ISRCTN12362945 https://doi.org/10.1186/ISRCTN12362945

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

Submission date 26/01/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 14/02/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/01/2025	**Condition category** Circulatory System	[_] Individual participant data [X] 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 Málly MD, PhD, dr.habil.mallyjudit@gmail.com

Study website
https://clinicalexamination.hu/

Contact information

Type(s)
Principal Investigator

Contact name
Prof Judit Málly

ORCID ID
https://orcid.org/0000-0003-4646-7952

Contact details
Institute of Neurorehabilitation
Major-köz 3
Sopron
Hungary
9400
+36 203920031
dr.habil.mallyjudit@gmail.com

Type(s)
Scientific

Contact name
Prof Judit Málly

Contact details
Institute of Neurorehabilitation
Major-köz 3
Sopron
Hungary
9400
+36 203920031
dr.habil.mallyjudit@gmail.com

Type(s)
Public

Contact name
Ms Hajnalka Balint

Contact details
Chief Assistant
Institute of Neurorehabilitation
Major-köz 3
Sopron
Hungary
9400
+36 203920031
balinthajnalka60@gmail.com

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 ≤ 65 years; patients with no paresis > 65 years; patients with paresis ≤ 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
Institute of Neurorehabilitation
Major-köz 3
Sopron
Hungary
9400

Sponsor information

Organisation
Neurorehabilitation Sopron

Sponsor details
Institute of Neurorehabilitation
Major-köz 3
Sopron
Hungary
H-9400
+ 36 20 3920031
neurorehabsopron@neurorehab.hu

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-publically available repository, https://clinicalexamination.com. Access can be requested through the contact name: Judit Mály MD PhD, 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?
Participant information sheet			08/02/2023	No	Yes
Protocol file			08/02/2023	No	No