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Evaluation of different types of treatments for chronic neck pain

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Registration date 18/09/2008	**Overall study status** Completed	
Last Edited 19/09/2008	**Condition category** Signs and Symptoms	

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. Cervikal 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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Swedish Council for Working Life and Social Research (Sweden)

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Sponsor type
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