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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	Recruitment status	[ ] Prospectively registered
27/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/08/2009	Injury, Occupational Diseases, Poisoning	[ ] 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)

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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