

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	☐ Prospectively registered
Registration date 20/02/2007	Overall study status Completed	☒ Protocol
Last Edited 24/02/2009	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ 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

Protocol serial number
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).

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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	01/04/2009		Yes	No
Protocol article	Study protocol	01/11/2006		Yes	No