FEDERAL UNIVERSITY OF BAHIA

PIETRO ARAÚJO DOS SANTOS

NINTENDO WII AND EXERCISES AT REHABILITATION OF INDIVIDUALS WITH PARKINSON'S DISEASE

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

NCT03235284

Salvador

11/09/2019

Intervention

Interventions were conducted in all groups for 50 minutes a day, twice a week for 8 weeks, accounting for 16 total sessions. All activities were performed under the direct supervision of trained physiotherapists, and assessments and interventions always occurred 1 hour after Levodopa (on-period) administration.

Virtual rehabilitation with NW was performed in a room with an area of 20m2, equipped with the NW system (Nintendo Company, Minami-ku-based, Kyoto, Japan) and a multimedia device that projected the image on the wall at a height of one meter and twenty centimeters. In addition, the NW Wii Balance Board (WBB) platform(used for Wii Fit gaming) was used, in which it has four pressure sensors that detect the movements of the player standing on it in the orthostatic position, instantly demonstrating the position of the feet, the weight distribution and the displacement of the center of mass18.

GNW performed 40 minutes of training with NW, where patients played 4 games (Wii Sport and Wii Fit) standing up. In the first session, they played Boxing and Soccer Heading, and in the second session Golf and Running. Each game was held for 20 minutes with intervals of 1 minute rest every 5 minutes of activity. The games were chosen to facilitate lateralization, rotation and extension of the trunk, mobility of the upper limbs, transfer of weight, equilibrium reactions and stationary gait.

The ECs were performed through diagonal, active-assisted and resisted active movements, based on the proprioceptive neuromuscular facilitation (FNP) patterns in the upper limbs, scapula, pelvis and lower limbs. The protocol was also composed of gait training, in which the "gait cycle" was performed, where the physiotherapist offered a manual resistance to the hip during the step movement.

The GEC performed 40 minutes of exercises with objectives similar to the GNW group. During each session, 30 minutes of specific diagonals were performed, being upper limbs (flexion- abduction-external rotation / extension-adduction-internal rotation); scapula (elevation and posterior depression), pelvis (anterior elevation / posterior depression), lower limbs (flexion-abduction-external rotation / internal extension-adduction-rotation), 10 minutes of orthostasis gait training or trunk extension training in Ductus dorsal, always respecting the interval of 1 minute of rest every 5 minutes of activity. In the first weekly session the exercises were performed for scapula, upper limbs and trunk, while in the second session exercises for pelvis, lower limbs and gait.

In GNWEC, the combination of therapies was administered for 40 minutes, with 20 minutes of training with NW and 20 minutes of EC. Each intervention was applied in a similar way to the other groups, and the games or exercises were distributed according to the weekly session. In addition, all groups performed muscle stretching of the upper and lower limbs for 10 minutes

before initiating the interventions, and all patients were verbally oriented and stimulated by the therapist to perform the activities.

2.2. Primary outcome

The primary outcome was the functional balance, which was evaluated through the Berg Balance Scale (BBS). This ferment is composed of 14 items, graduated from 0 to 4 points that allow to measure the balance through progressively more challenging tasks. It presents a total score varying from 0 to 56 points, and a higher score reflects a better body balance.

2.3. Secondary Results

The gait was evaluated through the Dynamic Gait Index (DGI) scale, a tool composed of 8 tasks, a score ranging from 0 to 3 points, involving gait in different sensory contexts, reaching a maximum score of 24 points.

The Timed "Up & Go" test (TUG) was also used to assess functional mobility, in which this test measures in seconds the time it takes for an individual to lift a standard armchair, walk a distance of 3 meters, walk back and sit again. The longer the time to perform the activity, the greater the physical mobility deficit.

Quality of life was assessed using the Parkinson's Disease Questionnaire (PDQ-39), which consists of 39 items divided into 8 domains: mobility, daily living activities, emotional well-being, stigma, social support, cognition, communication and bodily discomfort . The total score varies from 0 to 100, in which a lower score denotes a better perception of the patient's quality of life.

2.4 Statistical analysis Plan

Data were analyzed using statistical software SPSS 21.0 27. A descriptive analysis (mean, standard deviation, median and interquartile range for quantitative variables, and absolute and relative frequency for qualitative variables) was performed to identify the characteristics of the study sample. To test the existence of pre and post intervention differences, as well as between each group, in balance, mobility and quality of life, a mixed ANOVA of repeated measures was used. In addition, distribution symmetry and the Shapiro-Wilk test were performed to identify the normality of the data. The level of significance adopted for this study was 5%.