Effectiveness of manual therapy (according to the dutch school for Manual Therapy Utrecht) and physical therapy in patients with subacute and chronic non-specific neck pain. A randomized clinical trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23196

Source
NTR

Brief title
NECKproject (Nederlands Effectonderzoek Cervicale Klachten)

Health condition

subacute (more than four weeks) and chronic (more than 12 weeks) non-specific neck pain

Sponsors and support

Primary sponsor: Neckprojectgroup UMC ST Radboud Kwaliteit van Zorg
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Global Perceived Effect (GPE) and the NDI-DV (Neck disability index) will be applied.

Secondary outcome

VAS (Visual Analogue Scale) for pain and SF36 (Quality of life). The MHLC (Multidimensional Health Locus of Control), credibility/ expectancy, FABQ-DLV (Fear Avoidance Beliefs Questionnaire) will be measured to answer secondary questions.

Study description

Background summary

Manual Therapy applied to patients with non-specific neck pain has been investi-gated several times, both internationally and within the Netherlands. In the Netherlands different types of manual therapy treatment exist. To date Manual Therapy as practiced under the Utrecht School (one of the existing kinds) hasn't been subject of a randomised controlled trial. There is a need to evaluate the effectiveness of this type of manual therapy.

Objective of the study: The RCT will investigate the effectiveness of Manual Therapy according to the Utrecht School of Manual Therapy in the short and long-term up to 52 weeks in patient with sub acute (minimal two weeks) and chronic (maximum 52 weeks) since last episode of neck pain. Functional state, pain and global perceived effect will be measured.

Study design: The study is a single blind randomized controlled trial.

Study population: Men and women aged 18 to 70 years with neck pain for at least two weeks.

Intervention: The experimental group will be treated with manual therapy for a period of six weeks. The control group will be treated with physical therapy (usual care) also for a period of six weeks.

Primary study parameters / outcome of the study: Global Perceived Effect (GPE) and the NDI-DV (Neck disability index) will be applied.

Secondary study parameters / outcome of the study: VAS (Visual Analogue Scale) for pain and SF36 (Quality of life). The MHLC (Multidimensional Health Locus of Control), credibility/ expectancy questionnaire, FABQ-DLV (Fear Avoid-ance Beliefs Questionnaire) will be measured to answer secondary questions.

Data will be collected at baseline, 3, 7, 13, 26 and 52 weeks.

Study objective

N/A

Study design

0-3-7-13-26-52 weeks

Intervention

Manual therapy (according to the dutch school for Manual Therapy Utrecht) and physical therapy (usual care)

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with at least two weeks of neck pain

2. Last episode starts at a maximum of one year ago

3. Age between 18 and 70 years

4. Patient is willing to undergo the treatment

5. Neck pain is mechanical and can be provocated by movements or postures

6. Neck pain is the main problem to treatment

7. Neck pain may also give pain in the upper arm or cervicogene headaches

Exclusion criteria

1. Appearance of “red flags”

2. Cervical surgery in the past

3. Pregnancy

4. Whiplash trauma

5. Health conditions with may disturb the treatment or makes it impossible to undergo the treatment.

6. Not enough understanding of the Dutch questionnaires

7. Undergoing treatments like physical therapy, manual therapy, osteopathy, chiropraxis, acupuncture, exercise therapy according tot Cesar or Mensendieck during the last three months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	180
Type:	Actual

Ethics review

Positive opinion

Date:	10-03-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 31667
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1164
NTR-old	NTR1208
CCMO	NL21128.091.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON31667

Study results

Summary results
N/A