

# Intramuscular mechanisms underlying work related trapezius muscle pain - physical activity as intervention for rehabilitation

<b>Submission date</b> 21/02/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/06/2010	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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**  
KF 01-138/04

# Study information

## Scientific Title

## Acronym

RAMIN (Rehabilitating Af Muskelsmerter I Nakken; Rehabilitating Activity for Myalgia In the Neck)

## Study objectives

1. Metabolic and morphological differences exist in the trapezius muscle among female workers with and without neck/shoulder myalgia
2. Physical activity in terms of dynamic resistance training and bicycle training will via different mechanisms relieve pain and modulate muscle metabolism and morphology of the trapezius muscle in female workers with neck/shoulder myalgia

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Local Ethical Committee of Copenhagen, Denmark (ref: KF 01-138/04).

## Study design

Case control and randomised cluster balanced interventional trial

## Primary study design

Interventional

## Secondary study design

Case-control study

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

Musculoskeletal Disorders

## Interventions

Intervention amended as of 22/08/2007:

Participants are randomised to receive one of the following:

1. Dynamic resistance training: 20 minutes per session, three times a week, for 10 weeks supervised by an instructor

2. Leg bicycle training: 20 minutes per session, three times a week, for 10 weeks supervised by an instructor
3. Health promoting information but no physical training

Interventions provided at time of registration:

Participants are randomised to receive one of the following:

1. Dynamic resistance training
2. Leg bicycle training
3. Health promoting information but no physical training

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Primary outcome measures amended as of 22/08/2007:

The following will be assessed at baseline before the intervention and again immediately after the 10-week intervention training:

1. Perceived pain
2. Clinical findings
3. Muscle strength and function

Primary outcome measures provided at time of registration:

1. Perceived pain
2. Clinical findings
3. Muscle strength and function

### **Secondary outcome measures**

Secondary outcome measures amended as of 22/08/2007:

The following will be assessed at baseline before the intervention and again immediately after the 10-week intervention training:

1. Muscle biochemistry and histochemistry
2. Microdialysis
3. Ultrasound
4. Electromyography (EMG)
5. Near infrared spectroscopy (NIRS)
6. Exercise test performance

Secondary outcome measures provided at time of registration:

1. Muscle biochemistry and histochemistry
2. Microdialysis
3. Ultrasound
4. Electromyography (EMG)
5. Near infrared spectroscopy (NIRS)
6. Exercise test performance

### **Overall study start date**

01/08/2005

**Completion date**

31/12/2007

## Eligibility

**Key inclusion criteria**

1. Generally healthy female workers
2. Aged 30 - 60 years
3. With and without trapezius myalgia

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

20 without and 60 with trapezius myalgia

**Key exclusion criteria**

1. Trauma
2. Generalised muscle pain
3. Life threatening diseases

**Date of first enrolment**

01/08/2005

**Date of final enrolment**

31/12/2007

## Locations

**Countries of recruitment**

Denmark

**Study participating centre**

**National Research Centre for the Working Environment**

Copenhagen

Denmark

DK-2100

## Sponsor information

**Organisation**

The National Research Centre for the Working Environment (Denmark)

**Sponsor details**

Lersø Parkalle 105  
Copenhagen Ø  
Denmark  
DK 2100

**Sponsor type**

Government

**Website**

<http://www.arbejdsmiljoforskning.dk/>

**ROR**

<https://ror.org/03f61zm76>

**Funder(s)****Funder type**

Government

**Funder Name**

Danish Medical Research Council (Denmark) (ref: 22-03-0264)

**Funder Name**

The Danish Rheumatism Association (Denmark) (ref: 233-1149-02.02.04)

**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?
<a href="#">Results article</a>	results	15/01/2008		Yes	No
<a href="#">Results article</a>	results	01/06/2010		Yes	No