

# The effects of sensory stimulation on postural stability after whiplash injury

Published: 27-08-2008

Last updated: 06-05-2024

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32129

### Source

ToetsingOnline

### Brief title

Postural control after a whiplash accident

### Condition

- Other condition
- Muscle disorders
- Spinal cord and nerve root disorders

### Synonym

neck sprain; neck strain

### Health condition

symptomen als gevolg van whiplash trauma

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** chronische pijn, postural control, sensory information, sensory integration therapy, whiplash

## Outcome measures

### Primary outcome

From the COP time-series, recorded by the force plate, we will calculate several standard parameters that are often used to quantify postural regulation, using in-house software (MATLAB). We will derive measures related to: 1) the overall amount of sway, 2) the variability and consistency of the sway, 3) the frequency contents of the signal, and 4) the smoothness of the signal.

For the three questionnaires we will calculate the total sum score of each measure.

All statistical analyses will be performed using SPSS version 14.0. A mixed factors ANOVA will be used. The between-subject factor is group and the within-subject factor is condition. We will conduct a separate ANOVA for the static balance conditions (A1 to A4) and the dynamic balance conditions (B1 to B4). Level of significance will be set to  $p < 0.05$ .

### Secondary outcome

Spearman correlations will be calculated between balance scores and

## Study description

### Background summary

Individuals with chronic neck and shoulder problems caused by whiplash injury not only suffer from pain in these areas, but they also often tend to have dizziness complaints, concentration problems, hypersensitivity to sensory information/stimulation, and a disturbed balance system. These complaints are collectively known in the literature as whiplash associated disorders (WAD). A crucial factor in disturbed balance appears to be that the different sensory modalities that are used for the regulation of balance are not properly tuned. A key aspect of rehabilitation is aimed at reducing the whiplash associated sensory complaints. This is known in therapeutic circles as sensory integration therapy (SI). However, at the moment little scientific knowledge exists on how the senses work together in the regulation of balance. The aim of this research is to investigate -using posturography- what the effects are of sensory manipulations on the regulation of balance in WAD patients. A group of 15 WAD patients and 15 unaffected controls will perform a number of simple balance tests. At the same time, movements of the body center of pressure will be recorded using a force plate.

### Study objective

The aim of this research is to examine the effects of changes in proprioceptive and visual information on balance control in WAD sufferers. Although clinical experience suggests more effective balance control due to elevated proprioceptive information, this has never been quantified using objective posturographic measures. Balance will be measured by recordings of body sway, or more technically, the centre of pressure (COP) time-series registered with a force plate.

The following questions will be addressed:

- \* Is balance control in the WAD group less efficient than in a control group?
- \* In the WAD group, will balance control benefit from added proprioceptive input?
- \* In the WAD group, will balance control suffer from added visual input?
- \* What are the combined effects of the WAD syndrome and the availability of sensory signals on postural control?

### Study design

Before the experiment begins participants sign the informed consent. Prior to the recording of the balance, participants (both patients and controls) are

asked to fill out the Dutch equivalent of the following three questionnaires.

1) The Dutch version of the dizziness Handicap Inventory (DHI), which measures the subjective impact of dizziness on the everyday life of the participants.

2) The Tampa Scale for Kinesiophobia to assess pain related fear of movement. For unaffected controls the modified version of the TSK will be used.

3) The Beck Depression Inventory.

These questionnaires are standard use in clinical routine and scientific investigations of chronic pain patients, including WAD.

Upon arrival in the measurement lab and after the forms have been collected by the experimenter, patients are asked to indicate their level of actual experienced pain on a Visual Analogue Scale (VAS), on a 100-points scale (0 = no pain; 100 severe pain).

For the collection of the balance data, participants (patients and controls) will stand on a forceplate, adopting a natural and comfortable stance position, with the arms hanging relaxed alongside the body. Participants will be standing bare footed or wearing socks but no shoes or sandals, in order to maximize the quality of the posturographic measurements. In some conditions a belt weighing 500 g will be worn around the waist. This belt is part of the occupational therapist's toolbox when conducting sensory integration therapy.

Two different tasks will be performed. First, static balance capability (conditions A1 to A4) will be measured. During the static balance conditions participants will be asked to maintain quiet stance and to look straight ahead. In the experimental conditions the availability of visual and proprioceptive information is manipulated, as follows:

- A1: quiet standing (baseline)
- A2: quiet standing + 500 g waist belt

These 2 conditions are repeated, but participants will see a coloured spot (dot of approximately 5 mm) on a monitor in front of them that gives participants instantaneous visual information of the position (and changes therein) of their centre of pressure (COP). Thus, vision is added as an extra source of feedback for balance control. The instruction will be to keep this dot within the confines of a circle of a larger radius. This will result in 2 additional conditions:

- A3: quiet standing + visual feedback
- A4: quiet standing + 500 g waist belt + visual feedback

Second, dynamic balance (conditions B1 to B4) will be measured. During the dynamic balance conditions participants will be asked to periodically shift their weight from their left leg to their right leg and back again, which thereby results in medio-lateral displacements of their COP. In all conditions participants will receive visual feedback of their COP, similar to conditions A3/A4. In conditions B1 and B2 the task is to perform a set of rhythmic weight shifts so that the feedback dot on the screen oscillates rhythmically from left to right, thereby keeping the dot within the area enclosed by two vertical bars.

- B1: weight shifting (baseline)
- B2: weight shifting + 500 g waist belt

Also, participants have to perform a task, in which they are asked to

move the feedback dot between moving objects (slowly moving squares) and try not to \*collide' with any of the blocks:

- B3: virtual collision avoidance
- B4: virtual collision avoidance + 500 g waist belt

The static balance (A1 to A4) will have a duration of 1 minute each. The dynamic balance conditions (B1 to B4) will have duration of 2 minutes each. Each condition will be repeated 2 times. Between each condition, participants can take a rest upon request, during which they are allowed to leave the force plate and sit down if they want. All participants will wear headphones to filter out possible background noise, as this might distract attention from the task. No verbal cues will be given to the participants during the tests. The static balance and dynamic balance conditions will be presented in a block, but within a block the conditions 1 to 4 will be presented in a random order.

## **Intervention**

See Study design

## **Study burden and risks**

During the experiment participants will have the opportunity to grab a handrail, located on the left and right side of the force plate, if they experience dizziness or discomfort. Subjects will also be closely monitored by an experimenter. Participants are free to take a small rest (or even abort the experiment) when they experience too much discomfort, fatigue, or dizziness. We expect hardly any instances of discomfort, fatigue, or dizziness due to the very low level of physical activity of the conditions and due to the low complexity of the visual signal.

## **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

Age 18+ -

Patients are classified as having WAD grade II or III, according to the Quebec Task Force classification

Eligibility to participate in the sensory integration treatment program of the RCA

### Exclusion criteria

Other orthopaedic and/or neurological disorders, that are unrelated to WAD that might influence postural control.

Cognitive or mental impairments that might undermine the understanding of the task instructions.

## Study design

### Design

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

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-08-2008  
Enrollment: 30  
Type: Anticipated

## Ethics review

Approved WMO  
Date: 27-08-2008  
Application type: First submission  
Review commission: METC Amsterdam UMC

## 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	NL23767.029.08