L. D. & Fazio L. S. (Eds.), Play in occupational therapy for children, 375–393

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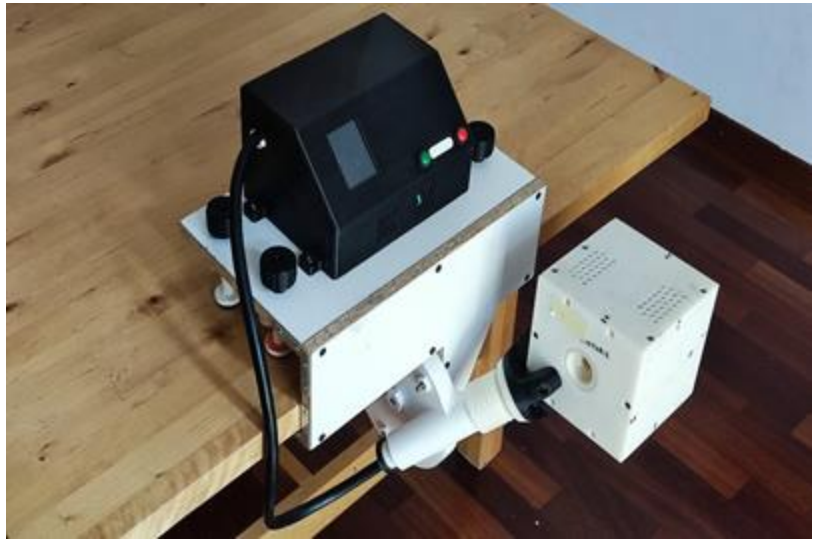
Hardware development

PhiCube 1.1
Usability Test

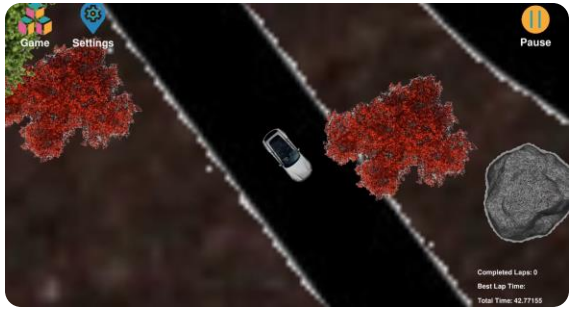
PhiCube 1.2
User interest

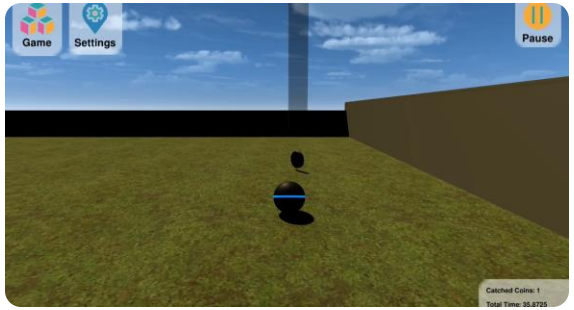
PhiCube 1.3
Clinical Validation

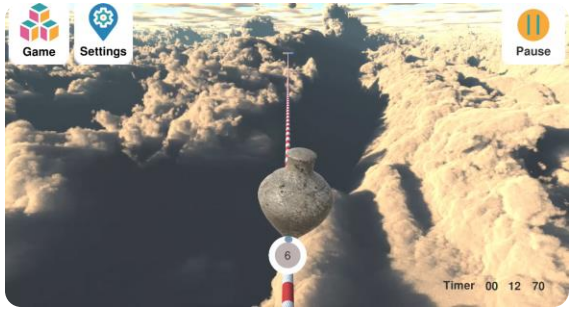


Software development

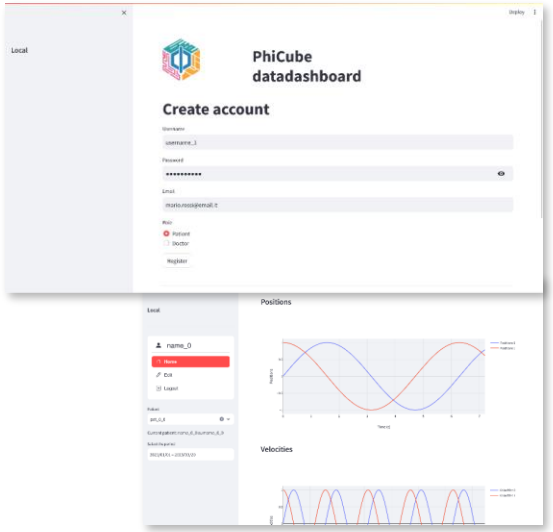
Games

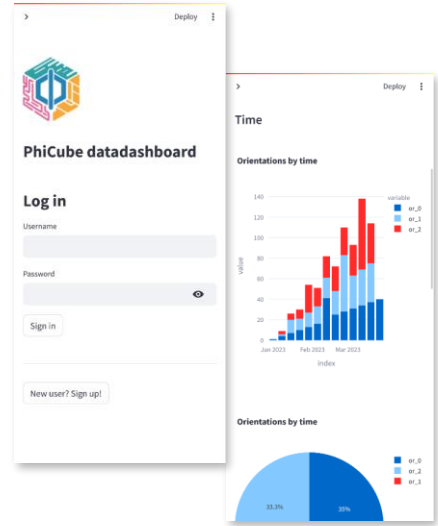




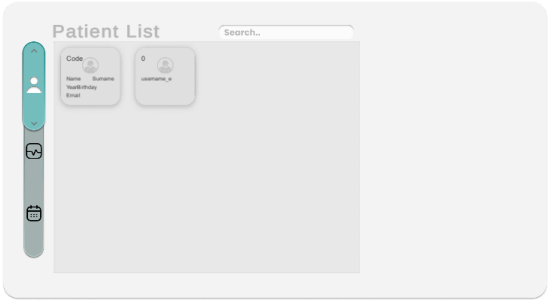


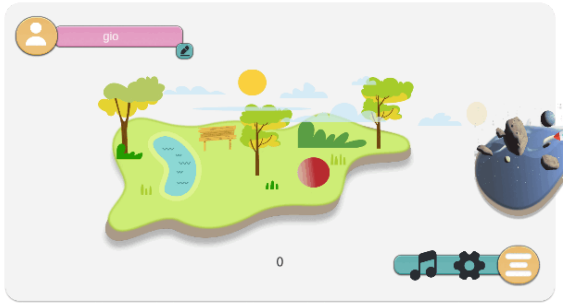
Dashboard





User interface





Results - Usability trials

Patient

children (9.01 ± 1.95 years, 63.1% male) with **CP** were enrolled

19

Session

30 min. each

Assessments:

- System Usability Scale (SUS).
- Technology Acceptance Model 3 (TAM-3).
- Ad hoc questionnaire (Focus, Results).
- Graphical representations with emoticons were included for clarity.

Results:

- **"double lever"** and the "**steering wheel"** emerged as the most enjoyable controllers, with nearly **80%** of respondents expressing complete agreement with the statement **"using the controllers was fun"**.

- The **83%** of participants would **recommend the game to a friend.**
- **Easy to use** and **maneuver**,
- **Very few reports of discomfort** associated with their use.

Pediatric Physical Medicine and Rehabilitation Service, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy in collaboration with IRCCS E. Medea, Bosisio Parini, Italy.

Pediatric upper-limb rehabilitation with PhiCube, a modular bilateral end-effector device

Objective: To evaluate the effectiveness of a motor rehabilitation treatment for upper-limbs, using the bilateral and portable end-effector robotic device

Patient

52

- Neurodevelopmental disorders
- DCD
  Age range: **4** and **18** years old

Session

30

- **2-3** per week
- **45** min. each

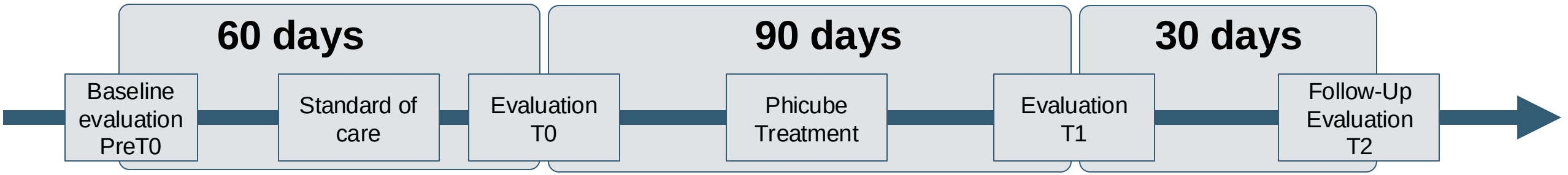
Aim: to evaluate improvement of upper-limb;
Primary outcome: Melbourn Assessement 2 scale;

Aim: to evaluate Neuropsychological and visuocognitive function;
Secondary outcome: ABILHAND-Kids, Leiter 3 subtest Sustained attention, NEPSY-II subtests, BRIEF P/2;

Aim: Evaluate treatment feasibility and technology sustainability;
Exploratory outcomes: Questionnaires, HTA;

FIT4MEDROB Fit for Medical Robotics

GASLINI · IRCCS FONDAZIONE STELLA MARIS · Fondazione Don Carlo Gnocchi Onlus · LA NOSTRA FAMIGLIA · IRCCS EUGENIO MEDEA



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Future Activities

Objective: To evaluate the effectiveness of a motor rehabilitation treatment for upper-limbs, using the bilateral and portable end-effector robotic device

Patient

100

- Stroke, Parkinson, ALS, Dementia, Spinal Cord injury
  Age range: **18** and **82** years old

Primary outcome: Fugle Meyer-Upper Extremity Scale (FMA-UE)

Secondary outcome: MBI, WCST, SC WT,TMT,MoCA,MMSE

Reengineering for Adult population

Maugeri

4 Sites

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Future Activities

Rehabilia technologies

Spin-off

Consiglio Nazionale delle Ricerche

Open to research collaboration!

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Thank you!
Questions?

Giovanni Tauro - STIIMA CNR