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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

Registration date
31/01/2005

Overall study status
Completed

Last Edited
02/10/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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
904-65-901

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Lower age limit
18 Years

Sex

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)
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Sponsor information

Organisation
Netherlands Organisation for Scientific Research

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, The Dutch Research Council (NWO), Dutch Research Council, Netherlands, NWO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/09/2004		Yes	No