

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

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| <b>Submission date</b><br>23/04/2004   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>31/01/2005 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>02/10/2008       | <b>Condition category</b><br>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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 21/09/2004   |            | Yes            | No              |

