# The acute effect of whole body vibration on spasticity of the calf muscle in stroke patients

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The purpose of this study is to investigate the acute effects of a single bout of WBV on spasticity of calf muscle in stroke patients.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Central nervous system vascular disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32738

**Source**
ToetsingOnline

**Brief title**
Whole body vibration and spasticity

### Condition

- Central nervous system vascular disorders

**Synonym**
cerebrovascular accident, stroke

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** Calf muscle, Spasticity, Stroke patients, Whole body vibration

## Outcome measures

### Primary outcome

EMG measurement:

- Hoffman(H-) reflex

- M-response

- H/M ratio

Spasticity assesment by the modified Ashworth scale.

### Secondary outcome

Goniometry of the ankle joint.

# Study description

### Background summary

Stroke is one of the most common causes of complex disability. Stroke patients have difficulty to walk because of their inability to make an effective dorsiflexion in their ankle during the swing phase. This problem is partly due to an inability to activate the ankle dorsiflexors and partly due to spasticity in the calf muscles. Treatment of spasticity is an important prerequisite for the restoration of normal gait in stroke patients who are suffering from spastic drop foot. Nowadays, various treatments such as antispastic drugs, electrical stimulation, ultrasonic therapy, and surgical procedures, have been used to decrease spasticity. However most of the current treatment options have certain limitations (e.g. short effects of the used physical therapy, and some side effects of the medications).
It is suggested that spasticity results from an exaggerated monosynaptic stretch reflex. Obviously any therapeutic intervention that would be able to inhibit the stretch reflex will be effective on reduction of spasticity. Whole Body Vibration (WBV) is a safe and efficient training method to improve muscle function. The direct effects of WBV on spasticity have not been examined so

far. Ahlborg et al. (2006) reported that 8-week training of WBV could increase muscle strength in adults with cerebral palsy without negative effects on spasticity.

### Study objective

The purpose of this study is to investigate the acute effects of a single bout of WBV on spasticity of calf muscle in stroke patients.

### Study design

It is a cross-over study design. The study consists of two sessions, with a one-week interval. During each session, the patient will stand on the device (Power Plate, Power Plate international, USA) for 3 minutes. In one session the device will be switched on (WBV- Condition; vibration frequency: 45 Hz, low amplitude) and in the other session (Control-Condition) it will be switched off. Before and immediately after standing on the device EMG and Range of Motion (ROM) will be measured. The pre-post intervention data of the WBV-Condition will be compared to the pre-post intervention data of the Control-Condition.

### Intervention

Exposure to whole body vibration for three minutes in a standing position.

### Study burden and risks

The whole body vibration training is not painfull or dangerous. During standing on the vibration device two persons are standing beside the patient to minimize risk of falling. The amplitude and frequency of whole body vibration are low and, therefore, the measurements have a low physical strain.

## 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

Single stroke at least one year ago,
Ability to stand on the device without aids,
Score Score >=4 (0 - 5) based on modified ashworth scale

## Exclusion criteria

Any associated central nervous diseases such as parkinson and multiple sclerosis. Recent or possible thrombosis, severe headache, vestibular disorders, advanced arthritis, lower limb implant, synthetic implants (e.g. Pace Maker), Lumbar disc problem and any discopathy in the vertebral column, acute systemic infection or inflammation, and all general contraindications for WBV such as recent fractures, gall bladder or kidney stones and malignancies.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Crossover |

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 30-09-2009 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 28-10-2008 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## 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 | NL24068.078.08 |