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Comparison of the effectiveness of a behavioural graded activity program and manual therapy in patients with sub-acute neck pain

Submission date
20/02/2007

Recruitment status
No longer recruiting

Registration date
20/02/2007

Overall study status
Completed

Last Edited
24/02/2009

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZonMw: 940-31-060, NTR81

Study information

Scientific Title

Study objectives
A behavioural graded activity program will be more effective than manual therapy in patients with sub-acute neck pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medisch Ethische Toestingscommssie (METC) VUmc on 23/10/2002 (ref: 2002/127).

Study design
Randomised, active controlled, parallel group, double blinded trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Neck complaints

Interventions
Behavioural graded activity program versus manual therapy

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. Global Perceived Effect (GPE)
2. Neck Disability Index (NDI)

Secondary outcome measures
1. Numerical Rating Scale (NRS)
2. Tampa Scale for Kinesiophobia (TSK)
3. Distress, coping
4. Four Dimensional Symptom Questionnaire (4 DKL)
5. Pain Coping and Cognition List (PCCL)
6. Costs

Overall study start date
01/04/2002

Completion date
01/04/2007

Eligibility

Key inclusion criteria
1. Patients visiting the general practioner with non-specific new complaint or new episode of complaint of the neck (four to 12 weeks). An episode of complaint is new if patients have not visited their General Practitioner (GP) for the same complaint the preceding six months
2. Aged between 18 and 70 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

Key exclusion criteria
Patients are excluded from the study if a fracture, malignancy, or rheumatoid arthritis caused the presented complaint.

Date of first enrolment
01/04/2002

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Centre
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (Netherlands)

Sponsor details
EMGO-Institute
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Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (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?
Protocol article	Study protocol	01/11/2006		Yes	No
Results article	Results	01/04/2009		Yes	No