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Efficacy of temporary work modifications on disability related to musculoskeletal pain and depressive symptoms

Submission date
11/10/2013

Recruitment status
No longer recruiting

Registration date
25/10/2013

Overall study status
Completed

Last Edited
27/04/2018

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Previous research suggests that continuing to work with a suitable workload is beneficial for people with muscular aches or depressive symptoms with regard to health, return to work and work retention in the long run. We will carry out a study to find out whether temporary work modifications are effective in helping workers with muscular pain or depressive symptoms to return to work or stay at work. The study's findings will give new knowledge about the possibilities of work modifications in enhancing recovery from musculoskeletal pain and depressive symptoms and the possibilities of enhancing return to work.

Who can participate?
Workers aged 18 to 60 who have sought medical advice in their occupational health service due to musculoskeletal pain or depressive symptoms will be invited to participate.

What does the study involve?
At the first stage of the study we will recruit workers and follow their symptoms and work disability for one year. At the second stage (intervention phase) seminars will be given to the participating occupational physicians about initiating temporary work modifications at the workplace. The physicians will then look carefully at the potential of temporary work modifications for eligible workers and initiate them when considered as beneficial.

What are the possible benefits and risks of participating?
Participating at the first stage does not involve benefits or risks to the worker. Participating at the second stage may improve recovery from pain or depressive symptoms. There is a possibility that the symptoms worsen if the work modifications are not adequate or you resume ordinary duties too early. In that case we will provide you a possibility to meet your doctor without delay.

Where is the study run from?
Finnish Institute of Occupational Health (Finland)

When is the study starting and how long is it expected to run for?
October 2013 to December 2017

Who is funding the study?
1. Finnish Work Environment Fund (Finland)
2. Academy of Finland (Finland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33713

Study information

Scientific Title
Efficacy of temporary work modifications on disability related to musculoskeletal pain and depressive symptoms: a non-randomised controlled trial

Study objectives
Our hypothesis is that continuing to work with a suitable workload is beneficial for subjects with musculoskeletal or depressive symptoms with regard to health outcomes, return to work and

work retention at a longer perspective. Moreover, temporary modification of workload will enhance return to work and work retention in subjects with musculoskeletal or depressive symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coordinating Ethics Committee of Hospital District of Helsinki and Uusimaa, 19/03/2013, ref: 35 /13/03/2013

Study design
Single-center controlled trial stepped-wedge design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Musculoskeletal pain, depressive symptoms

Interventions
We will apply the stepped wedge design, in which a group of participating occupational physicians recruits patients first to the control group and then starts to recruit patients to the intervention. Participating occupational physicians are enrolled to the study in small groups, who are first taught about the principles of the study (when starting to enrol controls) and will later participate in interactive seminars about how to initiate workplace modifications and discuss them with the workplace (when starting to recruit subjects to the intervention). This design enables the recruitment of cases and controls with a short time interval and we can thereby minimise the effects of changes in the work or societal environment on the results of the intervention.

Temporary work modifications prescribed by the occupational physician, e.g. workplace adaptations, amended duties, altered work hours or a phased RTW. Work modifications can be prescribed for a maximum of 1 month per visit and for a maximum of 3 months per disease spell.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
1. Sustained return to work (>4 weeks at work without a new sickness absence spell)
2. Total number of sickness absence days during 12 months following recruitment to the study

Secondary outcome measures
1. Intensity of musculoskeletal pain (VAS 0-10)
2. Interference of work (VAS 0-10) and sleep (VAS 0-10) by the pain and depressive symptoms (PHQ-9, http://www.terveysportti.fi), inquired via internet-based questionnaires at 0, 3, 6, 9 and 12 months after recruitment.

Overall study start date
28/10/2013

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Employees who seek medical advice in the occupational health service primarily due to musculoskeletal pain or depressive symptoms.
Specific inclusion criteria:
1. Age 18-60 years, male and female
2. Working full-time or nearly full-time (>30 hours per week)
3. Employed in current job for at least 4 months and employment likely to continue the following 12 months
4. Musculoskeletal pain (>4 on a scale of 0-10) or depressive symptoms (>1 positive response to two screening questions on depression (Arroll et al. BMJ. 2003 Nov 15;327(7424):1144-6)
5. Functional ability is not sufficient to perform current work tasks
6. Previous sickness absence <6 weeks during preceding 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Anticipated long absence from work during the following 12 months due to other reasons, e.g. pregnancy, studies, military service, alternation leave, absence due to other illness or its treatment (e.g. surgery, cytostatic therapy or radiation therapy)
2. Serious or acute disease requiring full sickness absence, e.g. febrile infection, active stage of inflammatory joint disease; serious mental disorder)
3. Other factors having significant effect on disability (e.g. serious conflict at the workplace, difficult personal life situation, current problem is due to a work accident, current insurance or workmen's compensation dispute, severe alcohol or drug dependency)

Date of first enrolment
28/10/2013

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
Finland

Study participating centre
Finnish Institute of Occupational Health
PL 40
Helsinki
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00251

Sponsor information

Organisation
The Finnish Work Environment Fund (Finland)

Sponsor details
Annankatu 34-36 B
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Sponsor type
Government

Website

http://www.tsr.fi

ROR
https://ror.org/02v046k89

Funder(s)

Funder type
Government

Funder Name
Finnish Work Environment Fund (Finland) (ref. 112257)

Alternative Name(s)
Finnish Work Environment Fund, Työsuojelurahasto Arbetarskyddsfonden, Työsuojelurahasto | Helsinki

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Finland

Funder Name
Academy of Finland (Finland) (ref. 267589)

Alternative Name(s)
Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Results and Publications

Publication and dissemination plan
One international peer-reviewed paper will be published on the main results.

27/04/2018: 2017 results in https://www.tsr.fi/documents/20181/478409/112257-loppuraportti-Tilap+Ty%C3%B6j%C3%A4rj+TSR+Loppuraportti+21.12.2017+FINAL.pdf

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated will not be made publicly available due to sensitivity of the data and the small number of participants.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/05/2015		Yes	No