Cost-effectiveness of vocational rehabilitation for chronic pain

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29456

Source
NTR

Brief title
Vocational Rehabilitation, Cost-effectiveness, Musculoskeletal, Pain

Health condition

Subacute musculoskeletal pain, chronic musculoskeletal pain, sick leave.
In Dutch: subacute klachten aan het houdings- en bewegingsapparaat, chronische klachten aan het houdings- en bewegingsapparaat, ziekteverzuim

Sponsors and support

Primary sponsor: Academic Medical Centre (Amsterdam).
Source(s) of monetary or material Support: Stichting Heliomare; Relweg 51 1949 EC Wijk aan Zee; Postbus 87 1940 AB Beverwijk; T 0889208148; c.van.bennekom@heliomare.nl

Intervention

Outcome measures

Primary outcome

The primary outcome in this study is work participation expressed as total sick leave days due to subacute or chronic musculoskeletal pain during the intervention period and from

discharge until 12-months follow-up. Sick leave will be measured using the absenteeism subscale of the iMTA (institute for Medical Technology Assessment) Productivity Cost Questionnaire (iPCQ), which measures sick leave on working days. The questionnaire has a recall period of 4 weeks and measures sick leave on a generic basis. We have made slight adaptations to measure sickness absence specifically related to subacute or chronic musculoskeletal pain, or other reasons such as flu. The iPCQ is the result of combining two existing Dutch questionnaires (i.e. PRODISQ and SF-HLQ), and is recommended by the Dutch guideline for health economic evaluations.

Secondary outcome

- Work ability will be measured using a single item of the Work Ability Index (WAI). The current work ability compared to lifetime best work ability can be scored on a 0-10 response scale, where 0 represents completely unable to work and 10 represents work ability at its best.

- Disability will be measured using the Pain Disability Index (PDI). The PDI is a 7-item questionnaire to investigate the magnitude of the self-reported pain-related disability, independent of region of pain or pain-related diagnosis. The PDI measures family/home responsibilities, recreation, social activity, occupation, sexual behaviour, self-care, and life support activity. The questionnaire is constructed according to a 0-10 numeric rating scale in which 0 means no disability and 10 maximum disability. Total scores can range from 0 to 70, with higher scores reflecting higher interference of pain with daily activities.

- Physical functioning will be measured using the physical functioning subscale of the RAND-36. The questionnaire assesses self-reported physical functioning independent of (pain) diagnosis. The physical functioning scale consists of 10 questions with three possible answers: yes, limited a lot, yes, limited a little, and no, not limited at all. The total score can range from 0 to 100, with higher scores indicating better physical functioning. The validity and reliability of the Dutch version are good.

- Quality of life. To allow comparison between several conditions and interventions, Quality Adjusted Life Years (QUALYs) will be calculated from the validated Dutch version of the EuroQol-5D (EQ-5D). The EQ-5D measures five dimensions: mobility, self-care, activities of daily life, pain and anxiety/depression on a categorical scale (1-3). The EQ-5D is a widely employed instrument used to assess health-related quality of life (QoL), and is recommended by the Dutch guideline for health economic evaluations.

Cost-effectiveness outcomes
The following outcomes will be assessed to evaluate the cost-effectiveness of the two programmes employed in this study.

- Presenteeism will be assessed using the presenteeism subscale of the iPCQ. The questionnaire measures the total days of mental or physical complaints at work, with a recall period of 4 weeks. The amount of work performed accompanied by mental or physical complaints are measured on a 0-10 response scale, where 0 represents I couldn't do anything, to 5 I could do about half as normal, to 10 I could do the same as normal.

- Health care usage will be assessed using the Trimbos iMTA questionnaire for measuring Costs of Psychiatric Illnesses (TiC-P), module 1. A recall period of 4 weeks is used in this questionnaire. Visits and consultations of the following health care providers were measured: general practitioner, physiotherapist, manual therapist, exercise therapist, occupational therapist, psychologist, insurance physician, medical specialists in hospitals, hospitalization (number of days), occupational physician, social worker, and dietician. Additional items were alternative care, home care, medication use, and job-related care like job coaches, ergonomic changes at the work site and reintegration specialists. Slight adaptations in the context and scope of health care practitioners were made to better match TiC-P to the target population (i.e. from psychiatry to pain and work). Another modification was that visits and consultations were measured in both generic and sickness-specific terms. Research shows that health care usage assessment by means of self-reported questionnaires is reliable.

Study description

Background summary

Background: Although vocational rehabilitation is a widely advocated intervention for workers on sick leave due to subacute or chronic non-specific musculoskeletal pain, the optimal dosage of effective and cost-effective vocational rehabilitation remains unknown. The objective of this paper is to describe the design of a non-inferiority trial evaluating the effectiveness and cost-effectiveness of a 100-hour multidisciplinary vocational rehabilitation programme compared with a 40-hour multidisciplinary vocational rehabilitation programme on work participation for workers on sick leave due to subacute or chronic musculoskeletal pain.
Methods: A non-inferiority study design will be applied. The study population consists of workers who are on part-time or full-time sick leave because of subacute or chronic non-specific musculoskeletal pain. Two multidisciplinary interventions following the bio-psychosocial approach will be evaluated in this study: a reference intervention of ~100 treatment hours and an experimental intervention of ~40 treatment hours, both delivered over a maximum of 15 weeks. The content of the reference intervention comprises five modules: work participation coordination, graded activity, cognitive behavioural therapy, group education, and relaxation. The content of the experimental intervention comprises work participation coordination and a well-reasoned choice from the other four modules. Four rehabilitation centres participate in this study, with each delivering both interventions. Patients will be randomized into one of the interventions, stratified for the duration of sick leave (<6 weeks or ¡Ý6 weeks) and type of sick leave (part-time or full-time). The primary outcome is work participation, measured by self-reported sick leave days, and will be assessed at baseline, mid-term, discharge, and at 2, 4, 6, 8, 10, and 12 months follow-up. Secondary outcomes are work ability, disability, quality of life, and physical functioning, and will be assessed at baseline, discharge, and at 6 and 12 months follow-up. Cost-effectiveness outcomes are absenteeism, presenteeism, and health care usage. Cost-effectiveness will be evaluated from the societal and employer perspective.
Discussion: The results obtained from this study will be useful for vocational rehabilitation

practice, and will provide stakeholders relevant insights into two versions of vocational rehabilitation.

The study will be performed in four vocational rehabilitation centres in the Netherlands.

Study objective

There is non-inferiority on return to work between moderate (40-hour) and extensive (100-hour) vocational rehabilitation, and there will be differences in cost-effectiveness in favour of the moderate program.

Study design

Self-reported data will be collected using web-based questionnaires at baseline (T0), mid-term (T1), at discharge (T2), and at 2, 4, 6, 8, 10 and 12 months follow-up after discharge (T3-T8). At each data point, participants will receive an email with login data and the request to complete questionnaires on a website. If participants do not complete the questionnaire within a week, they will be reminded by email. If the questionnaires are not completed after this reminder, patients will be telephoned by a researcher (TB).

Primary outcome T0-T8
Secundaire outcomes:
- WAI: T0, T2, T5, T8
- RAND-36: T0, T2, T5, T8
- PDI: T0, T2, T5, T8
- EQ-5D: T0, T2, T5, T8
- TiC-P: T0, T2, T4, T6, T8
- iPCQ (presenteeism): T0-T8

Intervention

Experimental 40-hour intervention
The experimental intervention is a multidisciplinary bio-psychosocial group-based vocational rehabilitation programme, and consists of work participation coordination (10 hours), and a choice of 30 hours of a set of modules offered in the reference intervention, such as graded activity, cognitive behavioural therapy, group education, and relaxation. These modules are described in detail in additional file 1. Since the choice of 30 hours of modules will be prioritized by the professionals after the multidisciplinary screening at baseline, the content may differ per patient. The experimental programme lasts a maxim of 40 hours in 15 weeks. The programme will be extended if: a 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 programme, compared with hours at work per week pertaining to contract hours at baseline), and the team expresses strong arguments that the patient will likely benefit from the extension. However, this should occur in no more than 5% of the cases.

Reference 100-hour intervention

The reference intervention is a multidisciplinary bio-psychosocial group-based vocational rehabilitation programme, and encompasses a set of modules: work participation 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 programme in the Netherlands conducted by fourteen rehabilitation centres, four of which will participate in this study. The reference intervention is delivered over a period of 15 weeks with two sessions (~3,5 h / session) per week. The reference intervention in this trial appears similar to other trials in the vocational rehabilitation field, but the reference programme has a longer duration (in weeks) and there are more graded activity hours as compared with similar studies.

Contacts

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Eligibility criteria

Inclusion criteria

The inclusion criteria for this study are: 1) individuals of working age (18-65 years); 2) suffering from subacute (6-12 weeks) or chronic (>12 weeks) non-specific musculoskeletal pain such as back, neck, shoulder, widespread pain, Whiplash Associated Disorder (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 the employment or self-employment will not be terminated in the year following the vocational rehabilitation programme; 5) having short-term (<6 weeks) or long-term (¡Ý6 weeks) part-time or full-time sick leave; 6) being able to understand Dutch and able to complete questionnaires in Dutch; 7) having the motivation to participate in the vocational rehabilitation programme aimed at optimizing work participation; 8)

reimbursement of the programme costs that are not covered by health care insurers; 9) having an email address; and 10) having granted informed consent.

Exclusion criteria

The exclusion criteria for this study is having comorbidities that are the primary reason for sick leave, such as acute or specific medical problems, clinical depression or burnout, severe asthmatic symptoms, diagnosed chronic fatigue, and neuropathy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	05-05-2014
Enrollment:	174
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-03-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39941
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4209
NTR-old	NTR4362
CCMO	NL41874.018.13
OMON	NL-OMON39941

Study results

Summary results
Cost-effectiveness of Moderate versus Extensive Vocational Rehabilitation on Work After receivement of a NTR number from the Dutch Trial Register we will submit the following article to BMC Musculoskeletal Disorders.

Title: Participation for Workers on Sick Leave due to Subacute or Chronic Musculoskeletal Pain: Design of a Non-inferiority Study