Effects of Robot-Assisted Gait Training in Patients with Multiple Sclerosis: A Single-Blinded Randomized Controlled Study NCT03801473 (01.03.2020)

Study protocol and statistical analysis plan

The study was designed as a single center, single-blinded, randomized, parallel-group trial.

Participants and interventions

Patients who were admitted to the neurology and physical medicine and rehabilitation outpatient clinics of a tertiary care hospital were randomized into two groups: Group 1 (robot-assisted gait training: RAGT) and Group 2 (conventional rehabilitation). All participants had an inpatient rehabilitation program for 4 weeks. They followed a 60-minute rehabilitation program involving active and passive range of motion exercises, transfer, balance and coordination training and upper extremity function exercises. In addition to this, RAT or Conventional rehabilitation were administered to the patients three times a week for a period of 4 weeks. Each session was performed in the morning and lasted for 30 minutes.

RoboGait, an automated locomotor therapy system, was used for treating the RAGT group (15). The system composed of a robotic lower extremity orthosis, adjustable dynamic gait support, synchronized treadmill and biofeedback utilities. Treadmill speed was adjusted individually to make the patients feel comfortable and was designed to simulate normal gait. Weight support was started with 40% of body weight and reduced gradually in each session.

Participants in the Conventional rehabilitation group had physiotherapist-assisted walking exercises on parallel bars and on the ground with aids/cane, tripod or walker.

Outcome measures:

All evaluations were performed in the morning by an investigator blinded to the treatment allocation. The assessments were made pre-treatment (T0), post-treatment (T1) and 3 months after the treatment (T2).

Primary Outcomes:

Fatigue Severity Scale

Hospital Anxiety Depression Scale (HADS)

Secondary Outcomes:

The Kurtzke Expanded Disability Status Scale (EDSS)

Functional ambulation category (FAC)

Berg Balance Test (BBT)

The 6-minute walk test (6MWT)

Multiple Sclerosis Quality of Life-54 (MSQoL-54)

Statistical Analysis:

IBM SPSS Statistics for Windows, Version 20,0 (Armonk, NY) was employed for the data analysis. Significance was assessed at $p<0.05$ level. The histogram and normality plots and Shapiro-Wilk normality test were used to evaluate normality of the distribution. Chi-square test was performed for the categorical data analysis. Student t test or Mann Whitney U test was applied for intergroup comparisons according to normality of the data. Friedman test was used for intragroup analysis because the data was not normally distributed. For pairwise comparison, Wilcoxon test with Bonferroni correction was performed. P values less than 0.017 (0.05/3) were determined as statistical significance for post-hoc tests.