# Can the predefined on-body sensing system be used for the qualification of the arm and balance function of patients after stroke.

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The predefined on-body sensing system can be used for the qualification of the arm and balance function of patients after stroke.

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON23377

**Bron**
Nationaal Trial Register

**Aandoening**

Stroke Beroerte

### Ondersteuning

**Primaire sponsor:** Primary sponsor - This project is part of the Seventh Framework Programme (FP7) funded by the European Union.
**Overige ondersteuning:** Primary sponsor - This project is part of the Seventh Framework Programme (FP7) funded by the European Union.

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Using on-body sensing systems, inertial sensors, force sensors and EMG-sensors; movement, forces and muscle activity will be measured. Measured data will be analyzed and the main study parameters will be calculated. These parameters are subdivided into three groups: temporal (number of movements), kinetic (centre of pressure, underneath the foot) and kinematic (step width, step size, range of motion). Each group contains several parameters of which a combination of parameters and/or (a)symmetry of parameters will be used to qualify motor function.

# Toelichting onderzoek

### Achtergrond van het onderzoek

With the aging of the population, the incidence of stroke is increasing in especially developing countries. Depending on the patient's impairments as a result of the stroke, a patient-specific rehabilitation program is started when he/she is discharged from the hospital after the acute phase. During the subsequent period of intensive training in a rehabilitation centre, the patient's motor function is regularly evaluated. When the patient has an adequate capacity to live at home, the patient is discharged and sent home. Between this moment and the next routine appointment (several months later), patients frequently show deterioration of motor function. In some cases, this deterioration is so severe that re-admission to a rehabilitation centre is necessary. Remarkably, the cause of the deterioration of motor function is unknown in many cases, since the patient's period at home is like a black-box for the physician. If the physician would be able to monitor the patient's motor function at home, he could intervene in case of deterioration and prevent an expensive re-hospitalisation. For this purpose, we develop body-mounted sensing systems that can eventually result in daily-life monitoring. In the current phase, we evaluate monitoring principles in a simulated ambulatory setting. In this cross sectional study described in this document, a combination of two ambulatory human movement analysis systems (Instrumented Force Shoes and an inertial sensing suit) will be used to assess balance and reaching tasks of stroke patients. The results will be evaluated and related to regular clinical tests.

Recruitment only in the Netherlands.

### Doel van het onderzoek

The predefined on-body sensing system can be used for the qualification of the arm and balance function of patients after stroke.

### Onderzoeksopzet

One moment.

**Onderzoeksproduct en/of interventie**

For all subjects the experiment will be the same. No randomization will be aplied, no control group will be included.

During the single measurement session, the sensors will be attached to the body. After calibration, subjects will be asked to perform some specific tasks and complete some clinical tests. The whole measurement session will take about 120 minutes.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age above 35 years;

2. Age below 75 years;

3. At least 6 months post-stroke;

4. Had only one unilateral ischaemic or haemorrhagic hemiparetic stroke;

5. Ability to lift the arm (at least partly) against gravity, without suffering;

6. Ability to walk (possibly with walking aid) for over 10 meters, without suffering;

7. Ability to walk without specific footwear (ability to walk on sandals);

8. No pain or other condition interfering with the mobility and/or strength of the arm;

9. Ability to understand and perform instructions and questionnaires;

10. Provide written informed consent (IC).

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Medical history of more than one stroke events;

2. Complicating medical history such as cardiac, pulmonary, or orthopaedic disorders that could affect performance of the included measurements;

3. Severely impaired sensation;

4. Suffering from comprehensive aphasia.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |

| | |
|---|---|
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-01-2013 |
| Aantal proefpersonen: | 20 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40017
Bron: ToetsingOnline
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL3490 |
| NTR-old | NTR3636 |
| CCMO | NL41791.044.12 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON40017 |

# Resultaten

**Samenvatting resultaten**
N/A