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The Shoulder Intervention Project

Submission date
25/09/2010

Recruitment status
No longer recruiting

Registration date
03/11/2010

Overall study status
Completed

Last Edited
04/05/2016

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Impingement disorder of the shoulder is a disorder that causes pain which is aggravated in bed at night and by activities like arm elevation. In Denmark, the number of keyhole operations for impingement disorder of the shoulder has increased fourfold since 1996. Although surgery improves symptoms in many cases, 7-15% of the patients leave the labour market permanently within 2 years after the operation due to health problems. Around 20% of operated patients experience long-term limitations in shoulder function. This study aims to find out whether a systematic physiotherapy training programme can improve shoulder function and whether occupational medical assistance can improve job retention as compared to usual care.

Who can participate?
Patients aged 18 to 63 from Danish public hospital departments of orthopaedic surgery who have received a keyhole operation for impingement disorder of the shoulder and still experience functional limitations around 10 weeks after the operation can participate.

What does the study involve?
All participants complete a questionnaire on shoulder function and a research physiotherapist performs physical testing. After this, the participant is randomly allocated to one of four groups. During a period of three months, participants receive either physiotherapy exercises, occupational medical assistance, both of these interventions, or usual care. Participants who do not work at least 25 hours per week can only be allocated to the first and fourth of these groups. The physiotherapy intervention has been developed for the purpose of this study. Exercises are individually tailored and performed under supervision by physiotherapists at municipal training centres. Patients visit the centre 8-15 times within 8 weeks and they are also instructed to perform exercises at home for all 12 weeks. Training activities are documented in diaries.
The occupational medical assistance is delivered by physicians who are specialists in occupational medicine at one of two hospital departments of occupational medicine. The intervention includes a clinical examination with assessment of limitations in shoulder function and an interview to assess shoulder loads in the patient's job with regard to forceful work, work with elevated arms, and repetitive movements. The patient's shoulder function is then weighted up against the overall shoulder load in the job. In this way, the need for job adjustments due to mismatches between physical demands in the job and the patient's actual shoulder function are identified and a plan for work adjustments is agreed on. The physician may visit the workplace to facilitate implementation of adjustments. After 6 weeks the physician contacts the patient by

telephone to assess any problems in following the plan. The time frame for completion of the plan is up to 12 weeks. At 12 weeks the physician sees the patient again for final evaluation and workplace-oriented advice.
To evaluate the effects of physiotherapy exercises at the end of the interventions (after 12 weeks), all participants complete the questionnaire on shoulder function again and the research physiotherapist repeats the physical testing. The questionnaire is also filled in after 1 year. To evaluate the effects of occupational medical assistance on work retention, the duration of sickness absence within 12 weeks after inclusion and the number of weeks where the patients received health-related economic support are summed up for the first and second year after inclusion.

What are the possible benefits and risks of participating?
If the interventions turn out to improve shoulder function and job retention, the participants will benefit from these effects and the intervention can be incorporated into clinical practice guidelines for rehabilitation after keyhole operations for shoulder pain due to impingement. We do not expect any side effects.

Where is the study run from?
The study has been set up by the Departments of Occupational Medicine at Aarhus University Hospital and Regional Hospital West Jutland in collaboration with the orthopaedic surgery departments and two municipal training centres in Central Denmark Region.

When is the study starting and how long is it expected to run for?
The study started in January 2011 and recruitment will continue until the middle of June 2014.

Who is funding the study?
The Danish Agency for Science, Technology and Innovation, the Danish Working Environment Research Fund, and the Danish Ramazzini Centre.

Who is the main contact?
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Type(s)
Scientific

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Study information

Scientific Title
Shoulder function and work disability after decompression surgery for subacromial impingement syndrome: a randomised controlled trial of physiotherapy exercises and occupational medical assistance

Acronym
SIP

Study objectives
Current hypothesis as of 07/05/2014:
The overall objective of the study is to improve shoulder function and promote work retention after arthroscopic surgical management of shoulder impingement syndrome in patients aged greater than or equal to 18 to less than or equal to 63 years, who have shoulder symptoms 10 weeks after surgery.

Specific hypotheses are that:
1. A standardised physiotherapy programme with graded exercises is more (cost-)effective than 'usual care' in reducing shoulder-related disability
2. An occupational case management programme with workplace-oriented advice is more (cost-) effective than 'usual care' in promoting work retention

Previous hypothesis:
The overall objective of the study is to promote return to work (RTW) after arthroscopic surgical

management of shoulder impingement syndrome in employed patients aged greater than or equal to 18 to less than 63 years, who are sick-listed due to shoulder symptoms eight weeks after surgery.

The main hypothesis is that the flow of surgical shoulder patients from hospital treatment to either prolonged sickness absence or disability pension or other health-related transfer incomes can be significantly reduced by early, coordinated rehabilitation involving hospital departments, municipal training centres and workplaces, and tailored to each individual patient to reduce his or her barriers to RTW. Specific hypotheses are that:
1. A standardised physiotherapy programme with graded exercises is more (cost-)effective than 'usual care' in:
1.1. Reducing shoulder-related disability
1.2. Promoting RTW
2. An occupational case management programme with workplace oriented advice is more (cost)-effective than 'usual care' in promoting RTW.

When the two interventions are combined, a more pronounced effect is expected on RTW.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Central Denmark Region Committees on Biomedical Research Ethics, 16/08/2010, ref: M-20100131
2. Danish Data Protection Agency, 23/02/2010, ref: 2010-41-4316

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Shoulder surgery

Interventions
Current interventions as of 07/05/2014:
The intervention period starts at randomisation approximately 10 weeks after surgery (baseline) and continues for 3 months. Participants are individually assigned to one of four intervention arms using a computerised random number generator with stratification by surgical department and blocking within strata using randomly varying block lengths (unemployed patients can only be randomised to one of the two arms that do not include occupational case management). The following intervention arms will be compared:

1. Occupational case management with workplace-oriented advice (+ usual training). At baseline the patient is seen by an occupational physician, who is blinded for group assignment with respect to physiotherapy. Based on a semi-structured interview and a clinical examination, the patient's work and health status is assessed. A 3-month action plan is constructed that addresses

three prioritized barriers for obtaining a more stable work situation. The employer is contacted if necessary, and a workplace visit may be performed to assess biomechanical exposures and arrange work adaptations. After 1½ months the patient is contacted by telephone to determine if the plan is followed, and to prompt the patient to adhere to the plan. If needed the employer is contacted again. Three months after baseline, the patient is seen for final evaluation and workplace-oriented advice.

2. Standardised physiotherapy with graded exercises (+ usual advice on return to work). The programme includes at least eight and a maximum of 15 physiotherapist-supervised exercise sessions and additional self-training. Three months after baseline, the patient is seen for final evaluation and advice on exercise.

3. Occupational case management with workplace-oriented advice and standardised physiotherapy with graded exercises, i.e. a combination of interventions 1 and 2.

4. Control intervention in terms of usual training and advice on work retention. The control intervention is documented by a questionnaire.

Before randomisation, baseline data is collected by questionnaire and clinical examination performed by a research physiotherapist. Three months after baseline, patients are followed up by questionnaire and clinical examination performed by a research physiotherapist, who is blinded for group assignment. Twelve months after baseline, patients are followed up by questionnaire, and 12 and 24 months after baseline they are followed up using data from the Danish National Register on Public Transfer Payments (DREAM).

Statistical analyses are performed according to the intention-to-treat principle, and the results may be compared to per-protocol analyses.

Previous interventions:
The intervention period starts at randomisation approximately eight weeks after surgery (baseline) and continues for three months. Participants are individually assigned to one of four intervention arms using a computerised random number generator with stratification by surgical department and blocking within strata using randomly varying block lengths. The following intervention arms will be compared:

1. Occupational case management with workplace oriented advice (+ usual training). At baseline, the patient is seen by an occupational physician, who is blinded for group assignment with respect to physiotherapy. Based on a semi-structured interview and a clinical examination, the patient's work and health status is assessed. A three months' RTW action plan is constructed that addresses three prioritized barriers for obtaining a more stable work situation. The employer is contacted if necessary, and a workplace visit may be performed to assess biomechanical exposures and arrange work adaptations. After 1 1/2 months, the patient is contacted by telephone to determine if the plan is followed, and to prompt the patient to adhere to the plan. If needed the employer is contacted again. Three months after baseline, the patient is seen for final evaluation and workplace oriented advice.

2. Standardised physiotherapy with graded exercises (+ usual advice on RTW). The programme includes at least eight and a maximum of 12 physiotherapist-supervised exercise sessions and additional self-training. The physiotherapist is blinded for group assignment with respect to occupational case mangement. Three months after baseline, the patient is seen for final evaluation and advice on exercise.

3. Occupational case management with workplace oriented advice and standardised physiotherapy with graded exercises, i.e. a combination of interventions 1 and 2:

4. Control intervention in terms of usual training and advice on RTW. The control intervention is documented by questionnaire.

Before randomisation, baseline data is collected by questionnaire and clinical examination performed by a research physiotherapist. Three months after baseline, patients are followed up by questionnaire and clinical examination performed by a research physiotherapist who is blinded for group assignment. Twelve months after baseline, patients are followed up by questionnaire, and 12 and 24 months after baseline they are followed up using data from the Danish National Register on Public Transfer Payments (DREAM).

Statistical analyses are performed according to the intention-to-treat principle, and the results are compared to per-protocol analyses.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 07/05/2014:
1. To evaluate the effectiveness of the physiotherapy intervention at 3 and 12 months: disability as measured by Oxford Shoulder Score
2. To evaluate the effectiveness of the occupational intervention at 3 months: number of hours of sick-leave due to symptoms from the operated shoulder in relation to the number of planned working hours within 3 months from baseline (self-report)
3. To evaluate the effectiveness of the occupational intervention at 12 months: number of weeks receiving temporary or permanent health-related transfer incomes within 12 months from baseline divided by 52 weeks, according to data from the DREAM register
4. To evaluate the effectiveness of both interventions at 24 months: for the employed subgroup, number of weeks receiving health-related transfer incomes within 13-24 months from baseline, divided by 52 weeks, according to the DREAM register

Previous primary outcome measures:
1. To evaluate the effectiveness of the physiotherapy intervention at three months: disability as measured by Oxford Shoulder Score
2. To evaluate the effectiveness of the occupational intervention at three months: duration of fulltime sick-leave due to symptoms from the operated shoulder assessed as number of calendar days within three months from baseline (self-report)
3. To evaluate the effectiveness of both interventions at 12 months:
3.1. Duration of sick-leave until lasting RTW, i.e. number of weeks on full- or parttime sick-leave until RTW for a continuous period of at least four weeks within 12 months from baseline according to data from the DREAM register
3.2. Direct and indirect costs
4. To evaluate the effectiveness of both interventions at 24 months: number of weeks receiving health-related transfer incomes within 24 months from baseline according to the DREAM register

Key secondary outcome(s)
Current secondary outcome measures as of 07/05/2014:
1. To evaluate the effectiveness of the occupational intervention at 3 months:
1.1. Disability as measured by Oxford Shoulder Score
2. To evaluate the effectiveness of the physiotherapy intervention at 3 months:
2.1. Disability as measured by Constant Score
2.2. For the employed subgroup, number of hours of sick-leave due to symptoms from the operated shoulder in relation to the number of planned working hours within 3 months from baseline
3. To evaluate the effectiveness of both interventions at 3 months:
3.1. Fear avoidance beliefs as measured by the Fear Avoidance Belief Score (modified to focus on the shoulder)
4. To evaluate the effectiveness of the occupational intervention at 12 months:
4.1. Disability as measured by Oxford Shoulder Score
5. To evaluate the effectiveness of the physiotherapy intervention at 12 months:
5.1. For the employed subgroup, number of weeks receiving temporary or permanent health-related transfer incomes within 12 months from baseline divided by 52 weeks, according to data from the DREAM register

Several supplementary outcome measures will be used including direct and indirect costs.

Previous secondary outcome measures:
1. To evaluate the effectiveness of the occupational intervention at three months:
1.1. Disability as measured by Oxford Shoulder Score
2. To evaluate the effectiveness of both interventions at three months:
2.1. Disability as measured by Constant Score
2.2. Work ability as measured by item 1 from the Work Ability Index
2.3. Patient Global Impression of Change since baseline
2.4. Patient satisfaction
2.5. Fear avoidance beliefs as measured by the Fear Avoidance Belief Score (modified to focus on the shoulder)
3. To evaluate the effectiveness of both interventions at 12 months:
3.1. Disability as measured by Oxford Shoulder Score
3.2. Full return to own or other work with equal earnings (yes/no, self-report)

Supplementary outcome measures:
4. Pain intensity in the operated shoulder within the last 24 hours, assessed at three and 12 months using an 11-point Numeric Pain Rating Scale ranging from 0 (no pain) to 10 (worst imaginable pain)
5. Mental health as measured by MH-5 from SF-36 assessed at three and 12 months
6. EQ-5D assessed at three and 12 months

Completion date
31/10/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 07/05/2014:
1. Aged greater than or equal to 18 to less than or equal to 63 years, either sex
2. Shoulder impingement syndrome or acromioclavicular osteoarthritis (International

Classification of Diseases 10th revision [ICD-10] group M75.1-M75.8, M19.8)
3. Arthroscopic surgery with a shoulder surgery code of KNBH51 or KNBH91 (or related codes depending on coding praxis at the participating surgical departments) according to the Danish version of the NOMESCO Classification of Surgical Procedures
4. Consent that the employer may be contacted as part of the study
5. Ability to complete questionnaires written in Danish
6. Ability to carry on a conversation in Danish without an interpreter
Inclusion criteria were adjusted in April 2012 due to slow recruitment.

Previous inclusion criteria:
1. Aged greater than or equal to 18 to less than or equal to 63 years, either sex
2. Shoulder impingement syndrome or acromioclavicular osteoarthritis (International Classification of Diseases 10th revision [ICD-10]: M75.1 - M75.8, M19.8)
3. Arthroscopic surgery with a shoulder surgery code of KNBH51 or KNBH91 (or related codes depending on coding praxis at the participating surgical departments) according to the Danish version of the NOMESCO Classification of Surgical Procedures
4. Employed with at least 25 hours of work per week
5. Fulltime sick-listed due to shoulder symptoms eight weeks after surgery with no firm date of returning to work within two weeks
6. Consent that the employer may be contacted as part of the study
7. Ability to complete questionnaires written in Danish
8. Ability to carry on a conversation in Danish without an interpreter

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 07/05/2014:
1. Fibromyalgia, rheumatoid arthritis
2. Traumatic shoulder lesion
3. Glenohumeral osteoarthritis
4. Full-thickness or complete rotator cuff tear observed during surgery

Previous exclusion criteria:
1. Previous shoulder surgery (same or opposite shoulder)
2. Fibromyalgia, rheumatoid arthritis, diabetes
3. Traumatic shoulder lesion
4. Glenohumeral osteoarthritis
5. Full-thickness or complete rotator cuff tear observed during surgery

Date of first enrolment
01/11/2010

Date of final enrolment
15/06/2014

Locations

Countries of recruitment
Denmark

Study participating centre
Aarhus University Hospital
Aarhus C
Denmark
8000

Sponsor information

Organisation
Danish Ramazzini Center (Denmark)

ROR
https://ror.org/00ttqn045

Funder(s)

Funder type
Research organisation

Funder Name
Danish Ramazzini Centre (Denmark)

Funder Name
Danish Agency for Science, Technology and Innovation (Denmark) (ref: 09-066985)

Alternative Name(s)

Danish Agency of Higher Education and Science, Danish Agency for Science, Technology and Innovation, Danish Agency for Science and Higher Education, The Danish Agency for Higher Education and Science, Uddannelses- og Forskningsstyrelsen, UFS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Denmark

Funder Name
Danish Working Environment Research Fund (Denmark) (ref: 20120220871/3)

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	01/08/2015		Yes	No
Protocol article	protocol	21/06/2014		Yes	No