# Motor learning in Parkinson*s disease: a randomised comparison of integrated and consecutive task gait practice

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON37534

**Source**
ToetsingOnline

**Brief title**
Duality-study

### Condition

- Other condition

**Synonym**
Parkinson's disease

**Health condition**

neurologische aandoening: ziekte van Parkinson

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** Jacques and Gloria Gossweiler foundation

## Intervention

**Keyword:** dual tasks, gait, learning, Parkinson

## Outcome measures

### Primary outcome

Primary outcome measure is Dual Task (DT) gait performance. DT gait performance will be evaluated by measuring gait speed at maximum levels while performing untrained cognitive tasks. At baseline, the appropriate cognitive task (sufficient level of cognitive challenge for each patient) will be determined

### Secondary outcome

• Cognitive performance during dual task walking; amount of errors are scored during the dual task assessment on the walkway.

• Gait performance during the trained cognitive tasks; as measured by the GAITRite system.

• Dual task interference outcomes; by comparing the gait performance on the single task and dual task assessment.

• Single task gait performance: speed, stride length and cadence; as measured by the GAITRite system.

• Single task cognitive performance (during sitting); amount of errors is scored during a single cognitive task which is similar to the cognitive task that is used in the dual task test session.

# Study description

### Background summary

The ability to perform two or more tasks together - for instance walking and talking - is impaired in Parkinson's Disease (PD). As a result, dual tasking evokes gait deterioration with possibly an increased risk of falling. In the European guideline for physiotherapy, it is therefore recommended to advise PD patients to avoid dual tasking. However, based on clinical experience and pilot work we argue that rather than avoiding, dual tasking should be trained and that this intervention will not enhance fall risk. To establish the right training method for this patientgroup two groups of integrated and consecutive dual task training are being compared.

### Study objective

To conduct a feasibility study to test 1) whether focused and intensive dual task gait training leads to sustained improvements in complex gait performance. The study will focus hereby on influencing the ability to resist dual task interference, the ability to transfer learning effects to an untrained but related task and the ability to retain the learning increments after a period without training (12 weeks). 2) To test whether training dual task walking is a safe intervention in PD and does not increase fall risk. And which training method suits the patients best (integrated or consecutive dual task training). 3) To determine whether disease stage, disease profile (with and without Freezing Of Gait) and cognitive factors predict the effect of dual task training.

### Study design

The design will consist of an international multi-centred, single blind, randomized controlled trial.

### Intervention

One hundred twenty subjects (sixty at each side) will receive a six week long therapy intervention program consisting of integrated dual task training,four times a week, for thirty minutes long. Twice a week this therapy will be guided by an especially trained therapist and the other two times, the patients have to practise by themselves. The consecutive dual task training group will receive the same amount of therapy however consisting of traditional gait training and separate training of cognitive tasks.

### Study burden and risks

It is envisioned that this study will not involve any risks for the patients. The testing procedures involve user-friendly equipment and mostly consist of administration of clinical scales and tests. Testing will be carried out in a standard movement laboratory setting. Measurement will be conducted in the on-phase of the medication cycle. As put forward above, dual tasking may distract attention and as such hamper gait performance. Therefore testing will be performed under supervision of a physical therapist to ensure safety. At home, training will be carried out by an experienced physiotherapist, who will set the level of training to the abilities of the patient. In case of fall risk patients will be advised to practice dual tasking on a safe level when practising on their own. Training will be provided for free as the physiotherapist will be employed by the project. Full reimbursement of transport cost for the patients will be provided by the Duality-PD project. Patients will be informed of the aims of study via an informed consent procedure without biasing them towards one or the other protocol. Medication intake and other interventions will be continued as normal. Only to assign the measured effect to the *new* treatment the common therapy, if patients are already receiving therapy, will be substituted for either the single or double task intervention during the six week intervention period.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1) Diagnosis of Parkinson's disease based on UK Brain Bank criteria;
2) Hoehn & Yahr stage II-III in the on-phase;
3) Able to walk for 10 minutes continuously (FAC>4 *);
4) Dual task interference of at least 5% using a cognitive secondary task;
5) Without cognitive impairment (MoCA > 24+MMSE>24);
6) On stable medication;;* M.K. et al. (1984)
Functional Ambulation Category 4: Patient can walk independently on level ground, but requires help on stairs, slopes or uneven surfaces.

## Exclusion criteria

1) Deep Brain stimulation; not an exclusion criteria when it is placed longer than a year ago and a stable result is being accomplished.
2) Severe medical conditions affecting gait;
3) Hearing and severe visual problems affecting testing;
4) Likely to change medication regimen;
5) Already receiving dual task training from their physiotherapist;

# Study design

## Design

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| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 11-12-2012 |
| Enrollment: | 60 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 11-05-2012 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 19-07-2012 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| ClinicalTrials.gov | nct01375473 |
| CCMO | NL39530.091.12 |