

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

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/06/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Judith Heinrich

Contact details
TNO Quality of Life
P.O. Box 718
Hoofddorp
Netherlands
2130 AS
+31 (0)23 55499922
judith.heinrich@tno.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR67

Study information

Scientific Title

Acronym

FysiOke

Study objectives

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 musculoskeletal disorders (MSDs).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee approved

Study design

Randomised active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Musculoskeletal disorders (MSDs)

Interventions

1. Physical training
2. Usual care

Participants in the intervention group will receive physical training by a physiotherapist. This tailored training takes place two or three 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 contraindications and aspects of motivation. Participants in the control group will receive usual care mostly by general practitioner or physiotherapist (or no treatment at all).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Disability
2. 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 measures

1. Level of pain
2. 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.

Overall study start date

01/07/2004

Completion date

31/12/2007

Eligibility

Key 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.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

300

Key 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).

Date of first enrolment

01/07/2004

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

TNO Quality of Life

Hoofddorp

Netherlands

2130 AS

Sponsor information

Organisation

TNO Quality of Life (The Netherlands)

Sponsor details

P.O. Box 718

Hoofddorp

Netherlands

2130 AS

Sponsor type

Research organisation

ROR

<https://ror.org/01bnjb948>

Funder(s)

Funder type

Government

Funder Name

Interpolis (a Dutch insurance company) (The Netherlands)

Funder Name

The Dutch Ministry of Health, Welfare and Sports (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/06/2009		Yes	No