

# Cost-effectiveness of vocational rehabilitation for chronic pain

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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.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving tijdelijk gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON29456

### Bron

NTR

### Verkorte titel

Vocational Rehabilitation, Cost-effectiveness, Musculoskeletal, Pain

### Aandoening

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

## Ondersteuning

**Primaire sponsor:** Academic Medical Centre (Amsterdam).

**Overige ondersteuning:** Stichting Heliomare; Relweg 51 1949 EC Wijk aan Zee; Postbus 87 1940 AB Beverwijk; T 0889208148; c.van.bennekom@heliomare.nl

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

## Toelichting onderzoek

### Achtergrond van het onderzoek

**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 ≥6 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.

## **Doel van het onderzoek**

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.

## **Onderzoeksopzet**

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

## **Onderzoeksproduct en/of interventie**

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 maximum 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.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 (≥6 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.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

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.

## **Onderzoeksopzet**

### **Opzet**

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

### **Deelname**

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	05-05-2014
Aantal proefpersonen:	174
Type:	Verwachte startdatum

## **Ethische beoordeling**

Positief advies	
Datum:	17-03-2014
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39941

Bron: ToetsingOnline

Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

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

## Resultaten

### Samenvatting resultaten

Cost-effectiveness of Moderate versus Extensive Vocational Rehabilitation on Work After receipt 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