ISRCTN42281022 https://doi.org/10.1186/ISRCTN42281022

Can patient education focused on coping with pain facilitate return to work and everyday life following lumbar spinal fusion surgery?

Submission date
12/12/2013

Recruitment status
No longer recruiting

Registration date
15/01/2014

Overall study status
Completed

Last Edited
25/05/2016

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Lumbar spinal fusion surgery (LSF) is a commonly offered treatment for chronic and severe back pain when other treatments have failed. In the past two decades the number of people undergoing LSF has been rapidly increasing in western countries, with the largest increase seen in the USA. This means that both the costs and the risk of adverse events and complications are increasing too. This may be justified if the benefits of the procedure are greater than the risks and costs. However, despite many years of research in this field, some speak in favour of conservative treatment in the shape of cognitive-behavioural therapy (CBT) for chronic low back pain (CLBP), whereas some conclude that surgery is better. Very few have examined whether a treatment strategy combining CBT with LSF can result in an altogether added effect for CLBP patients undergoing surgery. An additional two factors seem to be important in successful rehabilitation of surgically treated CLBP patients. The first is that the (CBT) rehabilitation should be managed by a team of health professionals with different professional backgrounds (e.g., doctor, therapist, social worker). The second concerns the timing of rehabilitation. Most often rehabilitation starts after surgery, but research points to the fact that if patients are well prepared before going to surgery, they may be discharged from hospital faster. The aim of the study is to examine whether patients participating in patient education focusing on pain behaviour and pain coping (CBT intervention) will be discharged from hospital faster, will have less disability and pain after 1 year, will have less sick leave and faster return to work in the first year following surgery, and will be less costly to the health system and society in the first year following surgery.

Who can participate?
Patients aged between 18-64, scheduled for LSF surgery due to CLBP, with a diagnosis of degenerative disease and the ability to speak and understand Danish.

What does the study involve?
Patients are randomly allocated to either the intervention or the control group. The patients in the control group receive the departments standard treatment. This consists of surgery and physical rehabilitation commencing 12 weeks after surgery. The patients in the intervention

group will also receive the standard treatment. In addition to this, the patients are offered a short patient education focusing on pain coping by the use of CBT. The patient education is managed by a multidisciplinary team (surgeon, psychologist, physical and occupational therapist and social worker).

What are the possible benefits and risks of participating?
We hope that our intervention can provide better functional outcome, less pain and earlier return to work after surgery. The study is expected to provide new knowledge that can increase consistency in patient treatment. We expect that the results will make a significant contribution to the development of guidelines for good rehabilitation of patients undergoing LSF. This study includes health economic analyses, which we hope can help with prioritization in health and social planning. There are no side effects from the treatment, except from the bother of driving to and from the hospital for the patients enrolled in the intervention group. Patients will have their travel expenses covered. All patients are as a minimum guaranteed the standard treatment. The patients in the intervention group further receive a patient education, providing them with additional information, and the possibility of asking questions and sharing worries with other patients.

Where is the study run from?
The study is run from the Aarhus University Hospital, but the intervention takes place at the Regional Hospital of Silkeborg, Denmark.

When is the study starting and how long is it expected to run for?
The study began in October 2011 and is expected to run until October 2015.

Who is funding the study?
The Danish Council for Strategic Research, The Health Research Fund of Central Denmark Region, The Rheumatism Association Research Foundation and The Health Foundation.

Who is the main contact?
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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
Effect and cost-effectiveness of a multidisciplinary preoperative cognitive intervention for lumbar spinal fusion patients: a randomized clinical trial

Study objectives
We expect that adding a preoperative multidisciplinary cognitive intervention to the standard treatment strategy for patients undergoing lumbar spinal fusion surgery:
1. Will reduce postoperative pain, enable an earlier and improved mobilization, and thereby decrease the length of hospitalisation following surgery.
2. Will have a positive effect on the patients level of function and quality of life, reduce time to return to work (RTW) and improve their ability to cope with pain.
3. Will be cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Danish Protection Agency, 05/05/2011, ref. no. 2011-41-5899
2. Research Ethics Committee of Central Denmark Region, 05/05/2011, j. no. M-20110047

Study design
Single-blind randomized clinical 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
Patients undergoing lumbar spinal fusion surgery at a maximum of three levels due to chronic low back pain caused by degenerative diseases or spondylolisthesis grade 1-2.

Interventions
Participants will be randomised to one of the following two groups:

Control
Treatment as usual, which includes surgery and the standard postoperative physical rehabilitation. Rehabilitation commences at 12 weeks after surgery and takes place in the primary sector (e.g., physical therapy clinic or a municipal rehabilitation center).

Intervention
Treatment as usual and in addition to this, a preoperative multidisciplinary intervention (patient education) using a cognitive approach. This intervention consists of six sessions, each of three hours duration, adding up to a total of 18 hours. Patients are to attend four of the sessions prior to surgery, while the fifth and sixth sessions are placed postoperatively, at three and six months respectively. The patient education is managed by a multidisciplinary team consisting of a psychologist, an occupational therapist, a physiotherapist, a spine surgeon, a social worker and an experienced patient. It includes group-based sessions and consists of:
1. Pain and coping
2. Problem-solving training
3. Physical training and pacing using cognitive principles
4. General ergonomic directions
5. Information on the patients return to work plans
6. The surgical procedure and the immediate postoperative course

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Disability: measured using the Oswestry Disability Index (0% = no disability, 100% = bed bound). Self reported at baseline, 1 month, 3 months, 6 months and 12 months.
2. Return to work/sick leave: data will be obtained from the DREAM Database, a national database administered by the Ministry of Employment at 12 months following surgery.

Secondary outcome measures
1. Pain: measured using the Low Back Pain Rating Scale (pain index). This is a self-report measure consisting of six scales (three for leg, three for back) questioning on pain right now, worst pain in the past 14 days, and average pain in the past 14 days. All scales are from 0 (no pain) to 10 (unbearable pain). Self reported at baseline, 1 month, 3 months, 6 months and 12 months.
2. Quality of life: measured using the Euroquol 5D (1 = full health, 0 = dead). Self reported at baseline, 1 month, 3 months, 6 months and 12 months. Self reported at baseline, 1 month, 3 months, 6 months and 12 months.
3. Coping strategies: measured using the Coping Strategies Questionnaire. The questionnaire is

a 31-item (seven subscales) self-report inventory, where participants rate to what extent they use a given coping strategy on a seven-point Likert scale, ranging from 0 = never to 6 = always. Self reported at baseline, 1 month, 3 months, 6 months and 12 months.
4. Fear avoidance: measured using the fear avoidance beliefs questionnaire. The questionnaire consists of two subscales with several items each, a Physical Activity subscale (0-24 points) and a Work subscale (0-42 points). A higher score is indicative of a higher (worse) level of fear avoidance belief. Self reported at baseline, 1 month, 3 months, 6 months and 12 months.
5. Readmission to hospital and use of healthcare services: data are obtained from self-report diaries and Danish registries. Measured at 12 months.

Overall study start date
01/10/2011

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Age 18-64 years
2. Scheduled for lumbar spinal fusion surgery due to degenerative disc disease or spondylolisthesis grade I to II
3. Ability to speak and understand Danish

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
The study aimed to include at least 80 patients, based on sample size calculations. A total of 96 patients have been included.

Key exclusion criteria
1. Psychiatric diseases
2. Co-morbidity such as infection, fractures or malignant disease

Date of first enrolment
01/10/2011

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
Denmark

Study participating centre
Aarhus University Hospital
Aarhus
Denmark
8000

Sponsor information

Organisation
The Danish Council for Strategic Research (Det strategiske Forskningsråd) (Denmark)

Sponsor details
Ministry of Science, Innovation and Higher Education
PO Box 2135
Copenhagen
Denmark
DK-1015

Sponsor type
Research council

Website
http://fivu.dk/en/research-and-innovation/councils-and-commissions/the-danish-council-for-strategic-research

ROR
https://ror.org/03ge1nb22

Funder(s)

Funder type
Research organisation

Funder Name

The Health Research Fund of Central Denmark Region (Region Midtjyllands Sundhedsvidenskabelige Forskningsfond) (Denmark), ref: 12110613522022565 81

Funder Name
The Rheumatism Association Research Foundation (Gigtforeningens Forskningsfond) (Denmark), ref: R111-A2612 and R102-A2083

Funder Name
The Health Foundation (Helsefonden) (Denmark), ref: 2008B127

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	03/03/2014		Yes	No
Results article	results	20/05/2016		Yes	No