# Effectiveness of behavioural graded activity compared with physiotherapy treatment in chronic neck pain: a randomised clinical trial

Submission date Recruitment status Prospectively registered 14/09/2004 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 15/09/2004 Completed [X] Results [ ] Individual participant data Last Edited Condition category Musculoskeletal Diseases 15/04/2009

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

**Prof Bart Koes** 

#### Contact details

PO Box 1738 Rotterdam Netherlands 3000 DR +31 (0)10 4087620 b.koes@erasmusmc.nl

## Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

#### Scientific Title

#### **Acronym**

Ephysion (Effectiveness Physiotherapy in Neck pain)

## **Study objectives**

A randomised clinical trial (RCT) has been designed to assess the effectiveness of behavioural graded activity compared with physiotherapy treatment in patients with chronic non-specific neck pain.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The study design has been approved by the Medical Ethics Technical Commission of the Erasmus MC, University Medical Centre in Rotterdam and is in compliance with the Helsinki Declaration.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

Chronic non-specific neck pain

#### **Interventions**

The behavioural graded activity program is based on an operant approach, which uses a time-contingent method to increase the patient's activity level. This program is compared with a physiotherapy treatment using a pain-contingent method.

## Intervention Type

Other

#### Phase

**Not Specified** 

## Primary outcome measure

'Global perceived effect' (neck complaint and functioning in daily activities) (1 - 7 on the Likert scale), measured at 4, 9, 26 and 52 weeks.

## Secondary outcome measures

- 1. Main complaint (0 10 on the Likert scale), measured at baseline, 4, 9, 26 and 52 weeks
- 2. Pain (Visual Analogue Scale [VAS]), measured at baseline, 4, 9, 26 and 52 weeks
- 3. Medical consumption (dose per day), measured at baseline, 4, 9, 26 and 52 weeks
- 4. Coping with Multi-dimensional pain (Multidimensional Pain inventory [MPI] Part I-II and 0 6 on the Likert scale), measured at baseline, 9, 26 and 52 weeks
- 5. Activity (MPI, part III) (0 6 on the Likert scale), measured at baseline, 4, 9, 26 and 52 weeks
- 6. Specific functional status (Neck Disability Index [NDI]), measured at baseline, 4, 9, 26 and 52 weeks
- 7. Quality of life, measured using the 36-item Short Form (SF-36) at baseline, 9, 26 and 52 weeks, and the Euroquol 5-Dutch language version (EQ-5d) at baseline, 4, 9, 26 and 52 weeks
- 8. Work activities Hours/week, measured at baseline, 9, 26 and 52 weeks
- 9. Satisfaction about treatment (1 5 on the Likert scale), measured at 4, 9 and 26 weeks
- 10. Compliance with treatment exercise (number and time per week), measured at 4, 9, 26 and 52 weeks
- 11. Additional treatments Discipline and number of treatments, measured at 4, 9, 26 and 52 weeks
- 12. Side-effects (yes no and any additional elucidation), measured at 4, 9, 26 and 52 weeks

## Overall study start date

01/01/2004

## Completion date

31/12/2005

# **Eligibility**

## Key inclusion criteria

- 1. Aged between 18 and 70 years old
- 2. Have suffered from neck pain for over three months
- 3. Have an adequate knowledge of the Dutch language

Excluded are patients diagnosed with a specific disorder (e.g. a slipped disc, a tumour or a lesion in the cervical spine), those who have had physical/manual therapy during the previous six months, those with a chronic disease (e.g. rheumatoid arthritis or coronary artery disease), or those who have to undergo surgery in the near future.

## Participant type(s)

Patient

## Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

## Target number of participants

80 per treatment group (160 total)

## Key exclusion criteria

- 1. Diagnosed with a specific disorder (e.g. a slipped disc, a tumour or a lesion in the cervical spine)
- 2. Have had physical/manual therapy during the previous six months
- 3. With a chronic disease (e.g. rheumatoid arthritis or coronary artery disease)
- 4. Who have to undergo surgery in the near future

#### Date of first enrolment

01/01/2004

#### Date of final enrolment

31/12/2005

## Locations

#### Countries of recruitment

Netherlands

## Study participating centre

**PO Box 1738** 

Rotterdam Netherlands 3000 DR

## Sponsor information

## Organisation

Erasmus Medical Centre (Netherlands)

### Sponsor details

Dept. of General Practice PO Box 1738 Rotterdam Netherlands 3000 DR +31 (0)10 4087613 b.koes@erasmusmc.nl

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.erasmusmc.nl/

#### ROR

https://ror.org/018906e22

# Funder(s)

## Funder type

Government

#### **Funder Name**

The Dutch Health Care Insurance Board (College voor zorgverzekeringen [CVZ]) (Netherlands) (ref: DPZ 01-01)

## **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?
<u>Protocol article</u>	Protocol	06/10/2004		Yes	No
Results article	results	01/05/2009		Yes	No