A Person-Centered Prehabilitation Program Based on Cognitive-Behavioral Physical Therapy for Patients Scheduled for Lumbar Fusion Surgery: A Randomized Controlled Trial

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Background. Prehabilitation programs have led to improved postoperative outcomes in several surgical contexts, but there are presently no guidelines for the prehabilitation phase before lumbar fusion surgery.

Objective. The objective was to investigate whether a person-centered physical therapy prehabilitation program, based on a cognitive-behavioral approach, is more effective than conventional care in reducing disability and improving functioning after lumbar fusion surgery in patients with degenerative disk disease.

Design. This study was a randomized controlled trial.

Setting. The study took place at 2 private spine clinics and 1 university hospital.

Patients. We prospectively enrolled 118 patients scheduled for lumbar fusion surgery.

Intervention. We actively intervened using a person-centered perspective and focused on promoting physical activity and targeting psychological risk factors before surgery. The control group received conventional preoperative care.

Measurements. The primary outcome was the Oswestry Disability Index score. Secondary outcomes were back and leg pain intensity, catastrophizing, kinesiophobia, self-efficacy, anxiety, depression, health-related quality of life, and patient-specific functioning, physical activity, and physical capacity. Data were collected on 6 occasions up to 6 months postoperatively. A linear mixed model was used to analyze the change scores of each outcome.

Results. No statistically significant between-group difference was found on the primary outcome (disability) over time (baseline to 6 months). Among secondary outcome measures, a statistically significant interaction effect ("Group × Time") was seen for the European Quality of Life 5 Dimensions Questionnaire. The largest between-group difference on the European Quality of Life 5 Dimensions Questionnaire index was seen 1 week prior to surgery and favored the active intervention. The largest between-group effect sizes at the 6-month follow-up favored the active intervention, and were seen for physical activity intensity, steps per day, and the One Leg Stand Test. Both groups reached the minimal important change for the primary outcome and, in several secondary outcomes (pain intensity, back and leg pain catastrophicizing; anxiety; health-related quality of life [EQ5D VAS]), already at 8-week follow-up.

Limitations. The participants’ preoperative level of disability was lower than normative values, which suggests selection bias.

Conclusions. Both interventions led to clinically important changes, but it is not clear what kind of prehabilitation program is the most effective.
Globally, low back pain (LBP) causes more disability than any other condition.1 Although only 0.5% of persons with LBP undergo back surgery, treatment costs afterwards are significant.1,2 Degenerative lumbar disease is the main reason for surgical intervention, and rates of surgery are expected to increase.3 Outcomes after surgery for degenerative lumbar diseases are, however, suboptimal, with persistent pain, poor functional status, and poor quality of life in up to 40% of patients.1,3

There is an increased interest in the use of prehabilitation to prepare patients for surgical intervention.4,5 The underlying theoretical idea of prehabilitation is that increasing functional capacity before surgery will lead to quicker recovery.6 The content of the prehabilitation program varies according to context and the patient’s needs.7–13 It can, for example, focus on increasing physical activity, decreasing anxiety, or improving nutritional status.4 Physical activity is identified as a major component of most programs,5 but at the start of this study there was only very low-quality evidence for the effectiveness of physical therapist interventions before lumbar fusion surgery.14

It is known that presurgical psychological states, such as catastrophizing15 and fear-avoidance beliefs,16 are significant predictors of pain and poor function after lumbar surgery. Likewise, 70% of potential candidates for lumbar surgery reported kinesiophobia.17 At the start of our trial in 2014, no prior study had evaluated the effect of targeting psychological factors before surgery. Rehabilitation programs have been designed to incorporate some of these factors but only postoperatively.18,19 Moreover, only 3 studies have investigated the effect of different prehabilitation programs before lumbar spine surgery.20–22 Louw et al investigated whether 1 session of pain neuroscience education before surgery would improve the surgical outcome.20 Rolving et al examined whether a multidisciplinary cognitive-behavioral therapy intervention (6 × 3 hours) would be beneficial.21 In the study of Lindbäck et al, patients received individual sessions of presurgery physical therapy twice a week for 9 weeks.22 None of these found a statistically significant difference between the groups on the primary outcome (reduction of disability) at the 1-year follow-up.

The content of our prehabilitation program was based on the evidence of benefit for healthy behavior in general and in particular for patients with chronic LBP. According to the World Health Organization, physical activity should be recommended to all people to achieve well-documented positive effects on health.23 This was recently acknowledged to be of the utmost importance for patients with LBP.24 Evidence-based practice for patients with chronic disabling LBP suggests that treatment should include physical activity in combination with cognitive-behavioral techniques.25 It is reasonable to propose the same for patients awaiting surgery.

The time before surgery has been acknowledged to be a window of opportunity for behavioral change:26 addressing psychological risk factors, such as catastrophizing and kinesiophobia, during prehabilitation might greatly benefit long-term outcomes. Based on this rationale, our prehabilitation program was based on the cognitive-behavioral fear-avoidance model.27,28 This model explains how catastrophizing thoughts and fear of movement can be barriers to recovery. Woby et al emphasized the relevance of supporting the patient’s self-efficacy in order to facilitate recovery.28 Person-centered care, implemented in earlier controlled studies, has shown positive effects on self-efficacy subsequently leading to significantly reduced costs, reduced uncertainty concerning illness and treatment, and decreased number of medical complications observed.29–31 To further enhance the patient’s self-efficacy, we therefore applied the principles of person-centered care.32

**Aim**

The overall aim of the trial was to investigate whether a person-centered physical therapy prehabilitation program based on a cognitive-behavioral approach is more effective than conventional care in reducing disability and improving functioning after lumbar fusion surgery in patients with degenerative disk disease.
Hypotheses

1. The primary hypothesis was that patients who received the active intervention would experience a greater reduction in disability levels after surgery than ones receiving conventional care.

2. Secondary hypotheses were that patients who received the active intervention would experience greater decreases in leg and back pain intensity, pain catastrophizing, pain-related fear, and depressive symptoms, and greater increases in self-efficacy for exercise, health-related quality of life, patient-specific functioning, physical activity level, and physical capacity after surgery than with conventional care.

All between-group differences were hypothesized to be largest at 6 months after surgery.

Methods

This was a prospective randomized controlled trial (RCT) with data collected at baseline and at 5 follow-up sessions (1 week before surgery, 3 and 8 weeks, 3 and 6 months postoperatively). This trial was approved by the Regional Ethical Committee of Göteborg, Dnr.586-11, with amendment 527-15, and registered with Current Controlled Trials (ISRCTN17115599). This study is reported according to the Consolidated Standards of Reporting Trials.33 The intervention is based on a modified version of the cognitive-behavioral fear-avoidance model27,28 (Fig. 1). Full details of the study design and the intervention have been given elsewhere.24

Participants

Eligible participants were recruited from 2 private spine clinics and 1 university hospital in Göteborg, Sweden, between April 2014 and June 2017. The patients were all awaiting lumbar fusion surgery with or without surgical procedures for disk herniation, foraminal stenosis, or isthmic spondylolisthesis.

Inclusion criteria were: (1) 18 to 70 years of age; (2) dominating chronic LBP with degenerative changes in 1 to 3 segments of the lumbar spine; (3) additional minor radiating symptoms; (4) reproducible pain at clinical examination in the relevant segment(s); and (5) scheduled for lumbar fusion surgery.

Exclusion criteria were: (1) previous decompression surgery for spinal stenosis; (2) spinal malignancy; (3) dominating radiculopathy; (4) confirmed neurological or rheumatic disorder; (5) deformities in the thoracolumbar spine (eg, idiopathic scoliosis); and (6) poor understanding of Swedish.

Eligible patients were invited to participate in the trial. If agreeable, patients were given an appointment with an independent observer for baseline measurements to be made. All participants gave written informed consent before randomization.

Randomization

An independent observer randomly assigned consecutive participants to either the intervention group or to conventional care. This was done with numbered sealed envelopes containing allocation sheets of information wrapped in colored paper. The envelopes were prepared by the senior research investigator (M.L.) before the start. The allocation sequence was determined by a computerized random list with a 1:1 allocation, concealed from the rest of the staff until completion of the trial.

Blinding

Neither the participants nor the physical therapist could be blinded but the independent observers responsible for the outcome measures were blinded to treatment allocation.

The postoperative physical therapists, hospital staff, and statisticians were unaware of group assignments. Data were entered into a coded electronic data file, only decoded for analyses after the final participant had reached the 6-month follow-up.

Interventions and Procedures

The active prehabilitation intervention. The prehabilitation phase started 8 to 12 weeks before surgery. Participants in the intervention group met the same physical therapist at a spine clinic for four 1-hour sessions before surgery and 1 half-hour session by telephone 2 weeks after surgery. Each session had a predefined structure, a specific aim, and included several cognitive-behavioral techniques as described in Lotzke et al.32 The physical therapist had more than 10 years of clinical experience of patients with LBP and 1½ years education and training, with a Graduate Diploma in Cognitive and Behavioral Psychotherapy. A detailed description of the active intervention is given in Figure 2.

Conventional care. Participants allocated to conventional care were advised to contact a physical therapist at the relevant surgical clinic. Conventional care in this region of Sweden is comprised of a single session with a physical therapist. In this, the patient should receive information about the postoperative mobilization routine and be introduced to a core exercise program to be initiated the day after surgery. Furthermore, the patient should be encouraged to stay active and to start performing the recommended exercises before surgery. In this study, the conventional care was delivered by local physical therapists and was not controlled for.

Treatment fidelity. In this study, ensuring treatment fidelity was understood as a process applied in the study design, training the provider, delivery of treatment, receipt of treatment, and enactment of treatment skills.34 The process, already commenced during study design, continued into the RCT.
Before the start of this RCT, the theoretical framework and elements of treatment fidelity were tested in a feasibility study. Based on this, changes were made to contextually adjust the active intervention. For example, the theoretical framework was adjusted by adding self-efficacy to the model. In addition, the detailed treatment manual developed elsewhere was tested, and then contextually adjusted for use in this RCT.
In this RCT, the following treatment fidelity strategies were applied. The treatment “dose” in the active intervention was controlled for by using the same pattern of sessions (number, frequency, and length of contact) as in the previously published study protocol,32 also displayed in Figure 2. Whether the therapist delivered the intervention as intended was checked by an observer only in a pilot study, and thereafter, the intervention delivered in the RCT was controlled for by use of a detailed treatment manual.35

Outcome measures. All outcome measures were selected based on the modified cognitive-behavioral fear-avoidance model of Vlaeyen et al.27,28 (Fig. 1). All variables, except physical activity and physical capacity, were measured by Patient-Reported Outcome Measures (PROMs). The time point for each measurement is presented in Figure 3.

Demographics and baseline characteristics. Baseline characteristics—age, sex, self-reported weight and height (body mass index, kg/m²), smoking status, education level, sick-leave status, previous spine surgeries, pain duration (back and leg), and comorbidity—were collected from the Swedish Spine Register (Swespine). Type of surgical procedure and fusion level were obtained from participants’ medical records (Tab. 1).

Primary outcome measure: PROM. The primary outcome, degree of disability, was measured by the Oswestry Disability Index 2.0 (ODI).36

Secondary outcome measures: PROMs.

- Back and leg pain intensity levels were measured using 100-mm visual analogue scales.37
- Pain catastrophizing was measured using the Pain Catastrophizing Scale, with 13 items assessing pain catastrophizing thoughts: higher scores indicate greater pain catastrophizing.38,39
- Kinesiophobia was rated using the Tampa Scale for Kinesiophobia. The total score ranges from 17 to 68, with higher scores indicating greater kinesiophobia.17
- Self-efficacy for exercise was measured using the Self-Efficacy for Exercise scale. Scores range from 0 to 90, with higher scores indicating greater self-efficacy for exercise.40
- Anxiety and depression were assessed using the Hospital Anxiety and Depression Scale: higher scores indicate greater symptoms of anxiety and depression.41
- Health-related quality of life was measured using the European Quality of Life 5 Dimensions Questionnaire (EQ-5D index), with general health on a visual analog scale (EQ-5D VAS)—higher scores indicate higher health-related quality of life.42

- Patient-specific functioning was measured with the Patient-Specific Functional Scale. Patients list 3 activities they have difficulty performing, rating them on a scale from 0 to 10, with 0 indicating that the patient cannot perform the activity at all.43

Secondary outcome measures: objective measures.

- Physical activity was objectively measured by a digital triaxial accelerometer (ActiGraph GT3X+-; ActiGraph, Pensacola, FL, USA).44 The variables, steps per day, time in moderate-to-vigorous physical activity, time spent in light physical activity, and time spent sedentary, were analyzed.45,46
- Physical capacity was measured by 5-minute walking; 50-foot fast walking; Timed “Up & Go” test; 1-minute stair-climbing; and the One Leg Stand (OLS) test.47–49

Sample Size
The number of participants was determined by a power analysis (80% power, α = .05), with disability as the primary outcome.50 The power calculation recommended a sample of 55 in each group for a statistically significant between-group difference of at least 8 points in the ODI (SD = 15).51 The between-group difference of at least 8 points on the ODI denoted a difference in mean changes from baseline to any of the 5 follow-up occasions. The time dimension of the assumed SD was cross-sectional.

Statistical Methods
Data analysis was performed with SAS 9.4 (SAS Institute, Cary, NC, USA) and SPSS 22 (IBM Corp., Armonk, NY, USA). Descriptive statistics were presented as mean [SD] and frequency (percentage).

All outcome measures were interpreted in relation to reference values and to the minimal important change (MIC).52 If a MIC value was not available for the same study population, we used a value as close as possible.

Statistical analyses used to respond to the first hypothesis. We used an “intention-to-treat” (ITT) approach to compare the effects of the different therapy conditions on the primary (ODI) and secondary outcomes from baseline to 6-month follow-up. For subjects lost to follow-up, all available data were used. A linear mixed model with a heterogeneous Toeplitz covariance matrix was used to evaluate the effect of the therapy conditions for the various time points. This takes the correlated nature of repeated measures for the same participant into account while allowing for missing observations. Each outcome had a separate model that included the change scores as the dependent variable. The change scores were calculated by subtracting the baseline value of each outcome from the follow-up values. This was performed to yield change scores for all 5 follow-up occasions and included all available data of the dependent variable. Time, treatment group, and the baseline value of each
**Figure 3.** An overview of outcome measures and the different time points for baseline and follow-up assessments. EQ5D = European Quality of Life 5 Dimensions Questionnaire; GT3X+ = ActiGraph GT3X+ (ActiGraph, Pensacola, FL, USA); HADS = Hospital Anxiety and Depression Scale; ODI = Oswestry Disability Index 2.0; PCS = Pain Catastrophizing Scale; PSFS = Patient-Specific Functional Scale; QoL, quality of life; SEES = Self-Efficacy for Exercise Scale; TSK = Tampa Scale for Kinesiophobia; VAS = visual analogue scale.

| Time Point                      | Measures                                                                 |
|--------------------------------|--------------------------------------------------------------------------|
| **BASELINE**                   | **FOLLOW-UP 1, 2, 3**                                                   |
| Primary: Disability (ODI)      | Primary: Disability (ODI)                                               |
| Secondary:                     |                           | Secondary:                                                                   |
| • Back + leg pain intensity (VAS) | • Back + leg pain intensity (VAS)                                      |
| • Pain catastrophizing (PCS)   | • Pain catastrophizing (PCS)                                            |
| • Fear of movement (TSK)       | • Fear of movement (TSK)                                                |
| • Self-efficacy for exercise (SEES) | • Self-efficacy for exercise (SEES)                                  |
| • Anxiety (HADS)               | • Anxiety (HADS)                                                       |
| • Depressed mood (HADS)        | • Depressed mood (HADS)                                                 |
| • Patient-specific functioning (PSFS) | • Patient-specific functioning (PSFS)                              |
| • Health-related QoL (EQ5D)    | • Health-related QoL (EQ5D)                                             |
| • Physical activity (GT3X+ accelerometer) | • Physical activity (GT3X+ accelerometer) |
| • Physical capacity            |                           | • Physical capacity                                                         |
| (Timed up-and-go, 5-minute walk, 50-foot walk, 1-minute stair climbing, One-leg stand) | (Timed up-and-go, 5-minute walk, 50-foot walk, 1-minute stair climbing, One-leg stand) | 8-12 weeks before surgery 1 week prior to surgery and 3 and 8 weeks after surgery 3 and 6 months after surgery |

Statistical analysis used to respond to the second hypothesis. Hedges $g$ for between-group effect sizes of the primary and secondary outcomes at each time point was computed using SEs from the mixed-model output to derive pooled and weighted SDs. Effect sizes (ESs) were categorized as small ($d \approx 0.20$ to $< 0.50$), medium ($d \geq 0.50$ to $< 0.80$), and large ($d \geq 0.80$) and presented with 95% confidence intervals (CIs). ESs at each time point (1 week before surgery and 3 weeks, 8 weeks, and 3 months after surgery) were compared with that at 6 months.

Per-protocol analyses. To be included in the per-protocol analysis, all participants should have undergone a surgical procedure for lumbar fusion. In addition, they should have received the active intervention for at least 4 of the 5 sessions. Forty-six patients from the active intervention and 54 participants from the conventional care group were included in the per-protocol analysis. In the sensitivity analysis, per-protocol data were compared with ITT data.

Role of the Funding Source
The funders of this study (AFA Research Funding, Eurospine Research Grants, Swedish Research Council, Health and Medical Care Executive Board of the Västra Götaland Region, Doctor Felix Neubergh Grants) played no role in the design, conduct, or reporting of this study.

Results
From April 1, 2014 to July 1, 2017, the inclusion criteria were met by 261 patients, who were asked to participate. Of these, 118 accepted and were randomly allocated to active intervention ($n = 59$) or conventional care ($n = 59$). All participants were included in the ITT analysis. In both groups, 54 participants underwent lumbar fusion surgery. The distribution of included patients is described in Figure 4, and the baseline characteristics of the participants are described in Table 1. Patients without
Table 1.
Patient Characteristics of All Participants, Baseline Data

| Characteristic                                      | All Patients (n = 118) | Active Intervention (n = 59) | Conventional Care (n = 59) |
|-----------------------------------------------------|------------------------|------------------------------|----------------------------|
| Mean [SD] age, y                                     | 45.7 [8.3]             | 44.8 [8.2]                   | 46.7 [8.5]                 |
| Sex (men/women)                                     | 55/63                  | 26/33                        | 29/30                      |
| Mean [SD] body mass index<sup>a</sup>                | 26.3 [3.7]             | 26.3 [3.9]                   | 26.4 [3.4]                 |
| Smoking, n (%)                                       | 8 (6.8)                | 3 (5.1)                      | 5 (8.5)                    |
| Missing data, n (%)                                  | 1 (0.8)                | 1 (1.7)                      | 0 (0.0)                    |
| Education, n (%)                                     |                        |                              |                            |
| Elementary school                                   | 7 (5.9)                | 1 (1.7)                      | 6 (10.2)                   |
| High school                                         | 51 (43.2)              | 24 (40.7)                    | 27 (45.8)                  |
| University                                          | 42 (35.6)              | 23 (39.0)                    | 19 (32.2)                  |
| Vocational education                                | 17 (14.4)              | 11 (18.6)                    | 6 (10.2)                   |
| Missing data                                         | 1 (0.8)                | 0 (0.0)                      | 1 (1.7)                    |
| Sick leave, n (%)                                    |                        |                              |                            |
| No sick leave                                       | 75 (63.6)              | 39 (66.1)                    | 36 (61.0)                  |
| Full-time                                           | 25 (21.2)              | 13 (22.0)                    | 12 (20.3)                  |
| Part-time                                           | 16 (13.6)              | 7 (11.9)                     | 9 (15.3)                   |
| Missing data                                         | 2 (1.7)                | 0 (0.0)                      | 2 (3.4)                    |
| Previous lumbar spine surgery, n (%)                |                        |                              |                            |
| 0 occasion (no previous back surgery)               | 108 (91.5)             | 55 (93.2)                    | 53 (89.8)                  |
| 1 occasion                                           | 7 (5.9)                | 4 (6.8)                      | 3 (5.1)                    |
| 2 occasions                                         | 3 (2.5)                | 0 (0.0)                      | 3 (5.1)                    |
| Pain duration, back > 2 y, n (%)                    | 87 (73.7)              | 41 (34.7)                    | 46 (39.0)                  |
| Pain duration, leg > 2 y, n (%)                     | 52 (44.1)              | 28 (47.5)                    | 24 (40.7)                  |
| Missing data                                         | 1 (0.8)                | 1 (1.7)                      | 0 (0.0)                    |
| Comorbidity, n (%)                                   | 13 (11.0)              | 6 (10.2)                     | 7 (11.9)                   |
| Surgical procedure, n (%)                           |                        |                              |                            |
| Instrumented posterior fusion                       | 103 (87.3)             | 53 (89.8)                    | 50 (84.7)                  |
| Instrumented anterior interbody fusion              | 1 (0.8)                | 1 (1.7)                      | 0 (0.0)                    |
| Instrumented combined posterior and interbody fusion| 4 (3.4)                | 0 (0.0)                      | 4 (6.8)                    |
| Did not go through fusion surgery                   | 10 (8.5)               | 5 (8.5)                      | 5 (8.5)                    |
| Fusion levels, n (%)                                 |                        |                              |                            |
| 1 level                                             | 62 (57.4)              | 32 (59.3)                    | 30 (55.6)                  |
| 2 level                                             | 41 (38.0)              | 20 (37.0)                    | 21 (38.9)                  |
| 3 level                                             | 5 (4.2)                | 2 (3.7)                      | 3 (5.6)                    |

<sup>a</sup>Body mass index measured in kg/m<sup>2</sup>.

Follow-up data at the 8-week follow-up (n = 16) had significantly higher baseline levels of fear of movement (Tampa Scale for Kinesiophobia) and depression (Hospital Anxiety and Depression Scale). Patients without follow-up data at the 3-month (n = 14) and 6-month (n = 17) follow-ups had significantly worse balance standing on 1 leg (OLS test: eyes open). No adverse event was reported in either group.

**Primary Hypothesis**

This could not be confirmed for the primary outcome (disability) because no statistically significant difference
Figure 4.
Flowchart of the included patients according to the format of the CONSORT Statement.
was found between groups in ITT analyses (see Group × Time Interaction, Tab. 2).

Secondary Hypotheses

Among secondary outcome measures, a statistically significant interaction effect was seen for EQ5D in the ITT analyses (Group × Time Interaction, Tab. 2). The largest between-group difference was seen 1 week prior to surgery and favored the active intervention. The difference did not, however, reach the MIC (Appendix).

The ODI change from baseline to 6 months was statistically significant in each group separately (see Time in Tab. 2). Moreover, at 8 weeks postoperatively, ODI had already decreased by at least 8 points (= MIC value for ODI) in both groups (Tab. 2).

For secondary outcomes, the change from baseline to 6 months was statistically significant for almost all variables in each group separately (Time Effect, Tab. 2). Both groups reached a stable plateau of change in primary and secondary outcomes by 8 weeks postoperatively (ie, no further change after 8 weeks). Also, by 8 weeks postoperatively, both groups had reached the MIC value in several secondary outcome measures: pain intensity, back and leg; pain catastrophizing; anxiety; and health-related quality of life (EQ-5D VAS) (marked in Tab. 2). The intervention group reached the MIC value for Patient-Specific Functional Scale (decrease of 2 points) at 3 months, whereas this MIC value was reached by the conventional care group at 6 months (Tab. 2). Some variables showed no statistically significantly change: these were physical activity measures (steps per day, moderate-to-vigorous physical activity, time spent sedentary), and physical capacity tasks (50-foot walk, and OLS test: eyes closed) (Appendix).

The between-group differences were not largest at 6 months after surgery for any outcome.

Medium ESs could be detected at separate time points, but because interaction effects were not statistically significant, these must be interpreted with caution. At 6-month follow-up, the largest ESs in favor of the intervention were for physical activity (time spent in moderate-to-vigorous physical activity per day) (ES = 0.42; 95% CI = 0.00–0.83) and OLS test (ES = 0.36; 95% CI = −0.05 to 0.77) (Fig. 5).

For the outcome measure Patient-Specific Functional Scale, there was also a positive but not statistically significant trend in favor of the intervention group at each follow-up point: ESs were small (ES = 0.14–0.33).

A positive trend of change was noted 1 week prior to surgery for the outcomes pain intensity (ES = 0.21; 95% CI = −0.18 to 0.59), pain catastrophizing (ES = 0.29; 95% CI = −0.11 to 0.69), fear of movement (ES = 0.30; 95% CI = −0.10 to 0.70), depressive signs (ES = 0.25; 95% CI = −0.14 to 0.65), and patient-specific functioning (ES = 0.23; 95% CI = −0.19 to 0.65) in favor of the intervention group (Tab. 2); however, ESs were small.

Per-Protocol Analyses

There were no statistically significant differences between per-protocol and ITT analyses on any outcome measures.

Discussion

The aim of the trial was to investigate whether a person-centered physical therapy rehabilitation program based on a cognitive-behavioral approach is more effective than conventional care in improving functioning after lumbar fusion surgery in patients with degenerative disk disease. No statistically significant between-group difference was found on the primary outcome (disability) over time (baseline to 6 months), but among secondary outcome measures, a statistically significant interaction effect was seen for EQ-5D index. The largest between-group effect sizes at the 6-month follow-up favored the active intervention and were seen for physical activity intensity, steps per day, and the OLS test.

Statement of Principal Findings

As with other studies of rehabilitation applied before lumbar spine surgery, no statistically significant difference was found between the groups on the primary outcome, that is, reduction of disability. However, our study mirrored previous ones in identifying statistically significant changes in each group separately. Among early clinical relevant changes after surgery were seen in the variable “pain intensity” and “catastrophizing,” but not for “kinesiophobia.” Similar patterns of early clinically relevant changes after surgery were seen in the variable “pain intensity” in other prehabilitation studies. However, because none of the comparable studies used the same additional outcome measures (catastrophizing, fear of movement, self-efficacy), no further comparisons could be made.

Lack of between-group differences might be due to the problem of treatment differentiation. It might mean that the active intervention was not strong enough or that the conventional care was more active than we hypothesized. The latter possibility is supported by our finding that participants in the conventional care group also experienced clinically relevant changes, as in other prehabilitation studies. A lack of treatment differentiation could be explained as a lack of “dose.” In the available prehabilitation studies, the dose (number of sessions, frequency, and length of contact) ranges from 1 educational session to 18 individual sessions. Furthermore, the content of the intervention needs to be taken into consideration.
Table 2.
Baseline Scores, Change Scores (From Baseline), and Hedges Effect Sizes for Between-Group Differences Between Active Intervention and Conventional Care in All Patients by Intention-to-Treat Analysis.

| Measure                  | Group or Parameter | Baseline Score | Mean (95% CI) for: | P for: |
|--------------------------|--------------------|----------------|-------------------|--------|
|                          |                    |                | Change Score       |        |
|                          |                    |                | From Baseline to 1 wk Before Surgery |        |
|                          |                    |                | From Baseline to 3 wk After Surgery |        |
|                          |                    |                | From Baseline to 8 wk After Surgery |        |
|                          |                    |                | From Baseline to 12 mo After Surgery |        |
|                          |                    |                | Group Effect       |        |
|                          |                    |                | Time Effect        |        |
|                          |                    |                | Group × Time Interaction |        |
| Disability (ODI)         | Active intervention| 35.7 (32.3–39.0) | 0.8 (−3.7 to 5.3) |        |
|                          | Conventional care  | 38.0 (35.1–40.9) | 2.9 (−1.5 to 7.3) |        |
|                          | Between-group ES   | 0.13 (−0.26 to 0.51) | −0.08 (−0.47 to 0.31) |        |
|                          |                    |                | −13.4 (−18.4 to −8.3) |        |
|                          |                    |                | −14.5 (−19.8 to −9.3) |        |
|                          |                    |                | 0.001 |        |
|                          |                    |                | .98   |        |
|                          |                    |                | .16   |        |
| Pain intensity in back (VAS) | Active intervention | 57.3 (51.7 to 62.9) | −1.0 (−5.8 to 3.7) |          |
|                          | Conventional care  | 65.0 (61.0–68.9) | 2.5 (−2.1 to 7.1) |          |
|                          | Between-group ES   | 0.21 (−0.18 to 0.59) | −0.22 (−0.62 to 0.17) |          |
|                          |                    |                | 0.29 (−0.11 to 0.69) |          |
|                          |                    |                | −0.09 (−0.47 to 0.30) |          |
|                          |                    |                | −0.08 (−0.43 to 0.35) |          |
|                          |                    |                | 0.001 |          |
|                          |                    |                | .99   |          |
|                          |                    |                | .19   |          |
| Pain intensity in leg (VAS) | Active intervention | 37.3 (29.3–45.3) | 3.0 (−10.9 to 17.0) |          |
|                          | Conventional care  | 33.5 (26.3–40.7) | −1.3 (−15.1 to 12.4) |          |
|                          | Between-group ES   | −0.09 (−0.47 to 0.30) | 0.00 (−0.39 to 0.40) |          |
|                          |                    |                | 0.01 (−0.39 to 0.40) |          |
|                          |                    |                | −0.04 (−0.43 to 0.35) |          |
|                          |                    |                | −0.08 (−0.47 to 0.3) |          |
|                          |                    |                | .47   |          |
|                          |                    |                | .90   |          |
| Pain catastrophizing (PCS) | Active intervention | 22.5 (20.5–24.4) | −4.4 (−6.4 to −2.3) |          |
|                          | Conventional care  | 23.1 (20.9–25.3) | −2.2 (−4.3 to −0.2) |          |
|                          | Between-group ES   | −0.29 (−0.11 to 0.69) | −0.03 (−0.45 to 0.36) |          |
|                          |                    |                | 0.27 (−0.12 to 0.67) |          |
|                          |                    |                | −0.08 (−0.47 to 0.3) |          |
|                          |                    |                | 0.02 (−0.37 to 0.42) |          |
|                          |                    |                | .47   |          |
|                          |                    |                | .20   |          |
| Fear of movement (TSK)   | Active intervention | 37.8 (35.6–40.1) | −3.4 (−5.0 to −1.8) |          |
|                          | Conventional care  | 38.5 (36.4–40.7) | −1.7 (−3.3 to −0.1) |          |
|                          | Between-group ES   | 0.30 (−0.10 to 0.70) | −0.13 (−0.53 to 0.27) |          |
|                          |                    |                | −0.10 (−0.50 to 0.30) |          |
|                          |                    |                | −0.14 (−0.53 to 0.25) |          |
|                          |                    |                | −0.09 (−0.49 to 0.3) |          |
|                          |                    |                | .79   |          |
|                          |                    |                | .22   |          |
### Table 2.  
Continued

| Measure                                | Group or Parameter | Baseline Score | Change Score | P for: |
|----------------------------------------|--------------------|----------------|--------------|--------|
|                                       | Mean (95% CI) for: | From Baseline to 1 wk Before Surgery | From Baseline to 1 wk After Surgery | From Baseline to 8 mo After Surgery | From Baseline to 3 mo After Surgery | From Baseline to 6 mo After Surgery | Group Effect | Time Effect | Group × Time Interaction |
|                                       |                    | From Baseline to 3 wk After Surgery | From Baseline to 3 wk After Surgery | From Baseline to 8 mo After Surgery | From Baseline to 3 mo After Surgery | From Baseline to 6 mo After Surgery |             |             |                      |
| Self-efficacy for exercise (SEES)     | Active intervention| 61.5 (56.4–66.6) | 0.6 (−6.1 to 7.3) | 6.8 (−5.0 to 14.2) | 5.3 (−1.6 to 12.1) | 6.1 (−0.8 to 12.9) | 4.9 (−2.5 to 12.4) | .54 | .02 | .30 |
|                                       | Conventional care  | 60.8 (55.4–66.3) | −0.4 (−6.9 to 6.1) | 0.5 (−6.7 to 7.7) | 6.6 (0.0 to 13.1) | 5.1 (−1.4 to 11.6) | 3.4 (−3.8 to 10.6) |            |             |                      |
|                                       | Between-group ES   | 0.04 (−0.35 to 0.46) | 0.25 (−0.16 to 0.65) | −0.05 (−0.45 to 0.34) | 0.04 (−0.35 to 0.43) | 0.06 (−0.34 to 0.46) |            |             |                      |
| Anxiety (HADS)                        | Active intervention| 6.9 (5.9–7.9) | −0.3 (−1.4 to 0.8) | −2.2 (−3.1 to −1.2) | −2.3 (−3.3 to −1.3) | −2.5 (−3.4 to −1.6) | −2.7 (−3.5 to −1.8) | .43 | <.001 | .85 |
|                                       | Conventional care  | 6.3 (5.5–7.2) | 0.3 (−0.7 to 1.4) | −1.8 (−2.7 to −0.9) | −1.7 (−2.7 to −0.8) | −2.4 (−3.3 to −1.6) | −2.6 (−3.5 to −1.8) |            |             |                      |
|                                       | Between-group ES   | 0.16 (−0.23 to 0.56) | 0.11 (−0.30 to 0.51) | 0.17 (−0.23 to 0.58) | 0.03 (−0.37 to 0.42) | 0.01 (−0.39 to 0.41) |            |             |                      |
| Depressed mood (HADS)                 | Active intervention| 5.1 (4.2–6.0) | −0.5 (−1.5 to 0.6) | −1.0 (−2.1 to 0.1) | −1.3 (−2.4 to −0.2) | −1.6 (−2.7 to −0.6) | −1.8 (−2.9 to −0.8) | .84 | <.001 | .34 |
|                                       | Conventional care  | 5.7 (4.8–6.6) | 0.6 (−0.1 to 1.5) | −1.0 (−2.0 to 0.1) | −1.4 (−2.4 to −0.3) | −1.8 (−2.8 to −0.8) | −2.1 (−3.1 to −1.1) |            |             |                      |
|                                       | Between-group ES   | 0.25 (−0.14 to 0.65) | 0.00 (−0.40 to 0.40) | −0.02 (−0.42 to 0.37) | −0.05 (−0.44 to 0.34) | −0.07 (−0.47 to 0.33) |            |             |                      |
| Health-related quality of life (EQ-5D Index) | Active intervention| 0.51 (0.44–0.58) | 0.09 (0.02–0.16) | 0.02 (−0.05 to 0.1) | 0.19 (0.13–0.25) | 0.20 (0.14–0.25) | 0.21 (0.15–0.27) | .52 | <.001 | .01 |
|                                       | Conventional care  | 0.47 (0.40–0.55) | −0.05 (−0.12 to 0.02) | 0.07 (−0.14) | 0.14 (0.08–0.20) | 0.20 (0.15–0.26) | 0.26 (0.21–0.32) |            |             |                      |
|                                       | Between-group ES   | 0.57 (0.16–0.98) | −0.18 (−0.57 to 0.22) | 0.23 (−0.16 to 0.63) | −0.03 (−0.42 to 0.35) | −0.25 (−0.64 to 0.14) |            |             |                      |
| Health-related quality of life (EQ-SD VAS) | Active intervention| 46.1 (41.6–50.7) | −1.6 (−9.0 to 5.8) | 5.4 (−3.1 to 14.0) | 18.8 (11.3–26.2) | 24.2 (17.4–31.1) | 23.2 (15.9–30.6) | .50 | <.001 | .53 |
|                                       | Conventional care  | 46.1 (41.5–50.8) | −2.3 (−9.4 to 4.9) | 10.7 (2.4–19.1) | 20.0 (12.9–27.2) | 24.1 (17.5–30.6) | 26.4 (19.2–33.5) |            |             |                      |
|                                       | Between-group ES   | 0.02 (−0.37 to 0.41) | −0.18 (−0.58 to 0.22) | −0.05 (−0.44 to 0.35) | 0.01 (−0.38 to 0.4) | −0.12 (−0.52 to 0.27) |            |             |                      |
### Table 2. Continued

| Measure                        | Group or Parameter          | Mean (95% CI) for: | Change Score | P for: |
|--------------------------------|------------------------------|--------------------|--------------|--------|
|                                |                              | From Baseline to 1 wk Before Surgery | From Baseline to 3 wk After Surgery | From Baseline to 8 mo After Surgery | From Baseline to 3 mo After Surgery | From Baseline to 6 mo After Surgery | Group Effect | Time Effect | Group × Time Interaction |
| Patient-reported functioning (PSFS) |                              | 2.8 (2.4–3.3)     | 0.2 (−0.3 to 0.7) | 0.2 (−0.5 to 0.9) | 1.5 (0.8–2.2) | 2.0 (1.3–2.6) | 2.9 (2.2–3.6) | .13 < .001 | .83 |
|                                 | Active intervention          | 2.9 (2.4–3.5)     | −0.2 (−0.7 to 0.3) | −0.1 (−0.8 to 0.5) | 0.7 (0.1–1.4) | 1.3 (0.6–1.9) | 2.5 (1.8–3.2) | .77 .91 .20 |
|                                 | Conventional care            | 0.23 (−0.19 to 0.65) | 0.15 (−0.27 to 0.57) | 0.35 (−0.06 to 0.76) | 0.30 (−0.10 to 0.70) | 0.17 (−0.25 to 0.59) | .22 .07 .33 |
| Steps/d                        |                              | 7811.8 (7088.3–8535.4) | −88.5 (−687.2 to 510.2) | 180.5 (−421.7 to 782.7) | .77 .91 .20 |
|                                 | Active intervention          | 7175.2 (6544.3–7806) | 42.3 (−549.3 to 633.8) | −183.8 (−780.1 to 412.6) | .77 .91 .20 |
|                                 | Conventional care            | −0.09 (−0.50 to 0.32) | 0.25 (−0.16 to 0.66) | .22 .07 .33 |
|                                 | Between-group ES             | .16 (−0.25 to 0.57) | .042 (0.00–0.03) | .16 (−0.25 to 0.57) | .042 (0.00–0.03) |
| Time spent in MVPA, min/d (total accumulated)² |                              | 29.9 (24.8–35) | 3.7 (−1.3 to 8.8) | 2.5 (−2.2 to 7.3) | .80 .03 .98 |
|                                 | Active intervention          | 26.5 (21.3–31.8) | 1.7 (−3.3 to 6.7) | −2.2 (−6.8 to 2.4) | .80 .03 .98 |
|                                 | Conventional care            | 0.16 (−0.25 to 0.57) | .042 (0.00–0.03) | .16 (−0.25 to 0.57) | .042 (0.00–0.03) |
|                                 | Between-group ES             | .07 (−0.33 to 0.48) | .06 (−0.35 to 0.47) | .07 (−0.33 to 0.48) | .06 (−0.35 to 0.47) |
| Time spent in light physical activity, min/d |                              | 276.4 (254.3–298.4) | −23.6 (−43.3 to −3.9) | −7.1 (−28.8 to 14.6) | .80 .03 .98 |
|                                 | Active intervention          | 279.8 (264.2–295.5) | −27.1 (−46.7 to −7.5) | −10.3 (−31.8 to 11.3) | .80 .03 .98 |
|                                 | Conventional care            | 0.07 (−0.33 to 0.48) | .06 (−0.35 to 0.47) | .07 (−0.33 to 0.48) | .06 (−0.35 to 0.47) |
|                                 | Between-group ES             | .07 (−0.33 to 0.48) | .06 (−0.35 to 0.47) | .07 (−0.33 to 0.48) | .06 (−0.35 to 0.47) |
| Time spent sedentary, min/d     |                              | 550.1 (524.0–576.2) | 27.9 (−13.9 to 69.8) | 19 (−24.9 to 63) | .39 .82 .23 |
|                                 | Active intervention          | 543.3 (521.5–565.1) | 27.8 (−12.8 to 68.3) | 40.9 (−1.8 to 83.7) | .39 .82 .23 |
|                                 | Conventional care            | 0.00 (−0.41 to 0.4) | 0.21 (−0.21 to 0.62) | .00 (−0.41 to 0.4) | .21 (−0.21 to 0.62) |

(continued)
### Table 2. Continued

| Measure                  | Group or Parameter          | Baseline Score | Change Score | P for:          |
|--------------------------|----------------------------|----------------|--------------|----------------|
|                          |                            | From Baseline to 1 wk Before Surgery | From Baseline to 3 wk After Surgery | From Baseline to 8 wk After Surgery | From Baseline to 3 mo After Surgery | From Baseline to 6 mo After Surgery | Group Effect | Time Effect | Group × Time Interaction |
| 5-min walk, m            | Active intervention        | 427.5 (405.6–449.3) | 47.0 (−0.3 to 94.2) | 58.8 (10.7–106.8) | .75 | .01 | .62 |
|                          | Conventional care          | 409.9 (389.9–429.9) | 41.5 (−4.8 to 87.9) | 58.3 (10.9–105.6) | .77 | .36 | .39 |
|                          | Between-group ES           | 0.05 (−0.35 to 0.45) | 0 (−0.40 to 0.41) |                | .57 | .36 | .39 |
| ~15-m (50-ft) walk, s   | Active intervention        | 8.9 (8.2–9.6) | −0.9 (−1.6 to −0.1) | −0.9 (−1.7 to −0.1) | .57 | .36 | .39 |
|                          | Conventional care          | 9.6 (8.9–10.3) | −1.0 (−1.7 to −0.2) | −1.1 (−1.9 to −0.4) | .57 | .36 | .39 |
|                          | Between-group ES           | −0.04 (−0.44 to 0.36) | −0.12 (−0.53 to 0.28) |                | .57 | .36 | .39 |
| Timed “Up & Go” Test, s | Active intervention        | 8.0 (7.1–8.9) | −1.5 (−2.1 to −0.8) | −1.7 (−2.4 to −1.1) | .44 | <.001 | .21 |
|                          | Conventional care          | 7.8 (7.3–8.3) | −1.2 (−1.8 to −0.6) | −1.7 (−2.3 to −1) | .44 | <.001 | .21 |
|                          | Between-group ES           | 0.19 (−0.21 to 0.59) | 0.05 (−0.35 to 0.46) |                | .44 | <.001 | .21 |
| 1-min stair climb, steps | Active intervention        | 107.1 (100.3–113.9) | 15.2 (10.6–19.8) | 19.2 (13.7–24.6) | .83 | <.001 | .37 |
|                          | Conventional care          | 101.1 (95.4–106.8) | 15.0 (10.6–19.5) | 21.5 (16.2–27) | .71 | <.001 | .37 |
|                          | Between-group ES           | 0.02 (−0.38 to 0.42) | −0.18 (−0.59 to 0.23) |                | .71 | <.001 | .37 |

(continued)
Table 2. Continued

| Measure | Group or Parameter | Baseline Score | Mean (95% CI) for: | P for: |
|---------|--------------------|----------------|-------------------|--------|
|         |                    | From Baseline to 3 wk Before Surgery | From Baseline to 1 wk After Surgery | From Baseline to 3 wk After Surgery | From Baseline to 6 mo After Surgery | Group Effect | Time Effect | Group × Time Interaction |
|         |                    | From Baseline to 8 wk After Surgery | From Baseline to 6 mo After Surgery |         |         |         |         |
| One-Leg Stand test: eyes open, s | Active intervention | 44.1 (38.6–49.6) | 5.1 (0.3–9.8) | 2.3 (0.8–3.7) | .97 | .016 | .29 |
|         | Conventional care | 38.7 (33.1–44.3) | 3.5 (−1.2 to 8.1) | 0.3 (−2.2 to 2.8) | .14 | .34 | .49 |
|         | Between-group ES | | 0.14 (−0.26 to 0.54) | −0.14 (−0.54 to 0.27) | |
| One-Leg Stand test: eyes closed, s | Active intervention | 4.7 (3.0–6.4) | 0.5 (−0.7 to 1.7) | 0.1 (−0.1 to 0.2) | .14 | .34 | .49 |
|         | Conventional care | 2.8 (2.3–3.2) | −0.1 (−1.3 to 1.1) | 0.1 (−2.1 to 2.3) | |
|         | Between-group ES | | 0.23 (−0.17 to 0.63) | 0.36 (−0.05 to 0.77) | |

*a* Fixed factors used in the linear mixed model analysis: treatment group, time, group × time interaction term, confounding factors (baseline values of depression, baseline steps/d, and sex), and the baseline value of the dependent variable; random factor: treatment center. EQ-5D = European Quality of Life 5 Dimensions Questionnaire; ES = effect size; HADS = Hospital Anxiety and Depression Scale; MVPA = moderate-to-vigorous-intensity physical activity; ODI = Oswestry Disability Index 2.0; PCS = Pain Catastrophizing Scale; PSFS = Patient-Specific Functional Scale; SEES = Self-Efficacy for Exercise Scale; TSK = Tampa Scale for Kinesiophobia; VAS = visual analogue scale.

*b* The change score reached the minimal important change 8 wk after surgery.

*c* In the model for anxiety, depression was not used as a confounding factor because of multicollinearity.

*d* In the model for time spent in MVPA/d, steps/d was not used as a confounding factor because of multicollinearity.
Figure 5.
Graphs of change scores in physical activity measured as (A) minutes per day in moderate-to-vigorous physical activity, (B) steps per day, and (C) minutes per day spent sedentary, with 95% confidence intervals.
During the period of our study, there has been increasing interest by physical therapists worldwide in behavioral change. Hence, it is possible that physical therapists, who delivered the conventional care, incorporated essential features of behavioral change techniques and psychologically informed physical therapy. Van Erp et al showed that Swedish surgeons recommend faster mobilization than their Dutch counterparts (direct vs 1 day postoperative), and more activities on the first day (sitting, standing, walking); there are no available studies of Swedish physical therapists’ attitudes toward mobilization. Study site randomization is a strategy to enable treatment differentiation. Although 3 study sites were included, 90% of the patients underwent surgery at the same spine clinic. This was also the clinic where the active treatment was delivered, which might have increased the risk of study contamination. We argue that these factors together might explain the lack of contrast between study groups.

An interesting finding was that the largest ES difference (0.57) between groups in health-related quality of life (EQ-5D index) at 1 week prior to surgery favored the active intervention. No other study on prehabilitation in the field has found such early effects on this outcome. Our study population started with an EQ-5D index of 0.51 vs 0.47 (intervention vs control) whereas the mean value for the degenerative disk disease population in Swespine is 0.35 at baseline. In similar studies, Lindbäck et al presented baseline values for EQ-5D index of 0.37 vs 0.36, whereas Rolving et al reported values of 0.65 vs 0.63. Moreover, the intervention group reached the MIC value for EQ-5D index 8 weeks postoperatively whereas the conventional care group reached it at 3 months. Although the group differences did not persist over time, we argue that the current prehabilitation program is a promising foundation for future efforts to optimize the results of surgery.

A central question about prehabilitation concerns the most opportune time to introduce recovery-optimizing behaviors. Santa Mina et al argue that the presurgical period is an ideal time to introduce new health behaviors that include physical activity. We argue that changes in physical activity measured at 6 months reflect changes in behavior. A small ES (0.41) in favor of the intervention was identified for physical activity at 6 months postsurgery. The same trend was shown for the OLS test (ES = 0.36 at 6 months postsurgery). It will be interesting to see if these patterns of change continue at the 1-year follow-up.

Strengths and Limitation of This Trial

The major strength of this trial is its underlying methodology. The study was designed on a clear theoretical framework, the foundation for treatment fidelity. There is a lack of longitudinal study designs putting the fear-avoidance model into practice. This study therefore adds to the theoretical development of the fear-avoidance model. Furthermore, the design and analyses followed the CONSORT statement and followed systematic steps by performing a pilot and feasibility study. This RCT had low levels of attrition (< 15%) and internal missing items of the PROMs (< 5%) due to our a priori strategy to promote retention. Questionnaires were kept short and participants were contacted by telephone to book appointments for follow-up visits. If we could not reach participants, we persevered with telephone calls, voicemail, and mailed questionnaires with prepaid envelopes.

Another strength is the use of a mixed model for statistical analysis. This takes the correlated nature of repeated measures for the same patient into account, while allowing for missing observations. The model uses all available data, maintaining the power of the study at different time points.

Selection bias might threaten internal validity. Participants in the present study were younger and less disabled (ODI = 35.7) than the same population group in Swespine (2013: ODI = 43). Healthier people with more a positive attitude toward activity are more likely to agree to participate in an active intervention. Even so, significant changes were achieved in almost all outcome measures among all participants. We hypothesize that these changes could be further improved by including patients who are more disabled from the start.

The difference in starting point for the participants varied between 8 and 12 weeks presurgery. This was purely for practical reasons, such as when the patient was available to start. All patients had pain for a long time before the surgery, so we did not believe that there would be a significant change in basic variables depending on when they started the study.

Understanding the level of treatment fidelity is crucial for interpreting an intervention’s effectiveness. With nonsignificant results and an unknown level of treatment fidelity, one cannot tell whether the problem was an ineffective treatment or a lack of treatment fidelity. Treatment fidelity was addressed in the study design as well as in the RCT. In retrospect, the planned-for strategies used to control for treatment integrity and treatment differentiation seem not to have been sufficient. Future studies should further monitor and optimize treatment fidelity, thus reducing random variability. This has been done by Boden et al, who, in another context, designed several studies to address treatment fidelity, and thereafter, designed a successful prehabilitation intervention. One of their strategies was to use a standardized protocol for control groups, including a site investigator who monitored and reported divergence from this. Another strategy to further distinguish between the active intervention and the control would be to use a protocol to control for treatment integrity, including, for
example, to conduct in vivo observations or recordings of the intervention’s delivery.

The results of our and previous studies cannot identify the best time point, number of sessions, and type of intervention appropriate for patients awaiting lumbar fusion surgery.\(^{20-22}\)\(^{61}\) We suggest, supported by others,\(^{21,22}\) that screening for psychological risk factors might increase the possibility of more effective prehabilitation intervention. In future studies it would, for example, be of interest to include only patients with high values on psychological risk factors such as catastrophizing and fear of movement.

**Conclusion**

Both the active intervention and the conventional care intervention delivered before lumbar fusion surgery contributed to clinically relevant changes after surgery. It is not clear what kind of prehabilitation program is the most efficient. Future studies should preferably include patients with a psychological risk profile for a poor outcome.

**Author Contributions and Acknowledgments**

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**Ethics Approval**

This trial was approved by the Regional Ethical Committee of Göteborg, Dnr.586-11, with amendment 527-15. All participants gave written informed consent before randomization.

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**Clinical Trial Registration**

This study is registered with Current Controlled Trials (ISRCTN17115599) and is reported according to the Consolidated Standards of Reporting Trials.

**Disclosures and Presentations**

The authors completed the ICJME Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.
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## Appendix.
Reference Values and Minimal Important Changes of the Outcome Measures

| Outcome (ODI) (0–100) | Reference Values | Minimal Important Change |
|-----------------------|------------------|--------------------------|
| Disability (ODI) (0–100) | 0–20: “minimal disability”; 21–40: “moderate disability”; 41–60: “severe disability”; 61–80: “crippled”; 81–100: “bed-bound or exaggerating their symptoms” (Fairbank et al69) | –8.0 points (Hägg et al70) |
| Pain intensity—back (VAS) (0–100) | 0–4 mm: “no pain”; 5–44 mm: “mild pain”; 45–74 mm: “moderate pain”; 75–100 mm: “severe pain” (Jensen et al71) | –15 mm (Asher et al72) |
| Pain intensity—leg (VAS) (0–100) | 0–4 mm: “no pain”; 5–44 mm: “mild pain”; 45–74 mm: “moderate pain”; 75–100 mm: “severe pain” (Jensen et al71) | –17 mm (Asher et al72) |
| Pain catastrophizing (PCS) (0–52) | Cutoff point for pain catastrophizing: ≥ 20 (Sullivan et al73) | –38% from baseline (Scott et al74) |
| Fear of movement (TSK) (17–68) | Cutoff point for kinesiophobia: ≥ 37 (Lundberg75) | –6.0 points (Monticone et al76) |
| Self-efficacy for exercise (SEES) (0–90) | N/A | N/A |
| Anxiety (HADS) (0–21) | Normative data, United Kingdom: 6.2 (Breeman et al77) | –1.5 points (Lindbäck et al78) |
| Depressed mood (HADS) (0–21) | Normative data, United Kingdom: 4.0 (Breeman et al77) | –1.5 points (Lindbäck et al78) |
| Health-related quality of life (EQ-5D index) (−0.59 to 1.00) | Normative data, United Kingdom, age 45–54: 0.85 (Szende et al79) | 0.17 points (Johnsen et al80) |
| Health-related quality of life (EQ-5D VAS) (0–100) | Normative data, Sweden, age 45–54: 83.7 (Szende et al79) | 4.4 points (Asher et al72) |
| Patient-reported functioning (PSFS) (0–10) | N/A | 2.0 points (Maugham and Lewis60) |
| Steps/d | < 5000: “sedentary”; 5000–7499: “low active”; 7500–9999: “somewhat active”; 10,000–12,499: “active”; ≥ 12,500: “highly active” (Tudor-Locke et al81) | N/A |
| Time spent in MVPA per day | Normative data, Sweden, age 40–59: 33.3 min/d (Hagström et al82) | N/A |
| Time spent in light physical activity per day | N/A | N/A |
| Time spent sedentary per day | N/A | N/A |
| 5-min walk | Pain-free sample, United States: 518.2 m (Simmonds et al87) | 21.4 m (Andersson et al83) |
| 50-ft walk | Pain-free sample, United States: 8.4 s (Simmonds et al87) | –0.7 s (Andersson et al83) |
| Timed “Up & Go” Test | Pain-free sample: 5.2 s (Simmonds et al87) | –3.4 s (Gautschi et al84) |
| 1-min stair climbing | N/A | 14.5 steps (Andersson et al83) |
| One-Leg Stand Test: eyes open | N/A | N/A |
| One-Leg Stand Test: eyes closed | N/A | N/A |

*EQ-SD = European Quality of Life 5 Dimensions Questionnaire; HADS = Hospital Anxiety and Depression Scale; MVPA = moderate-to-vigorous-intensity physical activity; N/A = not applicable; ODI = Oswestry Disability Index 2.0; PCS = Pain Catastrophizing Scale; PSFS = Patient-Specific Functional Scale; SEES = Self-Efficacy for Exercise Scale; TSK = Tampa Scale for Kinesiophobia; VAS = visual analogue scale."