ISRCTN51739408 https://doi.org/10.1186/ISRCTN51739408

Comparing a multidisciplinary intervention and brief intervention and two exercise regimes in sick-listed employees with shoulder or neck pain

Submission date
20/06/2011

Recruitment status
No longer recruiting

Registration date
29/06/2011

Overall study status
Completed

Last Edited
04/09/2012

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In 2005 33% of the Danish adult population reported pain or discomfort in the shoulder and/or neck within a period of 14 days. Employees often take sick leave because of musculoskeletal symptoms. Previous studies have indicated efficacy that both brief and more comprehensive multidisciplinary interventions work. However, it remains unknown which works best and which elements are important to facilitate return to work and improve health. For instance, there is moderate evidence for exercise in the treatment of acute and chronic non-specific neck pain, but it is unknown whether exercise should include strength training. The objectives of the present study are 1) to compare return to work (RTW), pain and disability in subjects offered a hospital-based multidisciplinary intervention or a brief intervention and 2) to compare the effects of two different home-based exercise programs on pain and muscle strength in patients on sick-leave for 4-16 weeks due to symptoms of the neck and/or shoulder.

Who can participate?
Patients are referred to the hospital clinic by general practitioners if they have been on sick leave for 4-16 weeks due to unspecific pain in the neck or shoulder and are not expected to have surgery. They are 18-60 years of age, understand Danish, are not pregnant and are not substance abusers.

What does the study involve?
The brief intervention comprises clinical examination and advice offered by a rehabilitation doctor and a physiotherapist. In the multidisciplinary intervention, this intervention is supplemented with the expertise of a team and the assignment of a case manager who makes a rehabilitation plan in collaboration with the patient and the multidisciplinary team.
The clinical examination is carried out by the doctor, relevant imaging and examinations are ordered and treatment options are discussed. Information is given in a reassuring way and medical pain management is adjusted. The participants are advised to resume work when possible. The physiotherapy examination included a standardized, mechanical evaluation before advice on exercise is given. General advice is given to increase physical activity and exercise. In order to ensure coordination between stakeholders, copies of the medical records are always

sent to the patient, the general practitioner and the municipal social services responsible for reimbursement of sick leave compensation. For all patients, a follow-up visit at the physiotherapist is scheduled two weeks later, and a follow-up visit at the doctor is arranged for patients needing answers in relation to test results.
After the initial clinical examination the patients are randomly allocated to brief or multidisciplinary intervention and to one of two exercise programs. The exercise programs are instructed by the physiotherapist, who recommends general exercise at least 3 times per week for all patients and additional strength training using rubber bands for the strength training group.
Patients allocated to the multidisciplinary intervention group are scheduled for an interview with a case manager two weeks later. The interview is standardised and includes questions about work history, private life and questions on how pain and disability is perceived. The patient is seen once or more times by the case manager depending on need and progress. The case manager and the patient make a tailored rehabilitation plan aiming at full or partial RTW. If this is unrealistic, a plan towards staying on the job market in other ways is made, for instance by jobs supported by the social system. Each case is discussed several times by the entire multidisciplinary team including the rehabilitation doctor, a specialist in clinical social medicine, a physiotherapist, a social worker and an occupational therapist. Appointments with other members of the team and meetings at the work place or at the social service centre are regularly arranged. The case manager keeps in contact with the participant and problems are discussed at regular team conferences where the participant is not present. The case is closed when the participant resumes work or no later than three months after the first visit. Three different peoples can be assigned as case manager (the specialist in clinical social medicine, the social worker or the occupational therapist). Every two weeks, supervision of the entire team is arranged for 1-2 hours by a former general practitioner specialized in cognitive therapy to ensure a standardized intervention.

What are the possible benefits and risks of participating?
There is no extra risk to the patients except for the potential discomfort associated with strength training.

Where is the study run from?
Spine Centre, Regional Hospital Silkeborg, Denmark.

When is the study starting and how long is it expected to run for?
The study was initiated in 2009 and should continue until 350 patients are enrolled by referral general practitioners to the Spine Centre, Regional Hospital Silkeborg, Denmark.

Who is funding the study?
The evaluation of the study is financed by the Danish Working Environment Research Fund.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Comparing a multidisciplinary and brief intervention and two exercise regimes with a 2*2 factorial design in sick-listed employees with shoulder or neck pain

Study objectives
1. Return to work, pain and disability improve more in sick-listed subjects with shoulder or neck pain if they receive a hospital-based multidisciplinary team-intervention in addition to a brief intervention than in subjects who only receive the brief intervention consisting of a clinical examination and advice given by a rehabilitation doctor and a physiotherapist
2. Pain and muscle strength improves more if these patients receive instructions on homebased exercise programs with strength training than if they receive instructions on exercise programs without strength training

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Scientific Ethics Committe, Central Region, Denmark. Journal No. M-20090027, 19 February 2009

Primary study design
Interventional

Study design
Randomised comparative trial with a 2*2 factorial design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sick leave due to pain in the neck, shoulder or upper back for 4-16 weeks

Interventions
Basic interventions:
1. A standard clinical examination was carried out by a doctor

2. Information was given in a reassuring way and medical pain management was adjusted
3. The participants were advised to resume work when possible
4. A physiotherapy examination included a standardised, mechanical evaluation and advice on general exercise was chosen accordingly

Exercise interventions:
1. Patients were allocated to an exersice program with or without strength training
2. Instructions were given on homebased exercise programs without or with strength training using rubber bands
3. Maximal voluntary isometric strength in neck flexion and extension and shoulder abduction are measured in all patients by the physiotherapist

For all participants, a follow-up visit at the physiotherapist was scheduled two weeks later and a follow-up visit at the doctor was arranged for participants needing answers in relation to test results

Multidisciplinary intervention:
1. In addition to the brief clinical intervention described above, participants allocated to the multidisciplinary intervention group were scheduled for an interview with a case manager after 2 weeks
2. This interview was standardised and included questions of work history, private life and questions on how pain and disability was perceived
3. It normally lasted for one to two hours
4. The participant was seen once or more times by the case manager depending on need and progress
5. The case manager and the participant together made a tailored rehabilitation plan aiming at full or partial RTW
6. If this was deemed unrealistic, a plan towards staying on the labor market in other ways was made, for instance by jobs supported by the social system
7. Each case was discussed several times by the entire multidisciplinary team including the rehabilitation doctor, a specialist in clinical social medicine, a physiotherapist, a social worker and an occupational therapist
8. Appointments with other members of the team and meetings at the work place or at the social service centre were regularly arranged
9. The case manager kept in contact with the participant and problems were discussed at regular team conferences where the participant was not present
10. The case was closed when the participant resumed work or if this was deemed impossible (in the latter case the social worker at the social service centre was contacted) 11. Three different persons could be assigned as case manager (the specialist in clinical social medicine, the social worker or the occupational therapist)
12. Every two weeks, supervision of the entire team was arranged for 1-2 hours by a former general practitioner specialised in cognitive therapy to ensure a standardised intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Comparison of brief versus multidisciplinary intervention:
1. Return to work
2. Two exercise programs
3. Pain

Key secondary outcome(s)
1. Disability
2. SF-36 subscales
3. Fear avoidance beliefs

Completion date
01/01/2012

Eligibility

Key inclusion criteria
1. Age 18 60 years
2. Complete or partial sick-leave from work for 4 to 16 weeks
3. Sick leave primarily caused by pain of the neck, shoulder or upper back
4. Speaks and understands Danish

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Continuous or progressive symptoms of nerve root compression indicating surgery
2. Surgery of the back, neck or shoulder within the last year
3. Presence of another specific or serious disease of the musculoskeletal system
4. Dominant psychiatric disease
5. Alcohol or drug abuse
6. Pregnancy

Date of first enrolment
01/05/2009

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Denmark

Study participating centre
Marselisborgcentret
Aarhus
Denmark
8000

Sponsor information

Organisation
The Danish Working Environment Research Fund (Denmark)

ROR
https://ror.org/05fm0gf36

Funder(s)

Funder type
Research organisation

Funder Name
The Danish Working Environment Research Fund (Denmark) ref: No. 20080016279/3

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration