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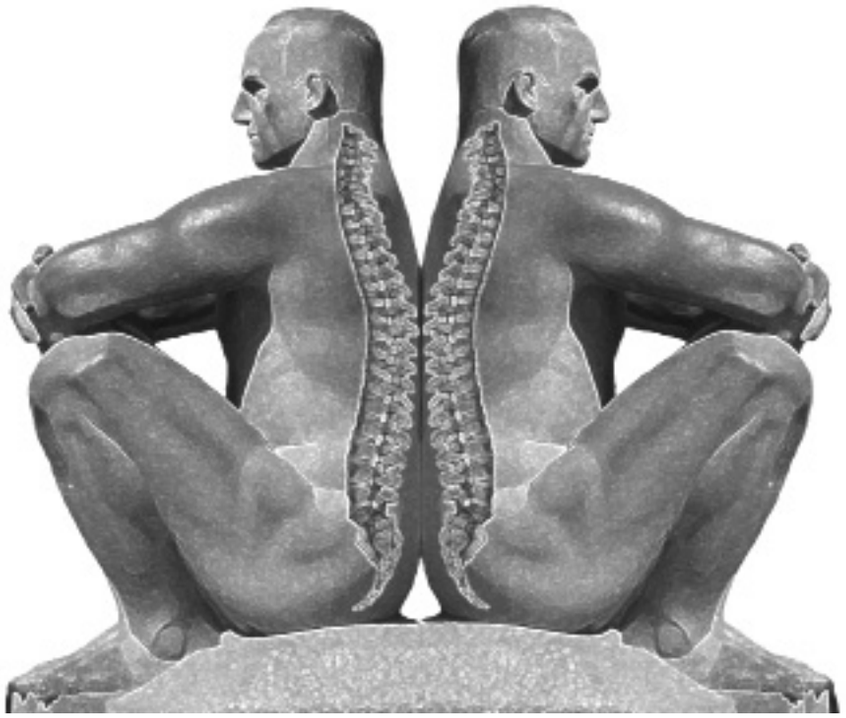
2010

# PHYSIOTHERAPEUTIC REHABILITATION AND LUMBAR FUSION SURGERY



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Karolinska Institutet

200 Years 1810 – 2010

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PHYSIOTHERAPEUTIC REHABILITATION AND LUMBAR FUSION SURGERY

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Allan Abbott

Stockholm 2010

The cover illustration is a personal impression of a granite statue, “Giano’s faces” from Vigeland Sculpture Park in Oslo. The reflecting images portray feelings of deliberation and uncertainty expressed by chronic low back pain patients in relation to lumbar fusion surgery.



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# ABSTRACT

Over the last two decades, the economic costs and rates of lumbar fusion surgery for chronic low back pain has risen dramatically in western industrialized countries. Data from the Swedish National Spine Register suggest that 25% of patients experience unimproved pain and up to 40% are not satisfied with the outcome of lumbar fusion surgery. Thus, there is a definite need to optimize the selection and management of patients to improve lumbar fusion outcomes.

**Aim:** To investigate the role of biopsychosocial factors in explaining disability and health related quality of life in chronic low back pain patients before and after lumbar fusion surgery and to evaluate the effectiveness of post-operative rehabilitation regimes.

**Methods:** 107 patients were recruited, aged 18 to 65 years, selected for lumbar fusion due to 12 months of symptomatic back and/or leg pain due to spinal stenosis, degenerative/isthmic spondylolisthesis or degenerative disc disease. Measures of disability, health related quality of life, pain, mental health, fear of movement/(re)injury, self-efficacy, outcome expectancy, pain coping, work status, health care use, analgesic use and sickness leave were collected with self-rated questionnaires at baseline *(Studies I-IV)*, 3, 6, 12 months (*Study II*) and 2-3 years after surgery (*Studies II-III*). In *Studies II-IV*, patients were randomised to psychomotor therapy (N=53) or exercise therapy (N=54) implemented during the first 3 post-operative months. Semi-structured interviews were conducted 3-6 months after surgery on 20 patients including 10 from each rehabilitation group to investigate experiences of back problems before and after surgery, post-operative recovery and expectations of rehabilitation analysed in terms of the International Classification of Functioning, Disability and Health (*Study IV*).

**Results:** Approximately 50% of the variability in baseline disability and 40% of the variability in baseline health related quality of life could be explained by baseline psychological variables. In particular, catastrophizing, control over pain, self-efficacy and outcome expectancy had significant mediation roles (*Study I*). For the short and long term outcome of lumbar fusion surgery, early post-operative psychomotor therapy is significantly more effective than exercise therapy with approximately 10-20% better outcome in measures of disability, fear of movement/(re)injury, pain catastrophizing, self-efficacy, outcome expectancy, sickness leave, health care utilization and return to work (*Study II*). A model with good outcome predictive performance which significantly predicts disability, back pain and health related quality of life outcomes 2-3 year after lumbar fusion surgery, was shown to involve pre-operative screening of disability, leg pain intensity, mental health, fear of movement/(re)injury, outcome expectations, catastrophizing, control over pain and the implementation of post-operative psychomotor therapy (*Study III*). Lumbar fusion patient's experiences of back problems before and after the operation, experiences of recovery and outcome expectations correspond well with the content of outcomes measures used in the study (*Study IV*).

**Conclusion:** Psychological factors strongly influence levels of disability and health related quality of life in lumbar fusion candidates as well as predicts post-operative outcomes. Early post-operative rehabilitation focusing on cognition, behaviour and motor control is recommended for improved lumbar fusion outcomes.



Keywords: Biopsychosocial factors, chronic low back pain, disability, health related quality of life, ICF, mediation, outcome prediction, rehabilitation, spinal fusion.

# LIST OF PUBLICATIONS

I. Abbott AD, Tyni-Lenné R, Hedlund R. The influence of psychological factors on pre-operative levels of pain intensity, disability and HRQOL in lumbar spinal fusion surgery patients.
*Physiotherapy* (2010), doi:10.1016/j.physio.2009.11.013

II. Abbott AD, Tyni-Lenné R, Hedlund R. Early rehabilitation targeting cognition, behaviour and motor function after lumbar fusion. A randomized controlled trial.
*Spine* (2010), 35(8):848-857, doi:10.1097/BRS.0b013e3181d1049f

III. Abbott AD, Tyni-Lenné R, Hedlund R. Leg pain and psychological variables predict outcome 2-3 years after lumber fusion surgery.
*Submitted*

IV. Abbott AD, Hedlund R, Tyni-Lenné R. Lumbar fusion patient's experience of back problems, recovery and expectations in terms of the ICF
*Submitted*

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# LIST OF ABBREVIATIONS

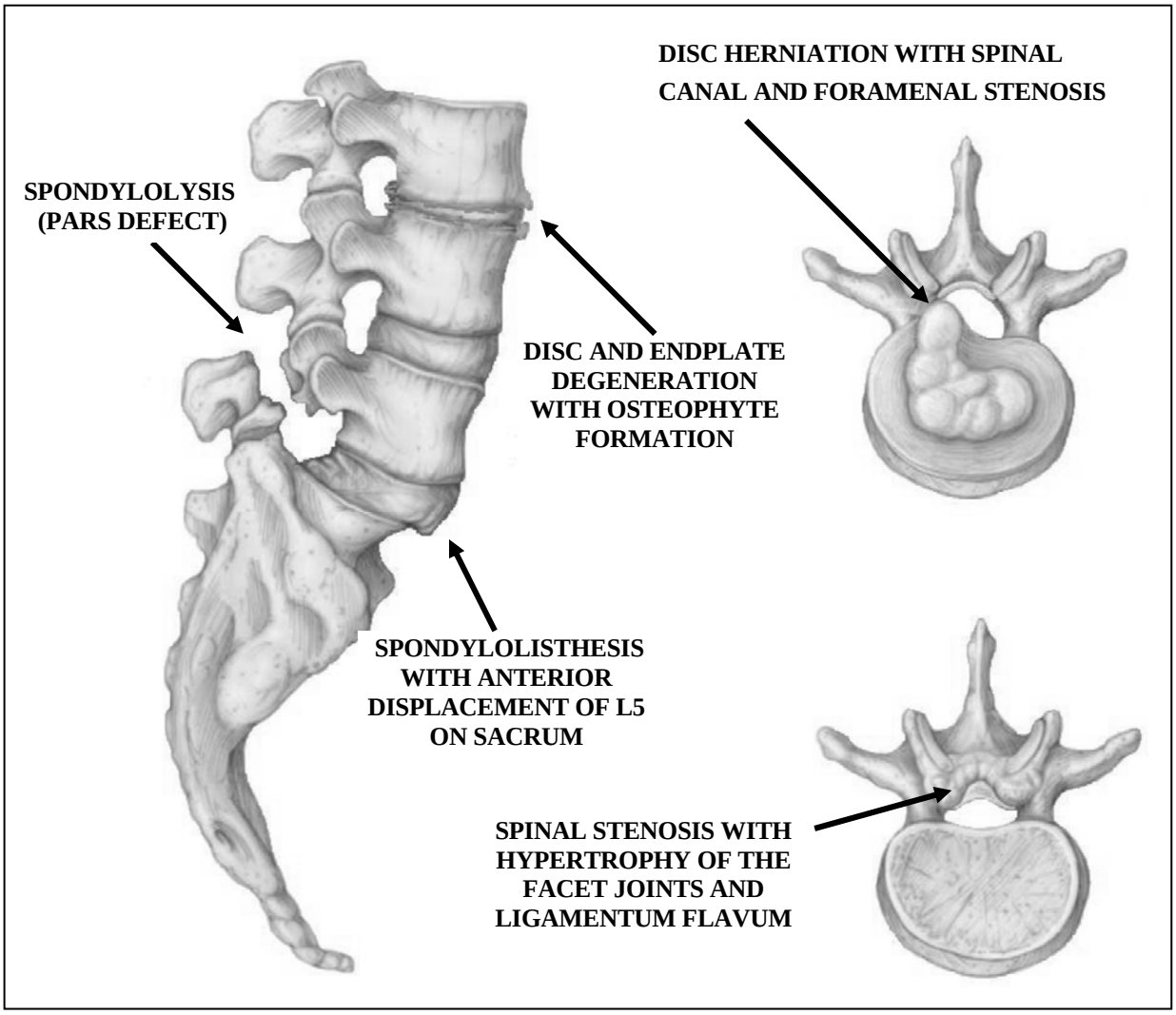
| | |
|---|---|
| CLBP | Chronic Low Back Pain |
| DDD | Degenerative disc disease |
| LBP | Low Back Pain |
| FAM | Fear Avoidance Model |
| PLF | Posterolateral Fusion |
| PLIF | Posterior Lumbar Interbody Fusion |
| TLIF | Transforaminal Lumbar Interbody Fusion |
| WCPT | World Confederation of Physical Therapy |
| ADL | Activities of Daily Living |
| ICF | International Classification of Functioning, Disability and Health |
| GP | General Practitioner |
| RCT | Randomised Controlled Trial |
| HRQOL | Health Related Quality of Life |
| BMI | Body Mass Index |
| ODI | Oswestry Disability Index |
| VAS | Visual Analogue Scale |
| EQ-5D | European Quality of Life Questionnaire |
| SF-36 | Medical Outcome Study Short Form 36 |
| TSK | Tampa Scale for Kinesiophobia |
| SES | Self-Efficacy Scale |
| BBQ | Back Beliefs Questionnaire |
| CSQ | Coping Strategy Questionnaire |
| CAT-CSQ | Catastrophizing subscale of the Coping Strategy Questionnaire |
| COP- CSQ | Control Over Pain subscale of the Coping Strategy Questionnaire |
| ADP-CSQ | Ability to Decrease Pain subscale of the Coping Strategy Questionnaire |
| MCID | Minimum Clinically Important Difference |
| BCa | Bias Corrected and accelerated |
| SPSS | Statistical Package for Social Sciences |
| ITT | Intention to Treat |
| ANCOVA | Analysis of Covariance |
| CATREG | Categorical Regression |
| ROC | Receiver Operating characteristic |
| AUC | Area Under the Curve |

# 1 INTRODUCTION

## 1.1 PERSPECTIVES AND FRAMEWORK

This thesis focuses on issues regarding physiotherapy and lumbar fusion surgery in chronic low back pain (CLBP) patients with lumbar spine conditions such as degenerative disc disease (DDD), spinal stenosis and spondylolisthesis. These conditions may be due to the effects of aging, secondary to trauma, wear and tear or degenerative disease. The pathophysiology associated with these conditions may involve the intervertebral disc, the vertebrae and/or the associated joints in the lumbar spinal segment (Figure 1). For example, DDD involves the deterioration of the disc's nucleus pulposus and annulus fibrosus with dense disorganized fibrous tissue affecting structural integrity. This may cause disc bulging, annular tearing, disc herniation, and contribute to deterioration of the vertebral endplate and facet joints. Spinal stenosis on the other hand involves the encroachment of the spinal canal from structures such as bulging discs, hypertrophy of the facet joints or ligamentum flavum. In degenerative spondylolisthesis, severe degenerative changes and excess motion of facet joints may produce spinal segment instability where forward movement of one vertebra over another may cause stenosis of the spinal canal. With isthmic spondylolisthesis, a cleft or break in the pars interarticularis (spondylolysis) divides the vertebra so the anterior part slips forward causing direct or indirect nerve root compression (Lindgren & Svensson, 2007).

**Figure 1.** The pathoanatomy of lumbar spine conditions

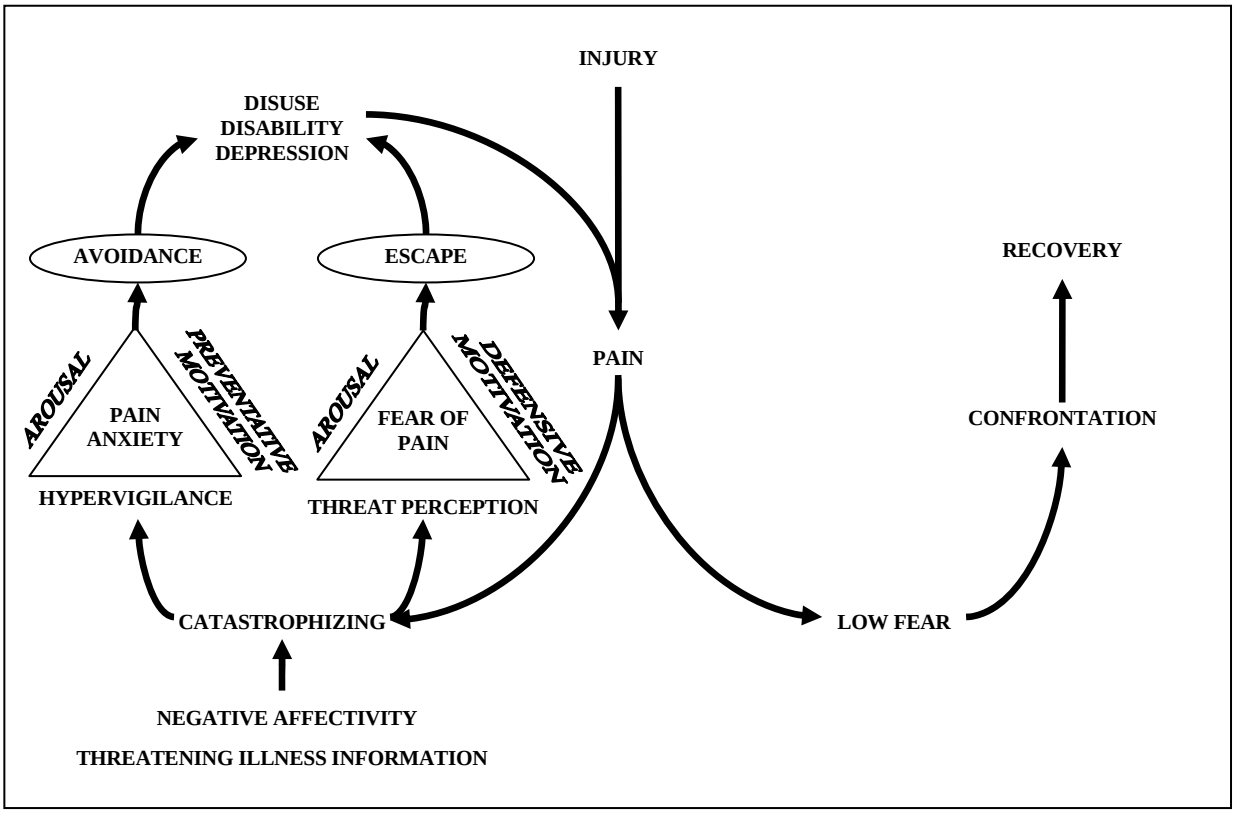


Low back pain (LBP) is defined as pain localized to the back below the line of the twelfth rib and above the inferior gluteal folds, and is often associated with referred leg pain (Andersson, 1986). Experimental studies suggest that low back pain may originate from the noxious, mechanical or chemical stimulation of innervated spinal structures including ligaments, facet joints, vertebrae, paravertebral musculature, fascia, blood vessels, the annulus fibrosus and spinal nerve roots (Bogduk, 2005). Studies have reported a lifetime prevalence of low back pain in the general population to range between 11-84%, the 1 year prevalence to range between 10-65% and the point prevalence to range between 7-33% (Reigo et al 1999; Walker 2000; Webb et al 2003, Von Korff et al 2005; Deyo et al 2006; Tsang et al 2008). In these studies, the higher range prevalence rates have been reported in western industrialized countries.

Chronic pain has often been defined as pain that extends beyond the expected period of healing (Turk & Okifuji 2001). The clinical course of CLBP is however characterized by fluctuating symptoms rather than a purely self-limiting course (Hestbaek et al 2003a). A review of studies investigating the long-term course of LBP shows that the reported portion of patients still experiencing pain after 12 months is on average 62% (range 42-75%) while the mean reported prevalence of LBP in cases with previous episodes was 56% (range 14-93%), compared to 22% (range 7-39%) for those without a prior history of LBP (Hestbaek et al 2003b). In approximately 15% of LBP patients, chronic symptoms can be given a specific pathoanatomical diagnosis (Deyo & Weinstein 2001).

Psychosocial factors have been suggested to strongly influence the perception of pain, as well as play an important role in the development of pain chronicity and disability (Gatchel et al 2007). The Fear Avoidance Model (FAM) has evolved from literature suggesting that the experience of pain is influenced by emotional and cognitive factors steering the use of pain coping strategies and pain behaviours (Vlaeyen et al 1995, 2000; Leeuw et al 2007).

**Figure 2.** The fear avoidance model of chronic pain (Leeuw etal 2007)



The FAM describes how negative mood (affectivity) influences the use of a catastrophizing pain coping style which in turn may influence fear of pain or pain anxiety to produce avoidance or escape behaviours may increase the risk of physical disuse, disability, depression and pain chronicity. On the contrary, a normal reaction to pain is the use of positive coping styles to reduce fear of pain, influencing confrontational behaviour where the person's mobility and strength successively recovers and their belief in their own functional ability and even ability to control or decrease pain is positively reinforced (Figure 2).

In addition to the role of pain catastrophizing, several other cognitive factors have been hypothesized to mediate the influence of pain on disability in chronic pain patients. Such factors include outcome expectancy (the beliefs that a chosen behaviour will lead to the desired outcome), self-efficacy beliefs (the belief that one can execute a desired behaviour), and self-control beliefs (the belief that one has control over events that affect them) (Bandura 1997, Turk 2002, Walker 2001). Self-efficacy with respect to pain management, pain coping and physical functioning has been demonstrated to mediate associations between pain intensity, pain related fear, disability and depression in CLBP patients (Arnstein et al 1999, Woby et al 2007), as well as the effect of cognitive behavioural therapy for treating chronic pain (Turner et al 2007). Research investigating mediation roles of outcome expectancies and perceived pain control is lacking. Significant associations between outcome expectancies and physical functioning have however been demonstrated (Council et al 1988, Lackner et al 1996, den Boer et al 2006). Similarly, perceived lack of control has been associated with psychological distress and depression in chronic pain patients (Rudy et al 1988, Walker & Sofaer 1998).

Spinal fusion surgery involves the use of arthrodesis between vertebrae to prevent movement at painful joints or to correct spinal deformities. Traditionally, a posterior midline incision is used cutting through the fascia and paraspinal muscle planes deflecting them from the spinous processes and retracting them to visualize and decorticate the posterior vertebral structures in preparation for fusion. Posterolateral Fusion (PLF) involves the implantation of bone grafts and/or fixation with pedicle screws and adjoining rods (Camillo et al 2007). Commonly, laminectomy and bilateral partial facetectomy is performed in Posterior Lumbar Interbody Fusion (PLIF) to allow removal of the intervertebral disc and insertion of bone spacers in the form of a bone graft and/or cage device bilaterally into the interbody space. In Transforaminal Lumbar Interbody Fusion (TLIF), a complete unilateral facetectomy is instead used to allow removal of the intervertebral disc and insertion of only one bone spacer into the middle of the interbody space (Camillo et al 2007) (Figure 3).

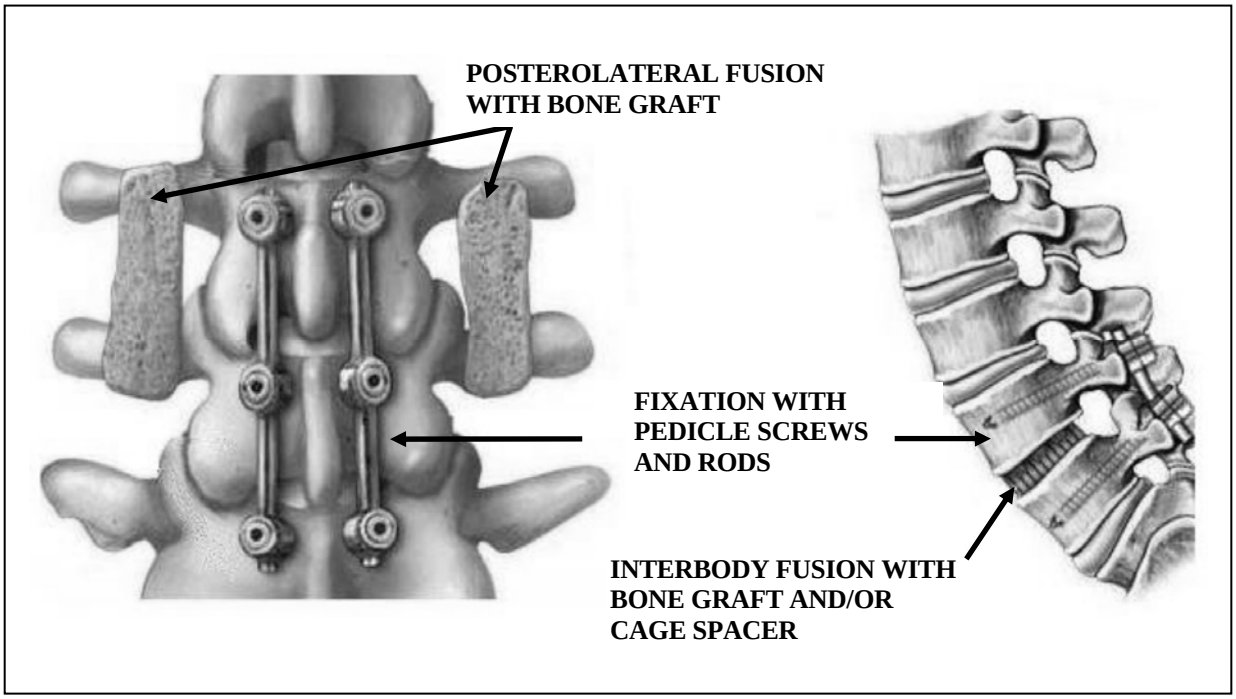
With the increased awareness of the important active role of the paraspinal muscles in stabilizing the spine (Macintosh & Bogduk 1986), minimized muscle damage has been found in less invasive mini-open midline techniques and paramedian techniques that split the fascial planes of the multifidus and longisimus muscles (Kim et al 2007, Tsutsumimoto et al 2009).

In 2001, over 300 000 spinal fusion surgeries were performed in the USA representing 100 surgeries per 100 000 population (Deyo et al 2004). Of these, 122 000 were lumbar fusions for degenerative conditions representing 40 fusions per 100 000 population, an increase of 220% from 1990 (Deyo et al 2005). Internationally, similar trends can be observed, but in a smaller scale. In Australia for example, in 2006, 4806 lumbar fusion surgeries were performed at 23 fusions per 100 000 population representing approximately a 170% increase in rates since 1997 (Harris & Dao 2009). In Sweden, data from the Swedish Spine Register indicates that

approximately 1000 spinal fusion surgeries were conducted for degenerative lumbar disorders in 2008 at a rate of 11 fusions per 100 000 population (Strömqvist et al 2008).

Apart from the widening of indications for spinal fusion surgery, technological advances such as the use of spinal fixation devices (Pedicle screws, intervertebral fusion cages), computed aided and minimally invasive surgical techniques, bone graft substitutes and supplements may also contribute to increased spinal fusion surgery rates (Bono & Lee 2004). Improved anaesthetic techniques for older patients have been associated with increased rates of spinal fusion and laminectomy surgeries in patients over 60 years old. Furthermore, financial incentives for surgeons, hospitals and from the device industry as well as more favourable reimbursements for spinal procedures in the medical systems of different countries may be factors influencing the increases in spinal fusion rates (Deyo et al 2004).

**Figure 3.** Types of spinal fusion



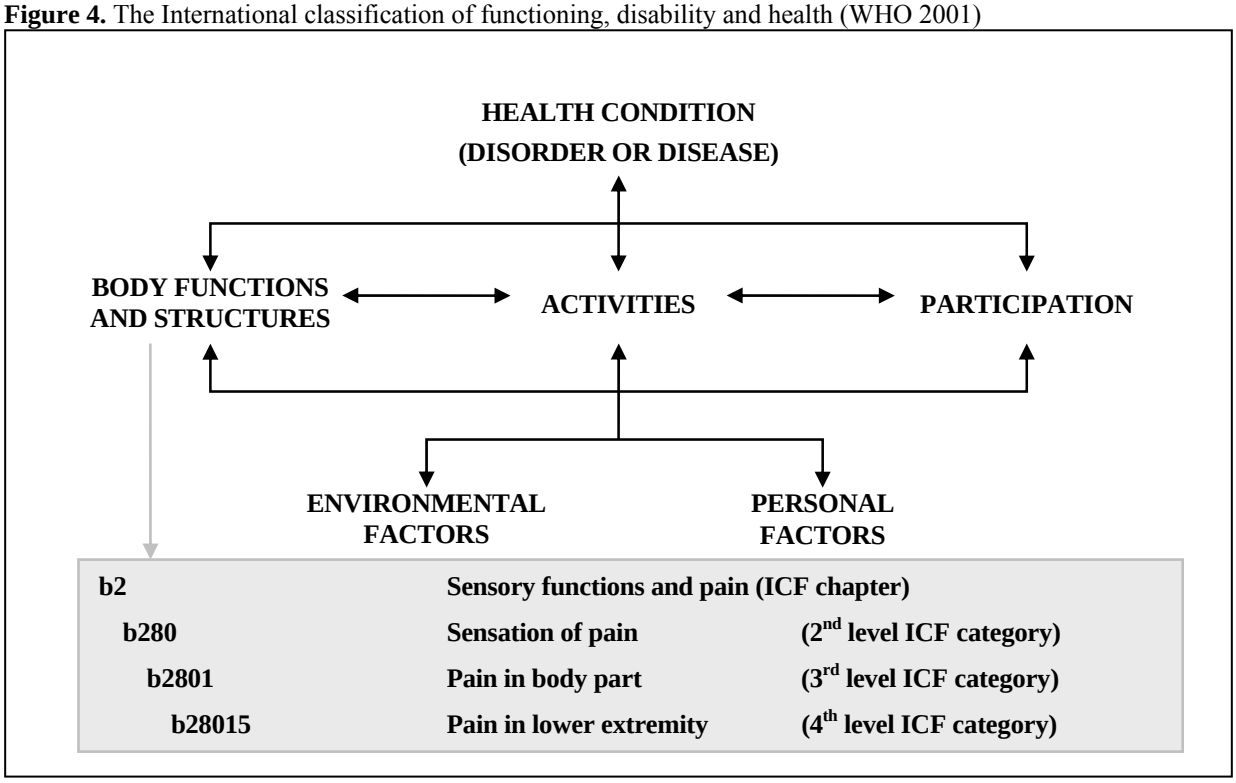

The World Confederation of Physical Therapy (WCPT) describes physiotherapy as a service concerned with identifying and maximizing quality of life and movement potential within the spheres of promotion, prevention, treatment/intervention, habilitation and rehabilitation. This encompasses physical, psychological, and social wellbeing. Physiotherapists are qualified and professionally required to perform comprehensive patient examination/assessment/evaluation, formulate diagnosis, prognosis and plan as well as to implement and evaluate interventions (WCPT 2010). In the past, the biomedical model of disease has been dominant in the physiotherapy profession. The biomedical model assumes that physical pathology is the sole cause of pain and disability. Physiotherapy for CLBP patients has previously focused on the reduction of pain and the use of pain as a guideline to determine the intensity of exercise as well as advice on Activities of Daily Living (ADL) and work (French & Sim 2004).

The biopsychosocial model has replaced the outdated biomedical model of disease. The biopsychosocial model is a conceptual model that proposes that psychological and social factors must also be included along with the biological variables in understanding a person's medical

illness, which in this thesis focuses on CLBP. In this model, pain is best viewed as an interactive, biopsychosocial behaviour pattern that cannot be separated into distinct, independent psychosocial and physical components. According to the International Association for the Study of Pain, biological, psychological, and social factors must all be treated simultaneously (based on this biopsychosocial model) for the most clinically effective and cost-effective approach to use in patients with chronic pain. Psychological aspects need to be integrated with other therapeutic components in physical therapy and medication management, to address all components comprising the experience of chronic musculoskeletal pain (IASP 2009)**.**

A part of the WCPT's mission, is the ongoing support of implementing the International Classification of Functioning, Disability and Health (ICF) into physiotherapy education, practice and research (WCPT 2010). The ICF is a framework and classification that provides a common language for describing health and health related conditions. The ICF is particularly helpful in providing a common language between different settings, disciplines and in mixed/multi method research for the appraisal of relationships between qualitative and qualitative data (triangulation) for the investigation of a research question. It is based on an integrative biopsychosocial model of functioning, disability and health developed by the World Health Organisation (WHO 2001). In the ICF, functioning denotes the positive aspects and disability denotes the negative aspects of the interaction between an individual with the health condition and contextual factors (environmental and personal factors). The first level classifications in the ICF are coded with a letter referring to the different components where b=body functions and structures, d=activities and participation, e= environmental factors and p=personal factors. Each component except for personal factors can be further coded with a number referring to second level chapters, third level categories and forth level sub-categories (Figure 4). Furthermore, core sets of codes have been developed that are most relevant for different health conditions.

**Figure 4.** The International classification of functioning, disability and health (WHO 2001)



## 1.2 PHYSIOTHERAPIST'S ROLE IN ORTHOPAEDIC SPINAL CLINICS

Referrals to spinal surgeons in hospital orthopaedic outpatient departments are often made by general practitioners (GP) who need specialist opinion on the diagnosis and possible surgical management of patients with low back pain. The waiting list time for a spinal surgeon consultation in Sweden has previously been reported to be approximately 3 months for prioritized cases and up to 12 months for non-prioritized cases (Kornerup et al 2007, Sveriges Kommuner och Landsting 2010).

In England and Australia, a successful strategy that has been commonly implemented in orthopaedic departments to reduce waiting lists is for physiotherapists to screen referrals from GP's (Byles & Ling 1989, Hockin & Bannister 1994; Hourigan & Weatherley 1994,1995, Weale & Bannister 1995, Weatherley & Hourigan 1998, Pearse et al 2006, Daker-White et al 2007, Oldmeadow et al 2007). In Sweden, this clinical praxis in orthopaedic departments is less common and only one study has been published in the area. A study conducted by Kornerup et al (2007) at Östersund Hospital's orthopaedic spinal clinic reported that after physiotherapist screening of referrals, assessment and treatment, only 44% of waiting list patients required surgical consultation. Increased clinical praxis of this physiotherapy service model in Sweden could possibly be beneficial on both a patient and socioeconomic level by reducing pain chronicity, disability, sickness leave, health care dependency and improving quality of life.

Physiotherapists working in this role require orthopaedic specialist competence. For orthopaedic specialist competence, physiotherapists generally require at least 5 years clinical experience including at least 3 years experience in the management of orthopaedic and musculoskeletal conditions and postgraduate education. Furthermore, specialist knowledge of neuromusculoskeletal conditions, pain science, investigations such as X-ray, scans and blood tests along with highly developed manual examination skills are required (Legitimerade Sjukgymnasters Riksförbund, 2009).

Durrell (1996) recommends a triage protocol where patients are considered suitable for an orthopaedic physiotherapy specialist consultation if their history suggests a benign musculoskeletal condition where immediate surgery is not indicated. Exclusion criteria include referrals between spinal surgeons, cases with tumours or masses, children under the age of 16 and cases with complex diagnostic problems. It is recommended that both patients and GP's are to be informed of when the spinal team triage considers orthopaedic physiotherapy specialist consultation appropriate but patients are given the option to instead remain on the non-priority referral waiting list. Furthermore, the physiotherapist is expected to discuss with the spinal surgeons the radiological examinations, referrals to other medical specialists and indications for invasive or surgical treatment. Staff at orthopaedic clinics has been reported to be supportive of orthopaedic physiotherapy specialists in this role (Milligan 2003).

For CLBP patients triaged as being suitable for orthopaedic physiotherapy specialist consultation, baseline assessment is conducted and a treatment plan is implemented. This may involve a functional restoration and pain management program lead by the physiotherapist using cognitive behavioural principles or in the case of more complex psychological co-morbidities, a multidisciplinary pain rehabilitation program involving a clinical psychologist or psychotherapist is advocated. Patients not responding to non-surgical treatment generally remain on waiting lists to spinal surgeons for final assessment of indications for surgical treatment. For

those patients selected for surgical intervention, physiotherapists take baseline physical and psychosocial measures and inform patients of post-operative management. The physiotherapist's role even extends into the implementation and assessment of post-operative rehabilitation.

## 1.3 EVIDENCE BASED PHYSIOTHERAPY FOR CHRONIC LOW BACK PAIN

In 2007, an extensive review of evidence on nonpharmacological therapies for acute and chronic low back pain was published by Chou & Huffman (2007) for an American Pain Society/American College of Physicians Clinical Practice Guideline. By reviewing the results of high quality systematic reviews and randomized controlled trials (RCT), they assessed the efficacy of acupuncture, back schools, psychological therapies, exercise therapies, functional restoration, multidisciplinary therapy, massage, physical modalities (interferential therapy, low-level laser therapy, lumbar supports, short-wave diathermy, superficial heat, traction, transcutaneous electrical nerve stimulation, and ultrasonography), spinal manipulation, and yoga for acute and chronic low back pain (with or without leg pain). Good evidence was shown that cognitive behavioural therapy, exercise therapy, spinal manipulation, and multidisciplinary rehabilitation which are all moderately effective compared to placebo, sham, waiting list or no treatment for patients with for chronic or subacute LBP.

Despite the evidence supporting the effectiveness of exercise therapy for CLBP, a great deal of heterogeneity exists in the literature with respect to the type of exercise, intensity, frequency, duration and delivery of exercise therapy programs. A systematic review conducted by Hayden et al (2005) used a meta-analytic approach to identify exercise intervention characteristics that decrease pain and improve function in LBP patients. The study found the most effective strategies to be patient individualized and delivered as home based exercise with regular therapist follow-up to encourage exercise program adherence. Adding other non-surgical treatments including advice to stay active, use of anti-inflammatory medication, and manual therapy were also reported to result in improved functional and pain outcomes. Furthermore, muscle strengthening exercises and stretching were the most effective types of exercise for improving functional and pain related outcomes, respectively.

In the late 1990's, a motor control exercise model was developed by Richardson et al (1999) based on the evidence from laboratory studies showing LBP patients to have impairments in control of deep trunk muscles stabilizing the spine (Hodges & Richardson 1996,1998,1999, Hides et al 1994,1996). With an increasing number of clinical trials evaluating motor control exercise, a recent systematic review by Macedo et al (2009) used a meta-analytic approach to compare the efficacy of motor control exercise compared to minimal intervention, general exercise therapy and spinal manipulation. Results showed that motor control exercise was significantly better than minimal intervention in reducing pain at short-term, intermediate and long-term, and in reducing disability at long term follow-up. Furthermore, motor control exercise was significantly better than spinal manipulation for pain, disability and quality of life at intermediate follow-up and significantly better than general exercise therapy in reducing disability in the short term. On the other hand, motor control exercise was just as effective as general exercise therapy in reducing pain and quality of life in the long term and the differences observed in short term disability may not be clinically important.

Another exercise therapy approach is the behavioural graded activity program based on the work of Fordyce (1973), Fordyce et al (1976) and Lindström et al (1992). It combines operant

behavioural conditioning with a graded physical exercise program to increase health behaviours and decrease pain behaviours. It therefore emphasizes a behavioural component rather than just physical training principles. The program uses contingent management to develop individually graded exercise prescriptions to teach patients that it is safe to move while increasing activity levels. To obtain initial baseline measurements, activities of importance identified by the patients are performed until the patient has to stop because of pain. The patient sets treatment goals for each activity and the therapist sets time contingent quotas starting below baseline which are then systematically increased to enable the patients to reach their goals. There is conflicting evidence in the occupational health care setting for the effectiveness of behavioural graded activity compared to usual physician based care for early return to work and reduced long term sick leave due to sub-acute or CLBP (Lindström et al 1992, Staal et al 2004, Hlobil et al 2005, Steenstra et al 2006). Behavioural graded activity has not been shown to significantly improve pain and disability outcomes more than usual care, active physical training or even in combination treatments (Smeets et al 2008). This is with the exception of intensive multidisciplinary biopsychosocial rehabilitation with functional restoration which in a meta-analysis study showed evidence of improved function and pain measures compared to non-multidisciplinary rehabilitation or usual care (Guzman et al 2001). Intensive multidisciplinary rehabilitation of CLBP patients however comes with high costs, requires high levels of organization and seems more suitable for rehabilitating CLBP patients with a history of long-term sickness leave or disability benefits (Loisal et al 2002, Skouen et al 2002).

A randomized controlled trial by Macedo et al (2008) is currently underway to investigate the effects of motor control exercise compared to a behavioural graded activity program in the treatment of CLBP. Macedo et al (2008) hypothesize that motor control exercise will be more effective than behavioural graded activity in improving pain and disability, especially in patients with impaired control of movement and stability of the spine. Furthermore they hypothesize that graded activity may have greater effect on patients who are deconditioned and have negative beliefs about their pain. To identify potential treatment effect modifiers at baseline, measures such as trunk proprioception, trunk stiffness, trunk muscle response and test of deep muscle control, aerobic fitness, habitual activity level, kinesiophobia and self-efficacy will be measured.

Macedo et al (2008) provide a demarcation analysis distinguishing the two interventions and displaying that motor control exercise covers nearly all facets of behavioural graded activity accept for time contingency, quota/pacing and reinforcement of wellness behaviour and ignorance of illness behaviour. It can however, be argued that a motor control exercise program can also involve behavioural operant conditioning through reinforcement of wellness behaviour and coping with illness behaviour. Furthermore, it is possible to deliver motor control exercise with time contingency, the setting of quotas and pacing, especially in conjunction with pain management strategies. Such pain management strategies could include cognitive coping strategies, respondent therapy or even pain analgesics. A recent systematic review of literature on behavioural treatment for CLBP has shown that combined respondent-cognitive therapy and progressive relaxation therapy are effective for pain relief (Ostelo et al 2008).

A combined motor control exercise and cognitive-behavioural approach to the treatment of CLBP emphasizes the interdependency of physical and psychological interventions. Richardson et al (2005) suggest that strategies should be implemented to improve aspects of self-efficacy, anxiety/depression and fear of movement/(re)injury to allow for motor control improvements. Likewise, positive progressions in motor control exercise reinforce improvements in self-

efficacy, anxiety/depression and fear of movement/(re)injury. The combined delivery of these interventions can be likened with the principles of a psychomotor therapy treatment approach. Psychomotor therapy originates from the work of a Norwegian physiotherapist, Aadel Bulow-Hansen and the psychiatrist Tryve Braatoy, claiming that physical aspects such as posture, respiration and movement are closely related to emotional states. They describe the aim of psychomotor therapy is to address identified bodily dysfunction and facilitate change by means of movements and exercises closely linked with body awareness and respiration (Thornquist & Bunken 1991). A psychomotor therapy treatment approach has been used in the treatment of patients with chronic musculoskeletal pain (Houge 1982, Ovreberg & Andersen 1986, Thornquist & Bunken 1991, Steinhaug et al 2001, Ekerholt & Bergland 2004, Dragesund & Råheim 2008).

## 1.4 EVIDENCE BASED FUSION SURGERY FOR CHRONIC LOW BACK PAIN

Systematic reviews applying meta-analytic methods by Gibson et al (2005), Mirza & Deyo (2007) and Chou et al (2009) investigated available evidence on procedures of spinal decompression, nerve root decompression and fusion. For non-radicular LBP with common degenerative changes, there was fair evidence that fusion may not be more effective than a structured rehabilitation program that includes cognitive behavioural therapy for improvement in pain and function. Brox et al (1999, 2003, 2006) and Fairbank et al (2005) for example, implemented structured rehabilitation programs including a combination of stretching, general muscle strengthening, motor control exercise, low impact aerobic exercise, cognitive coping strategies, relaxation strategies and behavioural conditioning which produced similar outcome in randomised comparisons to lumbar fusion in patients with DDD. Fusion has only been shown to be slightly to moderately more efficacious in comparison to unstructured heterogeneous non-operative care in CLBP patients with DDD (Fritzell et al 2001) and for structured exercise therapy without a cognitive behavioural component in isthmic spondylolisthesis patients (Möller & Hedlund, 2000). Follow-up 9 years post-surgery however, show no significant differences between surgical and exercise therapy groups except for in global perceived outcome (Ekman et al 2005).

The systematic reviews by Gibson et al (2005), and Chou et al (2009) conclude that for symptomatic spinal stenosis with or without spondylolisthesis, there is good evidence that decompressive surgery (laminectomy with or with fusion) is moderately superior to nonsurgical therapy through 1 to 2 years. There are conflicting results as to which instrumental fusion technique is superior over another and even in comparison with non-instrumented fusion. There is however evidence that instrumented fusion may be associated with higher complication rates. Furthermore, Ekman et al (2009) recently followed-up patients with lumbar fusion 13 years post-surgery and found evidence of accelerated degenerative changes at the level adjacent to fusion, especially in those who also received laminectomy. The clinical relevance of this did, however, seem to be limited. Disc replacement for DDD has become popular the last decade. Randomised trials have shown similar or better short term outcomes compared to fusion (Berg et al 2009).

## 1.5 EVIDENCE BASED POST-OPERATIVE MANAGEMENT

Post-operative deficits in physical function, continued suffering from pain and reduced quality of life have been reported in spinal surgery patients, with greatest deficits after spinal fusion

surgery (Mayer et al 1989, Bentsen et al 2007). A systematic review of literature on post-operative rehabilitation after first time lumbar disk surgery by Ostelo et al (2008) has shown that exercise programs starting four to six weeks post-surgery and high intensity exercise programs lead to faster decrease in pain and disability than no treatment or low intensity programs, respectively. Furthermore, no significant differences in outcome have been reported between patients receiving home or supervised exercise programs, and there is no evidence of increased re-operation rates with active programs after disc surgery. Only one study by Ostelo et al (2003a,b) has investigated the effect of a behavioural graded activity compared to standard physiotherapy. As only one study exists, currently only low quality evidence suggests significantly better global perceived outcome after standard physiotherapy in the short term while no significant differences exist between groups in the long term. Similar results were observed in a systematic review by Abbott et al (2009) who included an additional three recent RCT's by Erdogmus et al (2007), Choi et al (2005) and Donaldson et al (2006) in the development of Swedish national guidelines for post-operative rehabilitation after lumbar discectomy.

Taking into consideration that mostly younger patients undergo first time disc surgery, Mannion et al (2007) questioned if older patients can be expected to achieve comparable levels of success with muscle reconditioning programs. Mannion et al (2007) conducted an RCT comparing physiotherapy with spine stabilization exercises, physiotherapy with mixed techniques and a control group receiving advice to keep active. This involved older patients who had undergone surgical decompression with laminectomy and partial facet joint resection in cases of spinal stenosis and removal of compressive disc tissue in cases of disc herniation. Results showed that physiotherapy was no more effective than advice in reduction of short and long term back and leg pain and self-rated disability recorded after surgery.

With respect to rehabilitation after lumbar fusion surgery, only one previous RCT exists. Christensen et al (2003) investigated the effectiveness of different regimes beginning 12 weeks post-surgery. The rehabilitation regimes included a home based standard exercise therapy group, another group receiving home based standard exercise therapy supplemented with 3 patient group support meetings termed "Back Café", and final group receiving supervised outpatient based standard exercise therapy. The main finding of the study was that the "Back Café" intervention produced significantly better patient self-perceived function compared to the training only groups at long-term follow-up. Furthermore, a cost-effectiveness analysis also showed the "Back Café" intervention to be more cost-effective than exercise therapy alone (Sogaard et al 2007). One can however question if a program with more specific and structured cognitive behavioural content would be more effective and if delaying rehabilitation until 3 months after surgery may be unnecessary, since early exercise has been shown not to overload lumbar internal fixation (Rohlmann et al 2002).

## 1.6 CLINICAL OUTCOME PREDICTION

Statistics from the Swedish National Spine Register show that 25% of patients experience unimproved back and/or leg pain and up to 40% are not satisfied with the outcome of surgery 12 months after lumbar fusion (Strömqvist et al 2008). Similarly, a review of literature reported back surgery failure rates ranging from 5 to 50% (COST B13 Action, 2004). Considering a clear need to improve the outcome of spinal surgery, increased research into predictors of outcome has attempted to improve identification of patients who are likely to benefit from surgery.

Previously reported predictors of lumbar fusion outcome include negative personality traits (Riley et al 1995, Van Susante et al 1998, Trief et al 2000 2006, Hägg et al 2003), anxiety/depression (Trief et al 2000 2006, Block et al 2003, LaCaille et al 2005, Mannion et al 2007), fear avoidance beliefs (Mannion et al 2007), negative outcome expectations (Iversen et al 1998, Yee et al 2008), negative coping, duration of back pain and workers compensation (Trief et al 2000 2006, Block et al 2001, Hägg et al 2003), and female gender (Ekman et al 2009). Not one of these studies has however collectively tested a full range of factors previously reported to be predictive of long term disability outcome reported by the ODI, back pain outcome reported by a VAS or even Health Related Quality of Life (HRQOL) reported by the EQ-5D. To aid in clinical decision making in the screening and treatment of CLBP patients, clinical prediction models are needed to summarize the effects of predictors to provide individualised predictions of a diagnostic or prognostic outcome (Steyerberg, 2009).

## 1.7 RATIONALE

The rational for this thesis was to elucidate the importance of a biopsychosocial approach to the multi-professional management of lumbar fusion patients. Based on my clinical experience as a physiotherapist, there is a need to clarify the physiotherapist's role in an orthopaedic spinal team. In the background literature summarised in this thesis, it is evident that further research is needed to gain a better understanding of the influence of psychological factors on lumbar fusion patient's pre-surgical and post-surgical condition and to further develop methods of patient screening and post-operative rehabilitation.

## 1.8 SUMMARY OF PROBLEM AREAS

- It is unclear to what extent pain and psychological factors influence disability and HRQOL in spinal fusion candidates. When applying the FAM as theoretical model, the mediation roles of various cognitive factors hypothesised in the literature is unclear with respect to relationships between pain, mental health, fear avoidance, disability and HRQOL.
- There is a lack of RCT's on the management of early physiotherapeutic rehabilitation after spinal fusion
- There is a need to collectively test the predictive quality of a comprehensive range of biopsychosocial factors for the outcome of lumbar fusion. Furthermore there is a need to develop a clinical prediction model for the outcome of lumbar fusion surgery.
- Incite into lumbar fusion patient's experience of surgery and post-operative management is lacking.

# 2 OVERALL AIMS

1. To assess the level to which perceived pain and psychological factors influence levels of disability and HRQOL in CLBP patients scheduled for lumbar fusion surgery *(Study I)*.
2. To test our hypothesis that cognitive factors mediate the influence of chronic pain on mental health, fear of movement/(re)injury and as well as their further influence on functional disability and HRQOL in CLBP patients scheduled for lumbar fusion surgery *(Study I)*.
3. To evaluate the short and long term effectiveness of an early psychomotor therapy approach to rehabilitation compared to an early exercise therapy approach after lumbar fusion surgery *(Study II)*.
4. To investigate a comprehensive range of biopsychosocial factors and issues of validity related to the prediction of prospective disability, back pain and HRQOL outcomes in lumbar fusion patients *(Study III)*.
5. To describe within the context of the ICF, lumbar fusion patient's experiences of back problems, post-operative recovery, expectations of rehabilitation and to contrast with the item content of commonly used outcome measures and the ICF core sets for low back pain *(Study IV)*.

# 3 METHODS

## 3.1 RESEARCH DESIGN AND ETHICAL CONSIDERATIONS

A pragmatic mixed method research design including both quantitative and qualitative studies are comprised in this thesis. The study designs are presented in Table 1.

**Table 1.** Study design, number of subjects, data collection, measures and classifications used

| Study | Type of Study | Number of patients | Data collection | Measures and classifications used |
|---|---|---|---|---|
| **I** | Quantitative - Cross-sectional | 107 lumbar fusion candidates | Questionnaire | Disability<br>Pain<br>Quality of life<br>Mental health<br>Self-efficacy<br>Outcome expectancy<br>Fear avoidance beliefs<br>Pain coping |
| **II** | Quantitative – Prospective randomised controlled trial | 107 lumbar fusion patients | Questionnaire | Disability<br>Pain<br>Quality of life<br>Mental health<br>Self-efficacy<br>Outcome expectancy<br>Fear avoidance beliefs<br>Pain coping<br>Sickness leave<br>Work status<br>Health care utilization |
| **III** | Quantitative - Prospective cohort study | 107 lumbar fusion patients | Questionnaire | Disability<br>Pain<br>Quality of life<br>Demographic, clinical, psychological, and work related predictors |
| **IV** | Qualitative - Cross-sectional & Retrospective | 20 lumbar fusion patients | Semi-structured interview | ICF<br>ICF core sets for LBP<br>Consecutive measures in Study II |

The subjects involved in the studies were given written and oral information about participation. Their participation was voluntary and confidential in nature and patients were informed that they could withdraw participation at any time. Patients gave written informed consent of their participation. The ethics committee for medical research in Stockholm health region approved the studies.

## 3.2 STUDY POPULATION

The *studies I - III* in this thesis are based on a sample of 107 CLBP patients awaiting lumbar fusion surgery. *Study IV* includes a subgroup of 20 patients from the original 107 recruited patients. All patients were recruited from the Karolinska University Hospital's Orthopaedic Clinic at Huddinge, Stockholm, Sweden. The patients were recruited over a 2 year period between February 2005 and 2007. The **inclusion criteria** were: men and women aged between 18 and 65 years with a >12 month history of back pain and/or sciatica; a primary diagnosis of spinal stenosis, degenerative or isthmic spondylolisthesis or degenerative disc disease, selected for lumbar fusion with or without decompression, competence in the Swedish language. The **exclusion criteria** were: previous lumbar fusion, rheumatoid arthritis and ankylosing spondylitis co-morbidities. Baseline demographic and clinical data for the participants is outlined in table 2.

**Table 2.** Demographic and clinical baseline data of subjects in each study

| Variable | Studies I-III (n=107) | Study IV (n=20) |
|---|---|---|
| **Sex:** Observed number (%) | | |
| Male | 41 (38) | 10 (50) |
| Female | 66 (62) | 10 (50) |
| **Age:** mean in yrs ± SD | 50.6 ± 10.4 | 53.7 ± 9.1 |
| **BMI:** kg/m$^2$ ± SD | 27.2 ± 5.0 | 28.8 |
| **Smoking:** | | |
| No | 72 (67.3) | 14 (70) |
| Yes | 35 (32.7) | 6 (30) |
| **Work status:** Observed number (%) | | |
| Employed | 62 (58) | 15 (75) |
| Unemployed | 17 (15.9) | 1 (5) |
| Retired | 4 (3.7) | 1 (5) |
| Disability pension | 24 (22.4) | 3 (15) |
| **Sickness leave:** Observed number (%) | | |
| None | 26 (24.3) | 8 (40) |
| Part-time | 14 (13.1) | 0 (0) |
| Full-time | 47 (43.7) | 8 (40) |
| **Sick leave duration:** median in months (range) | 6 (0-48) | 7 (0-18) |
| **Analgesic consumption:** Observed number (%) | | |
| None | 10 (9.3) | 1 (5) |
| Sometimes | 54 (50.5) | 9 (45) |
| Frequently | 40 (37.4) | 10 (50) |
| **Diagnosis:** Observed number (%) | | |
| Spinal stenosis | 30 (28.0) | 7 (35) |
| Degenerative Spondylolisthesis | 13 (12.1) | 4 (20) |
| Isthmic Spondylolisthesis | 19 (17.8) | 1 (5) |
| DDD | 45 (42.1) | 8 (40) |
| **Planned fusion technique:** Observed number (%) | | |
| Transforaminal intervertbral fusion | 32 (29.9) | 6 (30) |
| Posterolateral fusion w ped. screws | 58 (54.2) | 11 (55) |
| Posterolateral fusion w/o ped. screws | 17 (15.9) | 3 (15) |
| **Functional disability:** ODI (0-100), mean ± SD | 44.7 ± 15.7 | 45.6 ± 22.3 |
| **Back pain intensity:** VAS (0-100), mean ± SD | 66.3 ± 21.9 | 64.3 ± 27.6 |
| **Leg pain intensity:** VAS (0-100), mean ± SD | 65.3 ± 25.5 | 62.7 ± 31.0 |
| **HRQOL:** EQ-5D (0-100), mean ± SD | 34.5 ± 30.7 | 32.2 ± 33.5 |
| **Mental Health:** SF36 (0-100), mean ± SD | 58.6 ± 20.8 | 72.9 ± 30.3 |
| **Fear of movement/(re)injury:** TSK (17-68), mean ± SD | 50.6 ± 7.9 | 66.9 ± 64.7 |
| **Outcome expectancy:** BBQ (9-45), mean ± SD | 21.9 ± 6.3 | 30.8 ± 14.4 |
| **Functional self-efficacy:** SES (8-64), mean ± SD | 26.1 ± 7.2 | 28.3 ± 14.3 |
| **Catastrophizing:** CSQ (0-36), mean ± SD | 14.9 ± 7.9 | 17.4 ± 9.2 |
| **Control over pain:** CSQ (0-6), mean ± SD | 2.9 ± 1.3 | 3.2 ± 1.6 |
| **Ability to decrease pain:** CSQ (0-6), mean ± SD | 2.5 ± 1.2 | 2.2 ± 1.5 |

## 3.3 PATIENT FLOW

A total of 162 patients satisfied the inclusion criteria during the recruitment period but 37 were excluded due to co-morbidities and an additional 15 cancelled their surgery. A total of 110 patients were asked to participate in the study. Three declined leaving 107 recruited participants. Random concealed allocation produced two statistically equivalent post-operative rehabilitation groups with 53 patients allocated to psychomotor therapy and 54 patients to exercise therapy (Figure 5).

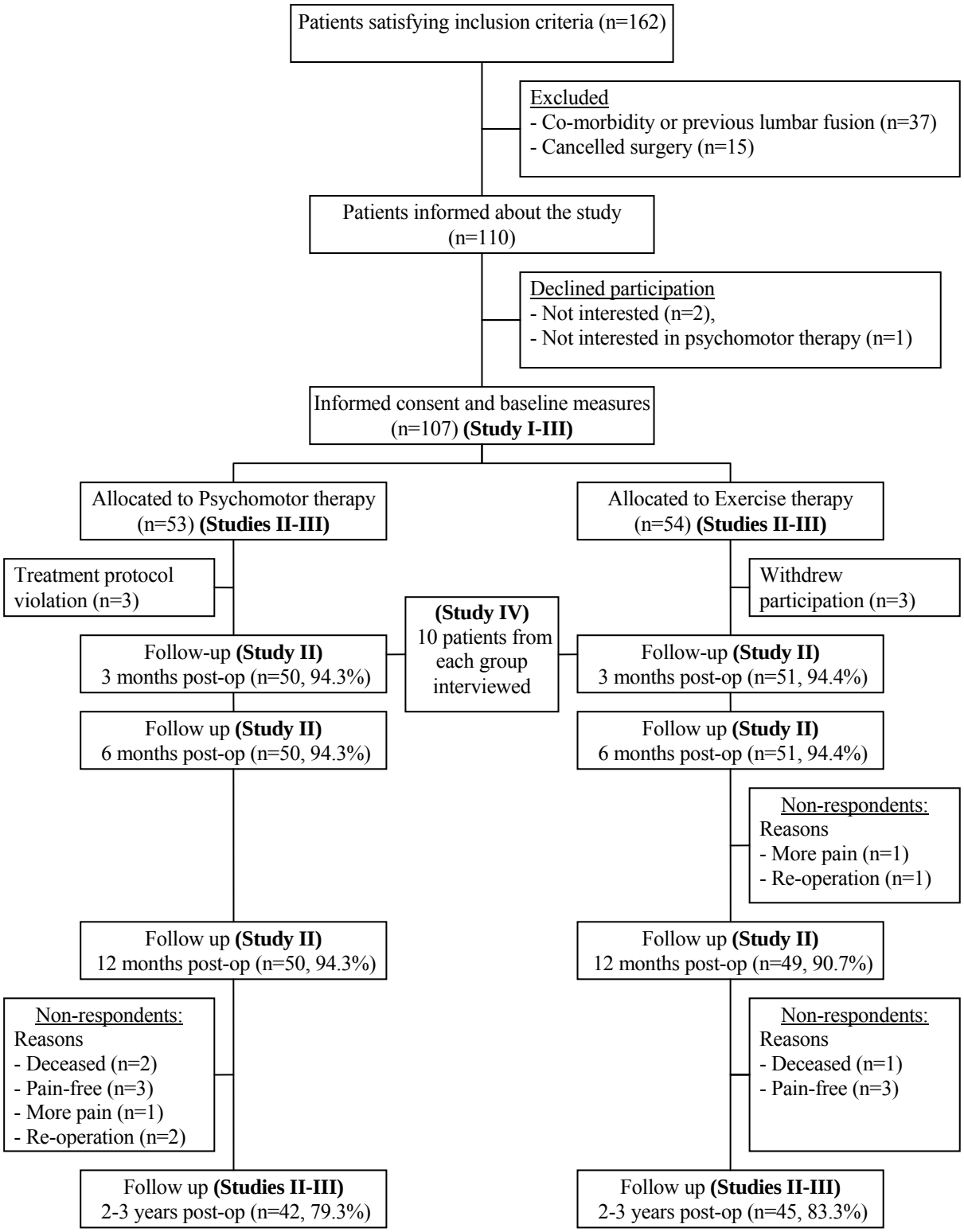



**Figure 5.** Patient flow throughout studies I-IV

During the rehabilitation period through the first three post-operative months, 3 patients from the psychomotor therapy group were withdrawn from the study as they did not fulfil the minimum level of training quotas while another 3 patients from the exercise therapy group withdrew as they did not want to remain in the study. A total of 94.3% of the psychomotor therapy group and 94.4% of the exercise therapy group responded to the 3 and 6 month follow-ups. Two patients in the exercise therapy group did not respond to follow-up at 12 months post-op, while an additional four patients did not respond at 2-3 years leaving a follow-up rate of 83.3%. From the psychomotor therapy group, eight patients did not respond to follow-up at 2-3 years post-op, leaving a follow-up rate of 79.3%. The total follow-up rate for the sample at the completion of prospective data collection was 81%.

## 3.4 DATA COLLECTION

All baseline data was collected within 1 month prior to lumbar fusion surgery. The following instruments and measures were used:

*Background and demographic data*
Patient background data on age, gender, body mass index (BMI), diagnosis and planned fusion technique were collected from Karolinska University Hospital's journal system. Data concerning pain duration, work status, sickness leave, and analgesic consumption were collected from a self-reported questionnaire.

*Disability*
The Swedish version of the Oswestry Disability Index (ODI) version 2.0 (Fairbank et al 1980, Fairbank & Pynsent 2000) was used to assess the disabling effects of pain on physical function. It is a low back pain specific self-reported questionnaire with 10 categorical items each with a 6 point ordinal scale (0-5). It assesses limitations in 10 areas of pain and activities of daily living (pain intensity, personal hygiene, lifting, walking, sitting, standing, sleeping, sexual activity, social activity and travelling). The combined subscale scoring range is 0-50, and can be calculated as a percentage score of patient perceived disability where lower scores represent lower levels of low back pain disability. The ODI has been shown to have good reliability and validity in the English version (Fairbank et al 1980, Fisher et al 1997, Kopec et al 1996). Unidimensional construct validity was even supported by Rasch item response analysis of the ODI version 2.0 (Davidson 2007). The Norwegian and Danish versions have shown good reliability and validity after cross-cultural adaptations (Grotle et al 2003, Lauridsen et al 2006). Hypothetically, these results can be valid even for the linguistic and culturally compatible Swedish version which is not cross-culturally validated.

*Pain intensity*
To analyse self-reported current back and leg pain intensity, a visual analogue scale (VAS) with a single line and scoring range from 0 for no pain to 100mm for unbearable pain was used. The VAS is the expert advisory panel of the World Health Organisation recommended measure for pain (Ehrlich & Khaltaev 1999). The VAS has good reliability and validity in the assessment of chronic pain (Carlsson et al 1983, Price et al 1983, Jensen et al 1986, Ogon et al 1996).

*Health related quality of life*
The Swedish version of the European Quality of Life Questionnaire (EQ-5D) (EuroQol Group, 1990) was used to measure HRQOL. It is a generic HRQOL self-report questionnaire where

respondents can classify there own health status in five dimensions including mobility, self-care, usual activities, pain/discomfort and anxiety/depression within three levels including no problems, moderate problems and severe problems. As there is no Swedish tariff index for scoring of the EQ-5D, the United Kingdom tariff index was used (Dolan 1997). In the United Kingdom tariff index, some health states are given negative scores. As health states regarded as being worse than death can be considered controversial, we chose to assign these health states a score of 0 which is consistent with methods used in previous studies (Burström et al 2001, Macran & Kind 2001). Sensitivity analyses performed in these previous studies and in our study show no significant differences in using the negative scores or assigning a score of 0. The EQ-5D has therefore a scoring range of 0-1 but is presented in our studies as a 0-100 score corresponding to health states ranging from death to full health.

*Mental health*

The mental health subscale of the Medical Outcome Study Short Form 36 (SF-36) (Ware et al 1992) also known as the MHI-5 is a summary score of 5 items investigating anxiety, depression, loss of behavioural/emotion control and psychological well-being experienced during the last month. The items are scored on a 6-point scale from "1 = All of the time" to "6 = Not at all". The scores of the items can be summed resulting in a range of 5-30. The sum score is linearly transformed to a 0-100 score according to the standard procedure for calculation of the MHI-5 (Ware et al 1993). The scale is scored so that higher score indicates better mental health and scores <76 indicate the presence of depression and anxiety (Kelly et al 2008). It has been shown to have good sensitivity and specificity for detecting anxiety (AUC=0.739) and depression disorders (AUC=0.892) (Berwick et al 1991).The MHI-5 has also shown to have a strong correlation with depression type in chronic pain patients (Elliot et al 2003) and with other instruments measuring depression (Strand et al 2003). The Swedish version has been shown to have reliability and validity (Sullivan et al 1992).

*Fear of movement/(re)injury*

The Swedish version of the Tampa Scale for Kinesiophobia (TSK) (Kori et al 1990) was used to assess the patient's current pain related fear of movement/(re)injury. The TSK questionnaire is comprised of 17 items, each with a 4-point scale with scoring alternatives ranging from "Strongly disagree" to "Strongly agree". After inverting the scores of items 4, 8, 12 and 16, a total sum of all 17 items ranging from 17 (low fear) to 68 (high fear) can be calculated. The Swedish version was proven to have good reliability and validity (Lundberg et al 2004). Good unidimensional construct validity was even supported by Rasch item response analysis of the Norwegian version of TSK tested on low back pain patients (Damsgård et al 2007).

*Functional self-efficacy*

The patient's belief in their own abilities to perform physical activities was assessed with the Swedish version of the Self-Efficacy Scale (SES) (Estlander et al 1994). The SES consists of 8 items related to various physical activities (walking, running, carrying weights of 4-5kg in both hands, standing, cycling, sitting in an armchair, sitting at a desk, and working in a forward leaning position). On an 8-point scale, the patients are asked to rate how long (less than 2 minutes, 2-5, 5-10, 10-15, 15-25, 25-35, 25-45, more than 45 minutes) they believe at that moment they would be able to perform the activity. Each item category is scored between 1 and 8 and summed to give a total score range of 8-64 with higher scores indicating higher positive beliefs. The Swedish version has been shown to have good internal consistency and test-retest reliability for use on LBP patients (Johansson & Lindberg 2000).

*Back pain outcome expectancy*
The Swedish version of the Back Beliefs Questionnaire (BBQ) (Symonds et al 1996) was used to investigate individual's beliefs about the expected outcomes of future low back pain. The questionnaire contains 14 items each with a 5-point scale where "1 = disagree" and "5 = agree". Only scores from 9 items (items 1,2,3,6,8,10,12,13,14) are taken and their scores inverted and summed giving a range from 9 – 45. A high score represents a more positive attitude and better ability to manage future back pain. To convert this to a score range of 0-100, the following formula is used (Actual score – lowest possible score/ largest possible score – lowest possible score) x 100. The Swedish version of the BBQ has been shown to have good internal consistency and test-retest reliability for use on LBP patients (Elfving 2006).

*Coping*
Three subscales of the Coping Strategy Questionnaire (CSQ) (Rosenstiel & Keefe 1983) were used to assess patient's current use of coping strategies. The catastrophizing subscale (CAT) assesses the use of negative thinking as a reaction to pain. Of the 36 items in the CSQ, items 5,11,13,25,33 and 37 belong to the catastrophizing subscale. The 6 items are scored on a 7-point scale with end values "0 = never" and "6 = always" and together provide a possible score range of 0-36 where lower scores represent lower levels of catastrophizing. The self-perceived control over pain (COP) and ability to decrease pain (ADP) with the use of coping strategies is measured by two single item scales of the CSQ. These items are also scored on a 7-point scale (0-6) measuring how well they control or decrease their pain (Abbott 2010). The Swedish version of CSQ has been shown to have good internal consistency and test-retest reliability for use on LBP patients (Jensen & Linton 1993).

*Patient Perspective*
A semi-structured interview guide listing open-ended question was used when interviewing the patients 3-6 months after surgery. Interviews were audio taped with the participant's consent and concluded when all areas of interest had been discussed. The hypothetical formulation of the questions was aimed at identifying all possible ICF components in the patient's experiences of back problems, post-operative recovery and in their expectations of rehabilitation. To be open with the informant's agenda, planed and unplanned probing questions were used (Ritchie 1999, Morse & Richards 2002). The following questions were used:

1) How do you think your back problems influenced your life before the operation?
    Probe – How did your back problems influence your family life?
    Probe – How did your problems influence your working life?
    Probe – How did your back problems influence physical activities?
2) How do you think your back problems influence your life now?
    Probe – How do your back problems influence your family life?
    Probe – How do your back problems influence your working life?
    Probe – How do your back problems influence physical activities?
3) Describe your experience of recovery after surgery?
    Probe – Related to family life?
    Probe – Related to working life?
    Probe – Related to physical activities?
4) What are your expectations with the outcome of rehabilitation after surgery?
    Probe – Related to family life?
    Probe – Related to working life?
    Probe – Related to physical activities?

## 3.5 INTERVENTIONS

Three physiotherapists with applied training and experience in behavioural medicine and physical rehabilitation methods for lumber fusion patients delivered the interventions. One primary clinician delivered 80% of the interventions while a further 2 clinicians delivered the remaining 20% of interventions. Each clinician had input in the design of the rehabilitation protocols (Table1) and had experience in using the protocol in daily clinical practice. Each therapist followed the protocol thoroughly to guarantee that all patients in the study were to receive equal intervention. Protocol violations in both groups were defined as intervention non-compliance or the self report of co-interventions for CLBP delivered by other health care providers during the first 3 post-operative months. Intervention non-compliance was defined as a less than 50% completed home exercise quota or absence from outpatient sessions for psychomotor therapy patients

*Group 1: Exercise Therapy*
During the first days after surgery, the physiotherapists instructed respiratory and circulatory exercises, training of transfers, walking and other ADL's relevant for the patient. Before discharge from hospital, patients received a one time 20 minute instruction of a home training program containing dynamic exercises intended to gradually enhance the endurance capabilities of the back, abdominal and leg muscles, stretches and cardiovascular exercise. Progressions in training intensity and quantity were contingent to the patients self perceived pain. A self-reported diary was used to motivate and evaluate patient compliance with exercise and instructions. A detailed description of the protocol is presented in Table 3. Patients were restricted from activities such as contact sports, running, heavy lifting and outer-range lumbar spine movements during the first 6 months after the operation. This was the hospital's standard post-operative physiotherapeutic rehabilitation approach after lumbar fusion.

*Group 2: Psychomotor Therapy*
The psychomotor therapy group received the same inpatient physiotherapy and specific activity restrictions as the exercise therapy group. Before discharge from hospital, patients received a one time 20 minute instruction of a home training program containing motor control exercises for lumbopelvic stabilization. The home program was upgraded during a 90 minute long outpatient physiotherapy session at 3, 6 and 9 weeks after the operation. A self-reported diary was used to motivate and evaluate patient compliance with exercise and instructions. The specific protocol for psychomotor therapy (Table 3) was based on a combination of condensed versions of Linton's cognitive-behavioural early intervention program for groups and Richardson and colleagues graded motor relearning approach to lumbopelvic stabilization training (Linton 2000 & 2005, Richardson et al 2005).

**Table 3.** Rehabilitation protocols implemented during the first 3 post-operative months

| Psychomotor therapy protocol | Exercise therapy protocol |
|---|---|
| **Home program 1 (0-3 weeks)**<br>▪ Lumbopelvic stabilization with transversus abdominis and lumbar multifidus co-contractions while maintaining neutral spinal posture in supine, sitting and standing. Dose: 10 second holds, 3 sets x 10 reps daily.<br>**Outpatient session 1 (3rd post-operative week)**<br>▪ Patient education on healing processes, physiological and psychological pain processes, relaxation techniques and cognitive coping strategies for pain management.<br>▪ Implement work and recreational time contingent functional goals with use of a Patient Goal Priority Questionnaire (Åsenlöf etal 2004).<br>▪ Homework: Diary self-monitoring of activity and home training according to quota, cognitions and emotions and goal progress.<br>▪ Introduction of home program 2. | **Home program (0-12 weeks)**<br>▪ Muscle strength and endurance exercises: Supine buttock lifts, contra-lateral hip extension and shoulder flexion in a 4-point kneeling position, prone push-ups, standing semi-squats, forward lunges and step-ups. Dose: 3 sets x 10 reps.<br>▪ Stretches: hamstrings, hip abductor/external rotator and quadriceps/iliopsoas musculature. Dose: 30 second holds, 2 times bilaterally.<br>▪ Cardiovascular fitness: Walking or stationary cycling Dose: 20-30 minutes.<br>▪ All exercises performed daily and training dose recorded in a diary.<br>▪ Progression of training intensity contingent to self-perceived pain. |
| **Home program 2 (3-6 weeks)**<br>▪ Integration of lumbopelvic stabilization exercise and closed kinetic chain functional exercise: Seated over-head elastic band raises, wall supported semi-squats, wall supported side lunges, forward lunges, and step-ups. Dose: 3 sets x 10 reps daily.<br>**Outpatient session 2 (6th post-operative week)**<br>▪ Motivational discussion and positive reinforcement of goal progress.<br>▪ Resource and hinder analysis for goal attainment.<br>▪ Homework: Formulate action plan to manage hinders, set-backs and flare-ups, continued diary self-monitoring.<br>▪ Introduction of home program 3. | |
| **Home program 3 (6-9 weeks)**<br>▪ Integration of lumbopelvic stabilization exercise and more advanced closed kinetic chain function exercises: semi-squats on uneven surfaces, semi-squats with elevated arms, wall supported semi-squats with overhead hand weights, forward lunges with overhead hands weights and step-ups with elevated arms. Dose: 3 sets x 10 reps daily.<br>**Outpatient session 3 (9th post-operative week)**<br>▪ Motivational discussion and positive reinforcement of goal progress and action plans for management of hinders, set-backs and relapses.<br>▪ Homework: Continued diary self-monitoring.<br>▪ Introduction of home program 4. | |
| **Home program 4 (9-12 weeks)**<br>▪ Integration of lumbopelvic stabilization and open kinetic chain function exercises: supine hip flexion, supine leg slide progressed to unsupported leg cycling, hip abduction in side lying, hip flexion in a seated position, hip flexion in standing with wall support, 4-point kneeling shoulder flexion, 4-point kneeling hip flexion, and contra-lateral hip extension and shoulder flexion in a 4-point kneeling position. Dose: 3 sets x 10 reps daily. | |

## 3.6 DATA ANALYSIS

Initial sample size calculations revealed that 104 patients were required to attain 90% statistical power while 78 patients were required to attain 80% statistical power. These calculations were based on the ODI as a primary outcome which has a minimal clinically important difference (MCID) = 10 units (Hägg et al 2003), a standard deviation = 15.5 units (Fairbank & Pynsent 2000) and a two sided significance level of $\alpha = 0.05$.

The data collected from instruments and measures was logged into a secure Microsoft Exel database directly after collection and checked a second time in January 2009. The patient's anonymity was maintained by assigning a code to each of patient identity in the database. The specific statistical methods for each of the studies are presented in Table 4.

**Table 4.** Statistical methods used in Studies I-IV

| | Study I | Study II | Study III | Study IV |
|---|---|---|---|---|
| **Non-parametric** | | | | |
| Spearman's rank correlation | ● | | | |
| Mann-Whitney *U* test | | ● | | |
| Bootstrap resampling | ● | | ● | ● |
| **Parametric** | | | | |
| Pearson's chi squares $\chi^2$ | | ● | | |
| Student's t-test | | ● | | |
| Analysis of covariance | | ● | | |
| **Reliability** | | | | |
| Cohen's Kappa | | | ● | |
| Krippendorff's alpha | | | | ● |
| **Mediation** | | | | |
| Preacher & Hayes's multiple mediation test | ● | | | |
| **Regression** | | | | |
| CATREG | | | ● | |
| Elastic net regularization | | | ● | |
| **Discrimination** | | | | |
| ROC curve | | | ● | |

### 3.6.1 Study I

To prepare the collected baseline data for cross-sectional analysis, questionnaires with more than 50% missing data received a group mean imputation score while questionnaires with less than 50% missing data were replaced by transformation scores. Regression techniques for imputing missing data were not used as they resulted in values that were outside the scale scoring ranges. The treatment of missing data is summarized in Table 5.

Table 5. Missing data analysis and imputation (N=107)

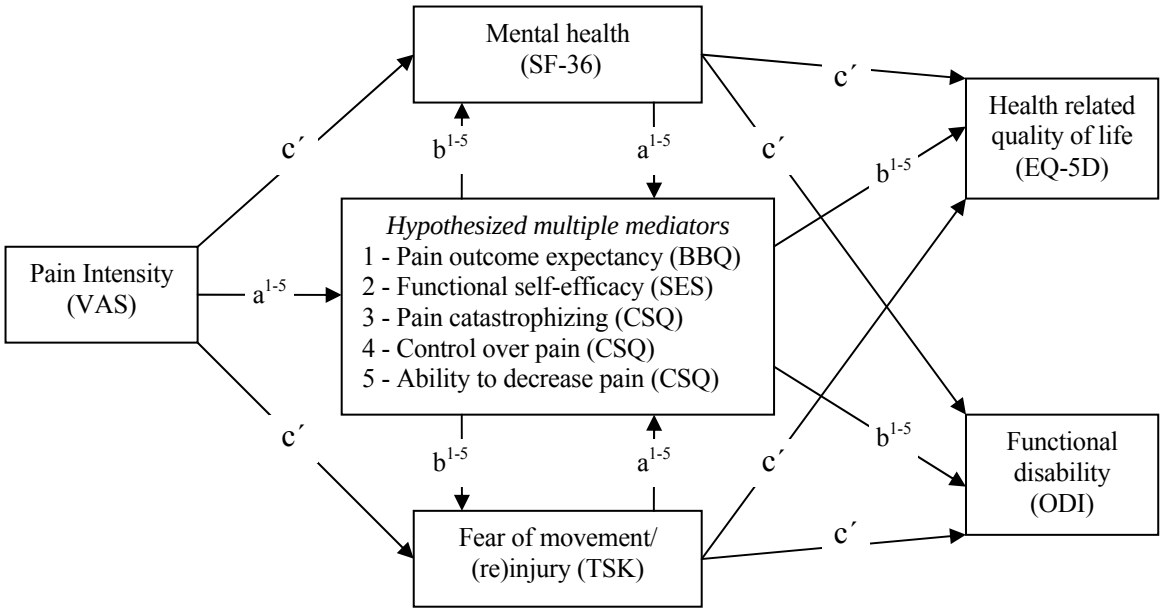
| Questionnaire | Group mean imputation of questionnaires with >50% missing data | Replaced items in questionnaires with <50% random missing data | Maximum replaced missing items per questionnaire | Random missing data replacement method |
|---|---|---|---|---|
| Pain Intensity (VAS) | 3 | 0 | 0 | |
| Mental health (SF-36) | 0 | 0 | 0 | |
| Fear of movement/(re)injury (TSK) | 0 | 2 | 1 | Transformation[a] |
| Pain outcome expectancy (BBQ) | 3 | 5 | 1 | Transformation[a] |
| Functional self-efficacy (SES) | 1 | 0 | 0 | |
| Pain catastrophizing (CSQ) | 1 | 13 | 3 | Transformation[a] |
| Control over pain (CSQ) | 2 | 0 | 0 | |
| Ability to decrease pain (CSQ) | 2 | 0 | 0 | |
| Functional disability (ODI) | 0 | 5 | 2 | Transformation[a] |
| HRQOL (EQ-5D) | 0 | 0 | 0 | |

[a] Sum score divided by the number of items in the questionnaire minus the number of missing items, multiplied by the number of items in the questionnaire. In formula: [sum score/(number of items – number of missing items)] x number of items.

In the screening of data, criteria for determining outliers were either one of a standard residual scores greater than three standard deviations (>±3.29) from the predicted values, Mahalanobis distances greater than 24.3 or Cook's distance greater than one (Tabacknick & Fidell 2007). No

univariate outliers were found in the distributions of the variables however 4 multivariate outliers were revealed after applying all factors into a linear regression. Furthermore, the distributions of the VAS were moderately negatively skewed and EQ-5D was moderately negatively kurtosed. The distributional assumptions related to normality, linearity and homoskedasticity between baseline variables were not entirely satisfactory, so non-parametric statistics were used. Non-parametric Spearman's rank correlations were used to assess bivariate associations between all measured variables. A non-parametric technique according to Preacher and Hayes (2008) was also used to test effects of hypothesized multiple mediators between pain intensity's influence on mental health, fear of movement/(re)injury and as well as their further influence on functional disability and HRQOL (Figure 6).

**Figure 6.** Hypothesised multiple mediators of pain intensity's influence on mental health, fear of movement/(re)injury and as well as their further influence on functional disability and HRQOL




Taking the relationship between pain intensity (X) and fear of movement/(re)injury (Y) in figure 2 as an example, the total effect of X on Y is the sum of the direct effect (c´) and all 5 of the mediator's specific indirect effects ($a^1b^1 + a^2b^2 + a^3b^3 + a^4b^4 + a^5b^5$). According to Preacher and Hayes (2008)**,** when several variables are hypothesized to mediate relationships**,** there are advantages of testing a single multiple mediator model rather than several separate single mediation models. These advantages include the possibility to test total indirect mediator effects of X on Y, to determine and compare the extent of specific indirect mediator effect of X on Y conditional to the presence of other mediators, and the reduced likelihood of parameter bias due to omitted variables.

As the Sobel test and the causal steps strategy are only simple single mediation tests, they are of little use in a multiple mediator context. A multivariate extension of the product of coefficients strategy exists but it suffers from limitations to multivariate normality. Furthermore, bootstrapping has been shown to have higher power and lower type 1 error rates than the sobel test, the causal steps strategy and the product of coefficients strategy (MacKinnon et al 2004, Williams & MacKinnon 2008) and bootstrapping dose not impose the assumption of normality of the sampling distribution.

To bootstrap the sampling distribution of specific and total indirect effects involves repeated resampling of the sample with replacement where individual cases can be selected multiple times. By repeating this procedure 5000 times, bias corrected and accelerated (BCa) estimates of the 95% confidence intervals for the indirect effect significance could be constructed. If the BCa 95% confidence interval does not include zero we can conclude there was a significant indirect effect (at alpha = .05). Statistical Package for Social Sciences Version 17 (SPSS Inc., Chicago, IL, USA) was used for statistical test along with a SPSS multiple mediation macro downloaded from www.quantpsy.org.

### 3.6.2 Study II

In this open label randomised controlled trial with 3, 6, 12 month and 2-3 year follow-up, an intention to treat (ITT) principle was used for continuous and discrete data, meaning that all patients, regardless of their loss to follow-up, drop-out or non-compliance, remained in the analysis of the group to which they were randomised (Hollis & Campbell 1999).

Because regression imputation of missing data produced out of range values and mean imputation considerably reduced variability in the data, an alternative method was considered. In accordance with methods used by Ostelo et al (2003), group percentile imputation of patient's missing data lost to follow-up, drop-out or non-compliance was decided by the following criteria:

1. Patients received the 50$^{th}$ percentile value of the group if loss to follow-up, drop-out or non-compliance had no association with allocated treatment, absence of pain, increased pain or reoperation,
2. If loss to follow-up, drop-out or non-compliance was due to increased pain or reoperation, the patient received the 10$^{th}$ percentile score,
3. If loss to follow-up, drop-out or non-compliance was due to the absence of pain, the patient received the 90$^{th}$ percentile score.

Questionnaires with more than 50% missing data received a group mean imputation score while questionnaires with less than 50% missing data were replaced by transformation scores. Sensitivity of missing data imputation was considered satisfactory after comparison to a per-protocol analysis of data exclusively from patients successfully followed-up. The treatment of missing data is summarized in Table 6.

Depending upon if distributional assumptions were met, student t-tests or Mann-Whitney *U* tests were used for continuous or discrete data while $\chi^2$ test was used for categorical data to confirm that no baseline differences occurred between groups after randomisation. According to Vickers (2005), when we are interested in seeing how variables change following an intervention, it is the screening of the distribution in change scores which is of interest. The change scores from baseline and between repeated measures approximate to a more normal distribution compared to post-treatment scores and therefore satisfy the assumptions of parametric statistical analysis. Analysis of Covariance (ANCOVA) has advantages over t-tests or non-parametric Mann-Whitney tests in that it has more power in most conditions, and it can be extended to incorporate time effects where measures are repeated (Vickers 2005). For statistical comparison between the 2 independent groups at 3, 6, 12 month and 2-3 years after the operation, ANCOVA adjusted for baseline score, sex and age as covariates was used. The effect of post-operative rehabilitation over all time points was assessed with repeated measures ANCOVA. Effect sizes of the

rehabilitation methods were assessed with Cohen's *d* where *d*=0.20 is considered a small effect, *d*=0.50 a medium effect and *d*=0.80-infinity a large effect size (Cohen 1992). Work status, sickness leave, analgesic consumption, satisfaction rate, training frequency and reoperation rate 2-3 years after psychomotor therapy and exercise therapy were compared using a $\chi^2$ test. Data was presented with means scores and standard deviations. Statistical significance was tested at the 5% level for all tests. For all analyses, SPSS 17.0 for windows was used.

**Table 6.** Missing data analysis and imputation of baseline and prospective data in the randomized controlled trial

| | Questionnaire data collection | ***Psychomotor therapy group (n=53)*** | | | | ***Exercise therapy group (n=54)*** | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Group percentile imputation of non-respondent or >50% missing data | | | Replaced items in questionnaires with <50% random missing data* | Group percentile imputation of non-respondent or >50% missing data | | | Replaced items in questionnaires with <50% random missing data* |
| | | 10th | 50th | 90th | | 10th | 50th | 90th | |
| ***Baseline*** | Pain Intensity (VAS) | | | | | | 3 | | |
| | Mental health (SF-36) | | | | | | | | |
| | Fear of movement/(re)injury (TSK) | | | | 1 | | | | 1 |
| | Pain outcome expectancy (BBQ) | | 1 | | 2 | | 2 | | 3 |
| | Functional self-efficacy (SES) | | | | | | 1 | | |
| | Pain catastrophizing (CSQ) | | 1 | | 11 | | | | 2 |
| | Control over pain (CSQ) | | 2 | | | | | | |
| | Ability to decrease pain (CSQ) | | 2 | | | | | | |
| | Functional disability (ODI) | | | | 3 | | | | 2 |
| | HRQOL (EQ-5D) | | | | | | | | |
| ***3 month post-op*** | Pain Intensity (VAS) | | 7 | | | | 7 | | |
| | Mental health (SF-36) | | 3 | | 12 | | 3 | | 13 |
| | Fear of movement/(re)injury (TSK) | | 3 | | | | 3 | | 2 |
| | Pain outcome expectancy (BBQ) | | 3 | | | | 4 | | 2 |
| | Functional self-efficacy (SES) | | 3 | | | | 3 | | |
| | Pain catastrophizing (CSQ) | | 3 | | 1 | | 4 | | 1 |
| | Control over pain (CSQ) | | 4 | | | | 4 | | |
| | Ability to decrease pain (CSQ) | | 4 | | | | 4 | | |
| | Functional disability (ODI) | | 3 | | 5 | | 3 | | 1 |
| | HRQOL (EQ-5D) | | 4 | | | | 3 | | |
| ***6 month post-op*** | Pain Intensity (VAS) | | 6 | | | | 9 | | |
| | Mental health (SF-36) | | 3 | | 3 | | 3 | | 8 |
| | Fear of movement/(re)injury (TSK) | | 3 | | | | 4 | | 7 |
| | Pain outcome expectancy (BBQ) | | 3 | | | | 3 | | 1 |
| | Functional self-efficacy (SES) | | 3 | | | | 3 | | |
| | Pain catastrophizing (CSQ) | | 3 | | 2 | | 5 | | 1 |
| | Control over pain (CSQ) | | 3 | | | | 6 | | |
| | Ability to decrease pain (CSQ) | | 3 | | | | 6 | | |
| | Functional disability (ODI) | | 3 | | 5 | | 3 | | 2 |
| | HRQOL (EQ-5D) | | 4 | | | | 3 | | |
| ***12 month post-op*** | Pain Intensity (VAS) | | 3 | | | 2 | 5 | | |
| | Mental health (SF-36) | | 3 | | 7 | 2 | 3 | | 3 |
| | Fear of movement/(re)injury (TSK) | | 4 | | | 2 | 3 | | 2 |
| | Pain outcome expectancy (BBQ) | | 3 | | | 2 | 3 | | 1 |
| | Functional self-efficacy (SES) | | 7 | | 2 | 2 | 3 | | 1 |
| | Pain catastrophizing (CSQ) | | 4 | | 1 | 2 | 3 | | |
| | Control over pain (CSQ) | | 4 | | | 2 | 3 | | |
| | Ability to decrease pain (CSQ) | | 4 | | | 2 | 3 | | |
| | Functional disability (ODI) | | 3 | | 5 | 2 | 3 | | 3 |
| | HRQOL (EQ-5D) | | 4 | | | 2 | 3 | | |
| ***2-3 year post-op*** | Pain Intensity (VAS) | 3 | 5 | 3 | | 2 | 4 | 3 | |
| | Mental health (SF-36) | 3 | 5 | 3 | 1 | 2 | 4 | 3 | 6 |
| | Fear of movement/(re)injury (TSK) | 3 | 5 | 3 | 1 | 2 | 4 | 3 | 2 |
| | Pain outcome expectancy (BBQ) | 3 | 5 | 3 | | 2 | 4 | 3 | 1 |
| | Functional self-efficacy (SES) | 3 | 5 | 3 | | 2 | 4 | 3 | 3 |
| | Pain catastrophizing (CSQ) | 3 | 5 | 3 | | 2 | 4 | 3 | 1 |
| | Control over pain (CSQ) | 3 | 6 | 3 | | 2 | 4 | 3 | |
| | Ability to decrease pain (CSQ) | 3 | 6 | 3 | | 2 | 4 | 3 | |
| | Functional disability (ODI) | 3 | 5 | 3 | 4 | 2 | 4 | 3 | 1 |
| | HRQOL (EQ-5D) | 3 | 5 | 3 | | 2 | 4 | 3 | |

* Sum score divided by the number of items in questionnaire minus the number of missing items, multiplied by the number of items in the questionnaire. In formula: [sum score/(number of items – number of missing items)] x number of items.

### 3.6.3 Study III

To identify the most important pre-surgical variables for the prediction of functional disability, back pain intensity and HRQOL 2-3 years after lumbar fusion, a categorical regression (CATREG) method in SPSS version 17 was used. In CATREG, optimal scaling methodology is used to find optimal numeric values to replace category values (Gifi 1990). This transformation process also known as "quantification" helps to linearize the relationship between response and predictor variables allowing both to have numerical properties that are optimal for regression (Gifi 1990).

The response and predictor variables that are interval scales were treated as rank-ordered variables to investigate possible nonlinear relations. Monotonic transformations were used for interval variables with a limited number of categories (Ability to decrease pain, control over pain) while a spline transformation was used for remaining interval variables with a larger number of categories. The spline transformation using second degree polynomials with 1 interior knot controlling the smoothness of the transformations was used as we found it to capture the most predictive information compared to other levels of spline coding. A nominal scaling level was used for variables such as age, gender, BMI, smoking, work status, sickness benefits, diagnosis, surgical technique and post-operative rehabilitation (Van der Kooij & Meulman 2004, Van der Kooij 2007).

Elastic net regularization was used to improve prediction accuracy by shrinking the regression coefficients making them more stable and reducing the estimation variance due to possible multicollinearity or when a large number of predictors are used relative to the number of observations (Zou & Hastie 2005). In elastic net regularization, shrinkage of regression coefficient occurs through applying a penalty to the regression model. When increasing the penalty, variables with the most stable coefficients will shrink to zero more slowly. A .632 bootstrap method drawing 200 bootstrap samples was used to select the most parsimonious (smallest) subset of predictors within 1 standard error of the model with minimum prediction error (Efron 1983).

Predicted values resulting from CATREG of the most parsimonious models for each response variable were used to test the discriminative power of the models. The median value was used for dichotomising each response variable. A Receiver Operating Characteristic (ROC) analysis was used to investigate the sensitivity (proportion of true positives) and specificity (proportion of true negatives) of the models. A measure of agreement between observed and predicted models was calculated with Kappa statistics. For the binary outcomes, the *c* statistic represented by the Area Under the Curve (AUC) was also calculated along with 95% confidence intervals. For measurement of agreement between observed and predicted values, Kappa statistics were used. Landis and Koch (1977) have proposed the following as standards for strength of agreement for the Kappa coefficient: 0=poor, .01–.20=slight, .21–.40=fair, .41–.60=moderate, .61–.80=substantial and .81–1=almost perfect.

### 3.6.4 Study IV

In this study, qualitative content analysis of textual data was used due to the possibility of applying a priori concepts such as the ICF (Graneheim & Lundham 2004, Krippendorff 2004). The units of analysis were the content of interview transcriptions, the complete and brief ICF core sets according to Ceiza et al (2004) and commonly used outcome measures for lumbar

fusion surgery. The ICF was applied to identify and classify the meaningful units. Analysis was performed in the following steps:

1) The interviews transcriptions and the questionnaires were read in their entirety to obtain an overall picture.
2) Using the content area of answers in the interview and the content of questionnaires, meaning units were constructed where words, sentences or paragraphs could be related to the ICF components such as body functions and structures, activities and participation, environmental and personal factors. The meaning units were read several times, scrutinized and agreed upon by two reviewers.
3) ICF linking rules according to Cieza et al (2005) were used to code meaning units into first and second level ICF categories that would accurately reflect their qualitative content. Questionnaires were coded at item level as the study aimed to contrast the experiences and expectations of spinal fusion patients with the main content of outcome measures. The two independent coders were physiotherapists with post-graduate training and practical experience in qualitative content analysis using the ICF. The ICF definitions used are available on WHO's website, www.who.org/classifications/icfbrowser.

The degree of agreement between the two health professionals was calculated at the component, 1st and 2nd ICF levels using Krippendorff's alpha. Krippendorff's alpha has been advocated as the standard reliability measure for content analysis. Unlike other reliability measures, it can generalize across scales of measurement, can be used with any number of observers with or without missing data, and it satisfies all of the important criteria for a good measure of reliability (Hayes & Krippendorff 2007). Krippendorff's alpha coefficient ranges from 0-1 where 1 indicates perfect agreement and 0 indicating no agreement. Bootstrap resampling (n=1000) of the observations in the sample was used to attain 95% bootstrapped confidence intervals indicating the precision of the estimated Krippendorff alpha statistic. SPSS version 17 was used for statistical tests along with an SPSS KALPHA macro downloaded from www.comm.ohio-state.edu/ahayes/macros.htm (Hayes & Krippendorff 2007).

# 4 RESULTS

## 4.1 STUDY I

Spearman rank correlations showed that the majority of variables were significantly correlated with each other (Table 7). This is with the exception of pain outcome expectancy associations with pain intensity, mental health, pain catastrophizing and ability to decrease pain which were non-significant. Furthermore, mental health associations with pain intensity, functional self-efficacy and the ability to decrease pain were also non-significant. Likewise, there was no significant association between pain catastrophizing and the ability to decrease pain. Correlation coefficients were all well less than critical values for collinearity or singularity (Tabachnick & Fidell 2007). Screening of multivariate association between variables displayed tolerance values >0.2 and variance inflations factors <4, suggesting that multicollinearity was not a problem (Tabachnick & Fidell 2007).

**Table 7.** Spearman's R bivariate correlations among model variables (n=107)

| | 1. | 2. | 3. | 4. | 5. | 6. | 7. | 8. | 9. |
|---|---|---|---|---|---|---|---|---|---|
| Pain Intensity | | | | | | | | | |
| Mental health | 0.13 | | | | | | | | |
| Fear of movement/(re)injury | 0.23* | -0.29** | | | | | | | |
| Pain outcome expectancy | -0.15 | 0.14 | -0.48*** | | | | | | |
| Functional self-efficacy | -0.31*** | 0.19 | -0.46*** | 0.45*** | | | | | |
| Pain catastrophizing | 0.23* | -0.49*** | 0.27** | -0.14 | -0.20* | | | | |
| Control over pain | -0.29** | 0.25** | -0.21* | 0.29** | 0.26** | 0.20* | | | |
| Ability to decrease pain | -0.22* | 0.19 | -0.28** | 0.10 | 0.27** | -0.11 | 0.55*** | | |
| Functional disability | 0.34*** | -0.27** | 0.33*** | -0.35*** | -0.68*** | 0.23* | -0.36*** | -0.29** | |
| HRQOL | -0.33*** | 0.41*** | -0.43*** | 0.48*** | 0.52*** | -0.44*** | 0.37*** | 0.30** | -0.66*** |

* P<0.050, **P<0.010, ***P<0.001

When controlling for all proposed mediators, the specific indirect effect of pain intensity on mental health was significantly mediated by pain catastrophizing (=-0.096, 95% BCa CI -0.223 to -0.006) while the specific indirect effect of pain intensity on fear of movement/(re)injury was significantly mediated by functional self-efficacy (=-0.032, 95% BCa CI 0.003 to 0.090). Significant total indirect effects of pain intensity on mental health (=-0.165, 95% BCa CI -0.329 to -0.021) and pain intensity on fear of movement/(re)injury (=0.066, 95% BCa CI 0.011 to 0.112) occurred through the combined effect of tested multiple mediators. The mediation model explained 27.7% of mental health levels (F=6.395, P<0.001) and 30.3% of fear of movement/(re)injury levels (F=7.256, P<0.001) in CLBP patients scheduled for lumbar fusion surgery.

When controlling for all proposed mediators, the specific indirect effect of mental health on functional disability was significantly mediated by control over pain (=0.038, 95% BCa CI -0.110 to -0.004) while the specific indirect effect of fear of movement/(re)injury on functional disability was significantly mediated by functional self-efficacy (=0.459, 95% BCa CI 0.184 to 0.756). Significant total indirect effects of fear of movement/(re)injury on functional disability (=0.494, 95% BCa CI 0.113 to 0.808) occurred though the combined effect of tested multiple mediators. A total of 52.2% of functional disability levels in chronic back pain patients scheduled for lumbar fusion surgery was explain by psychological factors adjusted for pain intensity levels (F=13.389, P<0.001).

When controlling for all proposed mediators, the specific indirect effect of fear of movement/(re)injury on HRQOL was significantly mediated by functional self-efficacy (-0.407, 95% BCa CI 0.886 to 0.167) and pain outcome expectancy (=-0.296, 95% BCa CI 0.751 to -0.002). Significant total indirect effects of mental health on HRQOL (=0.196, 95% BCa CI 0.013 to 0.410) and fear of movement/(re)injury on HRQOL (=-0.832, 95% BCa CI -1.383 to -0.325) occurred though the combined effect of tested multiple mediators. A total of 41.9% of HRQOL levels in CLBP patients scheduled for lumbar fusion surgery was explain by psychological factors adjusted for pain intensity levels (F=8.830, P<0.001).

## 4.2 STUDY II

Mean score changes from baseline, effect sizes and analysis of covariance data and repeated measures analysis of covariance are shown in Table 8 and 9. Mean scores (standard deviations) and significant differences between groups at follow-up are presented graphically in Figure 7. Both psychomotor therapy and exercise therapy significantly improved in all outcome measures from baseline to 2-3 years after surgery. These results are reflected in the generally very large effect sizes for psychomotor therapy and medium-large effect sizes for exercise therapy (Cohen 1992). Analysis of covariance showed that psychomotor therapy group scores for ODI, SES, BBQ and TSK improved significantly more (approximately 10-20%) than for the exercise therapy group scores at 3, 6, 12 months and 2-3 years after the operation. Furthermore, the psychomotor therapy group's back pain VAS at 3 and 6 months, EQ-5D at 12 months, CSQ-CAT at 6 months and 2-3 years as well as CSQ-COP and CSQ-ADP at 3, 6 and 12 months, significantly improved more than the exercise therapy group. Repeated measures analysis of covariance showed that controlling for the combined effects of all prospective measures gave significantly better outcome for the psychomotor therapy group in the ODI, back pain VAS, SES, BBQ, TSK, CSQ-COP and CSQ-ADP.

**Table 8.** Effectiveness of rehabilitation strategies on disability, back pain and HRQOL

| | **Psychomotor therapy (n=53)** | | **Exercise Therapy (n=54)** | | | **P value** | |
|---|---|---|---|---|---|---|---|
| Outcome | Mean change from baseline (SD) | Effect size† | Mean change from baseline (SD) | Effect size† | Between group mean difference (95% CI)* | Analysis of covariance* | Repeated measures analysis of covariance* |
| **ODI** | | | | | | | |
| 3 months | -19.9 (19.1) | 1.20 | -10.4 (14.1) | 0.58 | -9.7 (-15.8 to -3.6) | 0.002 | 0.003 |
| 6 months | -23.8 (20.2) | 1.32 | -13.7 (14.1) | 0.85 | -10.7 (-16.8 to -4.6) | 0.001 | |
| 12 months | -25.5 (20.6) | 1.39 | -15.0 (14.6) | 0.82 | -11.1 (-17.3 to -4.9) | 0.001 | |
| 2-3 years | -24.9 (24.0) | 1.43 | -15.5 (20.4) | 0.82 | -9.8 (-17.4 to -2.3) | 0.011 | |
| **Back pain VAS** | | | | | | | |
| 3 months | -29.9 (25.3) | 1.45 | -21.3 (24.8) | 0.98 | -11.7 (19.0 to 4.3) | 0.002 | 0.006 |
| 6 months | -35.9 (26.1) | 1.70 | -29.4 (25.4) | 1.29 | -9.9 (-17.6 to -2.2) | 0.012 | |
| 12 months | -38.1 (29.0) | 1.67 | -36.5 (30.5) | 1.33 | -5.4 (-14.8 to 3.9) | 0.250 | |
| 2-3 years | -39.2 (33.3) | 1.34 | -33.7 (36.5) | 1.29 | -9.8 (-20.7 to 1.2) | 0.080 | |
| **EQ5D** | | | | | | | |
| 3 months | 35.2 (34.3) | -1.32 | 23.8 (32.1) | -0.87 | 8.4 (-0.2 to 17.0) | 0.055 | 0.117 |
| 6 months | 40.9 (35.4) | -1.42 | 31.9 (32.4) | -1.21 | 6.3 (-2.7 to 15.3) | 0.170 | |
| 12 months | 44.0 (36.3) | -1.51 | 28.5 (33.3) | -0.98 | 13.3 (3.6 to 23.0) | 0.008 | |
| 2-3 years | 37.7 (34.9) | -1.21 | 27.9 (43.4) | -0.86 | 7.2 (-4.5 to 18.9) | 0.224 | |

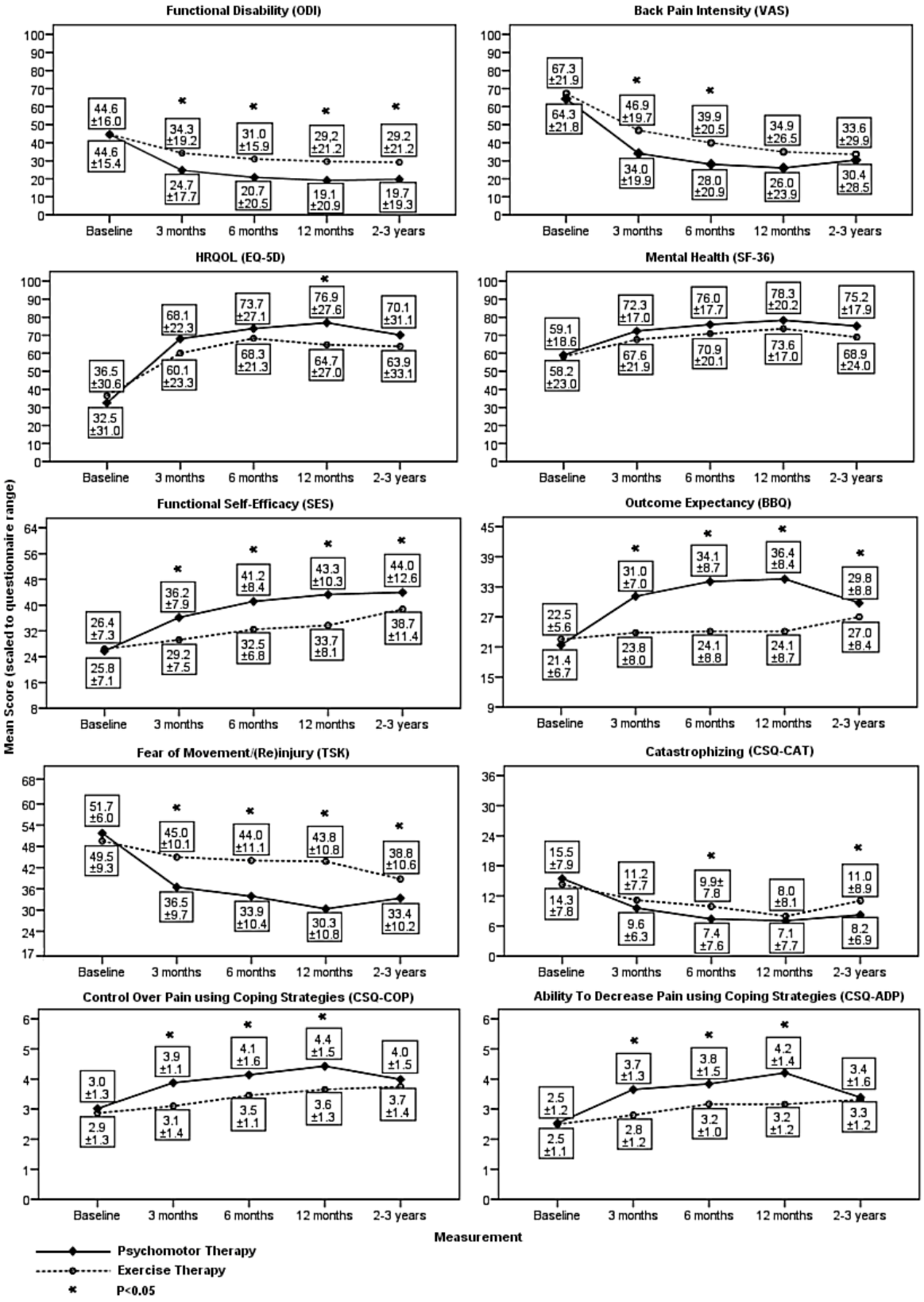
* Adjusted for score at baseline, sex, age. † Cohen's *d*

**Table 9.** Effectiveness of rehabilitation strategies on psychological variables

| Outcome | Psychomotor therapy (n=53) | | Exercise Therapy (n=54) | | | P value | |
|---|---|---|---|---|---|---|---|
| | Mean change from baseline (SD) | Effect size† | Mean change from baseline (SD) | Effect size† | Between group mean difference (95% CI)* | Analysis of covariance* | Repeated measures analysis of covariance* |
| **SF36-MH** | | | | | | | |
| 3 months | 13.2 (20.4) | -0.74 | 9.4 (20.0) | -0.42 | 4.4 (-2.1 to 11.0) | 0.185 | 0.082 |
| 6 months | 16.9 (22.3) | -0.93 | 12.6 (22.1) | -0.59 | 5.6 (-1.0 to 12.2) | 0.096 | |
| 12 months | 19.2 (24.1) | -0.99 | 15.4 (22.6) | -0.76 | 5.0 (-1.7 to 11.8) | 0.143 | |
| 2-3 years | 16.0 (22.7) | -0.88 | 10.7 (26.5) | -0.46 | 6.3 (-1.5 to 14.1) | 0.110 | |
| **SES** | | | | | | | |
| 3 months | 10.4 (8.6) | -1.38 | 2.8 (7.1) | -0.38 | 7.3 (4.6 to 10.0) | <0.001 | <0.001 |
| 6 months | 15.4 (8.8) | -1.98 | 6.1 (6.4) | -0.86 | 9.0 (6.4 to 11.5) | <0.001 | |
| 12 months | 17.6 (10.1) | -1.98 | 7.3 (8.6) | -0.95 | 10.0 (6.7 to 13.3) | <0.001 | |
| 2-3 years | 18.2 (12.9) | -1.78 | 12.4 (11.2) | -1.28 | 5.9 (1.6 to 10.1) | 0.007 | |
| **BBQ** | | | | | | | |
| 3 months | 9.7 (6.1) | -1.40 | 1.3 (6.0) | -0.19 | 8.2 (5.9 to 10.4) | <0.001 | <0.001 |
| 6 months | 12.7 (6.8) | -1.64 | 1.6 (6.6) | -0.21 | 10.9 (8.3 to 13.5) | <0.001 | |
| 12 months | 13.2 (8.1) | -1.97 | 1.6 (7.7) | -0.22 | 11.1 (8.1 to 14.0) | <0.001 | |
| 2-3 years | 8.4 (9.5) | -1.07 | 4.5 (7.4) | -0.63 | 3.4 (0.4 to 6.6) | 0.025 | |
| **TSK** | | | | | | | |
| 3 months | -15.3 (9.6) | 1.88 | -4.5 (8.6) | 0.46 | -9.7 (-13.1 to -6.3) | <0.001 | <0.001 |
| 6 months | -17.8 (10.3) | 2.10 | -5.5 (10.8) | 0.54 | -11.2 (-15.1 to -7.3) | <0.001 | |
| 12 months | -21.4 (10.5) | 2.45 | -5.8 (12.4) | 0.57 | -14.3 (-18.4 to -10.2) | <0.001 | |
| 2-3yrs | -18.4 (10.1) | 2.19 | -10.7 (12.4) | 1.07 | -6.3 (-10.2 to -2.4) | 0.002 | |
| **CSQ-CAT** | | | | | | | |
| 3 months | -5.9 (8.5) | 0.83 | -3.2 (8.0) | 0.40 | -2.1 (-4.6 to 0.4) | 0.102 | 0.143 |
| 6 months | -8.1 (8.9) | 1.04 | -4.4 (7.5) | 0.56 | -3.2 (-5.9 to -0.6) | 0.019 | |
| 12 months | -8.4 (9.5) | 1.07 | -6.4 (9.7) | 0.79 | -1.5 (-4.4 to 1.5) | 0.323 | |
| 2-3yrs | -7.3 (9.3) | 0.98 | -3.3 (8.2) | 0.39 | -3.7 (-6.4 to -1.0) | 0.008 | |
| **CSQ-COP** | | | | | | | |
| 3 months | 0.9 (1.5) | -0.75 | 0.2 (1.4) | -0.15 | 0.7 (0.3 to 1.2) | 0.002 | 0.004 |
| 6 months | 1.1 (1.7) | -0.75 | 0.6 (1.6) | -0.50 | 0.7 (0.2 to 1.2) | 0.011 | |
| 12 months | 1.4 (1.6) | -1.00 | 0.8 (1.7) | -0.54 | 0.8 (0.2 to 1.3) | 0.005 | |
| 2-3yrs | 1.0 (1.9) | -0.71 | 0.9 (1.6) | -0.59 | 0.2 (-0.3 to 0.8) | 0.401 | |
| **CSQ-ADP** | | | | | | | |
| 3 months | 1.1 (1.6) | -0.96 | 0.3 (1.2) | -0.26 | 0.9 (0.4 to 1.3) | <0.001 | 0.001 |
| 6 months | 1.3 (1.7) | -0.96 | 0.7 (1.4) | -0.67 | 0.7 (0.3 to 1.2) | 0.003 | |
| 12 months | 1.7 (1.8) | -1.30 | 0.7 (1.6) | -0.61 | 1.1 (0.6 to 1.6) | <0.001 | |
| 2-3yrs | 0.9 (2.0) | -0.64 | 0.8 (1.3) | -0.69 | 0.1 (-0.5 to 0.6) | 0.767 | |

* Adjusted for score at baseline, sex and age. † Cohen's *d*

**Figure 7.** Outcome after psychomotor therapy and exercise therapy (Mean ± SD) and between group differences



Significantly more patients in the psychomotor therapy group were employed 2-3 years after surgery (P=0.004) and fewer had sickness leave duration of longer than 6 months after surgery compared to the exercise therapy group (P=0.035). A statistically significant 64.4% of exercise therapy patients compared to the 42.9% of psychomotor therapy patients responding to 2-3 year follow-up had utilised external health care for continued back pain after the study's intervention completion (P=0.035). A larger percentage of the exercise therapy group's external health care utilisation was for continued physiotherapy or medical practitioner contact compared to a larger use of alternative therapies in the psychomotor therapy group.

## 4.3 STUDY III

For functional disability 2-3 year post-surgery the elastic net regularization method in 200 bootstrapped samples found the most parsimonious shrunken model to contain 8 pre-surgical predictors (functional disability, mental health, fear of movement/(re)injury, outcome expectancy, catastrophizing, control over pain, leg pain intensity and post-operative rehabilitation). The same pre-surgical predictors were found to form the most parsimonious shrunken model for back pain intensity 2-3 year post-surgery. The most parsimonious shrunken model for HRQOL 2-3 years post-surgery contained variables such as mental health, outcome expectancy, catastrophizing and control over pain.

The prediction models significantly explained variance in functional disability, back pain intensity and HRQOL 2-3 years post-surgery with an $R^2$= 0.416, 0.322, 0.256, an apparent error = 0.599, 0.690, 0.744 and an expected prediction error = 0.873, 0.979, 0.944, respectively. Significant predictors for functional disability 2-3 year post-surgery were pre-surgical leg pain intensity (β=-0.301, P=<0.001), post-operative rehabilitation (β=0.230 P= 0.024), pre-surgical catastrophizing (β=0.240, P= 0.041) and pre-surgical control over pain (β=-0.212, P= 0.040). Significant predictors for back pain intensity 2-3 years post-surgery were pre-surgical catastrophizing (β=0.283 P= 0.009) and pre-surgical leg pain intensity (β=-0.336, P= 0.001). Significant predictors for HRQOL 2-3 years post-surgery were pre-surgical control over pain (β=0.231, P= 0.031) and pre-surgical outcome expectancy (β=0.250, P= 0.002).

For the median dichotomised classification of functional disability, back pain intensity and HRQOL levels 2-3 years post-surgery, the discriminative ability of the models is shown in Table 10. The AUC for ODI = 0.781 (95%CI=0.691 to 0.868), back pain = 0.698 (95% CI=0.599 to 0.798) and EQ-5D = 0.685 (95%CI=0.585 to 0.786).

**Table 10.** Median dichotomised classification results for functional disability, back pain intensity and HRQOL 2-3 years post-surgery using the predicted values from regression models as test scores

| Observed | Predicted | | Sensitivity[a] | Specificity[b] | Efficiency[c] | PVP[d] | PVN[e] | k[f] |
|---|---|---|---|---|---|---|---|---|
| | 1. | 2. | | | | | | |
| Max. sensitivity | | | 0.87 | 0.67 | 0.77 | 0.72 | 0.84 | 0.54 |
| 1. ODI 0-21 | 46 | 7 | | | | | | |
| 2. ODI 22-100 | 18 | 36 | | | | | | |
| Max. specificity | | | 0.67 | 0.87 | 0.78 | 0.84 | 0.73 | 0.55 |
| 1. ODI 0-21 | 36 | 17 | | | | | | |
| 2. ODI 22-100 | 7 | 47 | | | | | | |
| Max. sensitivity and specificity | | | 0.77 | 0.77 | 0.78 | 0.77 | 0.78 | 0.55 |
| 1. ODI 0-21 | 41 | 12 | | | | | | |
| 2. ODI 22-100 | 12 | 42 | | | | | | |
| Max. sensitivity | | | 0.91 | 0.79 | 0.85 | 0.82 | 0.89 | 0.70 |
| VAS 0-27 | 49 | 5 | | | | | | |
| VAS 28-100 | 11 | 42 | | | | | | |
| Max. specificity | | | 0.79 | 0.91 | 0.85 | 0.90 | 0.83 | 0.72 |
| VAS 0-27 | 43 | 10 | | | | | | |
| VAS 28-100 | 5 | 48 | | | | | | |
| Max. sensitivity and specificity | | | 0.85 | 0.85 | 0.85 | 0.85 | 0.85 | 0.70 |
| VAS 0-27 | 46 | 8 | | | | | | |
| VAS 28-100 | 8 | 45 | | | | | | |
| Max. sensitivity | | | 0.93 | 0.77 | 0.87 | 0.86 | 0.89 | 0.72 |
| EQ-5D 0-70 | 33 | 10 | | | | | | |
| EQ-5D 71-100 | 4 | 60 | | | | | | |
| Max. specificity | | | 0.77 | 0.93 | 0.83 | 0.94 | 0.73 | 0.67 |
| EQ-5D 0-70 | 40 | 3 | | | | | | |
| EQ-5D 71-100 | 15 | 49 | | | | | | |
| Max. sensitivity and specificity | | | 0.85 | 0.85 | 0.85 | 0.90 | 0.79 | 0.69 |
| EQ-5D 0-70 | 37 | 6 | | | | | | |
| EQ-5D 71-100 | 10 | 54 | | | | | | |

[a] Proportion true positives of all observed positives. [b] Proportion true negatives of all observed negatives.
[c] Proportion correct of all cases. [d] Predictive value positive test (proportion true positives of all predicted positives).
[e] Predictive value negative test (proportion true negatives of all predicted negatives).
[f] Measure of agreement between observed and predicted (minimum 0, maximum 1).

## 4.4 STUDY IV

A total of 844 meaning units were identified in the interview manuscript and 867 concepts could be linked to 94 different ICF categories. Of the concepts that could be linked to the ICF, 276 were body functions, 31 were body structures, 464 were related to activities and participation and 88 were environmental factors. An additional 6 concepts were related to personal factors associated with coping style, beliefs and locus of control while another 2 were not definable physical health concepts. A summary of the main ICF components linked to interviews, the ICF core sets, quality of life measures and other measures used in this thesis is provided in Table 11.

When patients were asked how they think their back problems influenced their life before the operation, their responses covered 54 categories of the ICF. These 54 categories consisted of 11 (20%) body functions, 3 (6%) body structures, 29 (54%) activities and participation and 11 (20%) environmental factors. When patients were asked how they think their back problems influence their life in the present, their responses covered 50 ICF categories consisting of 18 (36%) body functions, 3 (6%) body structures, 19 (38%) activities and participation and 10 (20%) environmental factors. When patients were asked to describe their experience of recovery

after the surgery, their responses covered 45 ICF categories consisting of 15 (33%) body functions, 4 (9%) body structures, 19 (42%) activities and participation and 7 (16%) environmental factors. When patients were asked what their expectations were with the outcome of rehabilitation after surgery, their responses covered 49 ICF categories consisting of 16 (33%) body functions, 5 (10%) body structures, 21 (43%) activities and participation and 7 (14%) environmental factors.

**Table 11.** ICF components linked to patient interviews and compared to quality of life measures, other measures used in this thesis, and the ICF core sets

| **Interview content analysis: Ranking of ICF category frequency in interview textual data** | **Content of measures used in this thesis = ●** **Content of measures not used in this thesis = ○** | | | | | | |
|---|---|---|---|---|---|---|---|
| | Quality of life measures | | | Other measures used in this thesis | | ICF LBP core set | Brief ICF LBP core set |
| | ODI | SF36 | EQ5D | Psychological* | Others** | | |
| **Body Functions (Top 10)** | | | | | | | |
| 1. Sensation of pain (b280) | ● | ○ | ● | ● | ● | ○ | ○ |
| 2. Emotional functions (b152) | | ● | ● | ● | | ○ | ○ |
| 3. Energy and drive functions (b130) | | ○ | | | | ○ | ○ |
| 4. Temperament & personality function (b126) | | | | | | ○ | |
| 5. Sensations related to muscles and movement function (b780) | | | | | | ○ | |
| 6. Sensory functions related to temperature and other stimuli (b270) | | | | | | | |
| 7. Gait pattern functions (b770) | | | | | | ○ | |
| 8. Muscle power functions (b730) | | | | | | ○ | ○ |
| 9. Muscle endurance functions (b740) | | | | | | ○ | ○ |
| 10. Thought functions (b160) | | | | | | | |
| **Body structures** | | | | | | | |
| 1. Structure of trunk (s760) | ● | | | ● | ● | ○ | ○ |
| 2. Structure of lower extremity (s750) | | | | | ● | ○ | |
| 3. Spinal cord and related structures (s120) | | | | | | ○ | ○ |
| 4. Additional musculoskeletal structures related to movement (s770) | | | | | | ○ | ○ |
| **Activity and participation (Top 10)** | | | | | | | |
| 1. Walking (d450) | ● | ○ | ● | | | ○ | ○ |
| 2. Recreation and leisure (d920) | ● | ○ | ● | | | ○ | |
| 3. Changing basic body position (d410) | | ○ | ● | | | ○ | ○ |
| 4. Remunerative employment (d850) | | ○ | ● | | ● | ○ | ○ |
| 5. Moving around (d455) | ● | ○ | | | | ○ | |
| 6. Family relationships (d760) | | | ● | | | ○ | ○ |
| 7. Maintaining body position (d415) | ● | | | | | ○ | ○ |
| 8. Lifting and carrying objects (d430) | ● | ○ | | | | ○ | ○ |
| 9. Doing housework and caring for household objects (d640-50) | | ○ | ● | | | ○ | ○ |
| 10. Using transportation and driving (d470-5) | ● | | | | | ○ | |
| **Environmental factors (Top 5)** | | | | | | | |
| 1. Health service, systems and policies (e580) | | | | | ● | ○ | ○ |
| 2. Products of substances of personal consumption (e110) | | | | | ● | ○ | ○ |
| 3. Social security services, systems and policies (e570) | | | | | ● | ○ | ○ |
| 4. Labour and employment services, systems and polices (e590) | | | | | | | |
| 5. Products and technology for mobility and transportation (e120) | | | | | | | |
| **Personal factors** | | | | | | | |
| 1. Coping styles and beliefs | | | | ● | | | |

*TSK,CSQ,SES,BBQ
**VAS pain, work status, health care use, analgesic use, sickness leave.

Inter-rater reliability statistics between two independent raters of interview meaning units at the component, 1st and 2nd levels of the ICF are shown in Table 12.

**Table 12.** Estimated Krippendorff alpha coefficient and bootstrapped confidence intervals at the component, 1st and 2nd ICF levels

| ICF | α | BCI 95% |
|---|---|---|
| Component | 0.991 | (0.981 to 0.998) |
| Chapter (1st level) | 0.988 | (0.979 to 0.998) |
| Category (2nd level) | 0.988 | (0.979 to 0.998) |

α=Estimated Krippendorff alpha coefficient, BCI 95%= Bootstrapped 95% Confidence Interval for alpha.

A total of 10, 44, and 10 relevant concepts in common lumbar fusion outcome measures such as the ODI, SF-36 and EQ-5D respectively were identified and linked to the ICF. The items in the ODI covered 2 (20%) body function categories and 8 (80%) activities and participation categories. The LBP specificity of the ODI corresponds with structures of the trunk (s760). The items in the SF-36 covered 15 ICF categories consisting 3 (20%) body functions and 12 (80%) from activities and participation. The items in the EQ-5D covered 10 ICF categories consisting of 2 (20%) body functions and 8 (80%) from activities and participation. In Table 11, ICF categories for each ICF component linked to interview text are corresponded to the content of measures used in this thesis such as the ODI, SF-36, EQ-5D, TSK, CSQ, SES, BBQ, VAS, work status, health care use, analgesic use, sickness leave as well as the comprehensive and brief ICF LBP core sets.

# 5 DISCUSSION

The overall aims of this mixed method thesis were to investigate the influence of pre-operative CLBP and psychological factors on disability and HRQOL, to study the outcome of early post-operative physiotherapeutic rehabilitation, to investigate biopsychosocial predictors of prospective outcome and to explore the patients experiences of back problems, post-operative recovery and expectation for rehabilitation. Concisely, our results suggest that psychological factors are of primary importance in explaining pre-operative levels of disability and HRQOL, in the delivery of post-operative rehabilitation, and in predicting prospective outcome. Furthermore, experiences of back problems, recovery and expectations described by lumbar fusion patients were generally related to pain, psychosocial factors, motor functions, activities of daily living and employment.

## 5.1 STUDY SAMPLE

The long duration of CLBP symptoms, the patient's awareness of their pathology and their anticipation for lumbar fusion surgery distinguishes the sample studied in this thesis from other CLBP cohorts. These characteristics may partly explain the exceptionally high levels of pain, fear of movement/(re)injury and exceptionally low levels of mental health and HRQOL in our sample compared to non-specific CLBP cohorts (Vlaeyen et al 1995, Arnstein et al 1999, Crombez et al 1999, Ayre & Tyson 2001, Burström et al 2001, Denison et al 2004, Woby et al 2005 2007a 2007b, den Boer et al 2006). Approximately 80% of our sample displayed co-morbid anxiety and/or depression related mental health disorders defined as a SF-36 mental health subscale score of <76 points (Kelly et al 2008). This is much larger than the reported prevalence rates of mental health disorders recorded in chronic musculoskeletal pain patients (McWilliams et al 2003, Scott et al 2007, Bair et al 2008). These patient characteristics however do not reflect on levels of functional disability, pain outcome expectancy, functional self-efficacy, pain catastrophizing, control over pain and ability to decrease pain levels which are similar to levels observed in non specific CLBP patients (Rosenstiel & Keefe 1983, Estlander et al 1994, Fairbank & Pynsent 2000, Johansson & Lindberg 2000, Denison et al 2004, Woby et al 2005 2007a 2007b).

## 5.2 RELEVANCE OF MAIN FINDINGS AND CLINICAL IMPLICATIONS

In *Study I*, approximately half of the variance in pre-surgical disability and HRQOL levels in CLBP patients awaiting lumbar fusion surgery was explained by pain and psychological factors. This suggests the potential importance of pre-operative screening for psychological variables.

Among the significant combined contribution of multiple psychological mediators, self-efficacy and outcome expectancy are largely responsible for mediating the influence of CLBP on fear avoidance and resulting disability and HRQOL. This extends the work of Woby et al (2007), Arnstein et al (1999) and Turner et al (2007) supporting the importance of functional self-efficacy as a mediator in the fear-avoidance model. In terms of the Social Cognitive Theory by Bandura (1977 & 1986) our results also suggest that self efficacy and outcome expectancy mediates fear avoidance behaviour influencing not just physical but also psychosocial aspects of quality of life.

The significant mediation role of pain catastrophizing between pain intensity and mental health displayed in our study confirms the results of several previously published studies with CLBP samples (Severeijns et al 2002, Lamé et al 2005). These findings along with the significant mediation role of control over pain between mental health and disability, expands upon the anxiety-avoidance pathways proposed by Asmundson et al (2004) in their updated fear-anxiety-avoidance model. These associations and the scores of variables observed in this study can also be interpreted according to Crombez et al (2005) cognitive bias concepts. This infers that in the presence of catastrophizing, hypervigilance may unintentionally emerge and depending upon ones ability to control pain through disengaging attention from pain, avoidance and disability may be mediated. Parallels can also be drawn to the mood as input theory described by Martin et al (1993), where levels of mental health and the mediation effect of perceived control over pain may determine the choice and persistence of a certain stop rule which may in turn influence levels of disability. Knowledge of these variables mediating the influence of pain intensity on mental health, fear of movement/(re)injury and their further influence on disability and HRQOL could help the implementation of physiotherapeutic interventions aimed at improving disability and HRQOL.

*Study II* is the first to compare the effectiveness of rehabilitation methods implemented during the first 3 months after lumber fusion. Our study supports the results of a single existing study by Christensen et al (2003) as far as showing the importance of a biopsychosocial approach but adds new knowledge of the effects of earlier implementation, and a more detailed knowledge of psychomotor rehabilitation interventions. With respect to RCT studies on rehabilitation after discectomy, studies by Ostelo et al (2003a,b) and Johansson et al (2009) failed to show any advantages of behavioural treatment incorporated in the rehabilitation. A notable difference between our psychomotor therapy protocol and the graded behavioural activity protocols of Ostelo et al (2003a,b) and Johansson et al (2009) is their focus on operant behavioural conditioning using only graded activity prescriptions and positive reinforcement of fulfilled training quotas. Our psychomotor therapy protocol included not only operant behavioural conditioning but also the use of cognitive coping strategies and relaxation techniques to increase health behaviours and decrease pain behaviours. Furthermore, it may be that disorders involving fusion surgery, with often longer durations and more characterised by chronic pain, responds better to a biopsychosocial approach than simple disc surgery.

Both rehabilitation groups improved over time but the psychomotor therapy significantly improved functional disability, self-efficacy, outcome expectancy and fear of movement/(re)injury more than exercise therapy at 2-3 year post-surgery. Considering that psychomotor therapy produced approximately a 10 point larger decrease in the primary outcome measure (ODI) compared to exercise therapy at each follow-up, the observed improvement in disability in the psychomotor group compared to the exercise therapy group can be considered clinically significant (Hägg et al 2003b). Patients in the psychomotor therapy group had more employment and less long term sickness leave compared to the exercise therapy group at 2-3 years post-surgery. This could possibly be due to work related behavioural goal setting (Åsenlöf et al 2004) and even secondary effects of larger improvements in disability, self-efficacy, outcome expectancy and fear of pain/(re)injury. The larger use of external health care observed in the exercise therapy group might be due to the lack of psychosocial content in exercise therapy. The results support the use of psychomotor therapy as a standard for early rehabilitation after lumbar fusion surgery.

The results of *Study III* suggest that high pre-surgical levels of leg pain, outcome expectancy, control over pain, low levels of catastrophizing and post-operative psychomotor therapy predict good multidimensional outcome 2-3 years post lumbar fusion surgery.

Leg pain intensity has largely been ignored in predictive research in favour of testing the predictive value of back pain intensity. Leg pain intensity however proved to be the strongest predictor for functional disability and back pain intensity 2-3 years post-surgery. The finding is not surprising as leg pain most likely reflects somatic illness more than back pain, and a biological method such as surgery should be expected to affect particularly somatic illness. This, of course, suggests the importance of a thorough pre-surgical assessment of pain and neurology to distinguish patients with dominating peripheral symptoms. One could assume that diagnoses with characteristic peripheral symptoms would also show predictive strength but this was not the case in our study. Although the reason for this is unclear the results indicate that the underlying diagnosis for the result of spinal fusion is of less importance than the absence or presence of leg pain.

Previous studies that have included pre-surgical outcome expectations in multivariate models have found its predictive significance when testing pain, functional and HRQOL related outcomes (de Groot et al 1999, Iversen et al 1998, Mannion et al 2009, Saban & Penckofer 2007, Toyone et al 2005, Yee et al 2008). Our results showed that patient's expectations of future back pain related outcome was the most important predictor of prospective HRQOL, but was not predictive of pain or functional related outcomes. This may be explained by our inclusion of a more thorough range of psychological factors compared to a review of previous studies (Mannion & Elfering 2006) revealing control over pain and catastrophizing to be significant predictors of pain and functional related outcomes.

In previous studies predicting ODI and pain VAS outcomes specific for lumbar fusion patients, 25-30 % of the variance in the measures have been explained by linear regression models (Ekman et al 2009, Trief et al 2006). In our study, the models significantly explained 41.6%, 32.2% and 25.6% of the variance in the 2-3 year measures of ODI, back pain VAS and EQ-5D respectively. The analysis of nonlinear relations and the optimal scaling transformations of the variables used in CATREG may have helped to increase the predictor variable's beta values and the subsequent variance explained by the models due a better data fitting compared to linear regression modelling.

To discriminate between high and low levels of functional disability, back pain intensity and HRQOL 2-3 years post-surgery, the prediction models showed to have high specificity resulting in the possibility of only a few false positives receiving surgery when undesirable outcome were be expected. High sensitivity also showed that each prediction model correctly identified patients that responded positively to surgical treatment. Predictive model performance measures such as the AUC and kappa agreement between observed and predicted values showed good predictive model performance. These results suggest the possible usefulness of the prediction models in determining the prognosis of spinal surgery and/or as a tool for clinical decision making.

In *Study IV*, the patient's experiences with back problems, recovery and expectations related to body functions were most frequently associated with pain and sensory functions, psychological functions and motor functions located to the structures of the trunk, lower extremity, spinal cord and related structures. With respect to activity and participation, patient's experiences with back problems, recovery and expectations were most frequently associated with mobility, recreation, employment and domestic life. Furthermore, environmental factors such as use of health care, analgesics, the social security system, employment services and use of mobility aids were of importance. These factors were generally of similar importance to the patient's experiences of back problems before and after the operation as well as experiences of recovery and outcome expectations.

The issues most frequently discussed by the patients generally corresponded well with commonly used measures of outcome after lumbar fusion, such as the ODI, SF-36, EQ-5D, VAS, work status, health care use, analgesic use, sickness leave as well as the ICF comprehensive and brief LBP core sets. However several frequently discussed issues relevant for lumbar fusion patients not covered by the ODI items are remunerative employment (d850), changing basic body position (d410), family relationships (d760) and caring for household objects (d650). Similarly, the SF-36 also did not cover the category family relationships (d760). In the case of measuring the disability and HRQOL related outcomes of lumbar fusion surgery, the content validity of the ODI and SF-36 could possibly be improved by including items covering these categories. Furthermore, the sleep function item in the ODI could be replaced as it was to a much lesser extent relevant to the experiences described by lumbar fusion patients.

The ranking of the most frequently linked ICF categories to the experiences described by lumbar fusion patients were also similar to the ranking of categories chosen for the ICF comprehensive and brief core sets for LBP reported by Cieza et al (2004). In comparison to the comprehensive ICF core sets for LBP, the only categories not linked to the experiences of lumbar fusion patients were assisting others (d660), basic interpersonal interactions (d710) and community life (d910). Categories frequently linked to the experiences of lumbar fusion patients but not included in the brief ICF core sets for LBP include categories related to moving around and the use of transportation (d455-d475), and recreation and leisure (d920), products or substances for personal consumption (e120) and labour and employment services, systems and polices (e590) Therefore, the inclusion of these categories in the brief core sets is of relevance for improving the validity of outcome evaluation in lumbar fusion patients.

## 5.3 METHODOLOGICAL CONSIDERATIONS

In this thesis, the pragmatic paradigm described in Tashakkori & Teddlie (2003) was used to support our selection of applying mixed methodology. Pragmatism supports the use of both quantitative and qualitative research methods within a thesis and considers the research questions to be more important than the paradigm underlying the method. In this thesis, quantitative and qualitative methods were used simultaneously with a deductive theoretical drive. Quantitative data was primarily used while triangulation with qualitative description of patient experience was used to enhance the understanding of the studies outcomes.

In the interpretation of the results from *Study I*, it is important to take into account that the study design allows for only correlational and not causal interpretation of results. Furthermore, the refined sample of lumbar fusion surgery candidates reduces the ability to generalize results with

other back pain groups. The lack of a specific depression or anxiety measure is a possible limitation of this study. Several authors however support the use of a general measure of mental health and questioned the division of depression and anxiety constructs due to the high prevalence of their co-existence (Scott et al 2007, Mergl et al 2007, Shorter & Tyler 2003). The measurement of pain related disability required that patients rated how current pain influenced their functional ability while measuring functional self-efficacy required that patients rated their existing confidence in their ability to carry out function activities. Similarly, the extent of conceptual overlap between functional self efficacy, back pain outcome expectancy and even fear avoidance has previously been considered by Council et al (1988). It is possible that some patients may have not recognized the conceptual difference between some measures which perhaps could have augmented their correlation. Despite this, correlation coefficients, variance inflation factors and tolerance levels were all well below their critical values for multicollinearity verifying that all variables are in fact separate entities, with some more conceptually related than others.

The results from *Study II* are limited by incomplete follow-up at 2-3 years. Typically, loss to follow-up of <5% is of little concern, where as 5-20% is considered an intermediate threat to validity and >20% a serious threat to validity (Sackett et al 2000). Patient drop-out and loss to follow-up was minimal during the first 12 months and at 2-3 years the total follow up rate was 81.3% suggesting an intermediate level of threat to internal validity. Several possible limitations with regards to the integrity of treatment delivery exist. A total of 80% of interventions were held by 1 of the 3 physiotherapists and group sizes for the psychomotor therapy outpatient sessions were maximum 4 patients at a time and when there were shortages of patients to form groups, the patient received an individual session. These patients might be affected either more positively due to individual attention, or more negatively due to lack of interaction and support from fellow patients. It is even possible that the validity of the patients self-report of home based training frequency in training dairies was affected by memory recall or adjusted to satisfy the expectation of participation in the study. During intervention period in the first 3 months of the study it was possible to prevent patients from seeking external health care, but thereafter prospective outcome could possibly be contaminated by the effects of co-interventions.

In *Study III*, when investigating the bivariate relations between response and predictor variables, it was evident that the relationships were not entirely linear. When linear regression is applied to such data, this would result in an underestimation of the relationship between response and predictor variables, because linear regression is restricted to reveal only relationships showing a linear trend. CATREG was therefore utilised as it is capable of describing nonlinear relations by using a regression with transformation approach were nonlinear functions are added to a model with linear terms in order to provide flexibility to capture as much of the non-linearity as possible. The assumptions of linearity between variables, normality of residuals and ratio of cases to variables in standard linear or logistic regression do not apply to CATREG (Steyerberg 2009, Van der Kooij & Meulman 2004, Van der Kooij 2007).

In circumstances of multicollinearity or when a large number of predictors are used relative to the number of observations, ordinary least squares regression is known for not performing well, producing unstable and overestimated regression coefficients and inadequate prediction accuracy (Tabachnick & Fidell 2007, Steyerberg 2009). In many studies, authors have attempted to decrease model complexity by not including non-significant variables from univariate tests in the belief that the variables effects should be proven prior. For estimation, prior significance

testing is however not relevant if a variables effect is supported by subject knowledge (Steyerberg 2009). Another alternative is using a reduction while modelling approach such as backward stepwise selection to eliminate the least significant candidate predictors from a full model (Tabachnick & Fidell 2007). A disadvantage with stepwise methods is the instability of predictor selection and exaggeration of p-values especially when the number of observations to variable ratio is less than 10. Statistical texts however recommend 1 predictor to 50 observations and the use of bootstrap re-sampling for reliable selection among candidate predictors in standard linear/logistic regressions (Tabachnick & Fidell 2007, Steyerberg 2009). No previous study investigating predictors of spinal surgery outcome has been able to follow such recommendations.

Apart from the prediction of the observed response variables in our sample, prediction model external validity is also of interest. The use of bootstrap resampling allows the estimation of expected prediction error rate for applying the observed model parameters to predict the outcome of future observations. The expected prediction error rates of 0.873, 0.979, 0.944 for the models predicting functional disability, back pain intensity and HRQOL are quite high error rates compared to the apparent prediction errors of 0.599, 0.690, 0.744, respectively. The apparent error rates are within normal ranges as compared to earlier studies which suggest adequate internal validity, but the high expected prediction error rates suggest inadequate external validity. Van der Kooij (2007) has on the other hand shown that expected prediction error rates increase considerably with sample sizes <1000.

In *Study IV*, the ICF proved helpful in linking meaning units in both interview text and questionnaires. The subject matter most frequently of interest to the patients in the interviews generally corresponded well the content of outcome measures providing subjective support to complement objective findings in the triangulation of data in this thesis. With regards to the inter-rater reliability of the interview text meaning unit coding, the degree of agreement between the two health professionals was very high. The Krippendorff alpha measuring the reliability of component level ICF coding between two independent raters was 99.1% with only 4 of the 867 codes differing between raters. Furthermore, Krippendorff's alpha for coding at 1st and 2nd ICF levels was 98.8% with 5 out of 867 codes differing between raters. The reliability of the linking process in this study could have been strengthened by increasing the number of raters, especially from different professional backgrounds.

## 5.4 FURTHER RESEARCH

To develop stronger evidence for the most effective and efficient implementation of psychomotor therapy in lumbar fusion patients, further studies should investigate the benefits of rehabilitating all lumbar fusion patients with psychomotor therapy during the first 3 post-operative months contra using pre-operative screening to select subgroups most appropriate for post-operative psychomotor therapy. This can also be compared to screening at 3 months after the operation to select patients with persisting pain and functional disability appropriate for psychomotor therapy to provide stronger evidence for the most appropriate time to start post-operative psychomotor therapy.

More generally speaking, further RCT studies should also investigate the effectiveness of a psychomotor therapy contra other rehabilitation approaches in non-specific CLBP patients and also other musculoskeletal pain subgroups. To improve our basic science knowledge of the

neurophysiological mechanisms underlying the effect of psychomotor therapy, investigations into central nervous system changes as a result of cognitive behavioural therapy, motor control training and their combination in psychomotor therapy could be investigated.

# 6 CONCLUSIONS

- The high amount of variance in baseline disability and HRQOL in CLBP lumbar fusion candidates explained by psychological factors suggests the importance of screening for these factors and taking them into consideration for rehabilitation interventions.

- Knowledge of the observed mediating role of cognitive factors, especially catastrophizing, control over pain, self-efficacy and outcome expectancy in the influence of pain intensity on mental health, fear of movement/(re)injury and their further influence on disability and HRQOL could help improve the effective implementation of physiotherapeutic interventions aimed at improving disability and HRQOL.

- Post-operative psychomotor therapy, a combination of cognitive behavioural therapy and motor relearning, conducted during the first 3 months after lumbar fusion results in a better outcome than exercise therapy.

- A model with good outcome predictive performance which significantly predicts disability, back pain and HRQOL outcomes 2-3 year after lumbar fusion surgery, involves pre-operative screening of disability, leg pain intensity, mental health, fear of movement/(re)injury, outcome expectations, catastrophizing, control over pain and the implementation of post-operative psychomotor therapy.

- Lumbar fusion patient's experience of back problems, expectations and recovery in terms of the ICF corresponds well with the ICF related content of outcome measures such as the ODI, SF-36, EQ-5D, VAS pain, SES, TSK, BBQ, CSQ, work status, health care use, analgesic use, sickness leave as well as ICF LBP core sets.

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