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Comparing multidisciplinary and brief intervention in sick-listed employees with low back pain

Submission date
04/03/2011

Recruitment status
No longer recruiting

Registration date
17/03/2011

Overall study status
Completed

Last Edited
14/11/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised trial comparing multidisciplinary and brief intervention in sick-listed employees with low back pain

Study objectives
Return to work, pain and disability improves more in sick-listed subjects with low back 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was discussed with the regional research ethics committee. Approval was not considered necessary by the committee, because all participants received the best available clinical care and no biological material was involved.
We have later acquired a written response from the Research Ethics Committee of Central Region Denmark (komite@rm.dk) filed as:
Number: Forespørgsel 38/2010: The Study does not fall within the scope of the work of the Committee according to the Act on Biomedical Research Ethics Committee System and The Processing of Biomedical Research Projects 8, section 1 and 7, number 1 and therefore shall not be notified to the Committee.

Study design
Randomised single-centre comparative trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions

Brief intervention:
A standard clinical low backpain (LBP) examination was carried out by a doctor. Patients with non-specific LBP were informed about the difficulties of visualising the cause of pain with certainty, the best documented treatment being exercise and training and psychological distress possibly worsening and prolonging pain. Patients with nerve root pain were informed about the good spontaneous prognosis and about the possibility of surgery if no improvement occurred. Furthermore, they were informed about exercise being beneficial if leg pain did not worsen. Information was given in a reassuring way and medical pain management was adjusted. The participants were advised to resume work when possible. A physiotherapy examination included a standardised, mechanical evaluation and advice on exercise was chosen accordingly. General advice was given to increase physical activity and exercise. In order to ensure coordination between stake holders, copies of the medical records were always sent to the participant, the general practitioner and the municipal social services responsible for reimbursement of sick leave compensation. 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:
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 within two to three workdays. This interview was standardised and included questions of work history, private life and questions on how pain and disability was perceived. It normally lasted for one to two hours. The participant was seen once or more times by the case manager depending on need and progress. The case manager and the participant together made a tailored rehabilitation plan aiming at full or partial RTW. 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. 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. Appointments with other members of the team and meetings at the work place or at the social service centre were regularly arranged. The case manager kept in contact with the participant and problems were discussed at regular team conferences where the participant was not present. 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). Three different persons could 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 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 measure
Return to work using register-based data on sick leave.

Secondary outcome measures
1. Pain (Low Back Pain Rating scale)
2. Disability (Roland Morris Disability Questionnaire)

Overall study start date
01/10/2004

Completion date
01/07/2007

Eligibility

Key inclusion criteria
1. Age 16-60 years
2. Partly or fully sick-listed from work for 4 to 12 weeks due to Low Back Pain

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
350

Total final enrolment
351

Key exclusion criteria
1. Unemployed
2. Continuing or progressive signs or symptoms of nerve root affection implicating plans for surgery
3. Low back surgery within the last year or specific back diseases (e.g. tumor)
4. Pregnant
5. Known dependency on drugs or alcohol
6. Any primary psychiatric disease

Date of first enrolment
01/10/2004

Date of final enrolment
01/07/2007

Locations

Countries of recruitment
Denmark

Study participating centre

Marselisborgcentret
Aarhus C
Denmark
8000

Sponsor information

Organisation
The Danish Working Environment Research Fund (Denmark)

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Sponsor type
Government

ROR
https://ror.org/05fm0gf36

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	subgroup analyses	25/05/2011		Yes	No
Results article		25/08/2012	14/11/2022	Yes	No