

# Can we improve attention and movement functions with training in dual-tasks after a stroke

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<b>Registration date</b> 14/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/01/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Stroke can affect both motor and cognitive abilities. There is equipment that can be used for video games that can also help with exercise, called exergaming, which can detect both motor and cognitive deterioration at the same time. The overall disability caused by a stroke can be measured by reaction times in dual-task performances (like hitting and missing targets in a game). However, it is not known how these tests change in different levels of stroke severity. Our study will focus on groups of patients with and without muscle weakness or impairment (paresis) after a stroke. Cognitive disability can be found in the group without paresis, while both cognitive and motor disability can be found in the group with paresis. The study will investigate how dual-task activities affect the post-stroke state and how they can indicate both cognitive and motor impairment. The team is excited to explore if short-term training using dual-task activities can improve overall disability caused by a stroke.

### Who can participate?

All patients post-stroke aged from 18 to 80 years old and healthy volunteers

### What does the study involve?

Patients will be divided into two groups according to the severity of their paresis. Comparison will be made between them and age-matched healthy volunteer controls. The participants will be trained with dual-task tests for five consecutive days. The results will be analyzed every day. The measurements will be repeated after one month.

### What are the possible benefits and risks of participating?

The benefit for the participants involved in the study is the improvement in their attention and executive function after training with dual-task performances. The risk for the patients was the slipperiness of the glass plate, therefore they wore socks with rubberized soles.

### Where is the study run from?

Institute of Neurorehabilitation (Hungary)

When is the study starting and how long is it expected to run for?  
January 2019 to December 2023

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Judit Mály MD, PhD, dr.habil.mallyjudit@gmail.com

**Study website**  
<https://clinicalexamination.hu/>

## Contact information

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

**Study information****Scientific Title**

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

**Study objectives**

1. The results of dual-task performances in the post-stroke 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
2. Patients severely compromised by the post-stroke state will be improved by training with dual-task tests to a greater extent than the other groups
3. Measurement of cognitive function with dual-task performances can be done separately in the patient group without paresis
4. The delay of reaction time during dual-task tests will be correlated with the severity of the Modified Ranking State
5. Age-related differences will be observed between groups
6. Motor disability and cognitive deterioration will be affected differently in patients with post-stroke

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 25/05/2019, the Regional Ethics Committee of the Petz Aladár County Hospital (9024 Győr, Vasvári Pál u. 2-4, Hungary; +36 70 4510200; oharics@petz.gyor.hu), ref: 76-1-6/2019

## **Study design**

Open-label trial

## **Primary study design**

Interventional

## **Secondary study design**

Non randomised study

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

See trial outputs table

## **Health condition(s) or problem(s) studied**

Post-stroke state

## **Interventions**

Patients with stroke will be divided into four groups according to the severity of their paresis and age. For example, patients with no paresis  $\leq$  65 years; patients with no paresis  $>$  65 years; patients with paresis  $\leq$  65 years; patients with paresis  $>$  65 years. Comparison will be made between patients with stroke and age-matched healthy volunteer controls. The participants will be trained by a physiotherapist with dual-task tests using the Dividat Senso and play five games repeated daily for five days. There is no other intervention. The results will be analyzed every day. The measurements will be repeated after one month.

## **Intervention Type**

Device

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Dividat Senso

## **Primary outcome measure**

Participant's cognitive function measured using the following methods at baseline and following one week of dual-task performance training:

1. Ziehen-Ranschburg Word Pair Test (R Word Pair)
2. Trail Making Test (Trail MT)
3. Clock drawing
4. Distance walked in 6 mins (in m), and time taken to walk 10 m (in sec)
5. National Institute of Health Stroke Score (NIHSS)
6. Modified Ranking State (M Ranking S) Sum of the muscle strength upper limbs (1-5 points)

(SMSU), sum of the muscle strength lower limbs (SMSL) (1-5 points)

7. Dual-task performances (Bird, Simple, Divided, Habitat, Target Hits, Target Misses). The values of dual-task activities are given in sec except for the number of Hits and Misses.

### **Secondary outcome measures**

Participant's cognitive function measured using the following methods at baseline and following one month of dual-task performance training:

1. Mini-Mental Rating Scale (MMRS)
2. Trail Making Test (Trail MT)
3. Hamilton Depression Scale (Hamilton)
4. Clock drawing
5. Distance walked in 6 mins (in m), and time taken to walk 10 m (in sec)
6. National Institute of Health Stroke Score (NIHSS)
7. Modified Ranking State (M Ranking S) Sum of the muscle strength upper limbs (1-5 points) (SMSU), sum of the muscle strength lower limbs (SMSL) (1-5 points)
8. Dual-task performances (Bird, Simple, Divided, Habitat, Target Hits, Target Misses). The values of dual-task activities are given in sec except for the number of Hits and Misses.

### **Overall study start date**

01/01/2019

### **Completion date**

31/12/2023

## **Eligibility**

### **Key inclusion criteria**

1. Persons aged between 18 and 80 years old for patients and age-matched healthy volunteer controls
2. For patients with stroke, their symptoms are caused by one stroke event
3. Stroke happened more than three months ago
4. There are no joints problems
5. Patients with hypertonia and Type II diabetes mellitus can be included
6. Patients with non-fluent aphasia can be included
7. Standing balance can be maintained by catching a bar and the participant can step forward and sidelong

### **Participant type(s)**

Mixed

### **Age group**

Mixed

### **Sex**

Both

### **Target number of participants**

100 participants

### **Key exclusion criteria**

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

**Date of first enrolment**

01/01/2021

**Date of final enrolment**

01/01/2022

## **Locations**

**Countries of recruitment**

Hungary

**Study participating centre**

**Málly Judit**

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**Organisation**

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**Sponsor type**

Hospital/treatment centre

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

31/03/2025

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository, <https://clinicalexamination.com>. Access can be requested through the contact name: Judit Mály MD PhD, [dr.habil.mallyjudit@gmail.com](mailto:dr.habil.mallyjudit@gmail.com).

Data available: 31/12/2023. Data type: Measurement with dual-tasks on exergaming.

**IPD sharing plan summary**

Stored in non-publicly available repository, Published as a supplement to the results publication

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			08/02/2023	No	Yes
<a href="#">Protocol file</a>			08/02/2023	No	No