ISRCTN49538525 https://doi.org/10.1186/ISRCTN49538525

Training with dual tasks in Parkinson's disease

Submission date	Recruitment status	[_] Prospectively registered
08/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/09/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/08/2022	Nervous System Diseases	

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a condition in which parts of the brain become progressively damaged over many years.
Dual-task performance training (performing two tasks at the same time) has gained great interest in the treatment of patients with Parkinson’s disease. Movement (motor) function has received the most attention and walking can be improved significantly, but the present study includes an assessment of cognitive function in addition to motor parameters.
This study included assessments of short-term and long-term improvement with results on the duration of the shortest effective training protocol and on the maintenance of improvement.

Who can participate?
Patients with PD and healthy age-matched controls

What does the study involve?
Five dual-task tests (including primary cognitive and secondary motor tasks), were performed on five consecutive days and were repeated after 6 and 12 months.

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 was the sliding glass plate, therefore every subject 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?
December 2018 to December 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
76-1-6/2019

Study information

Scientific Title
Cognitive improvement after training with dual-tasks in Parkinson's disease. Follow up study.

Study objectives
Dual-task training on walking tests can improve the decline of gait parameters, although training on cognitive abilities in PD has received little study. In addition, it is not clear at what age or stage of PD it would be most appropriate and successful to employ dual-task performance testing for cognitive rehabilitation. The present study was therefore designed to examine the effect of short duration training with different dual-task tests on performance and to examine the duration of any improvement for up to 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/05/2019, The Regional Ethics Committee of the Petz Aladár County Hospital in Győr (Győr, Vasvári Pál u. 2-4, 9023, Hungary; +3696/507-900; oharics@petz.gyor.hu), ref: 76-1-6 /2019

Primary study design
Interventional

Study design
Interventional non randomized

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
The subjects were divided into two groups according to age (under and over 65 years).
The control group had no chronic disease, except for well-controlled hypertension.

Dual-task performances are examined using Dividat Senso equipment (HUR, Finland), with subjects standing on a glass platform overlying sensors. A cognitive task is 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 are asked to detect an object appearing at one edge (top, bottom, right or left) of the screen and are required to react using leg movements. Five dual-task tests will be applied.

For cognitive testing, a second ('Bird') task is used in which a bird had to be selected from different colored figures. In a 'Simple' task, red spots are shown at different positions. In the game 'Divided', red spots are linked to high and low sounds, which require patient movement. In the game 'Habitat' four different animals has to be allocated to their appropriate living area. Dual-task interactions are quantified by the average reaction times. In the game of 'Target', black bullets move around the monitor, with different speeds, the subject being asked to calculate the speed of the bullets. Correct and incorrect responses are recorded.

The following traditional tests are also applied; the Mini Mental Rating Scale. the Ziehen Ranschburg Word Pair Test, Trail Making Test, Clock Drawing Test, and the Hamilton Depression Scale Tests. For the detection and quantitation of Parkinsonian symptoms the Hoehn-Yahr Stages are used together with the Unified Parkinson Disability Rating Scale. Walking ability is measured as distance walked in 6 mins (in m), and time taken to walk 10m (in sec). The walking tests are performed on the first and fifth days of training.

Intervention Type
Other

Primary outcome(s)
Dual-task test performances are measured using Dividat Senso equipment for one and a half minutes each day and repeated each day for five consecutive days. This is repeated at 6 and 12 months.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Patients with PD and age-matched healthy controls

2. PD patients:
2.1 The presence of Parkinson’s disease responding well to levodopa
2.2 No evidence of dementia or any other chronic disease
2.3 Patients with PD in Hoehn-Yahr stages I and II (H-Y I-II)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
93

Key exclusion criteria
No evidence of dementia or any other chronic disease

Date of first enrolment
01/01/2019

Date of final enrolment
01/11/2019

Locations

Countries of recruitment
Hungary

Study participating centre
Institute of Neurorehabilitation
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9400

Sponsor information

Organisation
Institute of Neurorehabilitation

Funder(s)

Funder type
Other

Funder Name
None

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. dr.habil.mallyjudit@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			10/09/2021	No	Yes
Preprint results		04/01/2022	16/06/2022	No	No
Preprint results		29/04/2022	16/06/2022	No	No
Protocol file			09/08/2022	No	No