Patient-reported Outcomes After Surgery for Lumbar Disc Herniation

a Randomized Controlled Trial Comparing the Effects of Referral to Municipal Physical Rehabilitation Versus No Referral

Paulsen, Rune T.; Carreon, Leah Y.; Andersen, Mikkel Ø.

Published in:
Spine

DOI:
10.1097/BRS.0000000000003221

Publication date:
2020

Document version:
Accepted manuscript

Citation for pulished version (APA):
Paulsen, R. T., Carreon, L. Y., & Andersen, M. Ø. (2020). Patient-reported Outcomes After Surgery for Lumbar Disc Herniation: a Randomized Controlled Trial Comparing the Effects of Referral to Municipal Physical Rehabilitation Versus No Referral. *Spine*, *45*(1), 3-9. https://doi.org/10.1097/BRS.0000000000003221

SPINE An International Journal for the study of the spine, Publish Ahead of Print

DOI: 10.1097/BRS.0000000000003221

Patient Reported Outcomes after surgery for lumbar disk herniation, a randomized controlled trial comparing the effects of referral to municipal physical rehabilitation versus no referral.

Rune T. Paulsen*, MD, Leah Y. Carreon*, MD, MSc, Mikkel Ø. Andersen*, MD

*Spine Surgery and Research, Spine Center of Southern Denmark, Lillebaelt Hospital, Middelfart, Denmark and the Institute of Regional Health Research, University of Southern Denmark

Correspondence:

Rune Tendal Paulsen, MD

Spine Surgery and Research

Lillebaelt Hospital

Østre Houg vej 55, 5500 Middelfart Denmark

E-mail: rune.tendal.paulsen@rsyd.dk

Phone: 004560181440

The manuscript submitted does not contain information about medical devices or drugs.

The Research Council of Southern Denmark, Research Council of Lillebaelt Hospital and the Orthopedic Department, Lillebaelt Hospital funds were received in support of this work.

Relevant financial activities outside the submitted work: board membership, consultancy, employment, travel/accommodations/meeting expenses.

Abstract

Study Design: Randomized Controlled Trial

Objective: To investigate the effect of referring patients to municipal physical rehabilitation compared to no referral on Patient Reported Outcomes (PROs) after surgery for lumbar disc herniation.

Summary of Background Data: In surgical spine practice lumbar discectomy is one of the most frequent interventions. Post-operatively, patients are typically referred to physical rehabilitation at the time of hospital discharge; and in Denmark all patients are legally entitled to a personal rehabilitation plan and referral for free rehabilitation at the municipal facilities. However, whether postoperative rehabilitation is effective in this group of patients remains controversial.

Methods: This single-center single blinded study, randomized subjects into two groups. Patients in the REHAB group received municipal rehabilitation starting 4-6 weeks postoperative, while patients in the HOME group were discharged after surgery without any planned rehabilitation course. Primary outcome was Oswestry Disability Index after six months, while secondary outcomes included EuroQoL-5D and Visual Analogue Scale for leg and back pain. All PROs were obtained prior to surgery and at 1, 3-6, 12 and 24 months postoperative.

Results: A total of 146 patients were enrolled in the study: 73 allocated to the REHAB-group and 73 to the HOME-group. The groups were similar at baseline and the follow-up rate at 12 and 24 months was 78%. PROs in both groups improved significantly after surgery, but no statistically significant differences were observed between the groups at any follow-up time

point in either the intent-to-treat, as-treated and per-protocol analyses. Revision surgeries during the follow-up period were equally divided between the groups.

Conclusion: Surgery for lumbar disc herniation is effective in relieving pain, improving function and quality of life. The postoperative outcome is not altered significantly by referring patients to municipal physical rehabilitation compared to no referral.

Key words: Lumbar Disc Herniation; Spine Surgery; Discectomy; Rehabilitation; Physical Training; Recovery; Supervised Physical Exercise; Home Training

Level of Evidence: 1

Key Points

- This was a single center randomized controlled trial comparing the effects of referring patients to municipal physical rehabilitation versus no referral after surgery for lumbar disc herniation
- Patient Reported Outcomes improved significantly after discectomy and revision surgeries were equally divided between the groups.
- Oswestry Disability Index was not improved by referring to municipal rehabilitation compared to no rehabilitation at the six-month control.
- Secondary postoperative outcomes were not improved by referring to municipal rehabilitation compared to no referral in patients recovering after lumbar discectomy.

Introduction

Lumbar disc herniation (LDH) is characterized by radicular pain to the lower extremities with or without back pain. In more severe cases, the compressed nerve root can cause loss of both sensory and motor function in the innervated areas. The natural history of LDH is favorable and surgery is reserved for patients with loss of neurological function or persistent severe pain despite non-surgical treatment.

In Denmark, 1830 patients were treated with lumbar discectomy in 2017 (1) and the surgical rate has remained stable during the last five years. The surgical technique is mainly conventional discectomy with or without the use of microscope. Patients are typically hospitalized for 1-2 days depending on their postoperative pain. All patients are by law entitled to a personal rehabilitation plan and free postoperative rehabilitation at municipal facilities as a part of standard care. We published a study (2) which showed that all municipalities offered individual assessment of every patient followed by either team training, home exercises or individual training for the most complex patients.

A recent Cochrane review (3) concluded that exercise programs starting four to six weeks postoperative seems to lead to a faster decrease in pain and disability compared to no treatment. High-intensity programs might lead to faster decrease in pain and disability than low-intensity programs. The review found no differences between supervised exercise and home exercise programs and there was no evidence of increased reoperation rates due to active rehabilitation. Since this Cochrane review a number of other studies have been published, presenting conflicting results. Ebenbichler et al.(4) presented twelve-year outcomes and concluded that a comprehensive physiotherapy program following lumbar disc surgery was not superior to sham-therapy. Hebert et al. (5) found effect of rehabilitation, but no differences between two specific types of rehabilitation exercises.

Machado et al(6) concluded in an updated systematic review that early comprehensive physiotherapy soon after lumbar disc surgery provides moderate pain relief at short term, with lasting effects after 1-year follow-up. This finding was in contrast to a study by Oosterhuis et al(7) who concluded that referral for early postoperative rehabilitation is neither effective nor cost-effective.

Hence these conflicting results of previous studies, further studies are needed to provide more robust evidence. The aim of this study was to investigate the effects of routinely referral for municipal physical rehabilitation starting 4-6 weeks after discectomy compared to no referral on Patient Reported Outcomes (PROs).

Methods

This is a single center randomized controlled trial with 1:1 parallel group allocation. The study was performed in accordance with the CONSORT guidelines (8) and the details of this study are available at www.clinicaltrials.gov (NCT03505918).

Patients were scheduled for primary discectomy between September 2015 and January 2017 at the Spine Centre of Southern Denmark. Inclusion criteria were age between 18 and 65 years and MRI confirmed single-level symptomatic lumbar disc herniation with indications for discectomy. Exclusion criteria were previous spine surgery, psychiatric disorder, malignant disease, major surgical procedures within 12 months prior to inclusion and chronic non-specific pain disorders (fibromyalgia, whiplash etc.).

All patients participating in this study received standard operative treatment and postoperative hospitalization. At discharge all patients attended an informational meeting with the department's physiotherapists and they were informed of the postoperative course and instructed in standard exercises to be done the first 4 weeks as part of standard care.

Additionally, all patients received a standard informational booklet about disc herniation and common recommendations after surgery. All patients were scheduled for a standard care outpatient clinic visit conducted by a physiotherapist one month postoperative.

The control group (REHAB) of this study received standard care and started rehabilitation at 4-6 weeks postoperative, whereas the intervention group was sent home (HOME) without any other scheduled physical therapy visits or referrals. Both groups were advised to begin normal daily activities and work as soon as possible.

The municipal rehabilitation units in this study has previously been investigated (2) and the programs offered is overall comparable in terms of duration (8-10 weeks), frequency (1-2 times weekly) and type (team and individual training). All municipal centers has exercises for spinal stability as a key feature, but the exact type of exercise may vary.

Relevant approvals for conducting the study were obtained from the Regional Ethical Committee (S-20150051)

Outcome measures

Patient reported outcomes (PROs) consisted of pre- and postoperative Oswestry Disability Index (ODI)(9), EuroQOL (EQ-5D)(10), Visual Analogue Score (VAS) for back and leg pain. These PROs were collected preoperatively and then by postal questionnaires at 1, 3-6, 12 and 24 months. Our primary outcome was functional status (ODI) at six-month follow-up. Secondary outcome parameters were quality of life (EQ5D), pain status (VAS) and functional status (ODI) at the other respective follow-ups. The type and duration of rehabilitation were registered at the three month follow-up and by a phone interview after 1-2 years postoperative. Ancillary analyses included data from our DaneSpine register upon patient satisfaction, complications, new- and revision surgeries.

Sample size

Sample size calculation used Oswestry Disability Index (ODI)(9) as primary outcome measure with an estimated mean value for the control group of 24, standard deviation of 16 and a delta value between groups of 8. With a power of 80% and an alpha value of 5% we needed at least 64 patients in each group. Sample size was further increased by 15 % to account for drop-outs and death during the study. Thus, we needed to enroll 74 subjects in each arm and 148 in total.

This study used 1:1 block randomization with blocks of six. Randomization was done by a physiotherapist on the day of surgery before the surgical procedure. The randomization envelope and sheet were kept with the subject's research record. The primary investigator and surgeon were both blinded to the subject intervention throughout the course of the study.

Statistical Methods

To account for cross overs and drop-outs, all outcome parameters were compared and analyzed with both intent-to-treat, as-treated and per protocol analyses. Intent-to-treat analyzes patients in their original randomized groups. As-treated analyzes data from patients in their actual group after potential cross overs and drop outs. Per protocol analysis censors all patients crossing over or withdrawing during the study. Tables and figures are presented with intent-to-treat data only.

Assumptions of normality were controlled with q-plots and histograms for all continuous outcomes. Primary outcome parameter of ODI at six-month was analyzed through t-test, whereas the secondary outcomes of between and within group changes of were analyzed through repeated measures ANOVA. Continuous outcomes are presented with means, standard deviations and p-values. Categorical outcomes were analyzed with the chi-square

test and are presented by frequencies, percentages and p-values. All statistics were performed using STATA/IC 15 (College Station, Texas) and statistical significance was considered at a p-value threshold of 0.01.

Results

Participant flow and recruitment

Between September 2015 and January 2017, 192 eligible patients were referred to the primary investigator for inclusion and 162 of these agreed to participate. 146 participants were randomized and finally included in the cohort (Figure 1). 73 participants were assigned to the REHAB-group and 73 were assigned to the HOME-group. In total, 21 participants changed group during the study. 14 participants went from HOME to REHAB and 7 from REHAB to HOME. In total, 23 participants were excluded during the study period. 21 of these patients had new spine surgery and were excluded from the study. Two patients had cancer were therefore excluded (Figure 1). At 1, 3-6, 12 and 24 months we had follow-up rates of 99%, 83%, 78% and 78% respectively.

Baseline Data

Baseline characteristics were available on all included patients. Baseline characteristics and the comparison of these showed no statistical differences (Table 1). Type and duration of the performed rehabilitation is presented in Table 2.

Outcomes

ODI scores at 6-month follow-up had significantly improved compared to baseline from a mean of 45.2 to 16.4 ($p<0.001$) in the REHAB-group and from 43.4 to 13.6 ($p<0.001$) in the HOME-group. There was no statistically significant difference in ODI improvement with time between the REHAB and HOME groups. ODI improvements at specific follow-ups are

presented in Figure 2 and Table 3. Similarly, secondary outcome parameters showed statistically significant improvements in VAS back pain, VAS leg pain and EQ-5D in both groups at all follow-ups compared to baseline, but no differences between groups was observed in neither intend-to-treat, as-treated nor per-protocol analyses.

Ancillary analyses

77% of patients were satisfied after one year in the REHAB-group and 81% in the HOME-group. After two years 78% were satisfied in the REHAB-group and 88% in the HOME-group. Statistical analysis showed no difference between the groups in terms of satisfaction in either the intent to treat, as treated or per protocol analysis. The incidence of per- and postoperative complications was similar between the two groups (Table 4). Revision surgeries were equally distributed between the two groups (p=0.501), 9 in the HOME-group and 12 in the REHAB-group.

Discussion

Both groups showed statistically significant improvements on all patient reported outcome measures after discectomy. This suggests that the surgical procedure is effective in improving functional status, quality of life and pain in the short term and up to 2 years after surgery. More importantly, the current study found no differences between the groups in any of the PRO-data. In this study, referral for postoperative municipal physical rehabilitation provided no additional effect on PROs compared to no referral. There may be several reasons for this finding. First, compared to fusion surgery and wide decompression, discectomy is relatively less invasive with less injury from dissection to the tissues. Thus, there may be less potential for rehabilitation, compared to major orthopedic procedures such as hip or knee replacements. Additionally, the timing of rehabilitation might influence on our results. One could imagine that starting rehabilitation earlier could shorten the recovery period in this kind

of surgery. Second, both groups most likely performed some kind of activity comparable to actual rehabilitation physiotherapy. This could range from normal daily activities such as cleaning and walking to swimming, biking or fitness training. Given the fact that no clear evidence suggests one type of exercise is better over another (5), these daily activities might be just as good as supervised rehabilitation with physiotherapists (3). Third, we provided postoperative rehabilitation to all patients after lumbar discectomy, regardless of their level of pain and disability at follow-up. Thus, even patients who were doing well, and had no pain and disability were referred to rehabilitation. Thereby, one could imagine that various subgroups of patients might benefit from postoperative rehabilitation, but due to the design of this study and corresponding sample size, it was not appropriate to perform such sub-groups analyzes and this may be considered a limitation to this study.

Postoperative satisfaction in both groups was evaluated and 76% of the patients were satisfied at one-year follow-up with no significant differences between the groups. Patients from the REHAB group were overall satisfied with the provided postoperative rehabilitation and 77% scored rehabilitation as “good”, 15% as “in doubt” and 7% as “bad”. Patients, who scored the rehabilitation course as being good, described that they especially enjoyed the ongoing support and guidance from a physiotherapist during their recovery. They also enjoyed being together with other patients in the same situation to help them reflect on their own symptoms. Patients who scored the rehabilitation course as being bad mainly argued that they felt misplaced on the team which in some cases consisted mainly of old people.

Referral for postoperative rehabilitation did not influence on the incidence of revision surgeries (14%), but. the incidence was however higher compared to prior studies(11)(12) and published reports from our DaneSpine database (15). The majority (N=18) were due to reherniations and they were treated with decompressions and discectomies, three were due to failed primary surgery and they were treated with fusion.

The results of this study supports the study of Oosterhuis et al. who found referral for early rehabilitation neither effective nor cost-effective compared to no referral (7). Conflicting evidence still exists in this field, but as recommended by the latest Cochrane review (3) this high quality RCT study addressed many of the suggested research questions for future research. First, our rehabilitation programs were implemented in patient's daily practice and already a part of our standard care. Secondly, we found that routinely referral for postoperative rehabilitation is not effective. Thirdly, we found that a minimal intervention with the message of "return to an active lifestyle" was sufficient when rehabilitating patients recovering after surgery for LDH. We further evaluated both short- and long term effects after participating in postoperative rehabilitation and an additional strength is that all patients had surgery at the same spine unit and was included by the same primary investigator ensuring uniform patient selection and postoperative information at the hospital.

One of the important limitations of this study is that the rehabilitation was managed at the different municipality clinics. This implies a risk of differences in the performed rehabilitation exercises, course and information. In a recent qualitative study regarding postoperative rehabilitation, the authors concluded that the rehabilitation course should be planned individually in a joint-decision with the patients. This is consistent with rehabilitation offered in the Region of Southern Denmark, where all of the municipalities offer individual assessment of their patients and refers to either individual training, team training or home exercises depending on the patient status(2). To our knowledge the rehabilitation centers in our study implemented newest recommendations (3) and should be considered as a high-standard rehabilitation program. It would have been ideal if all patients were treated by the same physiotherapist at our spine clinic. However, due to pragmatic reasons, such a study could not be possible as patients would have to travel too far to get supervised rehabilitation. Additionally, a previous study found no outcome differences

between each of the rehabilitation units used in our study (2). Another limitation to our results is that this study might have been slightly underpowered as we did only include 146 patients and not the 148 as suggested by our sample size calculation. Additionally, the amount of patients crossing groups was higher than anticipated.

To summarize, this study found no differences between referral for municipal physical rehabilitation and no referral. This study contributed to the growing evidence regarding postoperative rehabilitation programs

Conclusion

Surgery for lumbar disc herniation is effective and provides both short and long-term improvements which are not altered significantly by routinely referring patients for municipal physical rehabilitation compared to no referral. In order to use limited health resources efficiently, future studies should seek to identify subgroups of patients who may benefit from a rehabilitation program.

Acknowledgments:

Jesper Rasmussen, MD for his valuable contribution to this study.

References

1. Andersen MØ et al. DaneSpine Annual Report 2017 [Internet]. 2017 [cited 2018 Sep 10]. Available from: http://drksdanespine.dk/wm420129

2. Paulsen RT, Bergholdt E, Carreon L, Rousing R, Hansen KH, Andersen M. No differences in post-operative rehabilitation across municipalities in patients with lumbar disc herniation. Dan Med J. 2015;

3. Oosterhuis T, Costa LOP, Maher CG, de Vet HCW, van Tulder MW, Ostelo RWJG. Rehabilitation after lumbar disc surgery. Cochrane database Syst Rev. 2014;

4. Ebenbichler GR, Inschlag S, Pflüger V, Stemberger R, Wiesinger G, Novak K, et al. Twelve-year follow-up of a randomized controlled trial of comprehensive physiotherapy following disc herniation operation. Clin Rehabil. 2015;

5. Hebert JJ, Fritz JM, Thackeray A, Koppenhaver SL, Teyhen D. Early multimodal rehabilitation following lumbar disc surgery: A randomised clinical trial comparing the effects of two exercise programmes on clinical outcome and lumbar multifidus muscle function. Br J Sports Med. 2015;

6. Machado GC, Pinheiro MB. Early comprehensive physiotherapy after lumbar spine surgery (PEDro synthesis). In: British Journal of Sports Medicine. 2018.

7. Oosterhuis T, Ostelo RW, van Dongen JM, Peul WC, de Boer MR, Bosmans JE, et al. Early rehabilitation after lumbar disc surgery is not effective or cost-effective compared to no referral: a randomised trial and economic evaluation. J Physiother. 2017;

8. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting

parallel group randomised trials. Int J Surg. 2012;

9. Fairbank JCT, Pynsent PB. The oswestry disability index. Spine (Phila Pa 1976). 2000;

10. Soer R, Reneman MF, Speijer BLGN, Coppes MH, Vroomen PCAJ. Clinimetric properties of the EuroQol-5D in patients with chronic low back pain. Spine J. 2012;

11. Häkkinen A, Kiviranta I, Neva MH, Kautiainen H, Ylinen J. Reoperations after first lumbar disc herniation surgery; A special interest on residives during a 5-year follow-up. BMC Musculoskelet Disord. 2007;

12. Heindel P, Tuchman A, Hsieh PC, Pham MH, D'Oro A, Patel NN, et al. Reoperation Rates after Single-level Lumbar Discectomy. Spine (Phila Pa 1976). 2017;

Figure 1: Flowchart of patient randomization, cross-overs and drop-outs during the study period

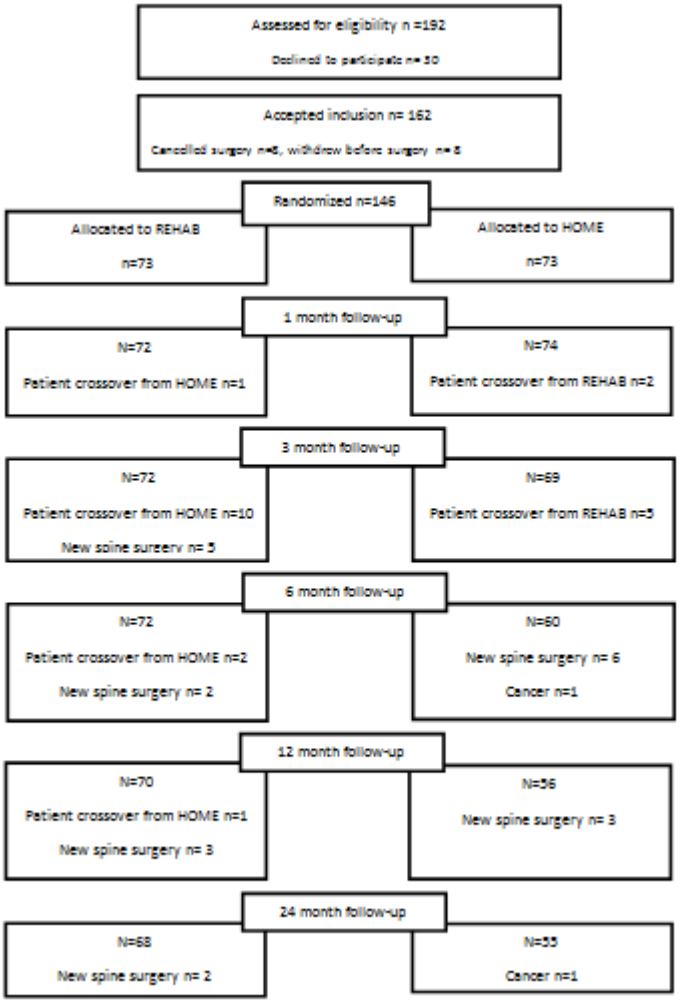

Figure 2: Graphs illustrating the development of patient reported outcomes during the study period between groups.

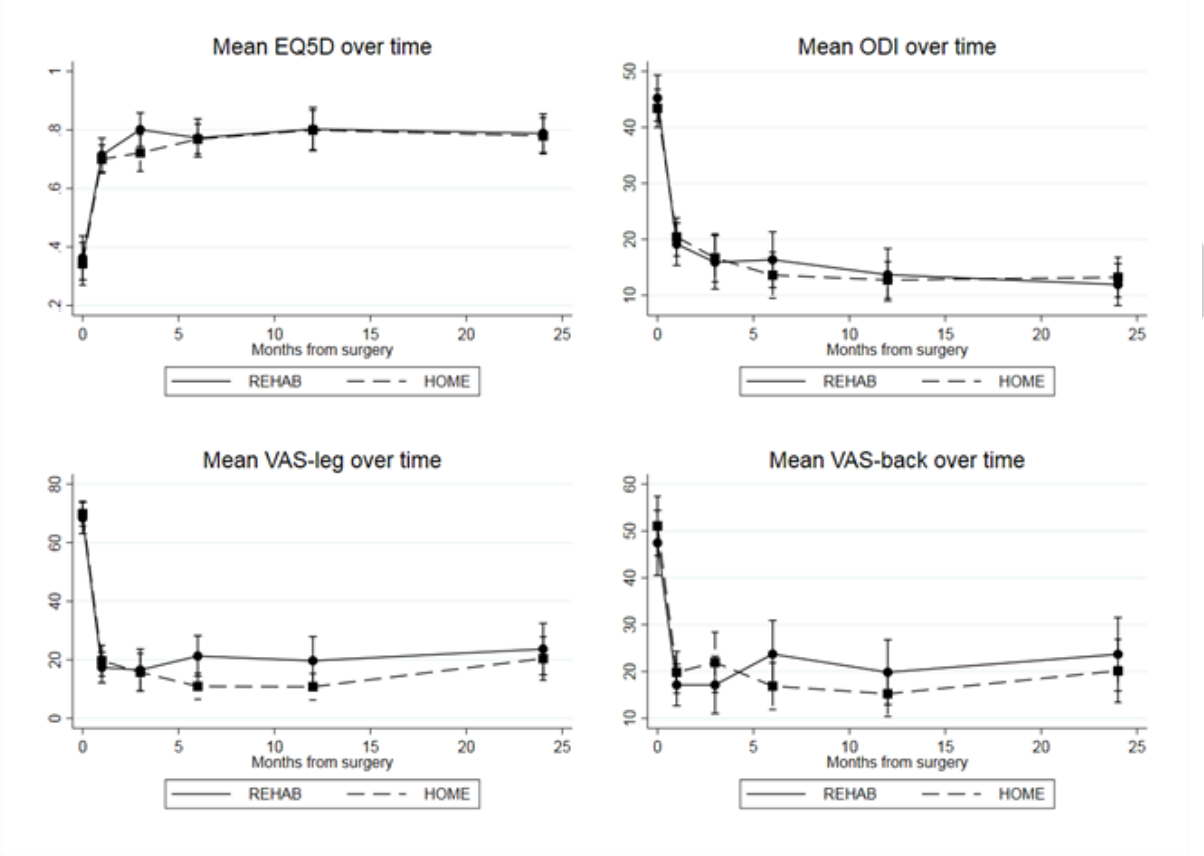

Table 1. Summary of baseline characteristics, Intent to treat

	HOME-group	REHAB-group	p-value
N (%)	73(50.0%)	73(50.0%)	
Age, years, Mean (SD)	42.8 (11.8)	42.9 (8.9)	0.981
Males, N (%)	46(63%)	46 (63%)	1.000
Smokers, N (%)	29 (39.7%)	25(34.2%)	0.453
BMI, kg/m^2, Mean (SD)	26.1 (3.9)	26.2 (4.0)	0.925
Duration of Leg Pain N (%)			0.490
No leg pain	0 (0 %)	1 (1.4 %)	
< 3 months	21 (28.8 %)	27 (36.9 %)	
3 to 12 months	34 (46.6 %)	33 (45.2 %)	
1 to 2 years	13 (17.8 %)	10 (13.7 %)	
> 2 years	5 (6.8 %)	2 (2.7%)	

BMI=Body mass index, VAS=Visual Analog Scale

Table 2 : Summary of rehabilitation

	REHAB
No. sessions per week	
1	45.2%
2	48.4%
> 2	6.4%
Duration of rehabilitation (weeks)	
1-5	26.4%
6-12	62.3%
>12	11.3 %
Type of rehabilitation	
Individual physiotherapy	45.3%
Group physiotherapy	50.9%
Independent training with follow-up	3.8%

Table 3. Clinical outcomes from intent to treat analysis

Patient Reported Outcome	HOME-group	REHAB-group	p-value
Oswestry Disability Index, Mean (SD)			0.602
Baseline	43.4 (14.5)	45.2 (17.6)	
1 month	20.4 (14.7)	19.1 (15.8)	
3 months	16.7 (14.7)	15.9 (15.4)	
6 months	13.6 (14.4)	16.4 (18.1)	
12 months	12.7 (10.9)	13.7 (15.2)	
24 months	13.2 (11.6)	11.9 (12.7)	
EuroQOL-5D, Mean (SD)			0.291
Baseline	0.34 (0.3)	0.36 (0.32)	
1 month	0.70 (0.2)	0.71 (0.24)	
3 months	0.72 (0.21)	0.80 (0.18)	
6 months	0.76 (0.18)	0.77 (0.24)	
12 months	0.79 (0.17)	0.80 (0.22)	
24 months	0.78 (0.21)	0.79 (0.24)	
VAS Back Pain, Mean (SD)			0.551
Baseline	51.1 (27.18)	47.5 (29.74)	
1 month	19.83 (19.07)	17.13 (18.78)	
3 months	21.94 (22.20)	17.14 (19.63)	
6 months	16.88 (17.53)	23.71 (26.05)	
12 months	15.23 (16.39)	19.84 (22.75)	
24 months	20.14 (21.87)	23.68 (26.67)	
VAS Leg Pain, Mean (SD)			0.815
Baseline	69.92 (18.10)	68.44 (22.96)	
1 month	19.66 (22.45)	17.38 (22.19)	
3 months	15.73 (22.15)	16.52 (22.88)	
6 months	10.94 (15.62)	21.28 (25.16)	
12 months	10.78 (15.32)	19.68 (27.11)	
24 months	20.41 (24.04)	23.66 (29.86)	

Table 4. Peri- and postoperative complications

	HOME-group, n	REHAB-group, n	P-value
Perioperative complications			0.503
Hematoma	0	0	
Dural tears	0	1	
Nerve Root damage	0	0	
Postoperative complications			
Wound infections			0.312
Actual	0	0	
Previously	0	1	
Urinary incontinence	1	0	0.319
Motor neuron deficits			0.220
New	4	0	
Unchanged	2	4	
Better than preoperative	7	8	
Worse than preoperative	1	0	
Sensory deficits			0.405
New	5	3	
Unchanged	8	4	
Better than preoperative	19	15	
Worse than preoperative	0	1	