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

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The RCT will investigate the effectiveness of Manual Therapy according to the School of Manual Therapy Utrecht in the short and longterm up to 52 weeks in patient with sub acute (minimal four weeks) and chronic (maximum 52 weeks) since last episode...

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON31667

Source
ToetsingOnline

Brief title
Manual therapy in patients with neck pain

Condition

- Joint disorders

Synonym
non-specific neck pain

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: eigen middelen van de onderzoeksgroep. Subsidieaanvraag wordt voorbereid.

Intervention

Keyword: manual therapy, neck pain, physical therapy, randomised controlled trial

Outcome measures

Primary outcome

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

applied

Secondary outcome

VAS (Visual Analoge 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 investigated several times, both in-ternationally 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. This trial is similar to the RCT of Hoving (2004) and will be compared with physical therapy (usual care).

Study objective

The RCT will investigate the effectiveness of Manual Therapy according to the School of Manual Therapy Utrecht in the short and longterm up to 52 weeks in patient with sub acute (minimal four 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.

Intervention

The experimental group will be treated with manual therapy (according to the School of Manual Therapy Utrecht) for a period of six weeks. The control group will be treated with physical therapy (usual care) also for a period of six weeks.

Study burden and risks

All patients will be treated for their neck pain with methods witch are the usual and standard care in the Netherlands. Most of the patients will benefit from the treatment by showing increase in function and reduction in pain. Serious adverse events are not common and not expected. Participants in the trial, however, will be required to fillin six questionnaires (taking approximately 20 minutes each). These questionnaires will be spread out over 52 weeks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with at least two weeks of neck pain
Last episode starts at a maximum of one year ago
Age between 18 and 70 years
Patient is willing to undergo the treatment
Neck pain is mechanical and can be provocated by movements or postures
Neck pain is the main problem to treat
Neck pain may also give pain in the upper arm or cervicogene headaches

Exclusion criteria

Appearance of specific neck pain
Cervical surgery in the past
Pregnancy
Whiplash trauma
Health conditions with may disturb the treatment or makes it impossible to undergo the treatment.
Not enough understanding of the Dutch language
Undergoing treatments like physical therapy, manual therapy, osteopathy, chiropractice, 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	180
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23196
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL21128.091.08
OMON	NL-OMON23196