

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/02/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof H C W de Vet

Contact details
VU University Medical Centre
EMGO-Institute
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT
+31 (0)20 444 8176
hcw.devet@vumc.nl

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 Toestingscommissie (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 practitioner 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

Van der Boechorststraat 7

Amsterdam

Netherlands

1081 BT

+31 (0)20 444 8180

emgo@vumc.nl

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