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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	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/07/2024	Musculoskeletal Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Thilo Oliver Kromer

Contact details
Physiotherapiezentrum
Grube 21
Penzberg
Germany
82377
-
Thilo.Kromer@epid.unimaas.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
29/03/2010

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
90

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
30/09/2011

Locations

Countries of recruitment
Germany

Study participating centre
Physiotherapiezentrum
Penzberg
Germany
82377

Sponsor information

Organisation
Physiotherapiezentrum T.O.Kromer (Germany)

Sponsor details
Grube 21
Penzberg
Germany
82377

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
University/education

Funder Name
Maastricht University (Netherlands) - Department of Epidemiology

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	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