

Effectiveness of early part-time sick leave in musculoskeletal disorders

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| Submission date 19/12/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 21/01/2008 | Overall study status Completed | <input checked="" type="checkbox"/> Protocol |
| Last Edited 26/06/2013 | Condition category 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

Protocol serial number
322139

Study information

Scientific Title

Study objectives

Our hypothesis is that employees whose work time is temporarily reduced and work load adjusted during early stage of disability will have less disability days and faster return to regular work duties than employees on conventional sick leave.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Coordinating Ethics Committee of Hospital District of Helsinki and Uusimaa on 20 December 2005 (HUS 461/E0/05). Amendment was approved on 24 October 2006.

Study design

Single-center randomized controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Musculoskeletal disorders

Interventions

Intervention: Part-time sick leave (daily work load reduced by restricting work time by about 50%, and, if necessary, remaining work tasks modified so that working should be possible despite the symptoms)

Control: Full-time sick leave

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Number of days from the initial visit to the return to regular work activities
2. Total number of part- and full-time sick leave days during one- and two-year follow-up

Key secondary outcome(s)

1. Pain, measured using numerical scale 0 to 10 (0 = no pain, 10 = unbearable pain) at 0, 1, 3, 8, 12 and 52 weeks
2. Self-assessed function (Oswestry back questionnaire; shortened Disabilities of the Arm, Shoulder and Hand questionnaire [Quick DASH]; Comprehensive OsteoArthritis Test [COAT]) at 0, 1, 3, 8, 12 and 52 weeks

Costs and benefits to the employee, employer and society will be estimated in both study groups.

Completion date

30/06/2009

Eligibility

Key inclusion criteria

Employees who seek medical advice in the occupational health service primarily due to musculoskeletal pain in the neck or shoulder region, back or upper or lower extremities, are eligible to the study. The symptoms and related disability must warrant prescription of full-time sick leave according to the current practice, but the physician considers the employee to be able to work part-time without the risk of the health condition to deteriorate.

Specific inclusion criteria:

1. 18 to 60 years of age
2. Permanent or long-term employment (30 hours or more per week)
3. No sick leave or other absence exceeding two weeks during the preceding month
4. Not more than 30 days on sick leave due to any health problem during three preceding months
5. Employee is not listed for any surgery that requires more than one week of sickness absence
6. No plan for longer absence from work during 12 months after enrollment
7. An employee can be enrolled only once

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. General exclusion criteria:
 - 1.1. Acute infections
 - 1.2. Major accidental injury
 - 1.3. Active inflammatory arthritis
 - 1.4. Suspected occupational injury or disease
 - 1.5. Malignant tumour diagnosed or treated during the preceding year
 - 1.6. Severe mental disorder;
 - 1.7. Pregnancy
 - 1.8. Severe pain (>7 on a scale from 0 to 10)
 - 1.9. Pain interferes with sleep severely (>7 on scale from 0 to 10)

Pain area specific exclusion criteria:

2. Back region:

- 2.1. Muscle weakness in the lower extremities related to back pain
- 2.2. Positive straight-leg-raising test

- 2.3. Pain-related trunk list
- 2.4. Painful spasm of the back when bending forward
- 3. Neck and shoulder region:
 - 3.1. Muscle weakness in the upper extremities related to the pain
 - 3.2. Head compression or movements induce radiating pain below elbow level
 - 3.3. Painful torticollis
- 4. Shoulder and upper extremity regions:
 - 4.1. Muscle weakness related to the pain
 - 4.2. Severe pain in movements interfering with most functions
- 5. Lower extremities:
 - 5.1. Pain prevents walking

Date of first enrolment

01/01/2008

Date of final enrolment

30/06/2009

Locations

Countries of recruitment

Finland

Study participating centre

Topeliuksenkatu 41 a A

Helsinki

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Sponsor information

Organisation

Finnish Institute of Occupational Health

ROR

<https://ror.org/030wyr187>

Funder(s)

Funder type

Government

Funder Name

Ministry of Social Affairs and Health, Social Insurance Department, the Finnish Work Environment Fund (ref. 106304)

Results and Publications

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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 01/03/2012 | | Yes | No |
| Results article | results | 01/01/2013 | | Yes | No |
| Protocol article | protocol | 25/02/2008 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |