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Rehabilitation of women with neck-shoulder pain: effect of individualized training and treatment

Submission date 21/07/2011	**Recruitment status** No longer recruiting
Registration date 02/08/2011	**Overall study status** Completed
Last Edited 10/10/2016	**Condition category** Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
2009-1403

Study information

Scientific Title
Rehabilitation of women with neck-shoulder pain: effects of individualized treatment and training, based on symptoms, clinical standardized tests and tests of functioning, on pain and physical functioning compared to either a non-individualized approach or treatment-as-usual

Study objectives
1. Individualized rehabilitation has a better short, intermediate and long-term effect than either non-individualized rehabilitation or treatment-as-usual, on primary and secondary outcomes
2. Individualized and non-individualized rehabilitation has a better short, intermediate and long-term effect than treatment-as-usual, on primary and secondary outcomes
3. Which treatment model is the most cost-effective from the health economics perspective?
4. What impact do physical and psychosocial factors at the workplace have on long-term treatment outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board in Uppsala, Sweden, 23/03/2011, ref: 2011/081

Study design
Interventional single-centre single-assessor blinded randomized controlled clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Non specific neck-shoulder pain, with evidence of impaired physical functioning in terms of self-rated neck disability and work capacity.

Interventions
1. Intervention is planned to start 22/08/2011
2. Group allocation will be concealed during data processing and analyses
3. One hundred and five participants with neck-shoulder pain and 35 participants without neck pain will be recruited into this study

4. The participants without neck pain will be involved only for baseline comparisons
5. The participants with neck-shoulder pain will be randomly allocated to one of the following 3 groups:
5.1. Individualized treatment based on symptoms, standardized clinical tests and tests of functioning
5.2. Non-individualized treatment
5.3. No intervention (However, the participants are free to receive "standard treatment" from the National Health Service if they so wish)
6. Group 1 and 2 will receive 40 min treatment on 27 occasions during 11 weeks (2 treatments first week and 3 times the second week and so forth)
7. Treatment components included in the intervention target different functions and include craniocervical flexion exercises, postural correction and re-education, mobilization treatment according to manual therapy principles, strength training for the neck-shoulder and arm muscles, myofeedback supported training of a relaxed work technique and eye-neck-hand coordination training
8. Progression and context of the training will follow motor learning principles
9. The individualized treatment (group 1) will be tailored for each participant according to results of the baseline assessment
10. Traig in the individualized group will be adapted to each persons activity limitations, obtained by the Problem Elicitation Technique
11. Participants in group 2, non-individualized treatment, will be given two treatment components taken at random from those that do not target the impaired functioning revealed at the baseline assessment for the specific participant

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Physical functioning, measured using the Neck Disability Index (NDI)
2. Average pain intensity last week, measured using the Numeric Rating Scale (NRS) (0 = no pain, 10 = worst imaginable pain)

Secondary outcome measures
1. General improvement, assessed by the Patient Global Impression of Change scale
2. Symptoms, measured by symptom index of the Profile Fitness Mapping neck questionnaire (ProFitMap-neck) (manuscript in preparation)
3. Capacity on the quality and quantity to work in the latest 6 weeks due to neck problems ([1 (quality/10) × (quantity/10)] × 100%)
4. Pain pressure threshold of m. trapezius, assessed with pressure algometer measurement

Other outcome measures (for exploratory analyses):
1. Self-estimated improvement during treatment, for General improvement, much improved or very much improved on PGICS; for Pain intensity, no pain last week
2. Functional limitations and compound total score, assessed by the Profile Fitness Mapping neck questionnaire (ProFitMap-neck)
3. Cervical range of motion (active flexion-extension; active axial rotation; passive flexion-rotation)
4. Peak speed in cervical axial rotation

5. Cranio-cervical flexion endurance (50% of maximum voluntary contraction)
6. Lifting capacity, assessed by the cervical progressive isoinertial lifting evaluation test (C-PILE)
7. Physical activity, measured with LIV 2000
8. Health-related quality of life for clinical and economic appraisal, assessed by the EQ-5D (The EuroQol Group 1990)
9. Questions on reporting sick, and consumption of care
10. Quality of life - Mental health, assessed by the Mental component summary in the Short Form Health Survey (SF-36)
11. Quality of life Physical Health, assessed by the Physical component summary in the Short Form Health Survey (SF-36)
12. Area of pain distribution, assessed by pain drawings
13. Adverse events. Open ended questions, and Patient Global Impression of Change scale (PGICS) administered after 10, 20 and the last treatment session. Much worse or Very much worse on the PGICS is equalized with an adverse event.

Overall study start date
16/08/2011

Completion date
15/02/2013

Eligibility

Key inclusion criteria
Participants with neck-shoulder pain:
1. Women, age 20-65 years
2. Non-specific neck-shoulder pain with duration of at least six weeks
3. Decreased physical functioning, ≥ 10 and ≤ 68 (0-100) on the Neck Disability Index (NDI)4. Self-rated impaired capacity on the quality or quantity to work the preceding month due to neck problems (measured with two questions according to Martimo et al. 2009)

Control group for baseline comparisons:
1. Women, age 20-65 years
2. Healthy volunteers without neck or back pain

Participant type(s)
Mixed

Age group
Adult

Sex
Female

Target number of participants
160

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 (self-ratings)
2. Cervical rhizopathy or vestibular dysfunction (according to specific diagnostic criteria)
3. Conditions of psychiatric, inflammatory, endocrinal, rheumatic, cancer, neurological or connective tissue disorders, stroke, heart infarct or type 1-diabetes (diagnosed by medical doctor)
4. Concurrent low back pain (defined according to pain drawing (Margolis et al. 1986) and a specific decision algorithm (Nyman et al. 2009)
5. Fibromyalgia/generalized pain according to the criteria of the American College of Rheumatology
6. Low treatment expectation or catastrophizing most or all of the time (5-point ordinal scale)
7. Anxiety or depression (assessed by the Hospital Anxiety and Depression Scale with cut off values of 10 for anxiety and 8 for depression (Lisspers et al. 1997)
8. Temporomandibular disorders (Criteria according to Storm and Wänman 2006)
9. Surgery the last 3 years in the neck, back or shoulder
10. Fracture in the neck or fracture the last 3 years in the shoulder or back
11. Luxation of a shoulder joint the last year
12. Severely restricted range of motion in cervical rotation (< 30° in any direction) or shoulder flexion (< 110°)

Baseline control group:
1. Trauma that has caused considerable problems in the head, neck or shoulder
2. Conditions of psychiatric, inflammatory, endocrinal, rheumatic, cancer, neurological or connective tissue disorders, stroke, heart infarct or type 1-diabetes (diagnosed by medical doctor)
3. Evidence of back, neck or shoulder operation or fracture

Date of first enrolment
16/08/2011

Date of final enrolment
15/02/2013

Locations

Countries of recruitment
Sweden

Study participating centre
University of Gävle
Gävle
Sweden
SE-801 76

Sponsor information

Organisation

The Swedish Council for Working Life and Social Research (Sweden)

Sponsor details
Box 2220
Stockholm
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Sponsor type
Research council

Website
http://www.fas.se/

ROR
https://ror.org/02d290r06

Funder(s)

Funder type
University/education

Funder Name
Centre for Musculoskeletal Research, University of Gävle, Sweden

Funder Name
Umeå Universitet

Alternative Name(s)
Umeå University, Ubmeje universitiähta, Universitas Umensis

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Funder Name

Forskningsrådet för Arbetsliv och Socialvetenskap

Alternative Name(s)
Swedish Council for Working Life and Social Research, FAS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Sweden

Funder Name
AFA Försäkring

Alternative Name(s)
AFA Insurance

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol results	20/05/2012		Yes	No

Results article	30/09/2016	Yes	No