Reintegration and Rehabilitation of patients at risk for job loss/work disability due to a Rheumatic condition (3R-project)

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The present study will evaluate the logistics and especially the effectiveness of the proposed multi-component intervention. The results will be an important factor for decisions on the further exploitation of the RRR foundation.

Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON36004

Source
ToetsingOnline

Brief title
3R-project

Condition

- Joint disorders

Synonym
non-traumatic complaints of the musculoskeletal system, rheuma

Research involving
Human

Sponsors and support

Primary sponsor: Stichting RRR (Reumacentrum Reintegratie Revalidatie)

Source(s) of monetary or material Support: Europese Unie (EFRO);Rijk en Provincie Limburg

Intervention

Keyword: rehabilitation, reintegration, rheumatic disorders, worker productivity

Outcome measures

Primary outcome

- Successful re-integration of an employee (worker) in their own work or adjusted (own) work in the same workplace within 16-18 weeks from the first day of sick leave (first day of the 16th week + 2 weeks) and sustained up to 6 months after the start of the sickness episode

Secondary outcome

- Successful reintegration within 16 weeks (+ 2 weeks) after the start of sickness-absence episode and after 6 months in any work (also at another workplace)
- Successful reintegration within 16 - 18 weeks or 6 months (in own (adapted) work or any work
- Sick leave in the follow-up period during the 6 months follow-up/ successfully reintegrated after the intervention but not at follow-up
- Improvement on HR-QoL after 16 weeks and 6 months
- Improvement of work productivity (presenteeism) after 16 weeks and 6 months

in all patients

- Incremental costs and consequences at the patient level, incremental cost per

QALY and incremental cost per additional successful integrated worker

- Evaluation of the RRR program and implementation in a larger referral setting

(unlimited inclusion)

Study description

Background summary

In the Netherlands, rheumatic conditions (non-traumatic complaints of the musculoskeletal system) are frequently diagnosed within the working population (18-65y). They are known as the second major cause of new cases of work disability.
Work loss does not only contribute to productivity loss at the level of the workplace and for society, but there are also indications that it can have adverse effects on emotional and physical health. Interventions aimed to improve work participation are usually complex. In the south of the Netherlands no holistic approach for a case management is available for workers at risk for job loss/work disability due to rheumatic condition.
RRR is a new foundation aiming to provide holistic care to workers with health related problems at the workplace in order to avoid long-term sickness absence and work disability.

Study objective

The present study will evaluate the logistics and especially the effectiveness of the proposed multi-component intervention. The results will be an important factor for decisions on the further exploitation of the RRR foundation.

Study design

It is aimed to perform a randomized controlled trial in which patients that fulfill eligibility criteria will be included on a weekly basis either into a multi-component vocational reintegration program or receive care as usual. Patients will be stratified according to rheumatological diagnosis into three groups (each =50): inflammatory rheumatic disease; degenerative rheumatic disease; local or generalised aspecific pain syndrome)

Intervention

Workers that are included in the re-integration program will receive a partly individualised multi-component reintegration program for a period of four weeks assuming total treatment duration of 30 hours per week. Subjects that are not

included in the program can receive care as usual. Individualized components are potentially added after screening the patient.

Study burden and risks

N/A

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Participants have absence from paid work due to a non-traumatic complaint of the musculoskeletal
system for a maximum of 10-12 weeks when referring

- They have (a) an employment contract for a minimum of 18 hours per
week and have an employment contract for at least one year after the start of the sickness episode and a duration at least another year after the randomization or (b) being self-employed/entrepreneur
-They experienced in the In the year preceding the start of the present sickness episode a maximum of in total 6 weeks sickness (30 days) or proportion according to the level of contractual hours.
- A non-traumatologic rheumatologic condition /complaint of the musculoskeletal
system is confirmed by a physician (which can be general practitioner, occupational physician or
medical specialist)
- Intrinsic motivation to return to own work (or adjusted work with the same employer) after the
program
- Commitment of the employer to collaborate in the re-integration program
- Commitment of the employee to take part in a four weeks
re-integration program

Exclusion criteria

Severe co-morbidity interfering with the RRR program such as
- Severe endogenous depression
- Severe cardial or pulmonary disease interfering with the re-integration program
- Insufficient knowledge of the Dutch language to be able to complete the study-questionnaires

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Not approved

Date:	29-09-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL37127.068.11