Participatory interventions for return-to-work for temporary agency workers and unemployed workers sicklisted due to musculoskeletal disorders.
A randomised controlled trial and cost-effectiveness evaluation.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30328

Source
ToetsingOnline

Brief title
STEP-UP

Condition

- Other condition

Synonym
musculoskeletal complaints, musculoskeletal disorder

Health condition

aandoeningen van het houding- en bewegingsapparaat

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: UWV/Kenniscentrum Verzekeringsgeneeskunde (Postadres: MF-kamer C507;Postbus 7057;1007 MB Amsterdam;E-mail: info.kvg@vumc.nl;telefoon: (020) 444 5688))

Intervention

Keyword: cost-effectiveness, musculoskeletal disorder, sicklisted temporary agency worker and unemployed worker, temporary adapted work

Outcome measures

Primary outcome

Primary outcome measure of this study is the period of sickness absence till complete recovery according to the terms of the sick benefits law (the insurance physician gives a written statement of full recovery according tot the terms of the sick benefits law).
Without such statement there can already be actual return-to-work by the participant. This is also a relevant outcome measure. Therefore actual return-to-work (amount and duration) will also be measured.

Secondary outcome

Secundary outcome measures are health complaints and functional status, coping and self-efficacy, perceived workload, satisfaction with the counseling and participatory return-to-work method and direct and indirect costs.

Study description

Background summary

Musculoskeletal disorders are next to mental disorders, the most common cause for sickness absence and workdisability in the working population of the Netherlands and other countries. The same applies to the vulnerable working population, i.e. temporary agency workers and unemployed workers.
The number of applications for and awarded disability benefits is significantly higher among this group, than for sicklisted employees.
For the vunerable working population there is a need for new return-to-work methods, which aim at activating concrete return-to-work and which are evidence-based.
Recently a protocol for participatory ergonomics as a return-to-work intervention was developed for employees sicklisted 2 to 6 weeks due to nonspecific low back pain.
This workplace intervention accelerated return-to-work with an average of 27 days and evaluation by the employees and professionals was positive.
A comparable method for temporary agency workers and unemployed workers, sicklisted due to muscoloskeletal disorders, is not available at present and cost-effectiveness is unknown.

Study objective

For this study the aim was first to adjust the parcipatory return-to-work method for employees with nonspecific LBP to the working methods and procedures of the national organisation, responsible for counseling, disability management and activating return-to-work of sicklisted temporary agency workers and unemployed workers. For this adaptation 'Intervention Mapping' was used, a structured method for development of interventions.
Based on a needs assessment and contextanalysis a concept protocol was developed. Important stakeholders were involved in this proces, i.e. insurance physicians, workexperts, staff and management of the national organisation, temporary agency workers and temporary agencies.
Next further 'fine-tuning' of the protocol took place after focusgroup interviews with the insurance physians, workexperts, staff and management of the national organisation.
The cost-effectiveness and applicability of this return-to-work method for sicklisted temporary agency workers and unemployed workers with musculoskeletal disorders will be evaluated.

Study design

Randomized Controlled Trial (n= 2 x 80)

Intervention

The participants will be randomized for the participatory return-to-work method and usual care (= treatment and counseling according to the operative guidelines) or only usual care.
The participatory protocol for temporary adapted work is guided by a specially trained procescoach. The aim of the protocol is reaching consensus, after inventarisation of the obstacles for return-to-work, between the sicklisted temporary agency worker or unemployed worker, the occupational professional and other possible stakeholders, about suitable temporary adapted work to promote lasting return-to-work. The interventiongroup will also receive the usual care.

Study burden and risks

For the participants there are no or only slight risks connected to this study.
The participatory return-to-work method will cost about 5 1/2 to 6 hours for a participant. This consists of an half hour consult with an insurance physician, an hour consult with a workexpert and two times two hours for the participatory protocol.
Participants will be asked four times to fill in a questionnaire. Each questionnaire takes about 30 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Sicklisted temporary agency workers and unemployed workers
Sickness absence between 2 and 8 weeks.
Sicklisted due to musculoskeletal complaints/disorders.
Age between 18 and 65 years.
Sufficient knowledge of the Dutch language.

Exclusion criteria

Sickness absence longer than 8 weeks.
Objection procedure concerning sick benefits or disability benefits.
Serious physical illness, such as malignant disease, terminal disease.
Psychiatric comorbidity.
Cardiovasculair comorbidity.
Pregnancy till 3 months after delivery.
Expected complete absence of workability on medical grounds for 3 months or longer (according to the terms in the sick benefits law).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL14533.029.06