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Treatment of Myofascial Trigger Points in common shoulder disorders by physical therapy: a randomised controlled trial

Submission date
03/07/2007

Recruitment status
No longer recruiting

Registration date
06/07/2007

Overall study status
Completed

Last Edited
25/02/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.praktijknsa.nl/ToMTRiP.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
NL16459.091.07

Study information

Scientific Title
Treatment of Myofascial Trigger Points in common shoulder disorders by physical therapy: a randomised controlled trial

Acronym
ToMTriP

Study objectives
The primary aim of this study is to investigate the effectiveness of inactivation of Myofascial Trigger Points (MTrPs) in shoulder muscles by physical therapy on symptoms and functioning of the shoulder in daily activities in a population of chronic a-traumatic shoulder patients when compared to a wait-and-see strategy. In addition, we investigate the recurrence rate during a one-year-follow-up period.

In the current study we will test the following hypothesis (H0):
A physical therapy treatment to inactivate MTrPs within a three months period is as effective as a wait and see approach of patients with chronic shoulder complaints in a three month period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Radboud University Nijmegen Medical Centre (The Netherlands) on 21/05/2007 (ref: CMO 2007 /22).

Study design
An examiner-blinded 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

Musculoskeletal chronic shoulder disorders

Interventions
The initial sample size is based on the assumption that the overall score of the primary outcome measure DASH shows a mean improvement of 15 points [SD = 22]. To test the null hypothesis of equality of treatment at a = 0.05 with 90% power and assuming a uniform dropout rate of 5%, it was calculated that 52 patients in each group would be sufficient.

The patients in the intervention group will be treated by a physical therapist once a week for a maximum period of 12 weeks. The treatment starts with inactivation of the active (pain producing) MTrPs by using manual techniques (compression on the trigger point, manual stretching of the trigger point area and the taut band) combined with intermittent cold application by using ice-cubes followed by stretching the muscle according to Travell to further inactivate the MTrPs. Manual pressure will decrease the sensitivity of the painful nodule in the muscle while other massage techniques will mobilise and stretch the contracted muscle fibres. The application of the ice-cubes has a desensitising effect, and makes it easier to stretch shoulder muscles. Each treatment session will end with a heat application to increase the circulation of the involved muscles.

Patients will be advised to do stretching exercises and will be taught to perform these correctly by means of surface-electromyography-assisted stretching. Furthermore they will be advised to perform relaxation exercises, and to apply heat (like a hot shower, hot packs) several times (at least twice) a day. If there is abnormal measurable higher electromyographic activity in the upper trapezius muscle (measured by surface Electromyography [sEMG] using a Myomed 932 [Enraf Nonius, Delft, the Netherlands]) during standing and/or sitting, relaxation exercises will be performed using a portable myofeedback device (Myotrac I, Thought Technology, Quebec, Canada). Abnormal sEMG activity is defined as a constantly measured value above 1 - 5% of the maximally voluntary contraction, which is in general above 10 microvolt, during several minutes and the patient is not able to relax the muscle spontaneously or on request.

Finally, all patients will receive ergonomic recommendations, and instructions to assume and maintain good posture. Manual high velocity thrust techniques of the cervical spine and the shoulder and dry needling are excluded from the treatment protocol, because not all participating physical therapists are skilled to perform these techniques. The content of each session may vary as it depends on the findings during the first treatment session and the results of the previous treatment sessions. Thus, there are differences in the content of the individual treatments, but within the limits of the treatment protocol.

The control group will not receive treatment, but are on a wait-and-see policy. They will be put on the waiting-list for three months. After three months of treatment the subjects will be followed for another nine months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The overall score of the DASH (Disability of Arm Shoulder and Hand) questionnaire - Dutch language version will be used as the primary outcome measure.

Timepoints:
T0 = baseline
T1 = 6 weeks later
T2 = 12 weeks later
T3 = 26 weeks
T4 = 52 weeks

Secondary outcome measures
1. The total number of shoulder muscles with MTrPs will be counted and compared to the baseline measurement findings
2. Passive range of motion of the shoulder will be measured by an handheld digital inclinometer (The Saunders group Inc, Chaska, MN)
3. The total number of treatment sessions will be counted

Timepoints:
T0 = baseline
T1 = 6 weeks later
T2 = 12 weeks later
T3 = 26 weeks
T4 = 52 weeks

Overall study start date
01/09/2007

Completion date
01/09/2008

Eligibility

Key inclusion criteria
Between September 2007 and September 2008, all consecutive patients referred to a physical therapy practice specialised in the treatment of individuals with musculoskeletal disorders of the neck, shoulder and arm are potential study participants. The referring physicians include general practioners, orthopaedic surgeons, neurologists and physiatrists. Patients are eligible if they:
1. Have unilateral shoulder complaints (described as pain felt in the shoulder or upper arm) for at least six months
2. Present with persistent shoulder pain that has not spontaneously recovered
3. Are between 18 and 65 years old
4. Because the questionnaires are in the Dutch language, subjects must understand written and verbal Dutch

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
52 patients per group

Total final enrolment
72

Key exclusion criteria
1. Diagnosed (prior to the referral) with:
1.1. Shoulder instability
1.2. Shoulder fractures
1.3. Systemic diseases (such as rheumatoid arthritis, Reiters syndrome, diabetes)
2. Medical history or examination suggests neurological diseases
3. Other severe medical or psychiatric disorders

The project leader will check all the available information from referral letters, additional information from the general practitioner and from the patients.

Date of first enrolment
01/09/2007

Date of final enrolment
01/09/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Paulus Potterstraat 46
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Sponsor information

Organisation
Radboud University Nijmegen Medical Centre (The Netherlands)

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Sponsor type
Hospital/treatment centre

Website
http://www.wokresearch.nl

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
All costs will be paid by the Private Practice for Physical Therapy Groningen and the Centre for Quality of Care Research, University Medical Centre Nijmegen (The Netherlands). The treatment sessions will be paid by the health insurance company.

Funder Name
External financing will be sought after the publication of the design paper.

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?
Protocol article	protocol	05/11/2007		Yes	No
Results article	results	24/01/2011	25/02/2021	Yes	No