

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

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N/A

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23791

Bron

NTR

Verkorte titel

FysiOke

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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, QBPS), 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.

Doel van het onderzoek

N/A

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2004
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	06-07-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL40
NTR-old	NTR67
Ander register	: N/A
ISRCTN	ISRCTN67766245

Resultaten

Samenvatting resultaten

N/A