

Cost-effectiveness of vocational rehabilitation for workers on sick leave due to subacute or chronic musculoskeletal pain

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1) For workers on sick leave due to subacute or chronic musculoskeletal pain, is a 40 hours vocational rehabilitation program non-inferior on work participation compared with a 100 hours vocational rehabilitation program? 2) For workers on sick...

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|------------------------------|---------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Other condition |
| Study type | Interventional |

Summary

ID

NL-OMON39941

Source

ToetsingOnline

Brief title

Cost-effectiveness of vocational rehabilitation for chronic pain

Condition

- Other condition

Synonym

chronic musculoskeletal disorders, chronic musculoskeletal pain

Health condition

chronische pijn aan houdings- en bewegingsapparaat

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Stichting Heliomare

Intervention

Keyword: Cost-effectiveness, Musculoskeletal, Pain, Vocational Rehabilitation

Outcome measures

Primary outcome

The primary outcome in this study is work participation, expressed as cumulative sick leave days due to subacute or chronic musculoskeletal pain during the training period and from discharge until 12-months follow-up.

Secondary outcome

Productivity loss, work ability, disability, quality of life, and physical functioning.

Study description

Background summary

Chronic musculoskeletal pain is a major health problem associated with decreased functioning and quality of life, sick leave, and increased direct and indirect medical costs. The majority of the costs (77-93%) are contributed to indirect costs due to sick leave from work or productivity loss while at work. Chronic musculoskeletal pain arises when acute musculoskeletal pain does not recover within six weeks, which occurs in 10-20% of the cases. Arbitrary after six weeks duration it is considered subacute musculoskeletal pain (SMP), and if the pain is still present after 12 weeks it is considered chronic musculoskeletal pain (CMP). If there is no clear medical explanation, the chronic musculoskeletal pain is called ****non-specific****. Vocational rehabilitation is a widely advocated intervention for absent workers with subacute or chronic non-specific musculoskeletal pain. Vocational rehabilitation is ****a multi-professional evidence-based approach that is**

provided in different settings, services, and activities to working age individuals with health-related impairments, limitations, or restrictions with work functioning, and whose primary aim is to optimize work participation^{**}. Research shows that vocational rehabilitation improves return to work. However, the dose-effect relation of (cost-)effective vocational rehabilitation is unclear. In literature and in vocational rehabilitation practice, there are two programs presented: extensive (>100 treatment hours) and moderate (≤40 treatment hours) vocational rehabilitation. There are two assumptions for the (cost-)effectiveness of these two programs. The first assumption is mainly based on one randomized controlled trial in which extensive vocational rehabilitation was compared with moderate vocational rehabilitation and usual care for workers on sick leave due to chronic musculoskeletal pain. Participants were classified based on prognosis for return to work, i.e. good, medium, or poor, and randomized to one of the three groups. The study found that patients classified with poor prognosis benefited most from the extensive program, and patients classified with medium prognosis benefited both from the moderate and extensive program on return to work. In addition, in a cost-effectiveness study which included the same study population (but without the classification), only the moderate program showed significant cost-effectiveness, and only in men. The second assumption is that moderate programs may be non-inferior or even superior compared with extensive programs in facilitating return to work and cost-effectiveness in patients with subacute or chronic musculoskeletal pain. This assumption is confirmed by a systematic review in which it was found that vocational rehabilitation programs comprising <32 treatment hours were more effective on return to work (RR = 1.45) in people with sick leave from work because of subacute or chronic musculoskeletal pain compared with more extensive vocational rehabilitation programs, comprising 33-70 treatment hours (RR = 1.09) or more than 70 treatment hours (RR = 1.00). However, the same review stated that these findings may reflect on subacute musculoskeletal pain, and that for the ^{**}difficult chronic cases^{**} extensive programs might be more (cost-)effective compared with moderate programs, as also stated in the first assertion. In summary, the optimal dosage of (cost-)effective vocational rehabilitation is currently unknown. Patients with difficult chronic cases with poor prognosis for return to work may benefit most from extensive programs, but other research suggests that moderate programs might be non-inferior or even superior compared with extensive programs. These findings have led to the hypotheses that there is non-inferiority on return to work between moderate and extensive vocational rehabilitation, and that there will be differences in cost-effectiveness in favour of the moderate program.

Study objective

- 1) For workers on sick leave due to subacute or chronic musculoskeletal pain, is a 40 hours vocational rehabilitation program non-inferior on work participation compared with a 100 hours vocational rehabilitation program?
- 2) For workers on sick leave due to subacute or chronic musculoskeletal pain, is a 40 hours vocational rehabilitation program more cost-effective compared

with a 100 hours vocational rehabilitation program?

Study design

A multi-center, randomized, 12-month follow-up, non-inferiority study design will be performed to evaluate the effectiveness and cost-effectiveness on return to work of 40 hours versus 100 hours of vocational rehabilitation for patients with subacute or chronic musculoskeletal pain and with sick leave from work.

Intervention

Reference 100 hours intervention:

The reference intervention is delivered over 15 weeks with two sessions (~3,5 h / session) per week. The reference intervention encompasses several modules: return to work coordination, graded activity, cognitive behavioural therapy, group education, and relaxation. The reference intervention consists of approximately 100 hours, and is an existing vocational rehabilitation intervention program in the Netherlands; conducted by fourteen rehabilitation centers, and of which four will participate in this study.

Experimental 40 hours intervention:

The experimental program lasts maximally 40 hours in 15 weeks. The experimental intervention consists of return to work coordination (10 hours), 30 hours which is dependent of the primary restriction of the client, and is a specific program of multidisciplinary modules.

In case: 1) patient has achieved 25-50% return to work (RTW) improvement (RTW improvement: the percentage of hours at work per week pertaining to contract hours at the end of the experimental program, compared with hours at work per week pertaining to contract hours at baseline), and, 2) when the training team expresses strong arguments that the patient will likely benefit from elongation, the program will be elongated. However, this may occur in no more than 5% of the cases.

Study burden and risks

There are no apparent risks for the participant being assessed by this study.

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

- 1) Working age individuals (18-65 years)
- 2) Suffering from subacute (6-12 weeks) or chronic non-specific musculoskeletal pain (>12 weeks) such as back, neck, shoulder, widespread pain, whiplash (WAD I or II), or fibromyalgia
- 3) Having paid work (employed or self-employed) for at least 12 hours per week
- 4) The expectation that there will be no termination of the employment or self-employment in the year following the vocational rehabilitation program
- 5) Having short-term (<6 weeks) or long-term (≥6 weeks) part-time or full-time sick leave
- 6) Being able to understand Dutch and to complete questionnaires in Dutch
- 7) Having the motivation to participate in the vocational rehabilitation program aimed to optimize work participation
- 8) Reimbursement of the program costs that are not covered by health care insurers
- 9) Having an email address
- 10) Having signed informed consent.

Exclusion criteria

- 1) having comorbidities which are the primary reason for sick leave, such as clinical

depression or burnout, severe asthmatic symptoms, diagnosed chronic fatigue, and neuropathy

2) having a conflict with the employer, which is the primary reason for sick leave

Study design

Design

| | |
|---------------------|-----------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 14-11-2014 |
| Enrollment: | 174 |
| Type: | Actual |

Ethics review

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|--------------------|--------------------|
| Approved WMO | |
| Date: | 07-02-2014 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO | |
| Date: | 28-08-2014 |
| Application type: | Amendment |
| 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

ID: 29456

Source: NTR

Title:

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL41874.018.13 |
| OMON | NL-OMON29456 |