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Evaluation of a work place directed intervention to enhance vocational prognosis among low back patients

Submission date
24/08/2010

Recruitment status
No longer recruiting

Registration date
25/10/2010

Overall study status
Completed

Last Edited
21/01/2016

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Back pain is a common problem that affects most people at some point in their life. It most commonly affects the lower back (Low Back Pain [LBP]). Counselling has been found to be effective at reducing pain, improving physical function and reducing the duration of sick leave for LBP patients. We wish to evaluate the possible long-term effects of the counselling during a 6-year follow-up period.

Who can participate?
LBP patients aged 17-63 who expressed concerns about their ability to maintain their current job.

What does the study involve?
Patients are randomly allocated to receive either usual care (a brief instruction in exercise) or the counselling intervention. The counselling intervention consists of counselling by an occupational physician, a workplace visit if needed, a 6-week interview and a follow-up interview after 3 months by the occupational physician.

What are the possible benefits and risks of participating?
Participants will benefit from a counselling session (occupational physician or usual care). The study follows the rules of using register data in Denmark, where it is a requirement that the participants in a study are protected and not recognisable. We are not aware of any risks involved in participating in the study.

Where is the study run from?
University Hospital Aarhus (Denmark)

When is the study starting and how long is it expected to run for?
January 2007 to January 2016

Who is funding the study?
Danish Research Fund for the Working Environment (Denmark)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
10-2005-09 in the Danish Research Fund for the Working Environment

Study information

Scientific Title
Vocational prognosis of participants in a randomised trial addressing counselling of low back patients in secondary healthcare - a 6 years follow-up study

Acronym
VAL-300

Study objectives
Low back worries, experienced work place barriers and general level of physical activity influence disability defined as level of sick leave, function and pain 3 months after the intervention start.

Added 19/01/2016:
The original randomised study found a statistical and clinical relevant effect on low back pain and function after 3 months in the intervention group. The research question in the actual trial is to investigate the long term effect on vocational prognosis during a 6 years follow up in the intervention group compared to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Danish Data Protection Agency, 06/03/2006, ref: 2006-41-6190
2. Local ethics and scientific committee, 13/02/2006, ref: 2006-2.0/8

Primary study design
Interventional

Study design
Randomised controlled intervention study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low back pain

Interventions
Patients are allocated to either usual care or intervention
Usual care typically consists of a brief instruction in exercises, or readmission to a general practitioner with further contact to physiotherapist or chiropractor treatment.

The intervention consist of a baseline interview and counselling by an occupational physician, a work place visit if needed, a 6-week midway interview, and a concluding follow-up interview with the occupational physician after three months. The focus of the start interview is concrete perceived work place barriers, physical activity and a concluding plan for the next 3 month.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Level of self assessed and register based sick leave
1.1. Cumulated days of sick leave
1.2. Proportion of patient with sick leave at 4, 8 and 12 weeks, compared between intervention and control group.
2. Low back function was assessed using the Roland Morris Disability Questionnaire (RMDQ) at baseline and 3 months
3. Generic health status concerning physical function (PF) and bodily pain (BP) was assessed by SF-36, at baseline and 3 months
4. Low back specific pain was assessed using a 11-point numerical rating scale (NRS) scoring mean pain during the last week

Primary outcome measures at 6 years follow up (added 19/01/2016):
Early retirement

Key secondary outcome(s)
1. Maximal oxygen uptake (ml O2*min-1*kg-1) measured at baseline and follow up
2. Self reported physical activity and fear avoidance assessed using the Fear Avoidance Believes Questionnaire

Secondary outcome measures at 6 years follow up (added 19/01/2016):
Cumulated sick leave and other non permanent work losses in the follow up period.

Completion date
01/01/2016

Eligibility

Key inclusion criteria
1. Adults aged 17-63
2. In paid work, paid employment or self-employed
3. Willing to accept a workplace visit if needed
4. Danish-speaking.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients referred for surgery
2. Patients with no need for advice concerning workplace barriers or physical activity
3. Pregnancy or becoming pregnant during intervention
4. Other serious illness

Date of first enrolment
01/01/2007

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
Denmark

Study participating centre

Arbejdsmedicinsk klinik
Aarhus
Denmark
8000

Sponsor information

Organisation
Danish Research Fund for the Working Environment (Denmark)

Funder(s)

Funder type
Research organisation

Funder Name
Danish Research Fund for the Working Environment (Denmark)

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?
Results article	results	01/01/2012		Yes	No