

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

Submission date 14/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/09/2004	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 15/04/2009	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

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Additional identifiers

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 Euroqol 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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	01/05/2009		Yes	No
Protocol article	Protocol	06/10/2004		Yes	No

