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# Effective Conservative Treatment for Chronic Low Back Pain

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## Abstract

Evidence suggests that effective conservative treatment is available for chronic low back pain. The effectiveness of conservative treatment has recently received attention following publication of several randomized controlled trials (RCTs) that reported similar improvements in outcomes from cognitive intervention with exercise as from spinal fusion surgery. This paper will explore the conservative treatment arms of these RCTs with the goal of educating the reader about the principles of cognitive intervention with exercise. These principles can be incorporated into the care of chronic low back pain patients both as primary treatment and as a means of augmenting surgical outcomes.

Recent randomized controlled trials (RCTs) by Brox (1) and Fairbank (2) captured the attention of spine surgeons and medical spine care providers. Both studies compared the effectiveness of two treatments for chronic low back pain - lumbar spine fusion (stabilization), and a cognitive intervention with exercise. Surprisingly, both studies demonstrated that each intervention produced statistically similar reductions in disability.

The findings of similar disability outcome from both arms of these RCTs are certainly intriguing, especially as lumbar fusion and cognitive intervention with exercise are completely different approaches to the problem of chronic low back pain. All spine surgeons understand the theoretical basis for lumbar fusion as a treatment for chronic low back pain. It is an intervention thought to reduce pain by eliminating the pain generator - the degenerative disc - and/or by limiting motion, and thus the ability to stimulate pain at the degenerated motion segments. Many spine surgeons have a less complete understanding of the comparative arms in these RCTs – cognitive intervention with exercise. Because of this, many surgeons are not as familiar with how to incorporate the principals of cognitive intervention with exercise into the care of both their surgical and non-surgical back pain patients. This article will attempt to improve readers' understanding of cognitive intervention with exercise by carefully reviewing these RCTs with special attention to the conservative treatment utilized. It will also review companion studies and other selected RCTs exploring cognitive treatment with exercise, with the goal of enhancing the understanding of the components of this intervention and exploring ways in which these components can be harnessed to maximize clinical outcomes in surgical and nonsurgical patients alike.

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## RCTs of Lumbar Spine Fusion versus Cognitive Intervention with Exercise

The effectiveness of lumbar spine fusion versus community based non-operative treatment was established in an RCT by Fritzell et al (3). Their study found greater reduction of both pain and disability at 2-year follow-up in the lumbar spine fusion subjects as compared to subjects randomized to non-operative care. This study was criticized because of the lack of standardized non-operative treatment, and more specifically, the omission of aggressive exercise based therapies that had shown some effectiveness for the treatment of chronic low back pain. Though these criticisms were legitimate, aggressive exercise based therapies were not universally accepted by all health care providers, nor generally available in most communities at the time of the study. Thus, the findings of Fritzell could be considered to have external validity relevant to the standard of care at that time.

Brox et al attempted to rectify this omission of standardized and effective non-operative care by developing a lumbar fusion RCT in which the non-operative treatment included a specific program of exercise with cognitive intervention (1). This study is summarized in Table 1.

As stated by Brox et al, “The goal [of exercise with cognitive intervention program] was to let the patients experience that it was safe to move.” The researchers recognized that fear-avoidance beliefs were important in the initiation and maintenance of chronic pain and disability, and that fear avoidance was the result of logical, but incorrect, notions about spine degeneration and the meaning of chronic pain. They also recognized that patients with chronic low back pain are often told to be careful by health care providers (physicians and physical therapists), who recommend the avoidance of physical and work activities that are perceived to stress the back and/or induce pain. These recommendations can potentially have the unfortunate result of reinforcing patients’ incorrect notions that activity is detrimental.

To counter the advice of prior healthcare providers and the common misconceptions about back pain that underlie fear-avoidance beliefs, subjects randomized to cognitive intervention and exercise attended a lecture given by a prominent physician associated with this study. This lecture described the structural elements of the back and important features of the neurology of pain. The lecturer’s goals were to convince subjects that they could not cause any harm to their back by engaging in ordinary daily activities, and that engaging in ordinary activities would be actually beneficial to their condition. All members of the cognitive intervention with exercise treatment team consistently reinforced these messages during the treatment period.

The second component of this intervention consisted of physical exercise individually prescribed for each subject. Exercises were linked to the information given during the introductory lecture and designed to reinforce the message that it was safe to use the back normally. Chosen exercises encouraged the movements and use of the back in ways that challenged prior conceptions of frailty of the spine, and successful exercise performance was theorized to weaken fear avoidance beliefs and build confidence for use of the back in normal daily activities. Subjects were supervised in endurance and coordination exercises and specific exercises that advocated co-contraction of trunk muscles during activities, often referred to as spinal stabilization techniques (4). Subjects attended three exercise sessions per day for one week, including aerobic and outside activities, water gymnastics and exercises specific for each individual. Subjects were sent home for two weeks during which time they were to continue with their prescribed exercises, and then returned to the exercise program for two more weeks. During these final two weeks, the intensity of exercise and activities were gradually increased. Individual consultations, group lessons about spine imaging and pathology, and peer group discussions occurred during these sessions – all of which reinforced that harm was not caused by normal use of the back. All subjects received instruction in home exercise programs and were given a training diary.

The sample size of this study was small, but the study was powered to detect a clinically meaningful change in the Oswestry Disability Index (ODI) of 10 points, and the compliance to treatment assignment and follow-up were good.

The results were surprising. Surgery reduced the primary outcome of disability (ODI scores) as expected, but cognitive intervention with exercise reduced disability to a clinically and statistically similar amount. Careful review of the results of this study confirms the unique mechanisms through which surgery and cognitive intervention with exercise improved disability. In the surgical arm of treatment, the secondary outcomes of back and leg pain significantly improved compared to baseline – an expected result, as pain reduction is the outcome most directly targeted by lumbar spine fusion surgery. All other secondary outcome variables did not change for the lumbar fusion group. Compared to the exercise group, leg pain was the only outcome measure on which the surgery group improved significantly more. We might conclude that the improvements in ODI scores were largely the result of the effectiveness of spine fusion for reducing back and leg pain.

In contrast to the results from surgery, patients assigned to cognitive intervention with exercise improved only modestly on back pain and not at all on leg pain from their baseline levels. Significant improvements were observed in fear-avoidance beliefs and forward bending ability – the cognitive and physical dimensions targeted by this treatment. In a companion paper by the same authors, results from trunk strength assessment on this same group of subjects revealed that back strength had also improved in the cognitive intervention with exercise group but not in those randomized to lumbar fusion (5). For the exercise group, it can be postulated that reducing fear avoidance beliefs and reversing impaired back function resulted in the documented reduction of disability, as indicated by the improvement in ODI scores. This effect was quite powerful and similar in magnitude to that of pain reduction noted in the spine fusion group. Also, it must be noted that exercise and increased physical activities did not increase overall pain, confirming the notion that using the spine for normal daily activities is not harmful.

It is important to note that the variables most influenced by the cognitive treatment with exercise – elevated fear avoidance beliefs and impaired back function - remained unchanged in the surgical treatment group during this study, indicating that these problems were not addressed during the post-operative care of these subjects. It is possible that post-surgical rehabilitation utilizing the concepts of cognitive treatment might have resulted in further improvements in disability by reducing fear avoidance beliefs and impaired back function.

The importance of fear avoidance beliefs and impaired back function to residual disability following spine surgery is further demonstrated in a second RCT performed by Brox et al (6), which involved patients with severe post-discectomy pain and disability of at least one year duration (Table 2). Review of initial subject characteristics reveals that these failed-discectomy patients were similar to those with degenerative disc disease, as they reported strong fear-avoidance beliefs (6) and had impaired back flexibility and strength (5). This study randomized subjects into lumbar fusion versus cognitive intervention with exercise, using identical study design, outcome measures and treatments as those in the disc degeneration study.

Study results revealed that disability improved concurrent with reduced fear avoidance beliefs and improved back function for the cognitive intervention with exercise group, and to a magnitude identical to that derived from fusion of the failed discectomy level. It is conceivable that identifying and addressing these issues with appropriate encouragement, education and exercise immediately following the initial decompression surgery might have improved these patients' outcomes long before additional surgery was contemplated.

In 2005, Fairbank et al published the second RCT comparing lumbar stabilization surgery and intensive rehabilitation for the treatment of chronic low back pain (2) (Table 3). All treatments

were administered at 15 hospital-based centers with similar, though not identical, treatment protocols for both surgery and rehabilitation. Intensive rehabilitation programs included both education and exercise, on five days per week for three consecutive weeks. All programs were lead by physical therapists, and all but one included psychologists as well as medical support staff. Education sessions were designed to overcome fears and unhelpful beliefs. Individualized exercise regimens were designed to improved participants' baseline physical abilities by increasing intensity and duration throughout treatment, and included stretching, strengthening, spine stabilization exercises and endurance training. This study included a much larger group of subjects than the Brox RCTs and was powered to detect a difference in ODI (4 points) much smaller than published standards for clinically meaningful change (7).

Two-year outcome results revealed a clinically similar reduction of disability for spine stabilizing surgery and intense rehabilitation. The surgery group did improve 4.1 points more on the ODI ($p = 0.045$) compared to the exercise group, though this difference is probably not clinically meaningful. This study did not measure fear avoidance beliefs and evaluated walking performance as the only measure of physical function. Therefore we cannot determine whether the intense rehabilitation program lessened fear avoidance beliefs and improved back function (i.e. back flexibility and strength) concurrent with the reduction of disability. Furthermore, back pain and leg pain were not measured as secondary outcomes, making it difficult to explore the relationships between final disability and secondary outcomes for either intervention. We can, however, conclude that chronic back pain rehabilitation programs utilizing education and exercise can be developed in multiple settings, and that these programs are a reasonable and effective treatment approach for patients with chronic low back pain.

## RCTs Examining the Components of Intense Rehabilitation as Treatment for Low Back Pain

For the practicing spine surgeon, optimizing patient selection for surgical procedures, maintaining surgical competence, maximizing procedural skills, and supervising post-operative care are tasks that consume nearly all available professional time. Developing and supervising multidimensional rehabilitation programs such as "cognitive intervention with exercise" or "intensive spine rehabilitation" would seem to be unfeasible additional professional tasks. For some surgeons, medical associates are available to offer such care to patients in their communities, but to many they are not.

For all surgeons, a potential path to improved clinical outcomes is to understand and incorporate the simplest components of cognitive intervention with exercise into their routine care of patients. Research has revealed that these components may not be complex at all, and providers (physical therapist, exercise trainers, etc.) willing to collaborate with surgeons to institute effective exercise are probably available in most communities.

Recent RCTs have tried to compare exercise alone to various combinations of exercise, education, individual counseling, and cognitive interventions for the treatment of chronic low back pain. Smeets et al (8) randomized 223 patients into four groups: 1) active physical treatment consisting of physical therapist supervised aggressive, non-pain contingent (performed regardless of pain) endurance and strength exercises; 2) cognitive-behavioral treatment in which a psychologist or social worker provided problem solving training and operant-behavioral graded-activity training to promote return to important activities; 3) combined active physical treatment and cognitive-behavioral treatment, and 4) a waiting list. After treatment, significant reduction in pain and functional limitations were observed in all three treatment groups compared to those subjects assigned to the waiting list. Of importance, the single component treatment of exercise alone was as effective as cognitive-behavioral treatment, or combined exercise and cognitive-behavioral treatments, even for the

psychological dimension of pain-catastrophizing (8). These results suggest that active physical therapy that utilizes non-pain contingent exercise is an effective unidimensional treatment for chronic low back pain, in part because it effectively delivers a message that pain need not be feared or avoided. The implication that we need not utilize intense cognitive-behavioral interventions to effectively deliver this message to patients is especially important, since cognitive-behavioral therapists with experience in treating chronic low back pain are not available in many communities.

The effectiveness of physical therapist-directed non-pain contingent exercise as compared to multidimensional rehabilitation is also demonstrated in an RCT by Roche et al (9). In this study, 132 chronic low back pain subjects were randomized to either active individualized physical therapy or a functional restoration program. The active individual physical therapy intervention was administered in one hour sessions, three times per week, for five weeks. Individual therapy consisted of stretching, muscle strengthening using isotonic exercises, and endurance training. The functional restoration intervention consisted of group exercise sessions including stretching, strengthening, and endurance training administered six hours per day, five days per week for five weeks. Exercise was accompanied by once per week meetings with a medical supervisor and at least one session with a psychologist. Results revealed that more intense (10X greater treatment time) exercise for the functional restoration group did result in greater improvements in flexibility, strength and endurance than did the individualized physical therapy program. However, the most relevant outcomes of pain and disability improved similarly, and return to work rates (86%) were identical for both treatments.

These studies indicate that physical therapy consisting of supervised exercises performed at an intensity that improves physical abilities delivered with the message that it is safe to function in the presence of tolerable pain results in significant improvements in pain and disability. Results from this type of physical therapy are comparable to multidimensional treatments but require substantially less staff and resources, minimizing barriers for development in many communities.

## Research Comparing the Types of Exercise Utilized for the Treatment of Chronic Low Back Pain

For the treatment of chronic low back pain, the convictions of some physical therapists and physicians about specific methods of exercise rival the devotion of some surgeons to particular surgical techniques. The studies that we have reviewed to this point have utilized a variety of exercise techniques, often in combination, to accomplish their therapeutic goals. The common thread in all of these studies is that exercise should be intense enough to accomplish physiological goals and presented in such a way that patients have a real world experience of successful physical function with or without chronic pain. Recent research has examined the effectiveness of different methods of exercise for accomplishing this, and the results are noteworthy as one considers exercise options available in our communities.

Some medical providers are advocates of spinal stabilization exercises. These exercises are theorized to improve the trunk muscles ability to stabilize or control the motion of the lumbar spine through co-contraction of abdominal and paraspinal muscles. In an RCT, Koumantakis et al randomized 55 patients with chronic low back pain into either treatment using general endurance trunk exercises alone or treatment that combined spinal stabilization exercise with general endurance trunk exercises (10). They found no measurable electrophysiological or clinical advantage for the addition of spinal stabilization exercises over general endurance trunk exercises alone. Goldby et al reported on an RCT of three interventions – ten sessions of spinal stabilization, ten sessions of manual therapy, and a control group (11). All subjects attended a back school. Three hundred two subjects qualified for the study, 213 completed one-year

follow-up, and a marked loss to follow-up resulted in only 91 subjects returning for two-year follow-up. Although the authors concluded that the spinal stabilization was more effective, their data showed that subjects in each treatment group reported similar reductions in pain and disability at three months. Given that the three month follow-up was the closest to the completion of the interventions, any differences in treatment effect should have been present at this point. At more distant follow-up, greater variance in outcomes are noted, with no conclusive evidence of superior outcomes for the spine stabilization group. These results suggest that spinal stabilization exercises do not offer any additional benefit over general trunk endurance exercises as a treatment for chronic low back pain. As such, they may be considered as a treatment option, but strong dedication to them is unsupported by the available evidence.

General exercise has also been compared to specific directional exercises as advocated by Robin McKenzie (12). McKenzie therapy is individually prescribed based on a clinical assessment, in which back and leg pain patterns during specific trunk movements are observed. To evaluate the efficacy of this treatment, Petersen et al randomized 270 patients to either intense strengthening training or McKenzie treatment (13). Both treatments were administered by physical therapists twice per week for eight weeks, with therapy sessions lasting between 60 to 90 minutes. Withdrawal from treatment was modest (30 percent) for both groups. Results were collected for eight months, and clinical improvements were noted following both treatments. However, the authors found no differences between treatments. Advocates of McKenzie therapy recommend specialized training and certification prior to administering this type of treatment, making McKenzie therapy less accessible as a treatment than general exercise. Equal effectiveness, however, suggests that either option can be useful for the treatment of this group of patients.

Over the last decade, Pilates-based exercises have become popular in many fitness facilities where they are performed to promote general health. Many Pilates-based exercises focus on trunk movements and are performed in a slow, precise manner to promote movement efficiency and muscle control. As exercises are advanced, continued awareness of trunk posture during exercise is advocated. These exercises can be performed on floor mats and with limited equipment that allows certain postures during exercise. With their focus on the trunk, Pilates-based exercises have attracted the attention of back care providers and researchers. In the only RCT of Pilates-based exercise to date, Rydeard et al randomized 39 subjects with chronic low back pain to Pilates-based therapeutic exercises (three one-hour sessions per week for four weeks and a home program) or to usual physician directed care (14). The authors observed that the Pilates-based exercise group had lower functional disability scores at treatment completion as measured with the Roland Morris Questionnaire compared with the control group, and these results were maintained at 12 months. Back pain also improved more in the Pilates group at treatment completion. This study suggests that Pilates-type exercise may be another reasonable exercise alternative for select and motivated patients with chronic low back pain. Further studies are needed to confirm these results, and additional studies should compare the effectiveness of community-based Pilates exercise classes with a generic fitness orientation to the Pilates-based programs designed specifically for low back pain patients. If equal effectiveness were to be noted, access would be improved since non-medical Pilates exercise groups are available at fitness facilities in many communities.

The most general form of exercise to receive study for the treatment of low back pain is aerobic training. Prior trials of general fitness have not included monotherapy with high-intensity aerobic exercise. In a pilot study enrolling only 20 subjects with chronic low back presenting to a primary health care facility, Chatzitheodorou randomized subjects to either supervised high-intensity aerobic training or passive modalities without any adjuvant physical exercise (15). Each group received treatment for a total of 12 weeks. Their results revealed significantly reduced pain (41 percent), disability (31 percent) and psychological strain (35 percent) in the

aerobic exercise group, but no changes in subjects that received the passive modalities without exercise. Though this is only a pilot study, with the need for verification through a larger clinical trail, the results are encouraging. If these results are reproducible, it would suggest that simple, high-intensity endurance exercises, which can be performed in a variety of ways and settings, could be recommended for our motivated low back pain patients.

## Summary and Conclusions

Effective conservative treatment of the multifaceted problem of chronic low back pain holds as many challenges as does surgical treatment of this disorder. While surgical treatment is primarily focused on the alteration of structures perceived to be the sources of pain, conservative treatment instead aims to improve patients' ability to function with or without concurrent improvement in pain. Most of the scientifically studied conservative treatment programs that are designed to accomplish this task involve multiple medical disciplines, are complex, and require significant time commitments from patients. These programs are effective treatments for reducing disability but are not widely available.

The essential components of these programs – delivering a clear message to patients that it is safe to use the back normally despite spinal degeneration and chronic pain, and the use of exercise to improve overall conditioning and to deliver a real world experience reinforcing that the back can be used for physical activities– can be incorporated into the clinical practice of spine care providers. The available evidence on the efficacy of exercise-based rehabilitation in improving back-related disability suggests that this effect may be mediated by an experience that actively modifies patients' fears and concerns. Additionally, it is probable that the type of exercise may in fact be less important than the message that exercise delivers, resulting in a wide variety of possible exercise options from aerobic training to aggressive flexibility and strength training. Perhaps it is most important that spine surgeons partner with other like-minded health care providers, so that a consistent message reinforcing that "the normal use of the back is not harmful" is delivered to patients undergoing conservative treatment prescribed either instead of or in addition to spine surgery. By utilizing physical therapists who reinforce this message through their treatments, our patients with chronic low back pain will have the best chance of reaching their full functional potential.

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## Table 1

Randomized clinical trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration. Brox, et al. 2003. Spine.

| | |
|---|---|
| **Study Design** | Single blind randomized study. |
| **Patients** | 64 total patients age 25–60. |
| **Inclusion Criteria** | Low back pain for greater than 1 year and evidence of disc degeneration at L4-L5 and/or L5-S1 on radiographic examination. Also: age 25–60, score of at least 30 on the Oswestry Disability Index. |
| **Exclusion Criteria** | Widespread myofascial pain, spinal stenosis with neurologic signs, recurrent disc herniation or lateral recess stenosis with radiculopathy, inflammatory disease, previous spinal fracture or spine surgery, pelvic pain, generalized disc degeneration on imaging, medical illness that excluded either interventions, medical abuse, reluctance to accept either treatments. |
| **Treatments Compared** | Lumbar fusion with posterior transpedicular screws and post-operative physical therapy vs. cognitive intervention (including a lecture to promote comprehension that ordinary activities are not detrimental to the spine) and 3 daily exercise sessions for 3 weeks. |
| **Loss to Follow-Up** | There was 3% loss to follow up. |
| **Outcome Measures** | **Primary:** Oswestry Disability Index (ODI)<br>**Secondary:** Questionnaire: pain index, use of pain medications, General Function Score, Hopkins Symptom Check List-25 (emotional distress), Waddel's Fear-Avoidance Belief Questionnaire (FABQ), life satisfaction score, Global Back Disability rating (overall function), work status, Prolo Scale (overall functional and economic status). Fingertip-floor distance measurement, isokinetic trunk muscle (extension) test, back muscle size and density (measured by a radiologist). |
| **Findings** | At 1 year, the ODI decreased from 41 to 26 after surgery and 42 to 30 after cognitive & exercise intervention. Mean difference between the groups was 2.3 (−6.7 to 11.4, $p = 0.33$), which was neither clinically relevant nor significant. Fear-avoidance beliefs and fingertip-floor distance had better outcomes after conservative treatment, while leg pain decreased more with surgery. Other outcome measures were not different. The ODI difference between patients who adhered to their assigned treatment was 1.3. There was no difference between groups in return to work status. Patients' overall ratings were not significantly different. |
| **Strengths** | Randomized, single blinded study that assessed many secondary outcome measures which took into account global function, work status, psychological well-being, spine motion, strength, and medication usage. |
| **Weaknesses** | Small size of the study, large variations between patients (wide confidence intervals), lack of "no treatment" group to assess natural history of the disease. |
| **Bottom Line** | Provides good evidence that at 1 year there was equal improvement in patients who were randomized to instrumented lumbar fusion or to cognitive intervention and exercise. Furthermore, the cognitive intervention and exercise also reduced fear-avoidance beliefs. |

## Table 2

Lumbar instrumented fusion compared with cognitive intervention and exercises in patients with chronic back pain after previous surgery for disc herniation: A prospective randomized controlled study. Brox et al 2006. Pain.

| | |
|---|---|
| **Study Design** | Randomized controlled trial. |
| **Patients** | 60 patients, age 25–60. |
| **Inclusion Criteria** | Low back pain lasting longer than 1 year after previous surgery for disc herniation, score of at least 30 on the Oswestry Disability Index, degeneration at L4-L5 and/or L5-S1 (spondylosis) on X-ray. |
| **Exclusion Criteria** | Widespread myofascial pain or comorbid medical issues, spinal stenosis with neurologic signs, recurrent disc hernation or lateral recess stenosis with radiculopathy, previous spine fracture or fusion, generalized disc degeneration, medical abuse. |
| **Treatments Compared** | Lumbar fusion with posterior transpedicular screws vs. cognitive intervention (lecture) and exercises (3 daily physical exercise sessions for 3 weeks). |
| **Loss to Follow-Up** | 3% loss to follow up at 1 year. |
| **Outcome Measures** | **Primary**: Oswestry Disability Index (ODI)<br>**Secondary**: Questionnaires, pain index, use of and type of pain medication, General Function Score, Hopkins Symptom Check List-25 (emotional distress measure), Fear-Avoidance Belief Questionnaire, Global Back Disability Question (function), work status, treatment beliefs and expectancies, Prolo Scale (functional status part), radiographic assessment of fusion. |
| **Findings** | No significant difference in the primary outcome of ODI. At 1 year, in the fusion group, ODI decreased from 47 to 38 and after cognitive intervention and exercises, ODI decreased from 45 to 32 ($p = 0.43$). The mean difference between treatments was −9.7 (−21.7, 1.7; $p = 0.09$) in favor of cognitive intervention, after adjusting for gender and treatment preference. The surgery group did not improve significantly in the secondary outcome measures other than back pain. Fear-avoidance for physical activity and fingertip-floor distance improved in the conservatively managed group. |
| **Strengths** | Randomized controlled trial, assessed many secondary outcome measures. |
| **Weaknesses** | Lack of true control group, small size, large variations between patients. |
| **Bottom Line** | Provides evidence suggesting that lumbar fusion did not show significant benefit over cognitive intervention and exercises in patients with chronic low back pain after previous disc herniation surgery. |

## Table 3

Randomised controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial. Fairbank et. al. BMJ 2005.

| | |
|---|---|
| **Study Design** | Multicenter randomized controlled trial. |
| **Patients** | 349 participants |
| **Inclusion Criteria** | Age 18 to 55 with more than a 12 month history of chronic low back pain (with or without referred pain) who were considered spinal fusion candidates, including those with previous root decompression or discectomy. |
| **Exclusion Criteria** | Medical comorbidities precluding intervention, previous surgical stabilization surgery. |
| **Treatments Compared** | Lumbar spine fusion vs. an intensive rehabilitation program (based on cognitive therapy). |
| **Loss to Follow-Up** | Overall, 20% lost to follow-up at 24 months. |
| **Outcome Measures** | **Primary:** Oswestry disability index (ODI) and shuttle walking test at baseline and at two years.<br>**Secondary:** Short form 36 general health questionnaire (SF-36) instrument, distress and risk assessment method (DRAM) including the modified Zung depression index and somatic perception questionnaire (psychological assessment) |
| **Findings** | Oswestry disability scores improved only slightly in favor of surgery with a mean difference of −4.1 (95% confidence interval −8.1 to −0.1, P = 0.045). There were no major differences between the two groups in any of the other outcome measures at 24 months. |
| **Strengths** | Relatively large, multicenter randomized controlled trial that used multiple outcome measures. Comprehensive, multidisciplinary, intensive rehabilitation program was used. |
| **Weaknesses** | The 20% loss to follow-up limited the internal validity of the study. There was some crossover between the intervention groups: 28% of patients randomized to rehabilitation had surgery by two years. 4% of subjects randomized to surgery had rehabilitation instead of surgery. Data were analyzed based on the intention to treat principle, so 28% of patients analyzed as receiving non-operative treatment actually had surgery. The difference in Oswestry scores between the interventions (4.1) just barely exceeded the 4 points specified in the sample size calculation, indicating a clinically small difference, though this treatment effect may have been decreased by the crossover. Furthermore, there was variation in the type of surgery performed since surgeons used their choice of procedure. No blinding of the trial research therapists. For some outcome measures, there were fewer subjects' results at 24 months than anticipated by the initial sample size calculation (although the power was within range for the Oswestry measure) and the authors noted that they had fewer subjects enrolled than planned. |
| **Bottom Line** | Provides good evidence to suggest that intensive rehabilitation with a cognitive behavior component may be an alternative to spinal fusion surgery in the management of chronic low back pain. Almost ¾ of the patients randomized to rehabilitation avoided surgery by two years and had improvement in outcomes. The benefit of surgery was small and likely below the minimal clinically important difference, though the high crossover may have diluted the treatment effect. This should be considered in light of the potential risks and costs of surgery. |