MULTICENTRE OBSERVATIONAL STUDY ON EFFICACY OF A PLAY-BASED MOTOR LEARNING APPROACH (A.MO.GIOCO) IN CHILDREN WITH BILATERAL CEREBRAL PALSY: STUDY PROTOCOL

MARIA FOSCAN [1], ANTONELLA LUPARIA [2], FRANCESCA MOLTENI [3], ELISA BIANCHI [4], SHARI GANDELLI [1], EMANUELA PAGLIANO [1], ERMELLINA FEDRIZZI [1]
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BACKGROUND

Bilateral clinical forms of CP have a **prevalence of over 50%** of cases of CP and result in varying degrees of disability in both **gross and fine motor skills often associated with neuro-visual disorders**, including peripheral ophthalmologic and central disorders, such as Central Visual Impairment (CVI).

- **Motor training based on specific tasks and parent empowerment** represents the new paradigm for the **rehabilitation of children with Cerebral Palsy**.
- **Motor functions** are considered an expression of a **perceptual-motor-cognitive process**, which occurs in the search for a **solution to a task** that arises from the **interaction between the individual and the environment.**
- **Most published studies** address the problem of the rehabilitation intervention **effectiveness without describing the treatment methodology** or briefly mentioning it.

AIM OF THE STUDY

Evaluate the **effectiveness** of a play-based **Motor Learning and Motor Teaching rehabilitative approach** titled **A.MO.GIOCO** (**A**pprendimento **MO**torio nel **GIOCO**) in children with bilateral palsy.

Multicentre study
Fondazione IRCCS Istituto Neurologico C. Besta, Milano, Italy
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Fondazione IRCCS E. Medea, Bosisio Parini, Italy
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METHODS

PARTECIPANTS

Experimental group: **15 children with bilateral CP, aged 2-6 years** undergoing 48 hours of rehabilitation treatment (for 6 -8 weeks) according to the **A.MO.GIOCO Approach.**

Control group: **15 children with bilateral CP, aged 2-6** years treated with **usual care** evaluated with the same protocol.

Inclusion criteria: clinical diagnosis of bilateral CP confirmed by neuroradiological findings; GMFCS, MACS, and VFCS levels between II and IV; General Developmental Quotient > 70 at Griffiths Scales III (excluding the motor subscale); no consumption of botulinum toxin for spasticity or orthopedic surgery in the previous 6 months; no drug-resistant epilepsy.

Need to **standardize** the rehabilitative **intervention**

Need to translate the **A.MO.GIOCO theoretical principles in rehabilitative practice**

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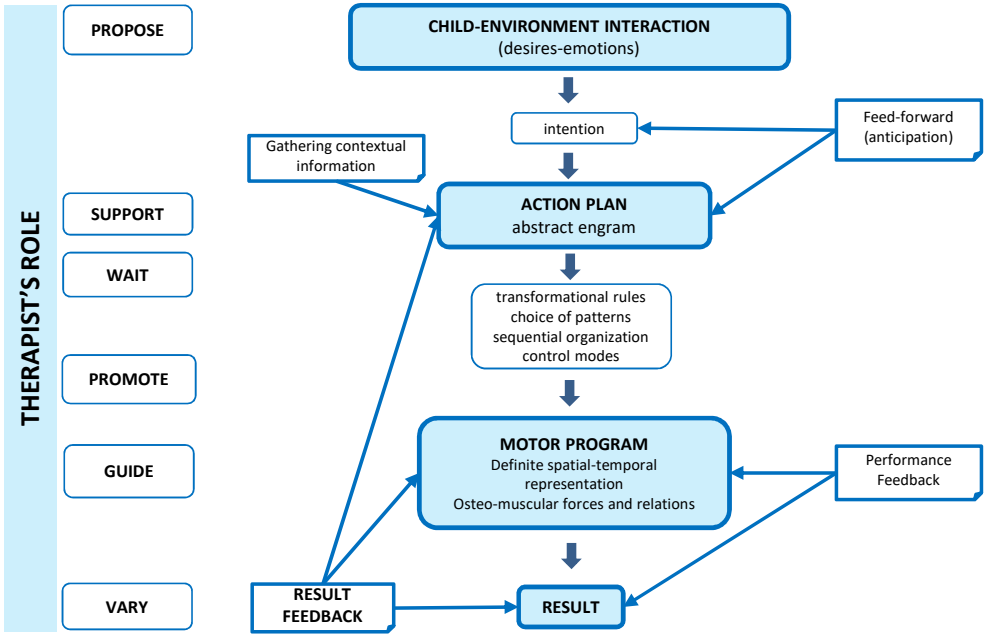
REHABILITATIVE INTERVENTION: A.MO.GIOCO MOTOR LEARNING APPROACH

MOTOR LEARNING MODEL



Levels of planning, execution, and motor behavior control according to the Motor Learning Model

- **Refers to the systemic cognitive model of learning and movement control implemented in the context of spontaneous play activities and in the therapist-child-family interaction.**
- The setting of a **spontaneous play**, in which tasks are natural and diversified, and in which the child is the actor who develops hypotheses, analyzes environmental information, identifies strategies, and verifies results, represents the essential elements for a rehabilitative project that favors not only motor learning, but also the overall cognitive and affective development of the child with CP.
- The **starting point for learning is the child's motivation**, which directs the action and also supports possible fatigue and frustration, therefore the child's play preferences, cognitive profile, emotional-affective, communicative and relational characteristics should be firstly considered.

OPERATIONAL GUIDE FOR THERAPISTS

1) **Therapist's role:** partner that supports and helps the child in all phases of motor learning in resolving a task: the elaboration of an action plan, the collection of necessary information for defining a motor program, the explication of rules, the selection and control of sequences, the verification of results, and the possible re-elaboration of the plan or motor program.

2) **Macro intervention areas** (gross motor, manipulative-praxis, visual and visuo-cognitive):
Goals (age range 2-4 and 4-6 years) for each area.
Materials and setting based on the different levels of functional classification (GMFCS, MACS e VFCS II-IV).

3) **Examples of play activities** (motor, imitative-symbolic, constructive, graphic, and visuo-cognitive games) with indications about how to "build" the activities.
Proposals related to self-care autonomies, to be considered transversal and must always be **shared with the family.**

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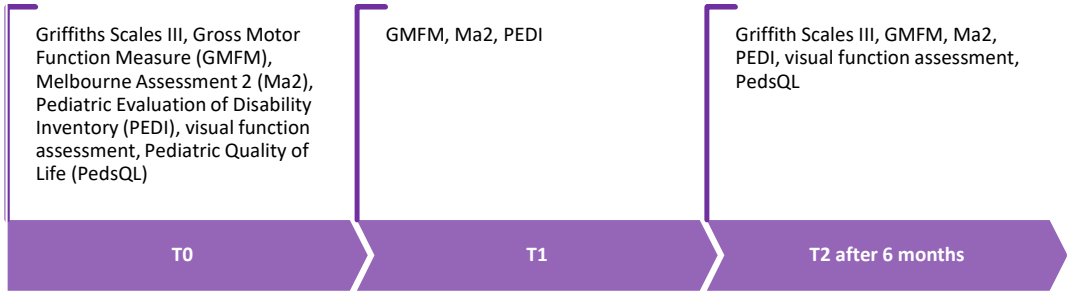
Assessment protocol



Acknowledgement: this work was supported by the Italian Ministry of Health (RRC). We are thankful to Mariani Foundation that supports our clinical and research activities.

Data analysis

Descriptive statistics on the main demographic and clinical characteristics will be performed in the two treatment groups. Categorical variables will be described using frequencies and percentages, while continuous variables using means and standard deviations, or medians, interquartile ranges, and ranges. Primary and secondary outcomes will be evaluated separately for each score of interest (primary outcomes: General Developmental Quotient and Griffiths-III subscores, PEDI scores/subscores; secondary outcomes: GMFM, Ma2, LEA, VMI, PedsQL scores). For each score, means and standard deviations at each time (T0 – baseline; T1 – when available; T2) will be calculated in each treatment group (standard, experimental), and compared between groups with the t-test. Differences within treatment groups between each follow-up time and baseline will also be calculated and compared between groups with the paired t-test. Treatment effect on each score will be quantified as, the difference between the two treatment groups in the mean variation at T2 or T1 compared to T0. The significance level will be set at 0.05 and tests will be two-tailed.

As there are no reference data to define the minimum clinically relevant difference in terms of variation in the two scales used to measure the primary outcome, and since this is a pilot observational study, the sample size was defined based on the number of children recruitable by the participating centers within the time frame of the study. With this number of children enrolled, the study will have 80% power to detect medium/high effect sizes (Cohen's d of 0.6) as statistically significant, with a 5% level of significance for a two-tailed test.

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