# Why humans fall: the next step to successful balance

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In the proposed project we aim to predict falls in daily life and to identify both aging- and disease-related impairments that underlie impaired postural control and an increased risk of falling in daily life.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Neurological disorders NEC |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON36681

**Source**
ToetsingOnline

**Brief title**
Mechanisms of balance recovery

### Condition

- Neurological disorders NEC

**Synonym**
Parkinson's Disease, Stroke

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** Nijmegen Centre for Evidence Based Practice (NCEBP);ZonMW

## Intervention

**Keyword:** accidental falls, elderly, Parkinsons' disease, stroke

## Outcome measures

### Primary outcome

The primary independent outcome measure is the limit of stability (LoS in m/s2), which will be determined as the highest perturbation intensity at which a successful balance recovery attempt is observed. The primary dependent variable is falling in daily life.

### Secondary outcome

Secondary study parameters/endpoints

*-Step variables: onset, step length, braking forces

*-EMG variables: onset, amplitude, activation patterns

*-Body movements: joint angles, joint torques

*-Stepping threshold: maximum perturbation intensity that can be overcome without taking a step

Other study parameters

-Demographic (e.g. age, sex) and clinical (e.g. disease severity) characteristics

*-Fear of falling

*-Physical activity

# Study description

## Background summary

Falls are a major health problem in our aging population. Since balance deficits are the most important risk factor for falls, it is not surprising that in the population of Parkinson and stroke patients, in whom balance deficits are very common, the problem of falls is paramount. For the rational development of therapeutic and fall-prevention strategies it is essential to understand the complex regulation of balance and the underlying (patho)physiological mechanisms. In postural control studies, the state-of-the-art method is to investigate responses to externally applied balance perturbations. Previous studies usually focused on feet-in-place balance recovery responses, whereas in real life, it are the stepping responses that are critical for successful recovery after a perturbation. With the new *Radboud Falls Simulator* we are able to assess human postural control, including reactive stepping responses, at the very limits of stability. On the basis of these assessments we expect to much better understand critical mechanisms of postural control, and to be able to predict fall risk in daily life.

## Study objective

In the proposed project we aim to predict falls in daily life and to identify both aging- and disease-related impairments that underlie impaired postural control and an increased risk of falling in daily life.

## Study design

Prospective cohort study

## Study burden and risks

Participants undergo an intake, consisting of a physical examination and a familiarization session on the RFS, and a balance assessment. During the balance assessment participants will be exposed to balance perturbations by sudden translations of the support surface. The risks of participating in the balance assessment are very small, since rails are mounted around the balance platform and participants wear a safety harness. After the assessment on the RFS, participants (in the older and patient groups) will be followed for one year to monitor their falls in daily life. In addition, their fear of falling and activity level (recorded by an ambulant registration system) will be measured every three months during follow-up. A possible benefit for individual patients may be that we will be able to identify treatable balance impairments. In this case, patients will be offered appropriate rehabilitation.

# 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

- Stroke: unilateral supratentorial stroke longer than 6 months ago
- Parkinson*s disease: Hoehn and Yahr stages 1-4
- Elderly: age 55 years and older
- Young: age 18-35 years
- All groups: ability to stand and walk *independently*, as defined by a score of 3 or more according to the Functional Ambulation Categories

## Exclusion criteria

- Any other neurological or musculoskeletal disorder affecting balance
- Severe cognitive impairments (mini mental state examination (MMSE) < 24)

- Medication negatively affecting balance (e.g. neuroleptics, antidepressants, anticonvulsants, sedatives)

# Study design

## Design

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| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 02-01-2012 |
| Enrollment: | 250 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 19-07-2011 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 08-01-2015 |
| 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 |
| --- | --- |
| CCMO | NL33977.091.10 |