

# Evaluation of different types of treatments for chronic neck pain

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<b>Registration date</b> 18/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/09/2008	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
Funder refs: 2006-1162; 51-1010/06

## Study information

**Scientific Title**

The effect of neck coordination training on sensorimotor function, symptoms and self-rated health and functioning for non-specific neck-shoulder pain

## **Study objectives**

Main hypothesis:

Specific neck coordination training has a better short-term and long-term effect than strength training for the neck-shoulders-arms, and massage, on the primary outcomes of the sensorimotor functions (see Primary outcome measures).

Further hypotheses:

1. Specific neck coordination training has a better long-term effect than massage on the primary and secondary outcomes of the self-rated health, symptoms and functioning, (see Primary and Secondary outcome measures)
2. Specific neck coordination training as well as strength training for the neck-shoulders-arms have a better long-term effect than treatment as usual on the primary and secondary outcomes of the self-rated health, symptoms and functioning (see Primary and Secondary outcome measures)
3. Specific neck coordination training has a better long-term effect than massage, on the secondary outcomes of the sensorimotor functions (see Secondary outcome measures)
4. Specific neck coordination training as well as strength training for the neck-shoulders-arms have a better long-term effect than massage and treatment as usual on fear of movement and re-injury due to movement, assessed by the TAMPA Scale of Kinesiophobia.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Regional Ethical Review Board in Uppsala, Sweden. Protocol was approved on 30/08/2007, complementary application approved on 25/06/2008 (ref: 2007/206)

## **Study design**

Randomised, single-blind, single-centre trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Not specified

## **Study type(s)**

Treatment

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Chronic non-specific neck-shoulder pain

## **Interventions**

One hundred forty participants with neck-shoulder pain and 40 participants without neck pain will be recruited into this study. The participants without neck pain will be involved in this trial only for the baseline assessments.

The participants with neck-shoulder pain will be randomly allocated to the following 4 treatment groups:

1. Neck coordination training ("index treatment"), 30 min treatment twice a week for 11 weeks
2. Strength training for neck, shoulder, arms ("best available treatment"), 30 min treatment twice a week for 11 weeks
3. Massage ("sham treatment" with respect to long-term effects), 30 min treatment twice a week for 11 weeks
4. No intervention (However, the participants are free to receive "standard treatment" from the national health service if they wish)

The group allocation will be concealed during data processing and analyses.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

1. Sensorimotor functioning (Timepoints of assessment: 1 week before start of treatment; 1 week and 6 month after end of treatment):
  - 1.1. Magnitude of fast and slow component of postural sway, calculated from force platform centre of pressure data
  - 1.2. Arm movement precision, measured as end-point precision (variability in horizontal, depth and vertical directions) in a goal-directed arm movement task
2. Self-rated health, symptoms and functioning (Timepoints of assessment: 1 week before start of treatment; 1 week, 6 month, 1 year after end of treatment):
  - 2.1. Nineteen selected questions addressing ability to perform all daily activity involving neck, shoulder, arm and hand from the DASH questionnaire

## **Secondary outcome measures**

The following will be assessed at 1 week before start of treatment, 1 week and 6 month after end of treatment:

1. Sensorimotor functioning:
  - 1.1. Jerkiness of cervical rotation, calculations based on the "minimum jerk" hypothesis
2. Self-rated health, symptoms and functioning:
  - 2.1. Measurements covering the 4 core chronic pain outcome domains recommended by Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT):
    - a. Pain intensity, assessed by a 0 to 10 numeric rating scale (NRS), 0 = no pain, 10 = worst pain imaginable.
    - b. Physical functioning, assessed by the function index of the Profile Fitness Mapping questionnaire, (under publication), a neck specific questionnaire measuring self-rated functional limitations.
    - c. Emotional functioning, assessed by the Montgomery Åsberg Depression Rating Scale, a

questionnaire which has shown high sensitivity to changes in depression.

d. Participant ratings of overall improvement, assessed by i) the Patient Global Impression of Change scale and ii) the Profile Fitness Mapping questionnaire - total score, neck-specific symptoms and functional limitations (under publication)

2.2. Fear of movement and re-injury due to movement, assessed by the TAMPA Scale of Kinesiophobia

Other outcome measures (these outcome measures will be used in exploratory analyses):

1. Sensorimotor functions:

1.1. Cervical range of movement.

1.2. Peak velocity of cervical rotation.

1.3. Ankle, hip and neck kinematic coordination during quiet stance

1.4. Arm joint kinematic coordination during goal directed movements

2. Self-rated health, symptoms and functioning:

2.1. Pressure pain threshold, assessed with an algometer, for 3 neck-shoulder points: i) the suboccipital insertion of spinal extensor muscles ii) the trapezius muscle iii) the scapular insertion of the levator scapulae muscle.

2.2. Area of pain distribution, assessed by pain drawings

2.3. Severity of disability assessed by the Neck Disability Index

2.4. Upper extremity disability and symptoms assessed by the DASH questionnaire

2.5. General health and wellbeing, assessed by the 36-item Short Form Health Survey (SF-36)

2.6. Psychologic wellbeing, assessed by the Ryff's Psychological Well-Being scales

2.7. Pain patients' cognitive, behavioural, and affective responses to their condition, assessed by the Multidimensional Pain Inventory

**Overall study start date**

01/03/2008

**Completion date**

18/12/2008

## **Eligibility**

**Key inclusion criteria**

Participants with neck-shoulder pain:

1. Women, age 25-65 years

2. Non-specific neck-shoulder pain with a duration of at least 3 months

3. Decreased physical functioning according to the Disability Arm Shoulder Hand (DASH) questionnaire (at least 9 normalised points on 19 selected questions addressing ability to perform all daily activity involving neck, shoulder and arm)

Baseline control group:

1. Women, age 25-65 years

2. Healthy volunteers without neck pain

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Female

**Target number of participants**

180

**Key exclusion criteria**

Participants with neck-shoulder pain:

1. Trauma to the head and neck associated with the onset or with any worsening of the symptoms
2. Conditions of rheumatic-, inflammatory- or neurological disease or fibromyalgia
3. Evidence of back-, neck- or shoulder surgery or fracture
4. Cervical rhizopathia
5. Signs of vestibular dysfunction

Baseline control group:

1. Trauma to the head, neck or shoulder that has caused considerable problems
2. Conditions of rheumatic-, inflammatory- or neurological disease or fibromyalgia
3. Evidence of back-, neck- or shoulder operation or fracture

**Date of first enrolment**

01/03/2008

**Date of final enrolment**

18/12/2008

**Locations****Countries of recruitment**

Sweden

**Study participating centre**

Centre for Musculoskeletal Research

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**Sponsor information****Organisation**

Swedish Council for Working Life and Social Research (Sweden)

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Government

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## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
Internal funding:

**Funder Name**  
Centre for Musculoskeletal Research, University of Gävle (Sweden)

**Funder Name**  
Department of Community Medicine and Rehabilitation, Physiotherapy, University of Umeå (Sweden)

**Funder Name**  
External funding:

**Funder Name**  
The Swedish Council for Working Life and Social Research (Registration number 2006-1162) (Sweden)

**Funder Name**

Forskning & Framtid ("Research & Future") (Registration number 51-1010/06) (Sweden)

**Funder Name**

Alfta Research Foundation (Sweden)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration