



Research

Early rehabilitation after lumbar disc surgery is not effective or cost-effective compared to no referral: a randomised trial and economic evaluation

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KEY WORDS

Rehabilitation
Exercise therapy
Intervertebral disc degeneration
Discectomy

ABSTRACT

Question: Is referral for early rehabilitation after lumbar disc surgery effective and cost-effective compared to no referral? **Design:** Multicentre, randomised, controlled trial, and economic evaluation with concealed allocation and intention-to-treat-analysis. **Participants:** Adults who underwent discectomy for a herniated lumbar disc, confirmed by magnetic resonance imaging, and signs of nerve root compression corresponding to the herniation level. **Intervention:** Early rehabilitation (exercise therapy) for 6 to 8 weeks, versus no referral, immediately after discharge. **Outcome measures:** In line with the recommended core outcome set, the co-primary outcomes were: functional status (Oswestry Disability Index); leg and back pain (numerical rating scale 0 to 10); global perceived recovery (7-point Likert scale); and general physical and mental health (SF12), assessed 3, 6, 9, 12 and 26 weeks after surgery. The outcomes for the economic evaluation were quality of life and costs, measured at 6, 12 and 26 weeks after surgery. **Results:** There were no clinically relevant or statistically significant overall mean differences between rehabilitation and control for any outcome adjusted for baseline characteristics: global perceived recovery (OR 1.0, 95% CI 0.6 to 1.7), functional status (MD 1.5, 95% CI -3.6 to 6.7), leg pain (MD 0.1, 95% CI -0.7 to 0.8), back pain (MD 0.3, 95% CI -0.3 to 0.9), physical health (MD -3.5, 95% CI -11.3 to 4.3), and mental health (MD -4.1, 95% CI -9.4 to 1.3). After 26 weeks, there were no significant differences in quality-adjusted life years (MD 0.01, 95% CI -0.02 to 0.04 points) and societal costs (MD -€527, 95% CI -2846 to 1506). The maximum probability for the intervention to be cost-effective was 0.75 at a willingness-to-pay of €32 000/quality-adjusted life year. **Conclusion:** Early rehabilitation after lumbar disc surgery was neither more effective nor more cost-effective than no referral. **Trial registration:** Netherlands Trial Register NTR3156. [Oosterhuis T, Ostelo RW, van Dongen JM, Peul WC, de Boer MR, Bosmans JE, Vleggeert-Lankamp CL, Arts MP, van Tulder MW (2017) Early rehabilitation after lumbar disc surgery is not effective or cost-effective compared to no referral: a randomised trial and economic evaluation. *Journal of Physiotherapy* XX: XX–XX]

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Introduction

Lumbosacral radicular syndrome, also called sciatica, is commonly caused by a herniated lumbar disc.¹ The syndrome is characterised by lower limb pain radiating below the knee in an area of the leg served by one or more lumbosacral nerve roots. Sometimes, there are other neurological findings such as sensory and motor deficits. The incidence of sciatica is estimated at 5 per 1000 adults in Western countries.² In the Netherlands, the incidence of sciatica has increased from 75 000 to 85 000 cases per year over the past decade.^{3,4} The direct and indirect costs of patients suffering from sciatica approximate €1.2 billion per year.³ The natural course of sciatica is favourable in the majority of patients;⁵ therefore, international consensus is that surgical treatment should only be offered if the radiating leg pain persists

despite a period of conservative management.⁶ Rates of spinal surgery differ across and within countries:⁷ in the United States they are 30% higher than in the Netherlands, 50 to 60% higher than in Canada, and 80% higher than in the UK.² It is estimated that in the Netherlands, about 12 000 operations per year are performed for herniated lumbar discs.⁴ Recovery rates after conventional microdiscectomy of 66% at 4 weeks, and 75% at 8 weeks follow-up have been reported,⁸ and return to work rates of 15% at 2 months follow-up.⁹ A recently published systematic review concluded that even 5 years after surgery, patients still experience mild to moderate levels of pain and disability.¹⁰

Two common options exist for postoperative management.¹¹ The first option is referral for early rehabilitation immediately after discharge. The second option comprises the advice to return to an active lifestyle, with postoperative rehabilitation only for those

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patients whose symptoms persist longer than 6 to 8 weeks. A recent systematic review investigated the effectiveness of rehabilitation following lumbar disc surgery.¹² For exercise programs starting 4 to 6 weeks after surgery, there is moderate evidence that they are more effective in improving physical function, and low-quality evidence that they are more effective than no treatment in decreasing pain. Moreover, there is moderate evidence that high-intensity exercises starting 4 to 6 weeks after surgery are more effective in improving physical function than low-intensity exercises, and low-quality evidence that they are more effective in decreasing pain than low-intensity exercises. Large, high-quality studies assessing the effectiveness of immediate postoperative interventions are lacking.¹² The effectiveness of early rehabilitation has been assessed in three mono-centre studies, which included a total of 124 patients.^{13–15} The first outcome measurement was at 6 weeks, showing better function in the early rehabilitation group,^{13–15} but no difference in pain.^{14,15} The next follow-up was at 12 weeks, showing better function but inconsistent results for pain.^{13–15} As referral for rehabilitation is associated with higher healthcare costs than no referral, it is important to assess its cost-effectiveness as well. However, cost-effectiveness studies on early rehabilitation are lacking.

Therefore, the research question for this multicentre, randomised, controlled trial was:

Is referral for early rehabilitation after lumbar disc surgery effective and cost-effective compared to no referral?

Method

Design

A multicentre, randomised, controlled trial was conducted with a 26-week follow-up period and repeated measurements within the first 12 weeks. This schedule of measurements was chosen because a change in outcomes was expected predominantly during and shortly after the first 6 postoperative weeks. Details of the design and methods of the trial have been published previously.¹⁶

Participants, therapists and centres

Eligible patients had a herniated lumbar disc confirmed by magnetic resonance imaging (MRI) and signs of nerve root compression corresponding to the level of disc herniation; were aged between 18 and 70 years; and were able to fill out questionnaires in Dutch themselves. Neurosurgeons referred potentially eligible patients to the research team. Research nurses checked the eligibility criteria and excluded patients if they met any of the following criteria: cauda equina syndrome, neurogenic claudication, co-morbidities of the lumbar spine (eg, fractures, carcinomas, osteoporosis), spinal surgery in the prior 12 months, contraindications to exercise therapy (eg, acute respiratory or cardiovascular complaints, acute systemic infections), pregnancy, or previous lumbar disc surgery at the same level and on the same side. To conceal treatment allocation, a computer-randomised list was generated for each hospital by an independent investigator prior to study commencement. To achieve the predetermined sample size for the experimental and control groups, weighted block randomisation (blocks of four) was used. Based on these lists and prior to the start of the study, the independent investigator prepared a set of numbered, opaque and sealed envelopes containing the assigned postoperative strategy for each hospital. Directly after having received the completed baseline questionnaire and prior to surgery, the research nurse opened the next consecutive envelope in order to inform the participant about the assigned postoperative strategy. The nature of the postoperative strategies and the use of patient-reported outcome measures precluded blinding of the participants and the therapists. Participant expectations were measured to assess a possible risk

of bias due to this lack of blinding of participants. Participants were recruited from 10 peripheral hospitals that were located in urban or regional areas of three regions in the Netherlands. Primary care physiotherapists and exercise therapists in the catchment areas of these hospitals provided the early rehabilitation following lumbar disc surgery.

Intervention

During hospitalisation (usually 1 to 2 days) all participants, regardless of treatment allocation, received usual postoperative care. More specifically, during one or two sessions, a physiotherapist or nurse provided advice and instructions for transfers (eg, bed to stand, chair to stand) and performing activities of daily living, in preparation for discharge. At discharge, participants received a booklet providing advice (mainly regarding activities of daily living) and suggestions for exercises, focusing on muscle strengthening, core stability and mobilisation.

Experimental group: referral for early rehabilitation

Participants in the experimental group received a referral for postoperative exercise therapy in primary care starting the first week after discharge. Over 6 to 8 weeks, participants received one or two individual, face-to-face, exercise therapy sessions of 30 minutes per week, conforming to a standardised treatment protocol based on a national clinical guideline.¹⁷ The 6- to 8-week period reflected the period before patients consulted their neurosurgeon again after surgery. The timing of this follow-up consultation and, therefore, the exact duration of the period until follow-up depended on the organisation in the hospital in which the participant was treated. The treatment protocol described the treatment in terms of treatment goals; the main goal of the exercise therapy was to gradually extend activities of daily living from personal care to housekeeping tasks in the short term, and return to work and prepare for sports and leisure activities in the long term. In the first week, therapists performed physical examinations, and focused treatment on the ability and possibility to execute personal care activities and perform transfers in the home situation. From the second week onwards, exercises were taught with gradually increasing intensity, targeting limitations that were found in the initial postoperative assessment. The exact type of exercises was left to the therapists' discretion, based on the outcomes of the physical examination and taking participants' preferences into account, which was in line with routine clinical practice. Therapists provided tailored advice on lifestyle and the execution of activities of daily living. Treatment could be terminated before the end of the 6- to 8-week period if the participant was fully recovered. At each treatment session, participating therapists filled out a registration form, including (amongst other information): treatment goals on both a global and more specific level; whether a home exercise regimen was prescribed or not; and, if applicable, the reason for terminating the treatment.

Control group: no referral for early rehabilitation

Participants assigned to the control group were not referred for rehabilitation after discharge from the hospital. Participants could consult their neurosurgeon or general practitioner in case of recurring or increasing complaints, but they were requested to refrain from referral for exercise therapy or other allied health interventions in the 6- to 8-week period before consulting the neurosurgeon after surgery. The research nurses limited the extent to which they provided advice when participants allocated to the control group called them. To prevent diminishing contrast between groups, only advice that had been given during the clinical phase was repeated.

Follow-up neurosurgeon consultation

Six to 8 weeks after discharge, a follow-up consultation with the neurosurgeon took place, which was in line with routine clinical practice (see above). Whether participants in the experimental group continued rehabilitation or control group participants started

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