# Functional gait training as complementary treatment to botulinum toxin type A in patients with disabling dystonia due to Parkinson*s disease: a double-blind randomized controlled clinical trial.

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To investigate whether treatment of dystonia causing varus tilt of the hindfoot in Parkinson*s disease is more effective when botulinum toxin type A is combined with complementary functional gait training compared to botulinum toxin type A treatment...

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Movement disorders (incl parkinsonism) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51253

**Source**
ToetsingOnline

**Brief title**
Gait training as complementary treatment in patients with dystonia.

### Condition

- Movement disorders (incl parkinsonism)

**Synonym**
Dystonia, Parkinson's Disease

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Dystonia, Gait training, Parkinson's Disease, Varus tilt of hindfoot

## Outcome measures

### Primary outcome

The primary outcome measure of the study is the evaluation of predefined

personal goals using the COPM. This outcome measure is measured at baseline,

and at 8 and 16 weeks after treatment with botulinum toxin.

### Secondary outcome

Secondary outcome measures include comfortable and maximum gait speed, balance

performance (Mini-BEST), gait variability, severity of dystonia (using the

MDS-dystonia rating scale) and time to re-injection.

# Study description

### Background summary

Approximately 6.2 million people worldwide have Parkinson*s disease (PD), with 50.000 people in the Netherlands alone. For a variety of reasons, the number of people with PD is expected to grow substantially, taking pandemic proportions. PD can lead to a broad spectrum of symptoms, one of which can be dystonia. Dystonia is defined as *a movement disorder caused by sustained or intermittent muscle contractions causing abnormal, often repetitive movement, postures or both*. Dystonia is thought to be present in 30 percent or more in people with PD, particularly in people with disease onset at a young age (i.e., before the age of 40). Dystonia of the foot can cause varus tilt of the hindfoot when walking and results in pain, risk of an ankle sprain, imbalance and falls. Treatment with botulinum toxin type A is the current gold standard. It is our

clinical experience that treatment effects of botulinum toxin type A are larger when this is combined with complementary functional gait training. This has, however, not been studied. Therefore, we hypothesize that botulinum toxin type A's treatment effects are more extensive when combined with complementary functional gait training in people with varus tilt of the hindfoot due to dystonia in PD.

## Study objective

To investigate whether treatment of dystonia causing varus tilt of the hindfoot in Parkinson*s disease is more effective when botulinum toxin type A is combined with complementary functional gait training compared to botulinum toxin type A treatment without functional training.

## Study design

This study is a double-blind randomized randomized controlled clinical trial. Primary outcome measure is the effect on personalized goals (using the Canadian Occupational Performance Measure (COPM)).

## Intervention

Next to the standard botulinum toxin treatment of varus tilt of the hindfoot, participants in the intervention group will receive additional daily functional gait training via home-exercises for 8 weeks. The control group will follow the same procedure, but with non-functional dance exercises. The treatment with botulinum toxin is not part of the intervention since this is the standard treatment.

## Study burden and risks

Benefit: We expect that subjects, both in the control and intervention group, will benefit from participation in the study since the treatment with botulinum toxin type A is the gold standard for PD patients with varus tilt of the hindfoot. Patients will also receive this treatment when not participating in this study. Additionally, the daily 10-minute functional gait exercises might be beneficial for the treatment of varus tilt of the hindfoot.
Burden: Subjects are asked to perform daily 10-minute exercises for eight weeks, and the burden is expected to be negligible.
Risks: We do not expect any potential issues of concern within this project. Treatment with botulinum toxin is the standard treatment for treating varus tilt in PD patients with dystonia. The daily exercises do not add any additional burden or risk to the participant.

# 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

The main inclusion criterium consists of idiopathic Parkinson*s disease and the presence of dystonia resulting in varus tilt of the hindfoot when walking. In addition, participants should be able to walk 100 meters and be able to follow instructions.

## Exclusion criteria

Participants will be excluded if they:
• Have severe cognitive impairments
• Have other neurologic or orthopedic impairments that cause problems when walking

• Are not able to walk 100 meters independently

# Study design

## Design

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 30 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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| Date: | 04-10-2021 |
| Application type: | First submission |
| 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 |
| --- | --- |
| CCMO | NL76688.091.21 |