Physiotherapy for shoulder impingement syndrome

Submission date	Recruitment status	[X] Prospectively registered		
02/03/2010	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/03/2010 Last Edited	Completed Condition category	☐ Results		
		Individual participant data		
29/07/2024	Musculoskeletal Diseases	Record updated in last year		

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 N/A

Study information

Scientific Title

Effectiveness of individualised physiotherapy on pain and functioning compared to a standard exercise protocol in patients presenting with clinical signs of subacromial impingement syndrome of the shoulder. A randomised controlled trial.

Study objectives

To investigate the effect of individually planned physiotherapy on pain and functioning compared to a standard exercise protocol in patients with clinical signs of subacromial impingement syndrome. To compare direct and indirect costs between both interventions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee of the Munich University Hospital, Ludwig-Maximilians-University Munich, Germany, approved on the 19th February 2010 (Project-No. 018-10).

Study design

Multicentre randomized controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Shoulder impingement syndrome

Interventions

Intervention group: Ten sessions (approximatly 30 minutes/session; two sessions per week) of individualised physiotherapy (including manual therapy for the shoulder complex, the cervical and thoracic spine, education) based on clinical examination results plus a home-based standard exercise protocol.

Control group: Ten supervised sessions of a standard exercise protocol (including stretching, strengthening, and mobility exercises for the rotator cuff and the shoulder girdle). Total duration of intervention: five weeks.

Follow up: five weeks, three and twelve months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

- 1. Shoulder Pain and Disability Index (SPADI); 13 items (5 for pain, 8 for function) scored on a 100mm visual analogue scale; will be assessed at baseline and after 5 weeks, 3 and 12 months
- 2. Patients' global impression of change; ordinal scale (1-much worse, 2-slightly worse, 3-no change, 4-slightly better, 5-much better); will be assessed after 5 weeks, 3 and 12 months

Key secondary outcome(s))

1. Generic patient-specific scale; 11 point visual numeric rating scale (end descriptors of 0 = impossible to do, 10 = no difficulties at all); will be assessed at baseline and after 5 weeks, 3 and

12 months

- 2. Average weekly pain score; 11 point visual numeric rating scale (end descriptors of 0 = no pain, 10 = worst pain possible); will be assessed at baseline, after 5 weeks and 3 months
- 3. Patients' satisfaction with treatment; 11 point visual numeric rating scale (end descriptors of 0 = completely dissatisfied, 10 = completely satisfied); will be assessed after 5 weeks
- 4. Shoulder exercise log book; will be assessed after 5 weeks, 3 and 12 months
- 5. Costs; cost diary (disease specific healthcare utilization, sick leave, drug use, paid help); will be assessed after 5 weeks, 3 and 12 months

Completion date

30/09/2011

Eligibility

Key inclusion criteria

Patients between 18 and 75 years of age presenting to primary care with clinical signs and symptoms of shoulder impingement syndrome.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Key exclusion criteria

- 1. Primary scapulothoracic dysfunction
- 2. Instability
- 3. Adhesive capsulitis
- 4. Loss of active shoulder function
- 5. Previous shoulder surgery
- 6. Cervical radicular symptoms
- 7. Rheumatoid arthritis
- 8. Intake of psychotherapeutic drugs

Date of first enrolment

29/03/2010

Date of final enrolment

Locations

Countries of recruitment

Germany

Study participating centre Physiotherapiezentrum Penzberg Germany 82377

Sponsor information

Organisation

Physiotherapiezentrum T.O.Kromer (Germany)

Funder(s)

Funder type

University/education

Funder Name

Maastricht University (Netherlands) - Department of Epidemiology

Results and Publications

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	09/06/2010		Yes	No
Other publications	Secondary analysis	01/12/2014		Yes	No

Other publications Secondary analysis 24/07/2024 29/07/2024 Yes No