

Manipulative Therapy added on Usual Medical Care in patients with shoulder pain and dysfunction: a randomized controlled trial

Submission date 23/04/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 31/01/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/10/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Geert JMG van der Heijden

Contact details
University Medical Center Utrecht (Str. 6.131)
Julius Center for Health Sciences and Primary Care
Postbox 85500
Utrecht
Netherlands
3508 GA
+31 (0)30 250 9377
g.vanderheijden@umcutrecht.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Shoulder pain and dysfunction

Interventions

Manipulative Therapy added on Usual Medical Care versus Usual Medical Care only

Manipulative therapy:

Included specific manipulations (low-amplitude, high-velocity thrust techniques) and specific mobilizations (high-amplitude, low-velocity thrust techniques) to improve overall joint function and decrease any restrictions in movement at single or multiple segmental levels in the cervical spine and upper thoracic spine and adjacent ribs. The choice of the applied techniques was determined by the manual therapist, based on location of the dysfunction and technique preferences.

Usual Medical Care:

All patients received usual care from their general practitioner. The treatment by the general practitioner was similar to the practice guidelines for shoulder disorders issued by the Dutch

College of General Practitioners, including information, advice and therapy. During the first two weeks information regarding the nature and the course of shoulder complaints was given, together with advice on how to use the affected shoulder in daily living, supplemented with oral analgesics or non-steroidal anti-inflammatory drugs (NSAIDs) if necessary. If there was any improvement, treatment could be prolonged by 1-2 weeks. If this approach lacked sufficient effect, up to three corticosteroid injections (in subacromial space or glenohumeral joint) could be given. If there was insufficient improvement after 2 weeks, the injection could be repeated. If there was no improvement after the second injection, further treatment with corticosteroid injections was not advisable. Physiotherapy was considered in complaints persisting for 6 weeks or more and consisted of treatment of the shoulder with exercises, massage and physical applications.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2005

Completion date

31/12/2005

Eligibility**Key inclusion criteria**

1. Patients with shoulder pain and dysfunction and a dysfunction of the cervicothoracic spine and adjacent ribs with a new episode of shoulder complaints.
2. Participants had to be at least 18 years of age.

Participant type(s)

Patient

Age group

Not Specified

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

1. Acute severe trauma, such as fractures, ruptures or dislocation in the shoulder-region
2. Previous (orthopedic) surgery
3. Clear treatment preference deviating from study treatments
4. Contraindications for manipulative therapy (e.g. hyper-mobility, instability or severe arthrosis of the cervicothoracic spine)
5. Signs of cervical nerve root compression
6. Presence of specific rheumatic disorders
7. Presence of dementia or other severe psychiatric, emotional or behavioral disorders
8. Shoulder disorders due to general internal pathology of thoracic and abdominal organs
9. Inability to complete Dutch written questionnaires

Date of first enrolment

01/01/2005

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Utrecht (Str. 6.131)

Utrecht

Netherlands

3508 GA

Sponsor information

Organisation

Netherlands Organisation for Scientific Research

Sponsor details

Laan van Nieuw Oost-Indie 300

The Hague

Netherlands

2593 CE

+31 (0)703440640

nwo@nwo.nl

Sponsor type

Research organisation

ROR

<https://ror.org/01bnjb948>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Scientific Research

Alternative Name(s)

Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, Dutch Research Council, Netherlands, NWO

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

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?
Results article	results	21/09/2004		Yes	No

