# Cost effectiveness of an occupational physical therapy programme on primary and secondary prevention of low back pain: economic evaluation alongside a cluster randomised controlled trial

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
02/11/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
02/11/2005	Completed	[X] Results		
<b>Last Edited</b> 29/10/2008	<b>Condition category</b> Musculoskeletal Diseases	Individual participant data		

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

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#### Additional identifiers

EudraCT/CTIS number

**IRAS** number

#### ClinicalTrials.gov number

### Secondary identifying numbers

**NTR395** 

# Study information

#### Scientific Title

#### Study objectives

What is the cost-effectiveness of a back training programme consisting of a combination of three parts: counselling and training to prevent back complaints, analysis and ergonomic adaptation of the work station, and quick intervention in the origin of (absenteeism due to) back complaints?

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Received from a local medical ethics committee

#### Study design

Economic evaluation alongside a cluster randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Prevention

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Low back pain (LBP)

#### **Interventions**

The physical therapy programme consists of an integrated approach of a primary prevention programme, including counselling and ergonomic training of working techniques/skills tailored for each companys specific work-site aimed at preventing back complaints, and a secondary prevention programme that consisted of a quick intervention with easy accessible in-company physical therapy in the origin of (absenteeism due to) back complaints.

Usual care is provided by the general practitioner or occupational physician according to Dutch health care guidelines.

#### **Intervention Type**

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

The primary outcome measure is the occurrence and duration of LBP and subsequent sickness absence.

#### Secondary outcome measures

Secondary outcome measures are pain intensity, functional disability due to low back pain complaints, general health and quality of life. The economic evaluation is conducted from a societal perspective and includes both direct and indirect costs due to LBP.

#### Overall study start date

15/01/2001

#### Completion date

15/08/2005

# Eligibility

#### Key inclusion criteria

The study population is recruited from companies throughout the Netherlands. Companies who want to take up the programme from the occupational health consultancy that executes the intervention under study within a year are asked to participate in the study.

Inclusion criteria for companies are:

- 1. Willingness to participate in the study
- 2. The possibility of forming a control group within the same company with workers with approximately the same physically demanding jobs and high prevalence of musculoskeletal complaints
- 3. Willingness to concur with randomisation of the intervention and study protocol.

#### Inclusion criteria for workers:

All workers in the work units of these companies who are working at least 3 days per week, are willing to comply with the research protocol and follow-up measurements are asked to participate in the study.

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

Both

#### Target number of participants

500

#### Key exclusion criteria

Does not comply with the above inclusion criteria

#### Date of first enrolment

15/01/2001

#### Date of final enrolment

15/08/2005

#### Locations

#### Countries of recruitment

Netherlands

# Study participating centre Erasmus Medical Center Rotterdam

Rotterdam Netherlands 3000 DR

# Sponsor information

#### Organisation

Erasmus Medical Center Rotterdam (The Netherlands)

#### Sponsor details

P.O. Box 1738 Rotterdam Netherlands 3000 DR

#### Sponsor type

Research organisation

#### **ROR**

https://ror.org/018906e22

# Funder(s)

#### Funder type

Research organisation

#### Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (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	01/04/2007		Yes	No