Date : 20/11/2024

Title : The Effect of Robot-Assisted Walking Training on Motor Functions, Respiratory Parameters, and Functional Capacity in Cerebral Palsy

PROTOCOL OF THE STUDY

Study Design and Participants

This study will be conducted as a **prospective randomized controlled trial** including children diagnosed with spastic type Cerebral Palsy (CP). Participants must have an official medical board report confirming the diagnosis.

Participation in the study will be voluntary. **Written informed consent** will be obtained from parents or legal guardians, and **assent will be obtained from the children** prior to inclusion in the study.

All evaluation and treatment sessions will be carried out at **Istanbul University-Cerrahpaşa**.

Participants who meet the eligibility criteria will be randomly assigned into two groups:

- **Group I: Neurodevelopmental Treatment Group (NDT)**
- **Group II: Neurodevelopmental Treatment + Robotic Rehabilitation Group (NDT+RR)**

Randomization will be performed using a **computer-generated randomization list**.

Sample Size Calculation

The sample size was calculated using **G*Power 3.1 software** based on a **two-tailed Pearson correlation analysis** to evaluate concurrent validity.

Assuming an expected correlation coefficient of **$r \geq 0.60$**, a **significance level of $\alpha = 0.05$**, and a **statistical power of 90%**, the required **total sample size was determined to be 24 participants**.

Inclusion Criteria

- Aged **8–15 years**
- Diagnosed with **spastic diplegic or spastic hemiplegic Cerebral Palsy**
- Classified as **Gross Motor Function Classification System (GMFCS) Levels I–III**
- Height **greater than 100 cm**
- Signed **informed consent and voluntary participation forms**

Exclusion Criteria

- Orthopedic surgery within the **last 12 months**
- **Botulinum toxin A injection** within the **last 6 months**
- History of **uncontrolled or irregular epilepsy/seizures**

- **Cognitive or communication impairments** preventing understanding or following instructions

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Treatment Protocol

Group I (Neurodevelopmental Treatment Group – NDT)

Participants in Group I will receive a **neurodevelopmental physiotherapy program** aimed at improving trunk control, balance, and lower extremity stabilization.

Exercise Protocol Applied to the NDT Group

Exercise Order	Exercise Name	Application
1	Diaphragmatic Breathing Exercise	10 inspirations – 10 expirations
2	Tandem Walking and Step Length Training	10 repetitions (forward and backward)
3	Sit-to-Stand Exercise on Supported Balance Platform	20 repetitions
4	Pelvic Elevation / Bridging Exercise	30 repetitions
5	Quadrupedal Balance Training (hands and knees)	15 repetitions of contralateral reaching
6	Functional Step Training Using Step Board	15 step-ups
7	Weight Transfer in Sitting Position	Approximation applied in all directions for 2 minutes

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Group II (Neurodevelopmental Treatment + Robotic Rehabilitation – NDT+RR)

Participants in Group II will receive the same **neurodevelopmental treatment program with reduced repetitions**, combined with **robotic-assisted gait training**.

Exercise Protocol Applied to the NDT+RR Group

Exercise Order	Exercise Name	Application
1	Diaphragmatic Breathing Exercise	10 inspirations – 10 expirations

Exercise Order	Exercise Name	Application
2	Tandem Walking and Step Length Training	5 repetitions (forward and backward)
3	Sit-to-Stand Exercise on Supported Balance Platform (BOSU)	10 repetitions
4	Pelvic Elevation / Bridging Exercise	15 repetitions
5	Quadrupedal Balance Training (hands and knees)	7 repetitions of contralateral reaching
6	Functional Step Training Using Step Board	7 step-ups
7	Weight Transfer in Sitting Position	Approximation applied in all directions for 1 minute
8	Robotic Gait Training	20 minutes

Robotic Rehabilitation Protocol

Robotic-assisted gait training will be performed using the **Woodway Locomot robotic gait training system**.

Participants will be positioned in the robotic system **under the supervision of a physiotherapist**.

Training parameters:

- **Speed:** 0.08 km/h
- **Inclination:** 0.0°
- **Training duration:** 20 minutes

Treatment Frequency and Duration

- Sessions will be conducted **twice per week**
- **Total intervention duration: 12 weeks**
- All interventions will be performed **individually by a physiotherapist**

Outcome Measures

Assessments will be performed at two time points:

- **Baseline (pre-treatment)**
- **Post-treatment (after 12 weeks)**

Evaluation Tools

Gross Motor Function Classification System (GMFCS)

The **GMFCS** will be used to determine the functional classification level of participants at baseline.

Respiratory Function Assessment

Respiratory function will be assessed using a **MicroQuark USB PC-based spirometer**.

The following respiratory parameters will be evaluated:

- **Forced Vital Capacity (FVC)**
- **Forced Expiratory Volume in 1 second (FEV1)**
- **FEV1/FVC ratio**

Gross Motor Function Measure (GMFM-88)

Gross motor performance will be evaluated using the **GMFM-88**.

The following dimensions will be assessed:

- **Dimension C – Crawling and Kneeling**
- **Dimension D – Standing**
- **Dimension E – Walking, Running and Jumping**

Ethical Considerations

- **Written informed consent** will be obtained from parents or legal guardians.
- Consent will be obtained for the **processing and use of personal data**.
- The study will adhere to **ethical principles for research involving pediatric populations**.

Statistical Analysis

Statistical analysis will be conducted using **SPSS software**.

- Data distribution will be assessed using the **Shapiro–Wilk test**.
- **Within-group comparisons** will be analyzed using the **paired t-test** or **Wilcoxon signed-rank test**, depending on the distribution of the data.
- **Between-group comparisons** will be performed using the **independent samples t-test** or **Mann–Whitney U test**.

The **level of statistical significance will be set at $p < 0.05$**.