

# Cost-effectiveness of physical training for self-employed persons with musculoskeletal disorders: the FysiOke study.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON23791

### Source

NTR

### Brief title

FysiOke

### Intervention

### Outcome measures

#### Primary outcome

Disability and Return to Work. These outcomes are measured at baseline and 6 and 12 months follow-up. The required information becomes available by registration of the insurance company.

#### Secondary outcome

Level of pain and functional restrictions. These outcomes are also measured at baseline and 6 and 12 months follow-up. The required information is gathered by self-report of participants through questionnaires.

# Study description

## Background summary

Objective:

To evaluate the cost-effectiveness of physical training in the reduction of musculoskeletal disorders and disability.

Both the insurance company and the Dutch government wants to know if this physical training is more cost-effective than usual care. Therefore, we started a randomised controlled trial (RCT) of 300 self-employed persons with MSDs. Participants are randomly assigned to either physical training, or usual care. Outcome measures are level of pain, functional restrictions, disability and return-to-work. Data are collected by questionnaire at baseline and at 6 and 12 months follow-up. These questionnaires contain questions on kind of job, physical and mental workload (VBA), type of complaints (Kuorinka), level of pain (VAS), functional restrictions (NDI, QBPDS), fear of movement (Tampa), treatment, return-to-work, general health and demographic variables. Additionally, data are derived from the insurance company (disability, costs) and physical training institutes (compliance). Besides, we started a cohort of persons who do not want to take part in the RCT but are willing to fill in the questionnaires. This gives us the opportunity to add these persons to the RCT population when possible or to change the study design when necessary.

Anticipated trial start date:

The study has started in July 2004, but inclusion of participants started at November 1th 2004.

Recruitment status:

At August 10th 2005 91 participants were included in the study.

## Study objective

N/A

## Study design

N/A

## Intervention

1. Psysical training;

## 2. Usual care.

Participants in the intervention group will receive physical training by a physiotherapist. This tailored training takes place 2 or 3 times a week during three months and consists of cardiovascular training, strengthening, relaxation and posture exercises. During an intake meeting each participant is screened for medical or physical contra indications and aspects of motivation. Participants in the control group will receive usual care mostly by general practitioner or physiotherapist (or no treatment at all).

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

All insured persons submitting a new disability payment because of musculoskeletal disorders and who are eligible for physical training according to standard procedures of Interpolis.

### **Exclusion criteria**

Insured persons with musculoskeletal disorders indicating a specific treatment, e.g. an operation (for a slipped disk) or an injection (for an inflammation).

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2004
Enrollment:	300
Type:	Actual

## Ethics review

Positive opinion	
Date:	06-07-2005
Application type:	First submission

## 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

<b>Register</b>	<b>ID</b>
NTR-new	NL40
NTR-old	NTR67
Other	: N/A
ISRCTN	ISRCTN67766245

## Study results

### Summary results

N/A