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

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/06/2009	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised active controlled parallel group trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

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