Official Study Title: Effects of Boccia Exercises on Upper Extremity Muscle Thickness and Grip Strength in Hemiparetic Individuals

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Study Protocol with Statistical Analysis Plan: Effects of Boccia Exercises on Upper Extremity Muscle Thickness and Grip Strength in Hemiparetic Individuals

Study Design

This is a randomized controlled trial (RCT) with a true experimental pretest-posttest control group design. The study aims to examine the effects of an 8-week Boccia exercise program on upper extremity muscle architecture and grip strength in hemiparetic individuals, in addition to their ongoing rehabilitation program.

- Duration: 8 weeks
- Frequency: 3 sessions per week for both physical therapy and Boccia exercises
- Groups:
    - Experimental Group: Physical therapy + Boccia exercises
    - Control Group: Physical therapy only

To standardize measurements, participants refrained from physical therapy sessions for 48 hours prior to assessment and avoided caffeine and alcohol for 24 hours. Two independent evaluators ensured blinding: Evaluator 1 conducted all measurements, while Evaluator 2 administered the Boccia program.

Participants

- Population: Adults aged 18–75 with hemiparesis post-stroke (6–24 months post-event)
- Inclusion Criteria: Clinically stable, able to follow instructions, attend sessions, and provide consent
- Exclusion Criteria: Severe spasticity, major comorbidities, recent upper extremity surgery, severe cognitive impairment, or participation in other trials

Interventions

Boccia Exercise Group (Experimental)

- Weeks 1–2: Flexibility training and introduction to basic Boccia throwing techniques
- Weeks 3–8: Physical therapy sessions plus one Boccia session per day; progressive complexity in throwing techniques, including tactical training and match play
- Supervision: Each session led by a physiotherapist and Boccia coach
- Session Duration: ~1 hour

Control Group

- Conventional physical therapy only: strengthening, range of motion, motor retraining, and functional exercises matched for duration and frequency

Outcome Measures

Primary Outcome

Grip Strength

- Measured with a Jamar Hydraulic Hand Dynamometer
- Participant seated with elbow at 90°, forearm neutral, wrist 0–30° extension
- Three trials per assessment; highest value recorded (kg)

- Assessment Timepoints: Baseline and post-intervention (8 weeks)

Secondary Outcome

Upper Extremity Muscle Thickness

- Measured using B-mode ultrasonography (SonoHealth dual-sector + linear probe)
- Muscles assessed: biceps brachii, brachialis, triceps brachii, anterior deltoid, forearm and hand muscles
- Measurement points standardized using anatomical landmarks
- Three images per site; average used for analysis (mm)
- Assessment Timepoints: Baseline and post-intervention

Statistical Analysis

- Conducted with IBM SPSS v21.0
- Normality tested with Shapiro-Wilk
- Categorical variables compared with Chi-square or Fisher's exact test
- Changes over time and between groups evaluated with two-way repeated measures ANOVA (2×2)
- Post hoc analyses applied if significant Time × Group interaction detected
- Significance Level: $p \leq 0.05$

Randomization & Blinding

- Participants randomly allocated to experimental or control groups
- Evaluator 1 blinded to group allocation
- Evaluator 2 administered Boccia exercises exclusively
- Participants aware of their intervention (cannot be blinded)

Safety & Monitoring

- All participants monitored for adverse events
- Physiotherapist present during all sessions to minimize risk of injury
- Session adherence and tolerance recorded

Ethics & Data Management

- Informed consent obtained from all participants
- Collected data anonymized for analysis
- Data stored securely and used solely for research purposes