Official Study Title: Investigation of the Effect of Elastic Lower Extremity Orthosis on Gait and Balance Parameters in Children With Spastic Cerebral Palsy: A Randomized Controlled Trial

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Study Brief Title: Effect of Elastic Lower Extremity Orthosis on Gait and Balance Parameters in Children with Spastic Cerebral Palsy

Study Period: Start: August 25 2025– End: November 01 2025

1. Study Objective

The primary objective of this study is to determine the effect of an elastic lower extremity orthosis, applied in addition to conventional neurodevelopmental treatment, on gait and balance parameters in children with spastic cerebral palsy presenting with an in-toeing gait pattern.

2. Study Design

Single-blind randomized controlled trial

Biostatistician will be blinded to group allocation

Groups will be assigned using simple randomization

3. Study Population

Inclusion Criteria

Voluntary participation

Diagnosis of spastic cerebral palsy

GMFCS level 1–3

Age 18–84 months

Written and verbal informed consent from parents

Exclusion Criteria

GMFCS level 4–5

Botulinum toxin injection or surgery to lower extremities/pelvis in the past 6 months

Sample Size

Each group: 13 participants

Total: 26 participants

Calculated using G*Power with 95% power and $\alpha = 0.05$

4. Intervention

Neoprene elastic lower extremity orthosis

7 days per week, 6–8 hours per day, 8 weeks

In addition to conventional neurodevelopmental therapy

5. Data Collection and Measurements

Demographics: age, sex, height, weight, CP type, GMFCS level

Gait: Edinburgh Visual Gait Analysis (17 parameters)

Balance: Pediatric Balance Scale (14 items, 0–4 points)

Measurements at baseline and after 8 weeks

Video recordings obtained

No personal identifying information included