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Effectiveness of early part-time sick leave in musculoskeletal disorders

Submission date	Recruitment status	[_] Prospectively registered
19/12/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/01/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/06/2013	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ttl.fi/osasairausvapaahanke

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Patient information in Finnish: http://www.ttl.fi/osasairausvapaa

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/01/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

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
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Sponsor information

Organisation
Finnish Institute of Occupational Health

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Sponsor type
Research organisation

Website
http://www.ttl.fi/internet/english

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

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	25/02/2008		Yes	No
Results article	results	01/03/2012		Yes	No
Results article	results	01/01/2013		Yes	No