ISRCTN88733332 https://doi.org/10.1186/ISRCTN88733332

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

Registration date
15/09/2004

Overall study status
Completed

Last Edited
15/04/2009

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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?
Protocol article	Protocol	06/10/2004		Yes	No
Results article	results	01/05/2009		Yes	No