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Comparing multidisciplinary and brief intervention in sick-listed employees with low back pain. Do job relations matter?

Submission date
04/08/2015

Recruitment status
No longer recruiting

Registration date
01/09/2015

Overall study status
Completed

Last Edited
14/02/2022

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Low back pain (LBP) is a common problem affecting most people during their lifetime. Many people who experience LBP will recover quickly with no significant impact to their lives, but for some people the pain turns into a long term condition which can affect their ability to work. There are two common treatment plans which are used for people suffering from LBP. The first is a treatment plan involving healthcare professionals such as doctors and physiotherapists (brief intervention). The second is a more in-depth treatment plan which takes into account occupational and social factors, as well as the medical care from healthcare professionals (multidisciplinary intervention).
In a recent study, the effects of multidisciplinary and brief interventions were compared, to find whether they had an effect on returning to work. It was found that there was no difference between the two types of intervention on the whole, but differences were found in subgroups of people with different work situations.
The aim of this study is to test whether people who have low influence within their job role and are at risk of losing their job would benefit more from multidisciplinary interventions than those with influence in their job role who are not at risk of losing their job.

Who can participate?
Adults on partial (working hours reduced by up to 25%) or full (working hours reduced by 100%) sick leave from work for 4 to 12 weeks due to low back pain.

What does the study involve?
Participants are split into two groups, one group including those not at risk of losing their job due to influence in the workplace, and the other including those at risk of losing their job due to low influence in the work place. These two groups are then randomly allocated into two further groups. The first group is provided with information about pain management and provided with a physiotherapist appointment. The second group is provided with the same, but their recovery is also supported by a group of experts to ensure that an individual treatment plan is provided.

What are the possible benefits and risks of participating?
Benefits of participating include receiving extra treatment to what is usually offered, as well as receiving treatment co-ordinated with social services. There are not risks of participating in the study.

Where is the study run from?
Marselisborgcenter (Denmark)

When is the study starting and how long is it expected to run for?
October 2010 to December 2019

Who is funding the study?
Central Region Denmark (Marselisborgcentret and Regional Hospital Silkeborg)

Who is the main contact?
Professor Claus Vinther Nielsen

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparing multidisciplinary and brief hospital-based intervention in sick-listed employees with low back pain

Study objectives
1. Return to work is faster in sick-listed subjects with low back pain, low influence at work or at risk of losing their job, 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. Return to work is faster in sick-listed subjects with low back pain, influence at work and without risk of losing their job, if they receive a hospital-based brief intervention as compared with a multidisciplinary team-intervention in addition to a brief intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Videnskabsetisk komite for Region Midtjylland, 01/10/2010, ref: M-20100193

Study design
Randomised single-centre comparative trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

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

Interventions
Brief intervention:
A standard clinical low backpain (LBP) examination is carried out by a doctor. Patients with non-specific LBP are 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 are informed about the good spontaneous prognosis and about the possibility of surgery if no improvement occurred. Furthermore, they are informed about exercise being beneficial if leg pain did not worsen. Information is given in a reassuring way and medical pain management was adjusted. The participants are advised to resume work when possible. A physiotherapy examination included a standardised, mechanical evaluation and advice on exercise was chosen accordingly. General advice is given to increase physical activity and exercise. In order to ensure coordination between stake holders, copies of the medical records are 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 is scheduled two weeks later and a follow-up visit at the doctor is 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 are scheduled for an interview with a case manager within two to three workdays. This interview is standardised and includes questions of work history, private life and questions on how pain and disability was perceived. This normally lasts for one to two hours. The participant is seen once or more times by the case manager depending on need and progress. The case manager and the participant together makes a tailored rehabilitation plan aiming at full or partial return to work (RTW). If this is deemed unrealistic, a plan towards staying on the labor 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 resumed work or if this is deemed impossible (in the latter case the social worker at the social service centre is contacted). One of three different persons could be assigned as case manager (the specialist in clinical social medicine, the social worker or the occupational therapist).

Intervention Type
Mixed

Primary outcome measure
Return to work (RTW), which will be measured during a follow-up period of one year. RTW is here defined as the first 4-week period after sick-listing, where sick-leave and disability benefits are not received. Data will be retrieved from registers of public social transfer income.

Secondary outcome measures
Disability will be measured based on pain and functioning based on questionnaire data retrieved one year after inclusion. The Roland Morris Disability questionnaire is used (23 items).

Overall study start date
01/01/2010

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Age 16-60 years
2. On partial (contracted hours reduced by at least 25%) or fully (contracted hours reduced by 100%) on sick leave 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
400

Total final enrolment
476

Key exclusion criteria
1. Unemployment
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. Pregnancy
5. Known dependency on drugs or alcohol
6. Any primary psychiatric disease

Date of first enrolment
01/10/2010

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
Denmark

Study participating centre
Marselisborgcenter
Sønder Jernbanevej 18, 2. sal
3400 Hillerød
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Study participating centre
Spine clinic, Regional Hospital Silkeborg
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Sponsor information

Organisation
Central Region Denmark (Marselisborgcentret and Regional Hospital Silkeborg)

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Sponsor type
Research organisation

ROR
https://ror.org/0247ay475

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Central Region Denmark (Marselisborgcentret and Regional Hospital Silkeborg)

Results and Publications

Publication and dissemination plan
Effects at one-year follow-up will be published at the end of 2017.

Intention to publish date
31/12/2017

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?
Protocol article	protocol	16/12/2017	15/01/2021	Yes	No
Results article		11/02/2022	14/02/2022	Yes	No