A randomized controlled trial to evaluate the impact of an exercise therapy program based on sports towards people with acquired brain injury: DISCOVER study protocol

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Study protocol

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Abstract

Background

People with acquired brain injury (ABI) frequently exhibit physical and psychosocial challenges, regarding the ‘body structure and function’, ‘activity’ and ‘participation’ ICF domains. Multidisciplinary approaches oriented to exercise therapy and social leisure activities seem to be fundamental to elicit neuroplastic adaptations to enhance physical recovery, as well as to improve the cognitive and behavioural sequelae after ABI. The DIScover trial has been designed to support the development of fundamental movement and participation skills through a exercise therapy program based on racket sports. This program is a tool with a high social component that allows to integrate different body synergies and complex motor strategies that promote functional performance on both lower and upper limbs.

Methods

This randomized controlled trial with two parallel groups will aim to design and determine the effectiveness of a racket sports-based exercise therapy program in improving upper limb motor function, functional capacity, mobility, balance and quality of life towards people with ABI.

Discussion

The current study provides an holistic approach that combines exercise therapy and sport-based functional demands that can be easily integrated into participants’ daily life activities. Results from this trial may guide healthcare professionals working with patients with ABI to better guide this population in reaching optimal levels of health and physical activity levels.

Trial registration number: NCT05358470

1. Background

Acquired brain injury (ABI) from both vascular and traumatic causes is a major global public health problem that increases each year. ABI refers to an affectionation generated on the mature brain, regardless of its severity and duration, resulting from different aetiologies such as stroke, traumatic brain injury, tumours or infectious diseases.\(^1,2\) People with ABI learn to predominantly use the non-affected upper or lower limb and ignore the most affected limb (mostly the upper one), which leads to non-use and abnormal postural patterns affecting their performance of daily activities. They will subsequently develop poor perception of quality of life, decreased cognitive and functional ability and their active participation in physical activity and sport community is altered.\(^3,4,5\)
The International Classification of Functioning, Disability and Health (ICF) is the main bio-psycho-social framework to design and implement rehabilitation programs for people with disability. Precisely, people with ABI frequently exhibit physical function challenges, regarding the 'body structure and function' ICF domain (e.g. spasticity, muscle weakness or poor motor control). In addition, these impairments can restrict the 'activity' domain (e.g. poor fine motor function) and limits the 'participation' domain (e.g. difficulty in engaging physical activities and sports) as well. Hence, evidence suggests that rehabilitation interventions for people with ABI should consider improving all of the aforementioned dimensions to be more effective.

Some systematic reviews point to the effectiveness of exercise therapy intervention programs, and favourable results of physical activity programs in people with ABI, leading to activation of supplementary motor areas, and augment more consistent motor recovery than only standard care. Multidisciplinary approaches oriented to exercise therapy and social leisure activities seem to be fundamental to elicit neuroplastic adaptations to enhance physical recovery, and to improve the cognitive and behavioural sequels after ABI. Considering the principles of motor learning, the dynamic interaction between systems including the demanding task of a real sport, allowing neuro-plastic adaptations and underlying behavioural improvement for the patients and achieving a motivating functional context. On one hand, participation in group-based therapy programs centered on physical exercise showed a positive influence on quality of life, self-esteem levels and social inclusion in patients with ABI. Moreover, a small group-based exercise program has been shown to achieve notable functional improvements in the rehabilitation process by maximizing engagement, motivation and participation. On the other hand, some studies have proposed programs that combine exercise and adapted physical activity based on different sports. Precisely, a program based on racket sports is an accessible tool with a high social component that allows to integrate different body synergies and complex motor strategies that promote functional performance on both lower and upper limbs. Several studies point out the lack of description of the structure and specific contents of this type of interventions, thus limiting their reproducibility and the development of standardised clinical practice guidelines. Additionally, to date, there are some gaps in terms of exercise programs towards people with ABI which provide answers and encompass all the aforementioned CIF dimensions. Finally, it should be noted that there is no study yet on the effects of a program using a multi-component racket sports-based intervention. Therefore, the objective of this study is to design and determine the effectiveness of an exercise therapy program based on racket sports towards ambulant adults with ABI. We hypothesise that an exercise therapy program based on racket sports in ambulant people with acquired brain injury will enhance upper limb motor function and participation, as well as increase the levels of functional capacity, mobility, balance and quality of life.

2. Materials And Methods
This protocol describes the methods for a randomized clinical trial to be conducted in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines. The protocol has been registered in the Clinical Trial Registry of on clinicaltrials.gov (NCT05358470) and was approved by the Regional Clinical Research Ethics Committee of Madrid (EC 07.22).

2.1. Trial design and setting

This study will use a randomized controlled trial (RCT) design to evaluate the effectiveness of an exercise therapy program based on racket sports compared to standard care for adults with acquired brain injury. It is a single-blinded RCT with two parallel groups: experimental group (EG) vs control group (CG). Study screening, intervention and assessments will be conducted at a rehabilitation centre located in Madrid, Spain. A summary of the study design schedule is shown in Fig. 1.

2.2. Eligibility criteria and recruitment

The study population consists of ambulant adults aged more than 18 years with a confirmed diagnosis of acquire brain injury at subacute or chronic stages. Eligibility criteria and rationale are summarised in Table 1. Potential patients from the rehabilitation centre database will be invited to participate in the study on site and via phone calls. Participants will be assessed for eligibility through prospective face-to-face interviews over a three-month time period to ensure the target sample size is reached, and then they will be enrolled in the study. During this process, signed written consent will be obtained, acknowledging that participants are aware of the study's objectives and requirements.

2.3. Randomization, allocation and blinding

Once the baseline assessment is completed, an independent centralised stratified block randomisation will be used to allocate the participants to either the intervention or the control group. The randomisation process will be conducted using a computer-generated random number sequence, with a 1:1 allocation ratio. Baseline and post-intervention assessments will be completed by two physiotherapists specifically trained to carry out the measuring who will be blinded to group allocation during the entire study period. Given the nature of the study, no intervention parties, neither participants nor program staff will be blinded to group assignment.

2.4. Interventions

Exercise therapy program based on racket sports (EG):
The experimental group will receive an 8-week exercise therapy program based on racket sports which consists of 60-min sessions twice a week, as well as their weekly standard care. Sessions will be delivered by groups (from four up to six participants) to optimise the rates of participation and engagement. The content of the program is designed and structured according to a synergy between adapted exercise therapy and racket sport components, so the physical demand is progressively adapted to the individual capacities of each participant. Some exercises or activities can be modified and adapted as required for each participant, to ensure correct posture, adequate support and comfort, as well to accommodate muscle shortness or postural difficulties. This adaptation process is based on the baseline physical screen by a physiotherapist. This design allows for an effective transition from specific motor function training to more global skills based on racket sports. To ensure complete reporting of intervention, a template for intervention description and replication (TIDieR) checklist is used (Table 2).  

Table 2

| Template for intervention description and replication checklist for DIScover trail. |
|<< Insert Table 2 here >>|

**Standard care (GC):**

The CG will continue with their standard care as usual for 8 weeks and then will be reassessed. Standard care consists of any therapy (e.g., occupational therapy, physiotherapy, psychologist) provided by the rehabilitation services from the centre. A phone interview will be performed by a physiotherapist every two weeks until post-intervention assessment. After post-intervention assessment (T2), the participants of the CG will be able to receive the program if they request it.

### 2.5. Harms

Risk assessments with mitigation strategies will be completed prior to study participation. Safety and adverse events associated with either intervention or standard care groups is monitored throughout the program duration and referred to the ethics committees if serious nature. All identified unintended effect or adverse event will be recorded by the local investigator and will be reviewed by the main researchers according to standard guidelines and reported it to the ethics committee.

### 2.6. Outcome measures

#### 2.6.1. Primary outcomes measures

1. **Fugl-Meyer Assessment – Upper Extremity scale (FM-UE)**

The FM-UE is a performance-based index used to assess the upper limb motor impairment. It measures performance at the body function domain. It assesses movement of the biceps, triceps, shoulder, elbow, forearm, hand, wrist, and finger with performance of 33 tasks. Clinicians rate patient performance on each task for quality of movement on a scale from 0 (no active motion) to 2 (motion seems to be
normal). The maximum score is 66 points and a high score indicates less impairment. The FM-UE has excellent psychometric properties, including high inter-rater reliability and excellent test-retest reliability and responsiveness.²⁹,³⁰

2. Ten-Meter Walk Test (10MWT) (Gait Velocity)

The 10MWT is used to evaluate the mobility and endurance on walking measuring gait speed in meters per second over a short distance, and it is calculated as distance divided by time. The patient is instructed to walk at a self-selected speed, using whatever walking aids might be needed. Although there is evidence for excellent internal consistency and test–retest reliability of the test among patients with chronic stroke, the evidence for responsiveness is scarce for this population. Validity evidence is also limited but can be inferred from its association with community ambulation.³¹,³²

3. Six Minutes Walk Test (6MWT) (Gait Endurance)

The 6MWT is used to assess aerobic capacity and endurance. The distance covered over a time of 6 minutes is used as the outcome by which to compare changes in performance capacity. The measurement is considered by meters, so the more meters the user is able to get, the more distance and "normal functioning" will register. The 6MWT has good test-retest reliability in older populations and precisely with acute stroke. However, the test has clear face validity among patients with chronic stroke.³³

2.6.2. Secondary outcomes measures

4. Timed Up and Go (TUG)

The TUG will be used to assess the ability to perform sequential motor tasks relative to walking and turning. This test is rated on a scale of second measurement, considering less than 10 second as “functional independence” and more than 30 seconds as “severely abnormal function”. The test-retest reliability of the TUG is high according to previous studies of individuals with stroke.³⁴,³⁵

5. Balance Berg Scale (BBS)

This scale is a functional balance measurement of 14 items in which each item consists of a five-point ordinal scale ranging from 0 to 4, with 0 indicating the lowest level of function and 4 the highest level of function. Scores can range from 0 to 56. The higher the score, the better the postural control. The BBS has a notable internal consistency, confidence interval and test-retest reliability.³⁶,³⁷

6. Short Form 36 questionnaire (SF36) version 2

This questionnaire is used to evaluate the general health status in eight domains: physical function, role physical, bodily pain, general health, vitality, social function, role emotional and mental health. Values above or below 50 (the normative score from the general population) are interpreted as better or worse
than the reference population, respectively. This questionnaire has a high validity and test-retest reliability. \(^{48}\)

7. **Global Physical Activity Questionnaire (GPAQ)**

This tool comprises 19 questions grouped to capture physical activity undertaken in different behavioral domains in which physical activity is performed. It is scored in minutes per day to provide meaningful behavioral units. The GPAQ had low to moderate validity for total PA when compared to PA surveillance questionnaires or accelerometers as well as good test-retest reliability. \(^{49,50}\)

Additionally, a physiotherapist will conduct a general clinical examination to determine if the participant has a physical condition that makes it difficult for him/her to perform any activity and must undergo an adaptation. Moreover, an exercise diary addressing duration, type and modality (aerobic, strength, flexibility) completed by participants in both groups will be used as complementary measurement.

2.6.3. **Sociodemographic and anthropometric data, and comorbid conditions**

A general screening questionnaire will be used to inquire about possible factors influencing the outcomes and to gather baseline information about the sample. Sociodemographic (date of birth, gender, and school type) and anthropometric data (weight and height to report BMI in kg/m\(^2\)); and medical diagnosis and comorbid conditions (e.g. controlled epilepsy or asthma medication) will be required.

2.7. **Study timeline**

All participants will attend baseline assessments (post-allocation, T1) before being randomly allocated into the groups and will be reassessed at the completion of the study period at 8 weeks (close-out, T2). The study timeline is depicted in Table 3.

<table>
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<tr>
<th>Study timeline.</th>
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<tr>
<td>&lt;&lt; Insert Table 3 here &gt;&gt;</td>
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</table>

2.8. **Sample size**

The sample size has been estimated to obtain significant improvements in the Fugl-Meyer Assessment-Upper Extremity. According to the previous studies, we expect to detect a difference of 10 points and a SD of ± 14 on the FM-UE total score to determine the minimal clinically important difference of the exercise therapy program compared with standard care. \(^{51,52}\) Sample size has been calculated with an alpha set at 0.05, a power set at 0.8, and an estimated effect size of 0.7 on FM-UE score. On the other hand, considering and based on previous studies that carried out exercise programs in persons with ABI, a sample size between 15 and 30 participants in each group is deemed adequate for the study. \(^{53,54,55,56}\)

2.9. **Data management and monitoring**
Data will be collected electronically through an encrypted online database designed for each study procedure (eligibility, baseline/post-intervention assessment, etc.) according to a composed data monitoring committee for the study. No identification data is recorded in this database. An identification code generated by a random number sequence is assigned each the patient’s clinical history in an independent table (pseudonymised procedure). All the information will be accessible on a corporate computer and only the main researchers will have access to the data. This process will monitor therapy fidelity and ensure that any confidential content was delivered as per the protocol. Once the data has been registered, data consistency will be evaluated, and any omissions or inconsistencies will be declared. Study updates and general outcomes will be sent to participants in a newsletter format.

2.10. Statistical methods

Comparability of intervention and control groups will be checked in terms of the similarity of the distribution of the variables of interest at baseline. Analysis will follow standard methods for randomized controlled trials using two-groups comparisons on all participants on an intention-to-treat basis. The chi-square test or Fisher’s exact test will be used to compare proportions. Student’s t test will be used to compare means between groups with a normal distribution data. The Mann-Whitney test will be used to compare quantitative variables between groups in case of a non-normal distribution, determined by the Kolmogorov-Smirnov test. Correlations between quantitative measurements will be determined by the Spearman’s rho correlation coefficient. Matched-pair data analysis will be also computed. Additionally, a multivariate analysis using multiple linear regression and logistic regression will be performed, according to the considered response, to adjust the effectiveness of the intervention as potential confounders and to determine which other variables are associated with each of the results. Statistical significance will be set at \( \leq 0.05 \). Data will be analyzed using the Statistical Package for the Social Science (SPSS) software, version 27.0 (IBM Corp, Armonk, New York, USA).

3. Discussion

This paper presents the background and design for a randomized controlled trial investigating the effectiveness of an eight-week exercise therapy program based on rackets sport for ambulant people with ABI compared with standard care. To our knowledge, this trial is the first aimed to investigate the effects of a sports-based exercise therapy program in people with ABI. Even though, previous studies reported that the application of exercise therapy based on sports such as basketball or soccer obtained positive results on people with physical disabilities. A possible strength of this clinical trial is its multicomponent design in both the intervention and the assessment: 1) the program will include rehabilitation contents as well as sport-based functional exercises which promote participation and social integration above the group of participants, and 2) the outcome measures include multiple recommended scales and questionnaires which reflecting status in the ICF domains of body function, activity and participation. Although models of rehabilitation for people with ABI mostly focus on physical and functional improvements, some studies point out the relevancy of the participation dimension. More studies integrating tools such as sport are needed to achieve higher levels of
The current designed program provides a more holistic approach that combines exercise therapy and sport-based functional tasks that can be easily integrated into participants’ daily life activities. If this program is found to be effective, multidisciplinary teams will have an evidence-based mode of therapy to offer, i.e. an engaging sport-based intervention that incorporates a social inclusion perspective and may provide valuable skills to patients with ABI. Moreover, results will guide healthcare professionals working with patients with ABI to better guide this population in reaching optimal levels of health and physical activity levels. Finally, it is anticipated that the results of this study will be disseminated through peer-reviewed journals and national and international academic conferences.

**Declarations**

*Ethics approval and consent to participate*

The trial was designed in compliance with the Helsinki declaration,\(^6\) i.e. detailed oral information will be given to the participants and their informant to ensure that the participants fully understand potential risks and benefits of the study. Full written informed consent will be obtained from all participants indicating voluntary participation in the study. Participants’ personal data will be de-identified. They will be allocated an identification code generated by a random number sequence, which will be used to deidentify participant information. No data that could identify the participants will be published. The study protocol has been approved by the Regional Clinical Research Ethics Committee of Madrid; CEIC reference number EC 07.22. Protocol modifications and amendments will be submitted to the Committee for a review and approval.

*Consent for publication*

The details of any data can be published, and the participants providing consent have been informed the article contents to be published.

*Availability of data and materials*

The datasets are available from the corresponding author on request.

*Competing interests*

The authors declare no financial disclosures or potential conflicts of interest.

*Dissemination policy*

The dissemination plan will be developed in the early phase of the trial and results will be disseminated through scientific publications in peer-reviewed journals, and national/international conferences regardless of the magnitude or direction of effect. No data that could identify the participants will be published.
Funding

The current study will not receive any kind of public or private funding.

Authors contributions

AGS is the chief investigator and together with BRR and MPR designed and established this research study. AGS and BRR were responsible for ethics applications and reporting. BRR, MPR and JJGH contributed to the preparation of this publication within their respective fields of expertise. All authors critically reviewed and approved the final version of this manuscript.

Acknowledgments

The authors wish to thank the “Lescer Centre” and the “Second Part Foundation” staff for their support. We specially thank assistance provided by the Spanish Badminton Federation. This study is conducted as a model of social inclusion through sports and the initial idea of the DIScover trail was designed based on previous projects as the national “PASABI project” and the international Erasmus+ ”B4All project” [Project Number: 590603].

References


Tables

<table>
<thead>
<tr>
<th>Table 1.</th>
<th>Selection criteria.</th>
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</thead>
<tbody>
<tr>
<td><strong>Inclusion criteria</strong></td>
<td><strong>Exclusion criteria</strong></td>
</tr>
<tr>
<td>Persons with a medical diagnosis of acquired brain injury in subacute or chronic stages.</td>
<td>Not have a completed and signed informed consent form.</td>
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<tr>
<td>To be aged &gt;18 years at study entry.</td>
<td>Non-attendance and/or non-collaboration to 70% of the program sessions.</td>
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<tr>
<td>To have an independent gait without the need of technical aids: a score of ( \geq 3, 4 ) or 5 from the Functional Ambulation Categories (FAC) walking test.</td>
<td>To have medical co-morbidities that contraindicate physical exercise safely (e.g. cardiac or respiratory instability, uncontrolled seizures).</td>
</tr>
<tr>
<td>Be able to understand simple instructions from the exercise therapy program as well as perform baseline and post-intervention assessments.</td>
<td>Non-collaboration during the pre-tests of the program.</td>
</tr>
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</table>
Table 2.
Template for intervention description and replication checklist for DIScover trail.

<table>
<thead>
<tr>
<th>TIDieR Items</th>
<th>Description of items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of the intervention for experimental/comparator group</td>
<td>Experimental group: Exercise therapy program based on racket sports. Control group: Usual care</td>
</tr>
<tr>
<td>Rationale</td>
<td>Currently, several studies have been carried out that propose a program that combines exercise therapy and adapted physical activity based on different sports (such as basketball or soccer). Nevertheless, no racket sport-based program has been implemented so far. Racket sport, as an accessible and inclusive source, integrates different body synergies that promote functional performance of both lower and upper limbs promotion complex motor strategies as well as a high integrated social component. To date, there is some gaps in terms of research regarding the approach of rehabilitation programs towards people with ABI, therefore, this study raises the need to design multi-component intervention which integrate the improving of body “structure and function”, “activity” and “participation” dimensions. It is based exercise therapy and racket sports specifically for this population.</td>
</tr>
<tr>
<td>Materials used in the intervention</td>
<td>Experimental group: The exercise therapy program is oriented to different racket sports skills, mainly badminton and tennis, which are adapted to the participants functional conditions, as well as different generic devices like balls, chairs, tables, platforms, among others.</td>
</tr>
<tr>
<td>Intervention procedures</td>
<td>Experimental group: The content of this program is designed and structured according to a synergy between therapeutic and adapted exercise, and sport components. This design allows an effective transition from the specific motor functional rehabilitation (first 8 sessions of the program) to more global skills based on racket sports (last 8 sessions of the program). Control group: Standard care consists of any therapy (e.g., occupational therapy, physiotherapy, psychologist) provided by the rehabilitation services from the center. After post-intervention assessment, this control group will be able to receive the same sessions from the program if they request it.</td>
</tr>
<tr>
<td>Provider</td>
<td>Experimental group: The program will be provided by a physiotherapist trained to treat neurological disorders and experienced in adapted physical exercise. Moreover, standard care for this group will be provided by professionals from the rehabilitation centre. Control group: Standard care for this group will be provided by professionals from the rehabilitation centre.</td>
</tr>
<tr>
<td>Mode of intervention delivery</td>
<td>Experimental group: Presential group-based sessions (from four up to six participants) to optimize the rates of participation and engagement. Control group: Presential, individual sessions.</td>
</tr>
<tr>
<td>Setting of intervention</td>
<td>Study screening, interventions, and assessments will be conducted at the physiotherapy departments of a rehabilitation center located in Madrid, Spain.</td>
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<tr>
<td>Dosage</td>
<td>Experimental group: It will receive an 8-week exercise program which consists of</td>
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sixteen sessions, 1 h session/day for 2 days/week.

Control group: This group will continue with their standard care as usual for 8 weeks and then will be reassessed. Conventional therapies as the centre regulations, which is 2 days/week.

| Tailoring | The content of the program is adapted to individual capacities and functional limitations of each participant. Some activities can be modified and adapted as required for each participant, to ensure correct posture, adequate support, and comfort, as well to accommodate muscle shortness or postural difficulties. This adaptation process is based on the baseline physical screen by a physiotherapist. Further progression of the intervention also will be tailor made to everyone based on the ability level, fatigue level and strength of the upper limb. When there is no movement possible in the affected limb, participants will be allowed to take assistance from the unaffected limb and simultaneously perform bilateral training. |
| Modifications | Not applicable |
| Fidelity assessment | A logbook will be provided to all the participants belonging to both groups. |
| | Experimental group: A weekly telephonic follow-up will be performed by the therapist delivering interventions to ensure their adherence to the intervention program. |
| | Control group: A phone interview will be performed by a physiotherapist every two weeks until post-intervention assessment. |

Table 3. Study timeline.
<table>
<thead>
<tr>
<th>TIMEPOINT</th>
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<tr>
<td>ENROLMENT:</td>
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<tr>
<td>Eligibility screen</td>
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<td>Allocation</td>
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<td>X</td>
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<tr>
<td>INTERVENTION:</td>
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<td>Exercise therapy Program (EG)</td>
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<td>Usual care (CG)</td>
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<td>ASSESSMENTS:</td>
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<td>Sociodemographics, anthropometric data, and comorbid conditions</td>
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<td>Motor function (FM-UE)</td>
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<tr>
<td>Functional capacity: gait velocity (10MWT)</td>
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<tr>
<td>Functional capacity: gait endurance (6MWT)</td>
<td>X</td>
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<tr>
<td>Mobility (TUG)</td>
<td>X</td>
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<tr>
<td>Balance (BBS)</td>
<td>X</td>
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<td>Health-related QoL (SF36)</td>
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<td>Physical Activity (GPAQ)</td>
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EG: Experimental group; CG: Control Group; FM-UE: Fugl-Meyer Assessment-Upper Extremity Scale; 10MWT: Ten-Meter Walk Test; 6MWT: Six Minutes Walk Test; TUG: Timed Up and Go Test; BBS: Balance Berg Scale; SF36: Short Form 36 Questionnaire; GPAQ: Global Physical Activity Questionnaire

Figures
Figure 1
Flow chart of study design

Supplementary Files
This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryTable.doc