Protocol

Cognitive and motor effects of dual-task performances in the patients with post-stroke state. Impact of the dual task training for a short period.

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Introduction

Background: The main symptoms of the post-stroke state are lesion of the motor pathway, postural instability and cognitive deterioration (Lo 2019, Einstad 2021)). Although it needs an expert and the testing is time consuming, the symptoms of cognitive and motor damage can be examined separately. An instrument called exergaming allows to do dual-task tests including cognitive and motor tasks at the same time. This equipment is the Dividat Senso (Altorfer 2021). This device measures reaction times, misses and hits of the dual -task activities. It is suitable to detect the disability compromised by cognitive and motor deterioration, namely the global disability, in post-stroke state. Correlation of the motor decay and the cognitive deterioration has been published (Einstad 2021). However, the extent of interference evoked by dual task performances in different severity of post-stroke state, is unknown. Cognition and movement restricted by post-stroke state can be affected differently. Previous studies stressed the priority of dual-task tests instead of simple cognitive test or gymnastics (Kannan 2019, Choi 2015). Lately, the improved effectiveness of dual-task training in the adaption of walking in virtual reality has been confirmed instead of training with floor exercises (Timmermans 2021). A meta- analysis raised the possibility of an improved cognitive function after dual-task training (Sun 2021). However, it is unclear, how fast will the achievement of the patients be improved with different conditions of poststroke state after dual-task training .

Goal of the study

- The dual task performances in patients with post-stroke will be compared with age matched healthy controls.
- Different groups with post-stroke will be compared. The groups will be selected according to the severity of their hemiparesis. The group with no hemiparesis will be

compared with the groups with mild, and middle rank hemiparesis to detect how the dual-task performance influences the participants' cognitive abilities.

- Both groups will be divided according to their ages (under and above 65 years).
- Do the reaction times of dual-task performances correlate with the severity of disability assessed by the Modified Ranking State? How can the parameters of dual task activity be compared to those of them on the Modified Ranking State?
- The cognitive function and motor disability will be tested with several scales and measurements. We form ratio pairs with the parameters of post-stroke patients and age matched healthy persons, and we want to discover which one of them and to what extent they affect the cognitive function and the motor disability.
- We want to detect the improvement after the daily training with dual-task performances for a short period, therefore we analyze the different parameters of dual-task tests every day during the training.

Hypothesis

- The results of dual task performances in the poststroke group will be significantly different from the control group. Those data will be modified by the training with dual-task activity for a short term.
- Patients compromised severely by post-stroke state will be improved by training with dual-task tests to a greater extent than by the other groups.
- Measurement of the cognitive function with dual-task performances can be separately done in the patient’ group without paresis.
- The delay of the reaction time of dual-task tests will be correlated with the severity of the Modified Ranking State.
- Age related difference will be observed between the groups.

- The motor disability and cognitive deterioration will be affected differently in the patients with post-stroke.

Design of the study

Data collection on a device. Open controlled trial. The comparison will be made between the group of healthy persons, and the post-stroke groups divided into sub-groups according to the severity of their hemiparesis

Onset of the study

First of January, 2021

The end of the study

31st of December, 2023

Place of the study

Ambulance of the Institute of Neuro Rehabilitation, Sopron, Major-köz 3., Hungary

Ethics

The Regional Ethics Committee of the Petz Aladár County Hospital in Győr, Hungary, provided permission for the present trial (The number of permission: 76-1-6/2019). The subjects gave their written informed consent at the onset of the trials, according to the Helsinki Declaration. The concept of the study was arranged by JM and the delivery of the protocol was supervised by an independent committee.

Persons recruited in the study

Fifty patients with post-stroke will be included, who appeared at the ambulance of the Institute of Neurorehabilitation and met the conditions of the study from 2021 to 2023.

Fifty healthy persons will be included as a control group. They will be recruited from the accompany persons and the members of the Institute.

Inclusion criteria

- Persons between 18 and 80 years old
- The symptoms are caused by one stroke event
- Stroke happened more than three months ago
- There are no joints problems
- Patients with hypertonia and Type II diabetes mellitus can be included
- Patients with non-fluent aphasia can be included.
- Standing balance can be maintained by catching a bar and the participant can step forward and sidelong.

Exclusion criteria

- If the informed consent will not be signed
- Non-fluent aphasia
- Dementia Mini Mental Rating Scale under 13 points
- Locomotor disease hindering standing and walking
- Severe hypertonia and diabetes mellitus

Drop out

- If the person refuses the cooperation
- New disease preventing to continue the examination.

Process of the investigation

- Detailed physical examination with laboratory tests.

- Psychologist administers Mini Mental Rating Scale, Ziehen-Ranschburg word pair test, Clock drawing, Hamilton Depression Scale, Trail Making Test.
- Walking for 6 minutes and walking along 10 m are tested.
- Patients and controls are divided into two groups according to their ages (under 65 years and above 65 years).
- The control subjects are selected from the staff of the Inst. of Neurorehabilitation and from the relatives of the patients.
- A physiotherapist controls the activity of participants. on Dividat-Sensor.
- Five dual-task performances with different difficulties are selected. Every test lasts for one and a half minutes.
- Every participant will perform the tests in the mornings of five consecutive days.
- Data analysis daily to follow the improvement during training
- Patients coming back after a month will repeat the same tests on the equipment of Dividat and all of the other tests will be replicated.

Methods

Measurement of the effect of dual-task performances on Dividat Senso

- Dual-tasks performances will be examined using Dividat Senso equipment (HUR, Finland) ((Swinnen et al. 2021; van het Reve and Bruin 2014). The exergaming is a computer assisted equipment, where the virtual world (games) has to be followed by motor activity, and it is suitable for the detection of attention and executive function.
- Participants standing on a glass platform overlying 20 sensors. Sensors are sensitive for foot pressure.
- A cognitive task will be combined with a motor activity task in each test period, with subjects asked to focus on a game presented on a visual monitor. For the motor task,

patients will be asked to detect an object appearing at one edge (top, bottom, right or left) of the screen and they will be required to react using leg movements. Five dual-task tests will be applied.

- For cognitive testing, a first ('Bird') task is used in which a bird will have to be selected from different colored figures.
- In a 'Simple' task, red spots will be shown at different positions.
- In the game 'Divided', red spots will be linked to high and low sounds, requiring the patient's movements.
- In the game 'Habitat' four different animals will have to be allocated to their appropriate living area, and steps need to be made, if they are in a wrong living area.
- Dual-task interactions will be quantified by the average reaction times.
- In the game of 'Target', black bullets will move around the monitor, with different speeds, the subject being asked to calculate the speed of the bullets. Correct and incorrect responses will be recorded.
- The tasks will last for one and a half minutes and are repeated each day for five consecutive days.
- Data analysis based on the average reaction times, hits and misses.

Other tests for detecting cognitive function and motor ability

- National Institute of Health Score Scale
- Modified Ranking State
- Muscle strength
- Mini Mental Rating Scale
- Clock Drawing Test
- Ziehen-Ranschburg Word Pair test

- Trail Making Test
- Hamilton Depression Scale
- Walking ability will be measured as distance walked in 6 mins (in m),
- Time required to walk 10 m (in sec).
- The walking tests will be performed on the first and fifth days of training and after one month.

Statistical analysis

Results are expressed as the mean ± standard deviation of mean and sample size for each age group with post-stroke state and controls. The normality of data was checked by applying the Shapiro-Wilk's test and the homogeneity of variances was assessed through the Levene's test. For baseline values, we performed the necessary statistical analysis with the nonparametric Mann-Whitney test to determine significant differences for the post-stroke age groups examined (<65,> 65 years), but no significant differences were found. The means of different date (baseline, after training for five days, after one month) were compared by nonparametric Friedman ANOVA, significance values have been adjusted by the Bonferroni correction for multiple tests. The analysis was two sided with a level of significance of $\alpha = 0.05$. All statistical analyses were performed using the SAS 9.4 (SAS Institute Inc., Cary, NC, USA) software package.

Expected results of the examination

- Dual-task test on exergaming is a new field in the central nervous system diseases. The method measures the global cognitive deterioration in a sensitive and objective way.
- Changes of global cognitive deterioration can be followed by an objective way with dual-task performances, mainly in those patients, who are without paresis.

- The reaction times of dual-task activities will correlate with the disability scale of the Modified Ranking State.
- The parameters of dual-task performances will significantly deviate from that of controls.
- Reaction times, hits and misses of both groups above 65 years will be significantly worse than in the younger groups.
- The training for a short period will improve the results of dual-task tests.
- This training with dual task activity effective, time consuming for rehabilitation interventions to improve cognitive function of patients with post-stroke events
- There is a demand from the present study to highlight the patients with-stroke in new aspects.

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