

A Randomised Clinical Trial to evaluate the effects of a new treatment of chronic neck-shoulder pain in Work-related MusculoSkeletal Disorder (WMSD) patients - Ambulant Myofeedback training

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/08/2009	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

NTR493; 001

Study information

Scientific Title

Acronym

NTR493; RCT Mfb

Study objectives

It is hypothesised that 4 weeks of ambulant myofeedback training is more effective in reducing pain intensity, disability, and normalising muscle activation patterns compared to traditional treatment of WMSD in the neck-shoulder region e.g. ergonomic counseling.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised open label active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Work-related Musculoskeletal Disorders (WMSDs), Complaints of Arm, Neck and Shoulders (CANS)

Interventions

The intervention is 4 weeks ambulant myofeedback training.
Control group receives traditional ergonomic counselling.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Pain intensity and disability

Secondary outcome measures

1. Health-related quality of life
2. Muscle activation patterns
3. Psychosocial characteristics

Overall study start date

01/04/2003

Completion date

01/10/2004

Eligibility**Key inclusion criteria**

1. Elderly female subjects
2. Above the age of 35 years
3. Performing predominantly computer work
4. Reporting complaints in the neck and/or shoulder region for at least 30 days during the last year including the last 7 days
5. Subjectively relating complaints to (computer) work

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

75

Key exclusion criteria

1. Severe cervical arthrosis
2. Other disorders in neck-shoulder region not related to WMSD
3. More than three body areas in which pain is reported
4. Colour blindness
5. Latex allergy
6. Use of muscle relaxants

Date of first enrolment

01/04/2003

Date of final enrolment

01/10/2004

Locations

Countries of recruitment

Netherlands

Study participating centre

Roessinghsbleekweg 33b

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Sponsor information

Organisation

Roessingh Research and Development b.v. (The Netherlands)

Sponsor details

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Sponsor type

Not defined

ROR

<https://ror.org/01dmjt679>

Funder(s)

Funder type

Charity

Funder Name

St. Hubert Foundation (Stichting St. Hubertus)

Funder Name

European New Project

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