ISRCTN17115599 https://doi.org/10.1186/ISRCTN17115599

PREPARE (PREhabilitation, Physical Activity and ExeRcisE) persons with severe low back pain for an optimal functional outcome after lumbar fusion surgery

Submission date
27/04/2015

Recruitment status
No longer recruiting

Registration date
18/05/2015

Overall study status
Completed

Last Edited
10/06/2025

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
Lower back pain (LBP) is a common problem affecting most people during their lifetime. Many people who experience LBP will recover within a few weeks and can manage the pain with painkillers, but for some people the pain turns into a long term condition. In cases of very severe pain, when all other treatments have failed to work, spinal surgery might be recommended. Spinal fusion surgery is a procedure carried out to stabilise the spine and reduce pain. The number of patients who undergo lower back (lumbar) spinal fusion surgery has increased worldwide. Elective spinal surgery often involves a long hospital stay and is not always successful. There is a risk that the surgery might have to be repeated later on, and there is also the risk of developing complications before and after surgery. Also, there are various factors which increase the likelihood of unsuccessful surgery outcomes, such as smoking, severe pain before surgery and a fear of physical movement that might cause pain. Physical activity and exercise are crucial parts of the rehabilitation programme following spinal fusion surgery, and fear of movement is a major problem that prevents recovery. At the moment, there are no set guidelines on how best to prepare patients with severe LBP for spinal fusion surgery. Cognitive behavioural therapy (CBT), a well-known psychological talking therapy, is a frequently used and effective way to treat a range mental health conditions, such as phobias and anxiety. However, CBT has not been tested as an approach to help patients manage fear of pain before spinal fusion surgery. The aim of this study is to see whether a combined physiotherapy and CBT programme (the PREPARE programme) can help patients prepare for surgery, and increase physical activity following surgery more than standard care alone.

Who can participate?
Adult patients from participating trial centres scheduled for spinal fusion surgery.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) have 4, 1 hour sessions with a CBT-trained physiotherapist and receive a guided exercise

plan. Participants are asked to monitor their physical activity before and after surgery. The first physiotherapy session takes place 12 weeks before surgery. Those in group 2 (control group) are given treatment as usual. All participants complete questionnaires. There is a follow up interview 1 week before surgery, then again at 3 and 8 weeks, 3 and 6 months, and lastly 1, 2 and 5 years after surgery. At follow-up participants complete questionnaires and carry out various functional performance tests.

What are the possible benefits and risks of participating?
Participants in the intervention group receive structured preoperative pain management in addition to standard care. There are minimal risks associated with participation in this study. Some participants may experience transient increased pain during treatment.

Where is the study run from?
1. Spine Center (Sweden)
2. Sahlgrenska University Hospital (Sweden)
3. Art Clinic (Sweden)

When is the study starting and how long is it expected to run for?
January 2014 to December 2021

Who is funding the study?
1. AFA Insurance (AFA Försäkring) (Sweden)
2. EuroSpine Research Grants (Austria)
3. Health and Medical Care Executive Board of the Västra Götalandsregionen (Sweden)
4. Félix Neubergh Foundation (Sweden)

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
PREPARE (PREhabilitation, Physical Activity and ExeRcisE) persons with severe low back pain for an optimal functional outcome after lumbar fusion surgery: a randomised controlled trial

Acronym
PREPARE

Study objectives
1. Patients with severe low back pain (LBP) that get specific guidance in exercises that target the patient' specific fear of movement and catastrophising thoughts will experience improved functioning, be less depressed, less fearful of movement and be more active postoperatively as compared to patients who get usual care. This will increase patient satisfaction and pain reduction postoperatively, and their level of activity and participation.
2. The intervention (PREPARE) is more cost effective as compared to usual care in terms of direct and indirect health care costs.
3. The patients' objective level of physical activity and her/his own functioning goal will better predict the outcome of surgery as compared to disability measures. There is a difference between three various measures of physical activity (movement registration, subjective report according to a questionnaire, and the patients reported functioning).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Review Board of Gothenburg, 25/03/2012, ref: D586-11.

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Severe low back pain (disc degenerative disease)

Interventions
1. Group A (n=55) will receive specific guidance from a physiotherapist on how to stay active despite pain based on cognitive behavioral therapy (CBT) principles.
2. Group B (n=55) will receive treatment as usual (general advice to stay active before surgery, and to make contact with a physical therapy for further guidance).

Intervention Type
Behavioural

Primary outcome measure
Disability measured by Oswestry Disability Index (ODI).

Secondary outcome measures
1. Patient Specific Function Scale will be used to measure patients' own functioning goal.
2. Physical activity levels (sitting/lying and time spent upright) will be measured by the movement registration system Actigraph (uniaxial accelerometer).
3. The Pain Catastrophising Scale (PCS).
4. Zung Self-Rating Depression Scale (Zung).
5. Functional performance testing: five-minute walking, 50-ft (15 m) fast walking, sit to stand, 1-min stair-climbing.
6. The Swedish version of Tampa Scale of Kinesiophobia (TSK-SV) questionnaire.
7. Self-Efficacy for Exercise (SEE) self-report scale to measure self-efficacy for exercise in nine specific situations.
8. European Quality of Life 5 Dimensions Questionnaire (EuroQol/EQ-5D) (mobility, self-care, usual activity, pain/discomfort and anxiety/depression).
9. Patients’ self-report the effect of treatment (surgery) measured by Global Assessment.
10. The patients perceived harmfulness of daily activities will be measured by Photographs of Daily Activities (PHODA).
11. Cost-effectiveness will be measured by estimating quality of life before and after the treatment (EQ-5D), the number of quality adjusted-life-years (QALY) will be calculated. Days of sick-leave will be collected from the Social Security Office. The days of hospital stay as well as number of health-care consultation will be collected through the patients’ charts in addition to the patient’s own recording.

Overall study start date
01/01/2011

Completion date
31/12/2021

Eligibility

Key inclusion criteria

Swedish speaking patients with persistent LBP scheduled for surgical intervention attached to the Orthopedic Department at Sahlgrenska University Hospital or Spine Center, Gothenburg

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
160

Total final enrolment
118

Key exclusion criteria
Patients with malignant pain, confirmed neurological disease or rheumatic disease, post traumatic changes, idiopathic scoliosis, isthmic spondylolisthesis, disc herniation, spinal stenosis or poor understanding of the Swedish language

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Sweden

Study participating centre
Spine Center
Gruvgatan 8
421 30 Västra Frölunda
Västra Frölunda
Sweden
42130

Study participating centre
Sahlgrenska University Hospital
Lundberg Laboratory for Orthopaedic Research
Gröna stråket 12
Gothenburg

Sweden
41345

Study participating centre
Art Clinic
Göteborgsvägen 95
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43137

Sponsor information

Organisation
Sahlgrenska University Hospital, Region Västra Götaland

Sponsor details
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43180

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04vgqjj36

Funder(s)

Funder type
Other

Funder Name
AFA Försäkring

Alternative Name(s)
AFA Insurance

Funding Body Type

Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Sweden

Funder Name
EuroSpine Research Grants (Austria)

Funder Name
Health and Medical Care Executive Board of the Västra Götalandsregionen (Sweden)

Funder Name
Félix Neubergh Foundation (Sweden)

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
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/08/2016		Yes	No
Results article	results	01/08/2019	31/12/2019	Yes	No
Results article	Kinesiophobia, self-efficacy and catastrophizing results	08/07/2022	11/07/2022	Yes	No
Results article	Long-Term Follow-Up	16/05/2024	10/06/2025	Yes	No