Movement Control Impairment is one subgroup of Non-Specific Low Back Pain. In this PhD thesis the efficacy of two different exercise methods is throughout investigated in order to find out which method is more efficient in improving disability and patient-specific functional limitations caused by Movement Control Impairment. The patients are in sub-acute stage of their Low Back Pain.
Movement control impairment in recurrent subacute low back pain

A randomized controlled trial between specific movement control exercises and general exercises
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To be presented by permission of the Faculty of Health Sciences, University of Eastern Finland and for public examination in Haartman-instituutti, Helsinki, on Thursday, January 26th 2017, at 12 noon

Publications of the University of Eastern Finland
Dissertations in Health Sciences
Number 393

Department of Physical Rehabilitation, Institute of Clinical Medicine, School of Medicine, Faculty of Health Sciences, University of Eastern Finland
Kuopio
2017
VESLA LEHTOLA

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ABSTRACT

Only 15% of patients with lower back pain (LBP) will get a specific diagnosis, and the majority of cases are categorized as non-specific LBP. Despite the recommendations of clinical guidelines, only a few studies have been published on subgroups of patients with LBP. Movement control impairment (MCI) is one potential subgroup, and clinical tests have been developed to identify it. Exercise is recommended in clinical guidelines, as it seems to be an effective treatment for chronic LBP, but little is known about the management of subacute LBP.

The effect of general exercises versus specific movement control exercises (SMCEs) was compared in a randomized controlled trial in a population with recurrent subacute LBP. Patients in both groups had five treatment sessions of either specific or general exercises, including short application of manual therapy. The primary outcome measure was the Roland-Morris Disability Questionnaire (RMDQ) evaluated at baseline, after 3 months of intervention, and at the 12-month follow-up.

The trial included 70 eligible patients. The 12-month follow-up was completed by 61 patients (n= 30 SMCE and n=31 general exercise, drop-out rate 12.9%, SMCE 14.3% and general exercise 11.4%). Patients in both groups significantly improved as a result of the therapeutic interventions. SMCE was superior according to the mean change in the RMDQ between baseline and the 12-month follow-up (-1.7 points; 95% CI -3.9 to -0.5). However, the difference was below the clinically significant three points and the Oswestry Disability Index (ODI) did not differ between the groups.

Combined SMCEs and manual therapy was slightly superior to general exercises combined with manual therapy for patients with non-specific recurrent subacute LBP and MCI. Disability was alleviated and function tended to improve more at the 12-month follow-up with the specific exercises. Before the trial started, the research group translated and validated an outcome measure Patient-Specific Functional Scale (PSFS) in Finnish language.
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National Library of Medicine Classification: Movement control impairment in low back pain
Medical Subject Headings: Randomized trial, Low back pain, Physiotherapy, Movement control impairment
TIIVISTELMÄ.

Tämän tutkimuksen tarkoituksena oli selvittää kumpi hoitomuodoista, yksilöllisesti suunniteltu liikekontrollin häiriötä korjaava harjoittelu vai yleinen harjoittelu, lievittää tehokkaammin epäspesifistä alaselkäkivusta aiheutuvaa haittaa kolmen kuukauden harjoittelun jälkeen ja 12 kuukauden kuluttua. Liikekontrollin häiriö -alaryhmäluokan diagnosoidut koehenkilöt saivat viisi fysioterapeutin käyntiä joko spesifejä tai yleisiä harjoitteita. Kullakin käyntikerralla koehenkilöt saivat lyhyesti myös manuaalista terapiaa. Päämittarina toimi yksilöllinen haitta-aste mitattuna Roland-Morris selkäoirekyselyllä. Tutkimukseen osallistui 70 koehenkilöä. 12 kuukauden seurannassa mittaukset suoritettiin 61 koehenkilölle (keskeytysprosentti 12.9 %). Tutkimustulos osoitti, että molemmat ryhmät paranivat merkittävästi kolmen kuukauden intervention jälkeen ja tulos säilyi 12 kuukauden seurannassa. Lähtötilanteen verrattuna, spesifejä harjoitteita saaneen ryhmän tulokset olivat tilastollisesti merkitsevästi parempia kuin yleisten harjoitteiden ryhmäläisillä. Haitta-asteen muutos oli -6.9 spesifille ryhmälle ja -5.2 yleisten harjoitteiden ryhmälle (ero -1.7, 95% CI -3.9:stä -0.5:een, p<0.01).

Movement control impairment in recurrent subacute low back pain. A randomized controlled trial between specific movement control exercises and general exercises
Itä-Suomen yliopisto, terveysstieteen tiedekunta, 2017
Publications of the University of Eastern Finland. Dissertations in Health Sciences Numero 393. 2017. 86 s.
ISBN (print): 978-952-61-2385-1
ISSN (print): 1798-5706
ISSN (pdf): 1798-5714
ISSN-L: 1798-5706

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Luokitus: Yeinen Alaselän liikekontrollin häiriö
Suomalainen asiasanasto: Satunnaisetettu tutkimus, Alaselkäkipu, fysioterapia, liikekontrollin häiriö
This research project has taken seven years of my life. During that period I have been working in my own physiotherapy clinics and conducting physiotherapy teaching all over Finland. This sort of commitment to research in this extent along with clinical practice would not have been possible without a major help from several people and institutions.

First I would like to acknowledge all my tutors; without their passionate attitude towards my issues this project would have been really, really hard. Hannu Luomajoki and Sean Gibbons helped with the study design and, as they both are experts in this research area, discussions with them opened my eyes several times. Ville Leinonen and Olavi Airaksinen helped in the subject and encouraged my studies and congress presentations.

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From the clinical expertise view I have had a real fundamental learning process in the field of manual therapy and movement control impairments. During the past twenty years I have taken advanced studies tutored by many worldwide famous physiotherapy teachers. It is unfair for many of them not to list their names here, but three of them should be taken into account; two of them are my tutors Hannu Luomajoki and Sean Gibbons and the third expert is Mark Comerford. Without the education I have gained from them this research would not have taken place at all. And let’s not forget my unofficial mentor during these years, and during my Master’s Thesis also: Thank you Petteri Koho.

Last, I want to thank my family; my parents, who were my first mentors have taught me to be honest in everything I do and with their own example they have shown me how hard work usually gets rewarded. Thank you my lovely children Emilia and Anttoni for your everlasting support. And you, my beloved Anita: You have seen me in those “Hello, Earth calling” – situations and have been patient with my writing. I will try to come back to normal life.

These seven years have brought me up. I do hope so. Sometimes lessons learned in life and your studies might lead to the same conclusion as described by Mick Jagger and Keith Richards already in 1969:
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“You can’t always get what you want
But if you try sometimes well you might find
You get what you need”

Kuopio, January 2017

Vesa Lehtola
List of the original publications

This dissertation is based on the following original publications:


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Abbreviations

AUC  Area under the curve
CI   Confidence interval
cm   centimetre
DEPS Depression screening tool
FABQ Fear-Avoidance Beliefs Questionnaire
FRI  Functional Rating Index
GRADE Grades of Recommendation Assessment, Development and Evaluation (GRADE) Working Group
ICC  Intraclass correlation coefficient
ICD  International statistical classification of diseases and related health problems codes
ICF  International classification of functioning, disability, and health codes
IVD  Intravertebral disc
kg   Kilogram
LBP  Low back pain
MCAQ Motor Control Abilities Questionnaire
MCI  Movement control impairment
MCIC Minimum clinically important change
MDT  Mechanical Diagnosis and Treatment
MD  Movement control dysfunction
MRI  Magnetic resonance imaging
MSI  Movement System Impairment
NDI  Neck Disability Index
NSCLBP Non-specific chronic low back pain
NSLBP Non-specific low back pain
Introduction

Several treatment approaches are recommended for subacute and chronic lower back pain (LBP), including cognitive behavioral therapy, counseling, and manual therapy. Therapeutic exercise is a common intervention for subacute LBP, though its effect size is modest. Two reviews (1, 2) and one meta-analysis (3) have supported the efficacy of exercise, resulting in a number of clinical practice guidelines recommending it (4-7). This raises the question of the relative effectiveness of general versus specific training in subacute LBP (8).

LBP is considered a multifactorial biopsychosocial pain syndrome, and clinical studies currently focus on better understanding the nature of these components (9). The current consensus on the diagnostic accuracy of LBP is that approximately 85% (10) to 90% (11) of cases have no apparent cause. One of the most challenging issues is the heterogeneity of patients with non-specific LBP (NSLBP). Current clinical guidelines for the treatment of LBP are based on randomized controlled trials (RCT's), which are often carried out without appropriate subgrouping. Two reviews published after 2010 support the targeted treatment of subgroups of patients with NSLBP, which seems to improve treatment outcomes (12, 13). Three almost similarly designed RCTs demonstrated a positive effect in chronic LBP (CLBP) patients. A similarity in design was cognitively changing or controlling the movement patterns of the patients (14-16). Altered movement control or impairment may occur at any stage of rehabilitation (17) and is not related to the duration of symptoms (18). In a mixed population study (acute, subacute, or chronic LBP), improved control of the lumbar spine improved symptoms in most subjects (19). Recent research has shown that spinal manipulative therapy is effective in subgroups of patients with LBP. Research suggests and supports manipulative therapy being used as part of a comprehensive management plan rather than alone. Advantages of manipulative therapy include pain relief and improved function (7). In clinical practice, manual therapy and exercise are often used in combined treatment modalities for LBP.

In this study protocol, we used the sub-classification model proposed by O’Sullivan, which is based on clinically different subgroups. The underlying mechanism of disorder is considered to be important in ensuring proper management (20). In this model, patients with movement control impairment (MCI) will have pain and physical maladaptive cognitive disorder compensation, which can cause constant symptoms (21). In theory, these patients cannot control their position when sitting or standing, or correctly during the desired movement of the spine. Thus, they are unknowingly increasing the risk of pain (20). O’Sullivan’s model has high reliability (22). A battery of six tests evaluating various MCIs demonstrated reasonable discriminative validity (23).

The aims of this study were to validate the Finnish version of the Patient-Specific Functional Scale used as one of the outcome measures in a subsequent RCT and to compare the effect of individually tailored specific movement control exercises (SMCEs) to that of general exercises for patients with MCI in recurrent subacute non-specific LBP.
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Review of the literature

2.1 ANATOMY AND BASIC BIOMECHANICS OF THE LUMBAR SPINE

The lumbar vertebral column consists of five vertebrae. Adjacent vertebrae are connected by intervertebral discs and two zygapophyseal joints (facet joints). The inner part of the intervertebral disc is the nucleus pulposus, and the outer part is the annulus fibrosus (Figure 1). The vertebral column (spine) forms a spinal canal with the spinal cord inside and rounded by the dural sac. The spinal cord usually ends at the L1-L2 vertebrae level and is caudally continued by lumbar and sacral nerve roots called cauda equina. Ligamentum flavum connects the laminae of the vertebrae. The spinal nerves (31 pairs) consist of the spinal cord's dorsal (sensory) and ventral (motor) roots. The spinal nerve roots exit the spinal canal through the subarticular (entrance) and foraminal (mid) zones. The lateral lumbar canal underneath the superior articular processes is located caudal to the lateral recesses. This is also called the subarticular zone (24).

Figure 1. Anatomy of vertebrae. (Wikimedia Commons).

Standing in an erect position requires lumbar spine curvature called lordosis (Figure 2). The pelvis anatomy and position interact with the spinal construct in architecture and position to adjust the sagittal balance between both the spine and pelvis (25,26). The more the sacrum is tilted, the steeper the lumbar curvature. Alternatively, when the sacrum is more horizontal, the lumbar curvature is flat.
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Figure 2. Different sagittal alignment of the lumbar curvature. Group 1 is considered as normal lordosis, Group 2 as decreased lordosis (static back), Group 3 and 4 as increased lordosis (dynamic back). Reprinted from J Korean Soc Spine Surg. 2010 Jun;17(2):66-73 with a permission from Korean Society of Spine Surgery. (27)

Lumbar lordosis can be reconstructed into superior (proximal) and inferior (distal) tangent arcs (25). In the degenerative spine, one angle is dependent on the other. The superior arc of lumbar lordosis is equal to the inferior arc of the thoracic kyphosis. For a balanced spine, thoracic kyphosis and lumbar lordosis are intrinsically associated, responding according to the other during degenerative evolution. The inferior arc of the lordosis corresponds to the sacral slope, indicating that it is substantially important for the determination of global lordosis (26). The results of two radiographic studies in healthy volunteers showed that sitting reduces lumbar lordosis and sacral slope compared to standing. These changes in lordosis and spinopelvic parameters were suggested to cause a spinopelvic imbalance (28,29).

The principal movements exhibited by the lumbar spine are axial compression, axial distraction, flexion, extension, axial rotation, and lateral flexion. Horizontal translation does not occur naturally as an isolated, distinct movement, but it is related to axial rotation. Both translation and rotation can occur in either of two opposite senses, which can be defined according to circumstances or convention. In anatomical terms, translation or rotation can occur in any of the three planes (i.e., sagittal, coronal, or horizontal) (Figure 3). Total range of motion is not of any diagnostic value because aberrations of total movement indicate neither the nature of a disease nor its location. However, total range of motion does provide an index of spinal function that reflects the biomechanical properties of the lumbar spine (30).
Lumbar lordosis can be reconstructed into superior (proximal) and inferior (distal) tangent arcs (25). In the degenerative spine, one angle is dependent on the other. The superior arc of lumbar lordosis is equal to the inferior arc of the thoracic kyphosis. For a balanced spine, thoracic kyphosis and lumbar lordosis are intrinsically associated, responding according to the other during degenerative evolution. The inferior arc of the lordosis corresponds to the sacral slope, indicating that it is substantially important for the determination of global lordosis (26). The results of two radiographic studies in healthy volunteers showed that sitting reduces lumbar lordosis and sacral slope compared to standing. These changes in lordosis and spinopelvic parameters were suggested to cause a spinopelvic imbalance (28,29).

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The lumbar spine is circled by muscles, which can be divided into three groups for descriptive purposes and on a functional basis: psoas major on the anterolateral side, intertransversarii lateralis and quadratus lumborum on the anterior side of the transverse processes, and the lumbar paraspinal muscles, which are behind and cover the posterior elements of the lumbar spine (30). The lumbar paraspinal muscles can further be divided into interspinales, intertransversarii mediales, multifidus, and lumbar erector spinae. The thoracolumbar fascia consists of three layers connecting the muscles of the lumbar spine (anterior, middle, and posterior layer). The posterior layer of the thoracolumbar fascia provides an indirect attachment for the transversus abdominis to the lumbar spinous processes (30).

2.2 EPIDEMIOLOGY OF LOW BACK PAIN

LBP is a very common problem that most people experience at some time during their lives. LBP is also an expensive problem with ambiguous management efficiency and high recurrence rate (31,32). LBP is still the primary reason for work absenteeism and disability in all industrialized societies (10). A recent systematic review reported that LBP is a major problem all over the world, with the highest prevalence in women aged 40 to 80 years (33). In
Finland, 41% of women and 35% of men had experienced LBP in the last 30 days according to the Health 2011 survey performed by the National Health Institute (34). The incidence had increased slightly from the year 2000 (34).

Patients developing CLBP (i.e., pain and discomfort persisting for more than 3 months) use more than 80% of all health care resources for back pain (10). A cross-sectional survey data model from three different data sources in Norway showed that, in 2012, 18% of men and 27% of women reported musculoskeletal diseases lasting at least 6 months. Thirty-seven percent of women and 30% of men utilized primary health care services for musculoskeletal diseases. Of these, 32% of the women and 26% of the men had links with the doctor, and 5 to 9% had adjustments by a physiotherapist or chiropractor or combined therapy. The corresponding numbers for specialist physicians was 5% of men and 7% of women, the majority of which were out-patient consultations. LBP and neck pain were the most common diagnostic reasons for the use of health care services (35).

Several individual and environmental factors influence the onset and course of LBP. Common risk factors include anxiety, depression, job dissatisfaction, low educational status, low levels of social support in the workplace, stress, and whole-body vibration (33).

Current practice guidelines indicate that acute LBP has a favorable prognosis. However, it was recently suggested that most people who experience activity-limiting LBP undergo recurrence. A systematic review of prognostic studies of acute LPB indicated that the perception of the spontaneous healing of LBP is imprecise. Typically, pain and disability are progressive and recurrences common. Up to 70% of the patients who initially improve suffer recurrent pain episodes within 1 year of follow-up (36). A large retrospective cohort study in Canada showed that the annual prevalence of LBP continuously declined between 2000 and 2007 among young adults (< 65 years) but increased among older adults (≥ 65 years) (37). These results indicated that younger men (< 65 years) are more likely than women to consult a doctor for LBP. This trend was reversed in patients older than 65 years of age.

2.3 CLINICAL PRACTICE GUIDELINES IN MANAGING SUBACUTE NON-SPECIFIC LBP

The duration of pain episodes in different phases of LBP is a widely used factor for subdividing LBP management. In most patients with LBP, pain or disability is short-term, and they soon return to normal activities and to work. However, a small number of cases develop chronic pain and disability. After LBP with significant disability lasting more than a year, only a few patients will return to normal activities and work (38).

**Acute LBP** – LBP lasting for up to 6 weeks. The *early acute phase* is defined as < 2 weeks and the *late acute phase* as 2 to 6 weeks with potential risk for delayed recovery or the development of CLBP. LBP can occur on a recurring basis and is considered acute recurrent in the case of complete recovery between episodes (5).
Subacute LBP – LBP with duration of more than 6 weeks after the onset of symptoms but no longer than 12 weeks after symptom onset (5).

Chronic LBP – LBP lasting more than 12 weeks. CLBP is frequently experienced as chronic symptoms that are severe enough to impair function or quality of life. CLBP may also occur periodically with intermittent worsening. These exacerbations are acute overlying chronic symptoms (5).

In the US LBP guidelines, experts were tasked to identify impairments of body function and structure, activity limitations, and participation restrictions according to International Classification of Functioning, Disability and Health (ICF) terminology. Patients should be categorized according to mutually exclusive impairment patterns upon which different treatment strategies are based and function over the course of treatment used as an outcome measure. The experts’ second objective was to describe the evidence for classification of the identified impairment pattern and interventions for patients with activity limitations and impairments in body function. The identified impairment should be consistent with the structural area of the body (7). A summary of the LBP expert group is shown in Figure 4.
### INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES AND RELATED HEALTH PROBLEMS (ICD) CODES

<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute and Subacute Low Back Pain with Mobility Deficits</td>
<td>M99.0</td>
<td>Lumbosacral segmental/somatic dysfunction</td>
</tr>
<tr>
<td>Acute, Subacute, and Chronic Low Back Pain with Movement Coordination Impairments</td>
<td>M53.2</td>
<td>Spinal instabilities</td>
</tr>
<tr>
<td>Acute Low Back Pain with Related (Referred) Lower Extremity Pain</td>
<td>M40.3</td>
<td>Flatback syndrome</td>
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<tr>
<td></td>
<td>M51.2</td>
<td>Other specified intervertebral disc displacement (lumbago due to displacement of intervertebral disc)</td>
</tr>
<tr>
<td>Acute, Subacute, and Chronic Low Back Pain with Radiating Pain</td>
<td>M54.1</td>
<td>Lumbar radiculopathy (neuritis or radiculitis)</td>
</tr>
<tr>
<td>Acute or Subacute Low Back Pain with Related Cognitive or Affective Tendencies</td>
<td>M54.5</td>
<td>Low back pain</td>
</tr>
<tr>
<td>Chronic Low Back Pain with Related Generalized Pain</td>
<td>M54.5</td>
<td>Low back pain</td>
</tr>
<tr>
<td></td>
<td>G96.8</td>
<td>Disorder of central nervous system, specified as central nervous system sensitivity to pain</td>
</tr>
<tr>
<td></td>
<td>F45.4</td>
<td>Persistent somatoform pain disorder</td>
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</table>

### INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY, AND HEALTH (ICF) CODES

#### ACUTE LOW BACK PAIN WITH MOBILITY DEFICITS

<table>
<thead>
<tr>
<th>Body functions</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>b28013</td>
<td>Pain in back</td>
</tr>
<tr>
<td>b28018</td>
<td>Pain in body part, specified as pain in buttock, groin, and thigh</td>
</tr>
<tr>
<td>b7101</td>
<td>Mobility of several joints</td>
</tr>
<tr>
<td>b7108</td>
<td>Mobility of joint functions, specified as mobility in a vertebral segment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Body structure</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>s76001</td>
<td>Thoracic vertebral column</td>
</tr>
<tr>
<td>s76002</td>
<td>Lumbar vertebral column</td>
</tr>
<tr>
<td>s7401</td>
<td>Joints of pelvic region</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Activities and participation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>d4108</td>
<td>Bending</td>
</tr>
</tbody>
</table>

#### SUBACUTE LOW BACK PAIN WITH MOBILITY DEFICITS

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<td>Joints of pelvic region</td>
</tr>
<tr>
<td>s7402</td>
<td>Muscles of pelvic region</td>
</tr>
<tr>
<td>s75901</td>
<td>Hip joint</td>
</tr>
<tr>
<td>s75002</td>
<td>Muscles of thigh</td>
</tr>
</tbody>
</table>

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There is no agreed upon “usual care” for any type of LBP (acute, subacute, or chronic). However, several national guidelines indicate a generally accepted approach to the management of acute LBP (4,6,7). In contrast, the management strategy for subacute LBP is unclear. Importantly, the appropriate treatment of acute and subacute LBP has the potential to reduce the number of patients with disabling CLBP, reducing the human, social, and economic burden. Prolonging sick leave increases the risk of long-term incapacity for work (37,38). A key priority is to help people with persistent NSLBP self-manage their condition by providing advice and information. Patient education and teaching (mini-interventions) are useful (38,39). The Finnish Current Care Guideline for managing subacute LBP presents similar treatment approaches, including the target of a patient’s active participation in the treatment (39). The
importance of psychosocial factors in the risk of the development of back pain is uncertain, but they increase the risk of chronic spinal pain; thus, the use of patient illness behavior questionnaires is recommended (39).

Active rehabilitation should be initiated at the latest when the back pain has been prolonged for 6 weeks. Rehabilitation aims to reduce the harm caused by illness or injury, to improve the patient’s functional and working capacity, or increase his chances of pain and life management and social survival. Rehabilitation also aims to influence the capacity to overcome restrictive physical, psychological, and social factors (39).

The aim of the recommended treatment strategies is to decrease pain and disability and their impact on patients’ daily life (38,39). The managing model of the American College of Physicians and American Pain Society is shown in Figure 5 and includes reassessment timing recommendations and different management strategies if the measurement shows the previously chosen therapy or medicine has not been efficient enough.
2.4 EXERCISE THERAPY IN SUB-ACUTE AND CHRONIC NSLBP

In clinical practice guidelines, therapeutic exercises are recommended interventions for subacute LBP (1-7). However, whether general or specific exercise is more beneficial and what intensity of exercises should be used for significant changes is unclear (8).

The term “general exercise” is wide-ranging because there are a number of different types of exercise that have been introduced into clinical practice and scientific studies (40). Muscle strengthening exercises and cardiovascular aerobic exercises were considered “general” in a study comparing general exercise, motor control exercise, and manual therapy for CLBP (41). Muscle strengthening exercises included weights. Koumantakis et al. (42) defined general exercise as exercise targeting abdominal and paraspinal muscles without conscious recruitment of the deep paraspinals (42). Originally, Dvorak et al. (43) defined general exercise as muscle strengthening, coordination, and aerobic fitness-improving exercises (43,44). Classic trunk strengthening exercises activate the abdominal and paraspinal muscles in general at a relatively high contraction level (45,46). Thus, general exercises can involve strengthening exercises of all of the primary muscle groups with or without the addition of weights and may involve exercises improving coordination, stretching, and aerobic fitness training (41-46).

According to a systematic review of the studies published after 1998, general exercises seem to be an effective treatment for NSCLBP (40-42,44,46-53), and the same conclusion was demonstrated by the Cochrane Back Pain Review Group earlier in 2000 (the included studies were done before 1998). The reported benefits consist of reduced pain disability, depression, and fear of pain, and improved working ability (40-42,44,46-53). A recent meta-analysis including 24 studies did not detect any clinically significant effect for the reduction of pain and disability between physical, behavioral/psychologically informed, and combined interventions (54).

Specific exercise methods are usually characterized by the terms “motor control” or “stabilizing exercises”. The main aim of these exercises is to enable the patient to regain control and coordination of the spine and pelvis via motor learning including segmentation and simplification. The intervention is based on the assessment of individual motor control impairments (40,41). The aims of the treatment are then determined in collaboration with the therapist. These exercises are usually guided to be performed daily and improvement assessed by the therapist (40,41). A recent Cochrane review demonstrated that motor control exercises are probably more effective at reducing pain than a minimal intervention but probably does not have an important effect on disability in patients with CLBP. No clinically significant difference was found between motor control and other forms of exercise or manual therapy for acute and CLBP (55).

Exercise methods have been investigated mainly in CLBP patients. There is a consensus that exercise therapy should be used as a therapeutic approach in CLBP, but no consensus has been reached regarding the preferential type of therapy. No clear effect of specific interventions have been found, probably due to the heterogeneity of the study populations. Another problem is the variety of outcome measures of different RCTs. The lack of effect in the investigated

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**Figure 5.** Management of LBP according to American Collage of Physicians and the American Pain Society. Reprinted from [http://annals.org/data/Journals/AIM/20145/6FF2.jpeg](http://annals.org/data/Journals/AIM/20145/6FF2.jpeg) with permission from American Collage of Physicians and the American Pain Society. (38)
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populations has been suggested to be caused by mixing a specific subgroup benefitting from the intervention and another subgroup with no effect (56). In the subacute stage of LBP, Finnish Current Care Guidelines propose active therapeutic exercise. According to these guidelines, the target is general fitness and muscle strength (39). In addition, there is a need for subgroup-based exercise interventions for subacute LBP patients.

2.5 MANUAL THERAPY IN SUB-ACUTE NSLBP

Thrust and non-thrust mobilization/manipulation are frequently used for acute, subacute, and chronic LBP. In clinical practice, spinal manipulative therapy combines the mobilization of joints with massage, exercise, and physical therapy. Manipulative therapy aims to relieve pressure on patients’ joints and muscles to improve nerve function and reduce pain. Despite extensive use, recent reviews have demonstrated only a marginal effect across heterogeneous groups of LBP patients (57,58). In addition, most trials have evaluated the efficacy of mobilization/manipulation separately rather than in combination with exercise therapies. Recent studies have indicated that spinal manipulative therapy can effectively reduce pain and disability in certain subgroups of patients and as a part of a comprehensive treatment strategy, rather than alone (7,59). In an updated Cochrane review, spinal manipulation appeared to be equally effective with other commonly prescribed therapies for CLBP, such as exercise therapy, standard medical care, and physiotherapy (60). The conclusion of the Cochrane group for acute LBP was that spinal manipulation is equally effective with inert interventions, sham manipulation, or as an adjunct to other therapy (61). Thus, spinal manipulation seems to not be superior to other recommended therapies (61).

Previous research identified a subgroup of patients prone to having a dramatic effect with the application of combined thrust manipulation to the lumbar spine, advice to remain active, and mobility exercise. A preliminary study by Flynn et al. (62) aimed to identify patients who were most likely to benefit from a general lumbopelvic thrust manipulation. Five variables were detected to predict rapid treatment success (Table 1). Two sessions of manipulative therapy led to a 50% reduction in Oswestry Disability Index (ODI) scores. The presence of four or more predictors increased the probability of achieving a benefit from thrust manipulation from 45% to 95% (62). However, the subacute stage of LBP seems to be under-represented in research on the efficacy of manipulative therapy compared to acute and chronic stages, similar to exercise therapy.
2.6  SUBCLASSIFICATION OF NSLBP

Exercise-based interventions in the physiotherapy management of LBP patients are common in spite of only modest effect sizes (0.07 to 0.61) (63). A failure to recognize heterogeneity within NSLBP and to individualize treatments has been suggested to be the reason for the modest effectiveness of the treatment approaches. Effect sizes seem to increase by matching the treatments to patient subgroups (12,13,15), but the results have been inconsistent (64).

Subgrouping approaches share a common assumption of favorable and better-predicted outcomes if an analogous appearance among individuals is recognized (i.e., a subgroup), and a subgroup-specific intervention is attributed (65). There are various definitions for distinguishing or categorizing the subgroups (65), including Treatment-Based Classification (TBC) (66), Mechanical Diagnosis and Treatment (MDT) (67), Movement System Impairment (MSI) (68), O’Sullivan Classification Scheme (OSC) (20), and Pathoanatomic-Based Classification (PBC) (69).

Three of these methods prioritize repeated spinal movements to identify individuals who respond to this approach (66,67,69). Diagnostic decision-making according to the responsiveness to certain treatment strategies is one method (66). Two models use movement patterns that provoke symptoms to correct the motion in order to reduce symptoms (20,68). Two of these schemes involve psychosocial factors (20,65,66).

Clinical practice guidelines have proposed that further classification should be adjusted based on a biopsychosocial construct (4-7,70). A number of leading clinical indicators of the region of pain and patient behavior support a key insight into the different mechanisms underlying and driving the pain disorder, allowing appropriate classification. The presence of anatomically defined pain related to specific and consistent mechanical provocative and relieving factors indicate that physical/mechanical aspects are likely to dominate the disorder, leading to primary peripheral nociceptive drive (70). In practice, the relationship between clinical examination and pathoanatomical findings is critical to elucidating their significance and correlation with the ongoing disorder. In the case of constant, non-remitting, widespread pain that is not significantly influenced by mechanical factors, inflammatory or centrally driven

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**TABLE 1.** Clinical prediction rule for spinal manipulation in LBP patients.

<table>
<thead>
<tr>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of symptoms of less than 16 days</td>
</tr>
<tr>
<td>No symptoms distal to the knee</td>
</tr>
<tr>
<td>Lumbar hypomobility</td>
</tr>
<tr>
<td>At least 1 hip with greater than 35 degrees of internal rotation</td>
</tr>
<tr>
<td>Fear-Avoidance Beliefs Questionnaire (FABQ) score less than 19</td>
</tr>
</tbody>
</table>

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**TABLE 1.** Clinical prediction rule for spinal manipulation in LBP patients.
neurophysiological factors likely dominate the disorder. In some cases, even minor mechanical irritation leads to a pathologically amplified pain response. High levels of anxiety, hypervigilance, fear of movement, and emotional stress presenting as primary provocative or accelerative factors, emphasize the influence of psychological and, in some cases, social aspects indicating the dominant forebrain drive of pain (70). In addition, social circumstances, work environment, lifestyle factors, and beliefs regarding the current disorder should be taken into consideration (10). Active coping strategies in managing the disorder strengthens a patient’s capacity to actively manage pain (70). A combination of the above-mentioned features is common, and the clinician is responsible for recognizing the dominant component of the disorder (20).

2.6.1 O’Sullivan Classification Scheme
The OSC proposes four distinct subgroups of patients that present with disabling CLBP associated with MCI (20).

The first subgroup (specific diagnosis) includes disorders with high levels of pain and disability, and the MCIIs are secondary and adaptive to defined pathological processes. These processes include certain specific pathoanatomical disorders, such as red flag disorders, disc herniation, and spinal stenosis with radicular pain and/or neurological deficits, inflammatory pain due to internal disc disruption or other specific processes, unstable grade 2–4 spondylolisthesis, or neuropathic and centrally or sympathetically mediated pain disorders. These patients may present an antalgic movement pattern and altered motor control driven directly by the underlying pain disorder. In the case of the restoration of the primary pathological process, the signs and symptoms such as motor control and movement impairments related to the disorder resolve (20).

In a second (small) subgroup (non-specific, non-mechanical disorders), the pain disorder is driven from the forebrain secondary to dominant psychological and/or social (non-anatomical) factors. Despite psychological and social factors being related to all chronic disabling pain disorders, this small group of patients represent dominant central drive according to O’Sullivan. These patients have severe disability, altered central processing of pain, exaggerated ceaseless pain, leading to impaired movement control. These disorders are frequently associated with dominant psycho-social characteristics, including overly expressed anxiety, anger, fear, depression, negative beliefs, poor coping strategies, un-resolved emotional issues, and negative social interaction (10,70). The psychological and social stresses act as co-existing, triggering, or primary provocative factors of the disorder (70). The main characteristics of these disorders are the lack of clear and consistent mechanical aggravating or relieving patterns or an inconsistent response to mechanical provocation that tends to result in abnormal and excessive pain, disability, and emotional feedback. Despite a poor response, strong opiates and passive therapies are often prescribed by clinicians (10,20).

O’Sullivan proposed that the third (large) subgroup includes mal-adaptive MCIIs associated with faulty coping strategies due to chronic abnormal tissue loading (either instability or increased stiffness), pain, disability, and distress. This mechanical disorder (movement impairment or
MCI) is classified according to the movement impairments or control impairments driving the CLBP. O’Sullivan suggested that a cognitive behavioral approach can normalize MCIs. Pain related to impaired movement control appears to have various underlying mechanisms motivating specific management strategies. These disorders may be related to specific (defined pathoanatomical diagnosis) or non-specific CLBP. Psychological, social, and neurophysiological (central sensitization) factors may contribute to the disorder but are not the main underlying etiology. These disorders respond to therapeutic intervention aimed at primary physical (movement control) impairments taking into consideration the cognitive aspects (20).

The reliability of this multi-dimensional mechanism-based classification scheme was demonstrated in two studies. The first study demonstrated high agreement ($\kappa = 0.96$, total agreement 97%) between two “expert” clinicians in a subgroup of 35 patients with non-specific CLBP (21). In another study, 13 clinicians from Australia and Norway classified 25 cases according to the patients’ subjective information and videotaped functional tests (22). Mean kappa coefficients of 0.61 (range 0.47-0.80) and 70% total agreement (range 60-84%) indicated substantial reliability. As expected, the reliability was improved by increased familiarity with the corresponding classification scheme (21,22). Figure 6 demonstrates the simplified OCS model.

![Figure 6](image_url.com).
2.7 MOVEMENT CONTROL IMPAIRMENT

Several studies have highlighted the relevance of sub-classification. In sitting postures, pain-free subjects and LBP patients perform equally (71-73). However, the differences were significant when the patients were sub-classified into flexion and active extension control impairments (included in the OCS). The direction of the movement defines how the patients sit (73), i.e., the flexion group had less activated superficial multifidus muscles compared to the active extension group (72).

According to a panel of LBP experts in the US (7), the ICD diagnosis of spinal instabilities and the associated subacute LBP with MCI has reasonable accuracy when the patient presents with the following clinical findings. Lumbar segmental hypermobility may occur in subacute worsening of recurring LBP with radicular pain when the symptoms are provoked by mid-range motions that further aggravate the condition, with end-range movements or positions and provocation of the involved lumbar segment(s). In addition, deficits of the thorax and pelvic/hip regional mobility may occur, decreased trunk or pelvic muscle strength and endurance, and MCI during usual activities (7).

MCI has been shown to be a feasible subgroup of NSLBP. Pathokinesiological movement patterns of the lumbar spine have been described in several studies and textbooks (68,74-79). Scholtes et al. (80) compared the capability to control lumbar spinal movements during knee flexion lateral hip rotation in two groups of people who played rotation-related sports. Patients with LBP had poorer control of their lumbopelvic movements, potentially changing their daily activities and sports to stress the lumbar spine, which may predispose the patient to pain (80). Luomajoki et al. (81) demonstrated a significant difference in the ability to actively control the movements of the lumbar spine between LBP patients and subjects without LBP with a large effect size between patients and controls (81). A recent longitudinal cohort study of middle-aged men and women indicated that an active life with higher physical fitness is related to better spinal control (82). Thus, altered spinal control is associated with pain and, probably even more, with the level of physical activity.

The reliability of a diagnostic test for MCI has been shown to be acceptable, especially when two expert examiners were compared (21). Van Dillen et al. (83) found very high inter-rater agreement for the assessment of symptoms (κ > 0.89, agreement > 98%) when using a battery of physical examination elements in order to categorize the patients into the dysfunction subgroup. Luomajoki et al. (23) studied 10 previously described movement control tests by four blinded physiotherapists. Subjects were evaluated by observing videos. Intra-observer reliability for five out of 10 tests showed excellent reliability (κ > 0.80). Four other tests had substantial reliability (κ = 0.6-0.8) and one had moderate reliability (κ = 0.51). Inter-observer reliability was substantial in five out of 10 tests (κ > 0.6), good (κ = 0.4 - 0.6) in four tests, and only fair (κ < 0.4) in one test. The percentage agreement varied between 65 and 97.5 (23). Figures 7-13 present these six movement control tests (23).
Several studies have highlighted the relevance of sub-classification. In sitting postures, pain-free subjects and LBP patients perform equally (71-73). However, the differences were significant when the patients were sub-classified into flexion and active extension control impairments (included in the OCS). The direction of the movement defines how the patients sit (73), i.e., the flexion group had less activated superficial multifidus muscles compared to the active extension group (72).

According to a panel of LBP experts in the US (7), the ICD diagnosis of spinal instabilities and the associated subacute LBP with MCI has reasonable accuracy when the patient presents with the following clinical findings. Lumbar segmental hypermobility may occur in subacute worsening of recurring LBP with radicular pain when the symptoms are provoked by mid-range motions that further aggravate the condition, with end-range movements or positions and provocation of the involved lumbar segment(s). In addition, deficits of the thorax and pelvic/hip regional mobility may occur, decreased trunk or pelvic muscle strength and endurance, and MCI during usual activities (7).

MCI has been shown to be a feasible subgroup of NSLBP. Pathokinesiological movement patterns of the lumbar spine have been described in several studies and textbooks (68,74-79). Scholtes et al. (80) compared the capability to control lumbar spinal movements during knee flexion lateral hip rotation in two groups of people who played rotation-related sports. Patients with LBP had poorer control of their lumbopelvic movements, potentially changing their daily activities and sports to stress the lumbar spine, which may predispose the patient to pain (80).

Luomajoki et al. (81) demonstrated a significant difference in the ability to actively control the movements of the lumbar spine between LBP patients and subjects without LBP with a large effect size between patients and controls (81). A recent longitudinal cohort study of middle-aged men and women indicated that an active life with higher physical fitness is related to better spinal control (82). Thus, altered spinal control is associated with pain and, probably even more, with the level of physical activity.

The reliability of a diagnostic test for MCI has been shown to be acceptable, especially when two expert examiners were compared (21). Van Dillen et al. (83) found very high inter-rater agreement for the assessment of symptoms (κ > 0.89, agreement > 98%) when using a battery of physical examination elements in order to categorize the patients into the dysfunction subgroup. Luomajoki et al. (23) studied 10 previously described movement control tests by four blinded physiotherapists. Subjects were evaluated by observing videos. Intra-observer reliability for five out of 10 tests showed excellent reliability (κ > 0.80). Four other tests had substantial reliability (κ = 0.6-0.8) and one had moderate reliability (κ = 0.51). Inter-observer reliability was substantial in five out of 10 tests (κ > 0.6), good (κ = 0.4 - 0.6) in four tests, and only fair (κ < 0.4) in one test. The percentage agreement varied between 65 and 97.5 (23). Figures 7-13 present these six movement control tests (23).

**Figure 7.** Movement control test “Waiter’s bow”. On the left column the correct and on the right column the incorrect (positive test result) way of conducting the movement. Reprinted on the courtesy of Hannu Luomajoki.
Figure 8. Movement control test “Posterior pelvic tilt”. On the left column the correct and on the right column the incorrect (positive test result) way of conducting the movement. Reprinted on the courtesy of Hannu Luomajoki.
Figure 8. Movement control test “Posterior pelvic tilt”. On the left column the correct and on the right column the incorrect (positive test result) way of conducting the movement. Reprinted on the courtesy of Hannu Luomajoki.

Figure 9. Movement control test “Sitting one leg extension”. On the left column the correct and on the right column the incorrect (positive test result) way of conducting the movement. Reprinted on the courtesy of Hannu Luomajoki.

Figure 10. Movement control test “Rocking backwards”. On the left column the correct and on the right column the incorrect (positive test result) way of conducting the movement. Reprinted on the courtesy of Hannu Luomajoki.
White and Thomas (84) reported satisfactory inter-rater reliability for 16 tests of the Movement System Balance approach (60), whereas Harris-Hayes and van Dillen (85) found 83% overall agreement for the classification (κ = 0.75, 95% CI 0.51-0.99) and indicated substantial inter-tester reliability (85). In addition, Trudelle-Jackson et al. (86) showed substantial inter-rater reliability between two physical therapists in the classification of CLBP patients into one of five impaired lumbar spine movement categories.

Excellent reproducibility was recently reported for five different commonly used quantitative tests for lumbar movement control (87). However, there appears to be no gold standard for movement control, leading to a lack of diagnostic accuracy statistics for MCI tests. Therefore, to establish values for the normal population, the diagnostic accuracy of MCI tests needs to be determined in a large number of people with and without LBP. The values of the measures should take into account the subject’s age, level of physical activity, and participation in sports (87).

Three RCTs indicated favorable outcomes for CLBP patients in the case of cognitively altered or controlled movement patterns (14-16). This altered movement control may occur at any stage of the ongoing pain disorder. In a mixed group of patients with acute, subacute, and chronic LBP, MCI was not related to symptom duration (18). Furthermore, in another mixed patient population, an improvement in movement control was associated with the recovery of symptoms in a majority of cases (19).

**Figure 11.** Movement control test “Rocking forwards”. On the left column the correct and on the right column the incorrect (positive test result) way of conducting the movement. Reprinted on the courtesy of Hannu Luomajoki.

**Figure 12.** Movement control test “Prone knee bending”. On the left column the correct and on the right column the incorrect (positive test result) way of conducting the movement. Reprinted on the courtesy of Hannu Luomajoki.
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2.8 OUTCOME MEASURES IN LBP INTERVENTIONS

The clinical outcome of LBP treatment is usually evaluated by objective measures or improvements in measurable physical findings, such as range of motion or muscle endurance. Subjective pain, disability, and dysfunction are the main characterization criteria for patients suffering from LBP. The relationship between the above-mentioned characteristics is subtle and complex, and these concepts are closely linked. Therefore, it is crucial to clearly distinguish pain, disability, and absenteeism or sick leave, and to assess each item separately. Clinicians recognize that patients’ perspectives are essential in the selection of treatment options and judging outcomes. Patients’ assumptions regarding their LBP determine the subjective expression of disability, their utilization of health care, and return to work. Patient-based outcome measures have become important, with rapid growth in number and type (88). A core set of measures have been suggested, including pain intensity, LBP-specific disability, ability to work, general functional status, and patient satisfaction for the process of care and treatment outcomes (89).

Patients with acute LBP seem to recover rapidly, and the impact of pain on disability and quality of life is only modest (90,91). In contrast, subacute LBP and CLBP do not tend to recover spontaneously, representing a major proportion of the social, clinical, and economical burden caused by LBP, with pain and disability being the main determinants of quality of life (10,90,91).

Functional capability is part of the disease process, as well as both target and outcome measures of health interventions. In LBP, disability is characterized by pain, activity, and participation limitations. A poor correlation between objective measures, such as imaging, indicate degenerative changes in the spine, and clinical symptoms and associated disability are largely recognized by researchers and clinicians treating LBP patients (92). Therefore, many efforts have been made to identify meaningful outcome measures.

2.8.1 Self-reported outcome measures

A large number of self-reported outcome measures are available, but these instruments usually vary according to the areas of function (93). The subjective ability to function and loss of daily activities due to LBP are implicitly defined based on the different measurements used in different studies (92). RCTs have focused on the significant change in outcome measure scores, reflecting both the degree and variability of treatment effects and sample size. Significance does not indicate the number of cases achieving a minimal clinically important change (MCIC) with the corresponding intervention. Definitions of important measurement properties are described in Figure 14.
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![Figure 14](image-url) Definitions of measurement properties. Reprinted from Ostelo RWJG, de Vet HCW. Clinically important outcomes in low back pain. Best Practice & Research Clinical Rheumatology. 2005 Vol. 19,4,593–607), with permission from Elsevier. (88)

In 2000, the expert panel that met to discuss different outcome measures recommended using the Roland–Morris Disability Questionnaire (RMDQ) (94) or ODI (95) as meaningful outcome measures for LBP when possible. These two self-reported outcome measures have been widely used in both scientific studies and clinical practice and are available in a number of languages (96). The ODI version 2.0 has been translated and validated in Finnish and is comparable with the original English version (97).

#### 2.8.2 The Roland-Morris Disability Questionnaire (RMDQ)

The RMDQ was developed from the Sickness Impact Profile (SIP), which is a 136-item health status measure covering all aspects of physical and mental function (98). The original authors selected 24 items specifically related to physical functions likely to be affected by LBP. All items were qualified with the phrase “because of my back pain” to distinguish back pain disability from disability due to other causes—a distinction that patients are generally able to make without difficulty (94).

The RMDQ focuses on only a limited range of physical functions, including walking, sitting, lying down, bending over, dressing, sleeping, self-care, and other daily activities. These aspects were selected to be relevant to all LBP patients. The expressions or wording in the RMDQ focus almost exclusively on physical function, with only a single question on mood. Certain specific aspects of physical function, such as lifting and twisting or turning, are included (94,96). Thus, the questionnaire includes only a limited range of problems, excluding psychological or social issues. Therefore, the RMDQ should be used together with specific measures of these items (94).

RMDQ scores correlate well with other measures of physical function, including the physical subscales of SF-36, the entire SIP (98), the Quebec Back Scale (99), and the ODI (95). RMDQ scores also correlate relatively well with numerical pain ratings (90). According to internal consistency and responsiveness with Cronbach’s α estimated as 0.93, 0.90, and 0.84 (96), the RMDQ has good clinimetric properties. The concept of test–retest reliability (reproducibility) may...
be debatable for a measurement that has been designed to pick up short-term changes in a changeable condition (96).

The responsiveness of the RMDQ and ODI was compared among subacute LBP and CLBP patients (100). Receiver operating characteristic (ROC) analysis revealed an area under the curve of 0.71 for the ODI and 0.64 for the RMDQ, indicating acceptable discriminating capacity (100). The best cut-off points for the dichotomous outcome in both subacute LBP and CLBP patients was 9.5 for the ODI (76% sensitivity and 63% specificity) and 2.5 for the RMDQ (62% sensitivity and 55% specificity) (100).

An essential element of the responsiveness of a questionnaire is the smallest clinically significant change. The smallest change in the RMDQ score that is likely to be clinically significant is between 2.5 and 5 points. Notably, this may vary depending on the level of disability. Stratford et al. (101,102) suggested that the minimum clinically significant change is 1–2 points for patients with only slight disability, 7–8 points for patients with high levels of disability, and 5 points in unselected patients. Patrick et al. (103) suggested that 2–3 points is the minimum clinically significant difference for a 23-item version of the RMDQ. These are the minimum changes in the score that should be regarded as clinically significant in individual patients, suggesting a recommendation of a 2–3 points change in the RMDQ be used for sample size calculations in clinical trials (96).

**2.8.3 The Oswestry Disability Index (ODI)**

The ODI was designed as a measure of both determination and outcome for CLBP interventions (96). The questionnaire can be completed by the patient in less than 5 minutes and scored by the physician in less than 1 minute. The ODI’s weighted mean for the different kinds of LBP groups is given (96). The ODI was validated and improved in a study by a Medical Research Council (MRC) group. The validated version (2.0) is recommended for general use (96).

Beurskens et al. (104) analyzed 81 patients over a 5-week period, confirming an expected improvement in ODI scores, which seemed to confirm the face validity of the ODI. They calculated an effect size of 0.8. Fisher and Johnson (105) performed a detailed validation of the questionnaire (version 2.0). Two claims of the questionnaires (sitting and walking) correlated with the responses of LBP patients, but the correlation was less satisfactory for lifting (105). The ODI correlates with the SF-36 (96). The ODI was demonstrated to be a better predictor of return to work than two different mechanical methods of LBP assessment (106). The ODI score predicted isokinetic performance, isometric endurance, (106), and performance with sitting and standing (105). Two studies have demonstrated an acceptable degree of internal consistency (0.76 to 0.87) (104,107). The ROC index for the ODI was found to be 0.76, which is acceptable (104).

For functional disability as measured by the ODI, a minimal clinically significant change of at least 10 points was suggested by Ostelo and de Vet (88). In another study of subacute LBP and CLBP patients, the best cut-off point for the dichotomous outcome was 9.5 (76% sensitivity and 63% specificity) (99).

Thus, the consensus of an expert panel and several studies is that both the RMDQ and ODI perform as well as most other currently available instruments. The RMDQ may be more
suitable to settings in which LBP patients have mild to moderate disability, and the ODI to situations in which LBP patients have persistent severe disability (88,89,95,96,100-102,104,105,107).

Disability and functioning are core issues in the assessment and treatment of patients with LBP, and items comprising outcome measures should reflect these important domains. Current outcome measures may not adequately capture the specific problems and consequences that patients describe, and there is sometimes a discrepancy between patients’ scores and their feedback (92). In order to assess the impact of a given condition on a patient’s ability to achieve their desired individual activities, outcome measures have started to target more on functional limitations. Consequently, a wide range of different outcome measures have been assessed and validated (93). One of the most growing popularity of these instruments is the Patient-Specific Functional Scale (101). Before this study the PSFS was not translated or validated in Finnish language.
The general aim of this study, after validating an outcome measure for the trial, was to compare the effect of individually tailored SMCEs combined with manual therapy to that of combined general exercises and manual therapy on disability.

The specific aims of the study were as follows (Roman numerals refer to original publications):

1. To translate and validate a Finnish version of the Patient-Specific Functional Scale (PSFS) questionnaire by testing its content validity and responsiveness, and to conduct a cross-cultural adaptation of the measure. (I)

2. To describe and register a randomized controlled trial for comparing individually tailored SMCEs with general exercises for reducing disability in patients with recurrent, subacute NSLBP after they have been sub-classified with MCI. (II)

3. To compare individually tailored SMCEs to general exercises in the reduction of disability in patients with recurrent, subacute NSLBP after they have been sub-classified with MCI. (III)

4. To evaluate the clinical benefit of specific exercises compared to general exercises in regards to the reduction of disability and improved self-reported problematic function in patients with LBP after they have been sub-classified with MCI. (III)
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Content validity and responsiveness of a Finnish version of the Patient-Specific Functional Scale

Abstract

Background: The Patient-Specific Functional Scale (PSFS) questionnaire was developed by Stratford and colleagues to provide a method for eliciting, measuring and recording descriptions of patients' disabilities. It can be used to guide treatment and assess patient outcome. The aim of the study was to translate and validate a Finnish version of the internationally used PSFS questionnaire, by testing its content validity and responsiveness, and to conduct a cross-cultural adaptation of the measure.

Methods: The final version of the Finnish questionnaire underwent a cross-cultural adaptation before the validation study. The subjects of the study were patients receiving physiotherapy for low back pain (n = 78). They completed the PSFS questionnaire prior to physiotherapy treatment and after treatment series. Roland–Morris Disability Questionnaire (RMDQ) and the visual analogue scale (VAS) were recorded before and after the treatment series.

Results: For content validity, a good correlation of the scores between baseline measures of PSFS and RMDQ were 0.65 (Pearson’s rho) (p < 0.01). For responsiveness, moderate to good correlation among the measures between changes of the PSFS, RMDQ and VAS (0–100 mm) scores were analysed.

Conclusions: The Finnish translation of the PSFS questionnaire performs as the original, is proven to have adequate content validity and responsiveness, and could be recommended as an assessment tool for clinical and research use.
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4.1 INTRODUCTION

The Patient-Specific Functional Scale (PSFS) was developed to provide a method for eliciting, measuring, and recording descriptions of patients’ disabilities (101). It can be used to guide treatment and assess patient outcome. The PSFS intended to complement the findings of generic or condition-specific measures. The shortcoming of such measures is that they are limited in detecting small but important disabilities and changes in disability over time. (101)

The PSFS is administered at the initial assessment, during the history taking, and prior to the assessment of any impairment measures. The rationale for administration prior to the physical examination is to maximize the patient's focus on activity limitation. ("I have difficulty walking down stairs") rather than impairment ("I can't flex my knee"). Patients are asked to identify up to five important activities that they are having difficulty with or are unable to perform. In addition to specifying the activities, patients are asked to rate, on an 11-point scale, the current level of difficulty associated with each activity. The scale anchors are 0 ("unable to perform activity") to 10 ("able to perform activity at same level as before injury or problem"). The clinician's role is to read the script (instructions) to the patient and record the activities, the corresponding numerical difficulty ratings, and the assessment date. At subsequent reassessments, the clinician reads the follow-up script, which reminds the patients of the activities that they identified previously. Because patients identify between one and five activities and this activity set is unique to each patient, the PSFS is not a comprehensive measure of disability and was not designed to compare disabilities between patients. (101;108;109)

The PSFS has been studied on patients with LBP and evidence proofs it to be reliable [intraclass correlation coefficient (ICC) .97], valid (individual activity-specific correlations with the RMDQ, a condition-specific measure, varied from r=.55 to .74), and sensitive to change over time (Norman’s .70 to .81) (101). PSFS has been applied also to the patients with knee dysfunction. In comparison with SF-36 it was found that test-retest reliability (ICC .84) and sensitivity to change (Pearson's r = .78) were excellent. Validity was also confirmed (109). Results of a cohort study provide construct and predictive validity evidence for the PSFS as an indicator of functional limitation in workers’ compensation claimants (110). Excellent reliability (ICC .92), validity (r =.73-.83 compared with the Neck Disability Index, and r =.52-.64 compared with the prognosis rating), and sensitivity to change (r =.79-.83 compared with NDI change scores, and r =.46-.53 compared with the prognosis rating) are demonstrated (111). PSFS and NDI were similar in their ability to detect change over time (111). So far, PSFS has been translated and validated to Brazilian-Portuguese. These language versions of the RMDQ, the Functional Rating Index (FRI) and the PSFS have been shown to have similar clinimetric properties to each other and to the original English versions. Of all the measures tested in this study the PSFS seemed the most responsive (112). According to previous study, the RMDQ and PSFS both demonstrate good responsiveness according to the definitions given in previous guidelines (113). The PSFS is more sensitive than the RMDQ for patients with low levels of activity limitation but not for patients with high levels of activity limitation (113). The PSFS exhibited poor reliability in patients with cervical radiculopathy and it showed adequate responsiveness in this patient population (114). The PSFS demonstrated good responsiveness, moderate reliability, and good
construct validity for patients attending a musculoskeletal physiotherapy clinic with upper extremity problems (115). One study investigated the extent to which patient-generated PSFS items reflect the International Classification of Functioning, Disability and Health (ICF) domains. The ICF activity component was most commonly represented by patient-nominated PSFS items, the participation component was moderately represented, but impairment was least represented. Hence, the PSFS would complement impairment-based clinical outcome measures (116). In an extensive search through medical databases (PubMed, Pedro, Cinahl), eight randomized controlled trials were found to use PSFS as a primary outcome measure (40;117-123).

The original English version has been translated in many languages, but validated only in English and Brazilian-Portuguese (112). The validation process of a translated questionnaire is required to test its adaptability in a new linguistic and cultural environment. The translated version should perform as the original to enable cross-cultural exchange and interpretation of study results.

The aim of the study was to translate and validate a Finnish version of the Patient-Specific Functional Scale (PSFS) questionnaire, by testing it’s content validity and responsiveness and also to conduct a cross-cultural adaptation of the measure.

4.2 MATERIALS AND METHODS

To be eligible for inclusion patients had to have acute, sub-acute or chronic low back pain (LBP), aged between 16 and 65 years, and had given written informed consent. The ethics committee of the Kymenlaakso Hospital District approved the study design in 31st January 2009.

4.2.1 Translation and Cross-Cultural Adaptation
The Finnish version of the PSFS was tested for face validity in a sample of LBP patients attending 2 physiotherapy clinics. These two clinics located in different dialectical areas of Finland. Thus, the final version of the Finnish questionnaire underwent a cross-cultural adaptation before the validation study. (124) During the adaptation process of the final version of the translated questionnaire there were no minor or significant problems.

A Finnish PSFS likert version was constructed by a repeated back-and-forth translation process of the original English version at an independent translation agency. Translation/retranslation of the English version of the PSFS was done blindly and independently by 2 different individuals and adapted by an expert team. The team checked the questionnaire for linguistic clearness and went through consensus process to come up with a pre-final version of the questionnaire. The consensus process was done by three experienced physiotherapy teachers. They followed the instructions given in ISPOR Task Force for Translation and Cultural Adaptation (124) (Appendix 1).
4.2.2 Participants
Participants were patients seeking treatment for LBP and had Finnish as domestic language. They were referred to seven outpatient physiotherapy clinics for treatment by their local GPs and occupational health physicians during the period of March 2009 to August 2010. They were briefed regarding the study and agreed to participate.

4.2.3 Procedures
During the first visit each patient was interviewed and they completed the Finnish versions on PSFS, RMDQ (86) and Visual Analogue Scale 0-100mm (VAS) (125). The measurements were repeated during the last session of physiotherapy. Of the clinics involved two were public and four were private. Because of the variability of the seven different clinics the amount of treatments varied from one to 15 within different patients and clinics.

4.2.4 Content validity
Content validity was defined to be similarity within PSFS and RMDQ baseline measurements. The PSFS and RMDQ are constructed to find out the level of disability and VAS is a measurement for pain intensity. With the PSFS questionnaire the score ranges from 0 to 30, a higher score indicating higher functional ability (101;126). The RMDQ is a 24-item questionnaire with a range of scores of 0 to 24, a higher score indicating higher disability (94).

4.2.5 Responsiveness
Responsiveness was defined to be similarity within the change scores of PSFS, RMDQ and VAS between the baseline and final measurements. Ideally, responsiveness should be tested in a follow-up study using pre-validated instruments and a global assessment scheme as an external criterion of change (127). Within this study the VAS measurement was used as an external validation tool. The VAS is widely used as asking patients to show their pain intensity level on a 100 mm scale (ranging from 0 “no pain” to 100 “pain as bad as could be” (125;128).

4.2.6 Statistical analyses
Statistical analyses were performed with SPSS for Windows 17.0 (SPSS Inc. Chicago USA). External content validity was evaluated by correlating the Finnish versions of PSFS and RMDQ scores for the patients at baseline using Pearson’s r; a score of 0.70 being recommended for instruments that measure the same construct. When similar constructs are compared, scores lower than 0.70 are acceptable. Very high correlation is defined being over 0.80. (129) To test external responsiveness, the change of the PSFS, RMDQ and VAS scores at baseline and after the last treatment were analysed using Pearson’s r; a score of 0.70 being recommended for instruments that measure the same construct. When similar constructs are compared, scores lower than 0.70 are acceptable. (129)

4.3 RESULTS
The study included of 78 subjects (25 male and 53 female) with mean age of 45.4 (SD 12.2). The baseline characteristics of the study participants are shown in Table 2.
Participants were patients seeking treatment for LBP and had Finnish as their domestic language. They were referred to seven out-patient physiotherapy clinics for treatment by their local GPs and occupational health physicians during the period of March 2009 to August 2010. They were briefed regarding the study and agreed to participate.

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<table>
<thead>
<tr>
<th>VARIABLE AT BASELINE</th>
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<tbody>
<tr>
<td>Gender: Female (%)</td>
<td>53 (67.9)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>45.4 (12.2, 19 to 70)</td>
</tr>
<tr>
<td>Symptom onset: 1-14 days (%)</td>
<td>9 (11.5)</td>
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<tr>
<td>Symptom onset: 2 weeks-3 months (%)</td>
<td>29 (37.2)</td>
</tr>
<tr>
<td>Symptom onset: over 3 months (%)</td>
<td>40 (51.3)</td>
</tr>
<tr>
<td>Medication: none (%)</td>
<td>22 (38.5)</td>
</tr>
<tr>
<td>Medication: pain med. (%)</td>
<td>31 (28.2)</td>
</tr>
<tr>
<td>Medication: other (%)</td>
<td>26 (33.3)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>75.6 (15.8, 50 to 120)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>171.9 (9.0, 154 to 190)</td>
</tr>
<tr>
<td>Physical activity: very active (%)</td>
<td>7 (9.0)</td>
</tr>
<tr>
<td>Physical activity: moderate (%)</td>
<td>55 (70.8)</td>
</tr>
<tr>
<td>Physical activity: low (%)</td>
<td>16 (20.5)</td>
</tr>
</tbody>
</table>

Continuous data are mean (SD), categorical data are n (%). PSFS, Patient-Specific Functional Scale; RMDQ, Roland – Morris Disability Questionnaire; VAS, visual analogue scale.

Ninety-one patients completed the questionnaires only at baseline, and thirteen subjects dropped out (14.3%). Within eight subjects that was due to a misunderstanding of the way two clinics were meant to undertake the final PSFS measurement with three new expressions of discomfort. Five subjects did not complete the questionnaires at the final measurement at all or they had forgotten to complete all the questionnaires. The results of the Total scores of PSFS, RMDQ and VAS at baseline and final measure are shown in Table 3.
TABLE 3. Total scores of PSFS, RMDQ and VAS at baseline and final measure (n=78).

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>AT BASELINE</th>
<th>AT FINAL MEASURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSFS (0-30)</td>
<td>14.1 (6.2)</td>
<td>20.4 (6.7)</td>
</tr>
<tr>
<td>RMDQ (0-24)</td>
<td>7.5 (4.6)</td>
<td>4.1 (4.4)</td>
</tr>
<tr>
<td>VAS (0-100)</td>
<td>46.3 (22.0)</td>
<td>25.4 (22.0)</td>
</tr>
</tbody>
</table>

A test of normality showed the data was normally distributed and therefore the Pearson’s r was used.

Content validity: Correlations of the scores between baseline measures of PSFS and RMDQ were 0.65 (Pearson’s r) (p< 0.01).

To test responsiveness, the change of the PSFS, RMDQ and VAS scores at baseline and after the last treatment were used. Correlations of the change scores between baseline and final measures of PSFS and RMDQ were 0.63 (Pearson’s r) (p< 0.01). A scatterplot of these changes is shown in Figure 15. Correlations of the change scores between baseline and final measures of PSFS and VAS were 0.59 (Pearson’s r) (p< 0.01). A scatterplot of these changes is shown in Figure 16.

*Figure 15. Change scores of Patient-Specific Functional Scale (PSFS; x -axis) and Roland – Morris Disability Questionnaire (RMDQ; y -axis).*
TABLE 3. Total scores of PSFS, RMDQ and VAS at baseline and final measure (n=78).

<table>
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Figure 15. Change scores of Patient-Specific Functional Scale (PSFS; x-axis) and Roland – Morris Disability Questionnaire (RMDQ; y-axis).

Figure 16. Change scores of Patient-Specific Functional Scale (PSFS; x-axis) and visual analogue scale (VAS; y-axis).

4.4 DISCUSSION

The aim of the study was to translate and validate a Finnish version of the Patient-Specific Functional Scale (PSFS) questionnaire, by testing it’s content validity and responsiveness and also to conduct a cross-cultural adaptation of the measure. Overall, the results indicate good content validity and responsiveness of the Finnish version of the PSFS and there were no significant problems involved during the cross-cultural adaptation process. The content validity was analysed by correlating the baseline scores of PSFS and RMDQ. Satisfactory correlations among the measures between the baseline scores of PSFS and RMDQ were observed with Pearson`s r 0.63. With LBP patients the similar results have been shown in earlier studies both in English (varied from 0.55 to 0.74) and Brazilian-Portugese (0.51) versions of PSFS and RMDQ (101;112).

The responsiveness analysis was done by correlating the change scores of PSFS, RMDQ and VAS. The results of this study implicate that both the PSFS and RMDQ change scores and PSFS and VAS change scores have a good correlation (0.63 and 0.59, respectively). In an earlier study of the clinimetric properties the PSFS has been shown to have a higher external responsiveness than the Functional Rating Index (FRI) and the RMDQ when analysed with Effect Sizes (112). The Brazilian research group analysed internal responsiveness with calculating the AUC from the ROC curves and concluded that the FRI and the RMDQ are less useful than the PSFS in measuring small improvements in a patient’s condition.
Terwee et al suggested in 2007 in Journal of Clinical Epidemiology in an article “Quality criteria for measurement properties of health status questionnaires” that at least 50 patients should be necessary to analyse the relevant clinimetric properties: internal consistency (by Cronbach’s alpha), reproducibility, construct validity, ceiling and floor effects, and responsiveness (129). The 91 patients of this study at the baseline measurements and also the 78 patients at the follow-up are enough to assess the reliability of the Finnish version of PSFS. The high drop-out rate was due to a misunderstanding of the way two clinics were meant to undertake the final PSFS measurement with three new expressions of discomfort. Those questionnaires had to be excluded and this is one weakness of this study.

This study lacks a reproducibility analyses. The test - re-test analyses of the PSFS should have been within the study design. It was in fact done by the research group, but the interval between the two measurements was too short, 15 minutes, to get reliable answers from the subjects. In the study of the Brazilian-Portuguese version of the PSFS the interval time was 24 hours and the results showed a good reproducibility evidenced by ICC (2,1) values higher than 0.80 (112).

When integrated in the International Classification of Functioning, Disability and Health (ICF) category, the PSFS measures numerically the participation level of the patient. The PSFS indicates the unique to each patient change in disability at subsequent reassessment. Further studies are needed to better understand the use and clinical implications of the PSFS.

4.5 CONCLUSION

The Finnish translation of the PSFS questionnaire performs as the original, is proven to have adequate content validity and responsiveness and could be recommended as the assessment tool for clinical and research use.
5 Efficacy of movement control exercises versus general exercises on recurrent sub-acute nonspecific low back pain in a sub-group of patients with movement control dysfunction. Protocol of a randomized controlled trial

Abstract

Background: Practice guidelines recommend various types of exercise for chronic back pain but there have been few head-to-head comparisons of these interventions. General exercise seems to be an effective option for management of chronic low back pain (LBP) but very little is known about the management of a sub-acute LBP within sub-groups. Recent research has developed clinical tests to identify a subgroup of patients with chronic non-specific LBP who have movement control dysfunction (MD).

Method/Design: We are conducting a randomized controlled trial (RCT) to compare the effects of general exercise and specific movement control exercise (SMCE) on disability and function in patients with MD within recurrent sub-acute LBP. The main outcome measure is the Roland Morris Disability Questionnaire.

Discussion: European clinical guideline for management of chronic LBP recommends that more research is required to develop tools to improve the classification and identification of specific clinical sub-groups of chronic LBP patients. Good quality RCTs are then needed to determine the effectiveness of specific interventions aimed at these specific target groups. This RCT aims to test the hypothesis whether patients within a sub-group of MD benefit more through a specific individually tailored movement control exercise program than through general exercises.
5.1 BACKGROUND

5.1.1 LBP epidemiology
LBP is a common, costly problem, often associated with high recurrence rates and equivocal management efficacy (31,32). LBP remains the primary cause of absenteeism and disability in every industrialized society (10). Patients who develop chronic LBP (pain and disability persisting for more than 3 months) use more than 80% of all health care for back pain (10).

A recent systematic review of the prognosis of acute LBP showed that the view of spontaneous healing is inaccurate. Pain and disability are typically ongoing, and recurrences are common. Up to 70% of those who initially improve, experience repeated fluctuating pain episodes (36). Thus, effective treatments for patients whose pain and disability persist beyond the acute phase are needed.

We are interested in the sub-acute phase, which is the transition period from acute (duration less than 6 weeks) to chronic (duration over 3 months) LBP.

The European Guidelines for Management of Chronic Non-Specific LBP recommend supervised exercise therapy as a first-line treatment for chronic LBP (5). Exercise therapy appears to be slightly effective in decreasing pain and improving function in adults with chronic LBP, particularly in healthcare populations. In sub-acute LBP there is evidence that a graded activity program improves absenteeism outcomes, though evidence for other types of exercise is unclear (1,3).

A cost effectiveness study compared the costs and benefits of a graded activity intervention to usual care for sick-listed workers with nonspecific sub-acute LBP. After a 3-year follow-up it could be concluded that the graded activity intervention for non-specific LBP is a cost-beneficial return-to-work intervention (130). An RCT compared the effects of stabilizing training and manual therapy in sub-acute and chronic LBP. The results did not indicate any clear short-term differences between the groups in the accessed outcome measures. In the long term, however, stabilizing training seemed to be more effective than manual treatment in terms of improvement of individuals and the reduced need for recurrent treatment periods (131). Another RCT indicated that in participants with sub-acute LBP, physiotherapist-directed exercise and advice were each slightly more effective than placebo at 6 weeks. The effect was greatest when the interventions were combined. At 12 months, the only effect that persisted was a small effect on participant-reported function (132).

A few studies have tried to find out the prognostic factors and the transition from acute or sub-acute LBP to chronic pain. A prospective cohort study of patients with episodes of acute or sub-acute LBP, seeking physical therapy in primary care, with follow-up at weeks 2, 4, 8, and 12 strongly revealed pain-related items to be essential factors in the development of chronic and long-term disability in primary care physical therapy. Health status at 8 weeks seemed crucial in developing chronic pain (133). A Dutch cluster RCT provided no evidence that general practitioners should adopt a new treatment strategy aimed at psychosocial prognostic factors in patients with sub-acute LBP (134).
A prospective cohort study demonstrated that physical parameters did not have a prognostic value with regard to outcome of treatment. Furthermore, the data confirmed that patients' subjective estimation of pain and disability already displays a prognostic value for therapy outcome that cannot be increased significantly by the assessment of physical parameters (135).

Chronic non-specific LBP has been studied with many exercise interventions. The types of exercise programs for chronic LBP vary widely e.g. land-based exercise versus exercise in water, individual exercise versus group exercise, isolated trunk exercise versus whole body exercise. Unfortunately there is little or no evidence to help clinicians select the most effective type of exercise for an individual patient. This absence of evidence means that care is likely to be sub-optimal. While some trials of exercise have reported large, durable and clinically important effects (136), others have not (137). The types of exercise programs, and patient presentations for chronic LBP vary widely so it is unlikely that all programs are equally effective for all patients (2).

5.1.2 General exercise and standard therapy
There is not a 'standard therapy' for any type (acute, sub-acute, chronic) of LBP that is agreed upon to use as a comparison in clinical trials. Exercise therapy is recommended by various guidelines (4;5), but it is not clear which type of exercises are best.

The use of general exercise is problematic because there are so many types of exercise that may be considered under this umbrella term (40). One study (41) compared general exercise, motor control exercise and manual therapy in treating CLBP. Within this study design cardiovascular aerobic and main muscle group strengthening exercises were considered general exercise. Muscle strengthening exercises were conducted with weights. Koumantakis et al. (2005) defined general exercise as targeting abdominal and paraspinal muscles without the involvement of the deep muscles activation (42). A systematic review by Keating et al. (2006) referred to general exercise as muscle strengthening, coordination and aerobic fitness improving exercises (43). The same approach had been used by Dvorak et al. (2001) (44). Classic trunk exercises performed in physical therapy activate the abdominal and paraspinal muscles as a whole and at a relatively high contraction level (45;46). As a conclusion the term general exercises can involve strengthening exercises for all the main muscle groups with or without the addition of weights. In addition, the term can involve exercises improving coordination, stretching and aerobic fitness training.

According to the literature, general exercises seem to be an effective treatment for NSCLBP in physiotherapy. The benefits include: pain reduction, improved working ability, increased function, reduced depression and reduced fear of pain. However, the results are comparable to those with specific exercise, especially in the longer term. The short-term benefits for specific training methods are potentially more effective in reducing pain (41;47-53).

5.1.3 Sub-classification of low back pain patients
The heterogeneity of the patients with non-specific LBP has been problematic. The sub-grouping these patients was declared to be one of the main focuses for future research a decade ago. Emphasis is to view LBP as a multi-factorial biopsychosocial pain syndrome (9).
A systematic review with a meta-analysis has been published to determine the integration of sub-classification strategies with matched interventions in RCTs evaluating manual therapy treatment and exercise therapy for chronic non-specific LBP. Only 5 of 68 studies (7.4%) subclassified patients beyond applying general inclusion and exclusion criteria. In the few studies where classification and matched interventions have been used, meta-analysis showed a statistical difference in favour of the classification-based intervention for reductions in pain (both for short-term and long-term) and disability. Effect sizes ranged from moderate (0.43) for short term to minimal (0.14) for long term. The authors concluded that a better integration of sub-classification strategies in chronic non-specific LBP outcome research is needed. They proposed the development of explicit recommendations for the use of sub-classification strategies and evaluation of targeted interventions in future research evaluating chronic non-specific LBP. (12)

Another systematic review (13) tried to determine the efficacy of targeted treatment for subgroups in adults with non-specific LBP. The results provide cautious evidence supporting the notion that treatment targeted to subgroups of patients with non-specific LBP may improve patient outcomes. However, the results of the studies included in this review are, inconsistent and the samples investigated are too small to make recommendations for clinical practice. The research suggests that adequately powered clinical trials using designs capable of providing robust information to support the modification of clinical practice are uncommon. Considering how central the notion of targeted treatment is to manual therapy principles, further studies using this research method should be a priority for the clinical and research communities.

A recent study emphasized stratification of management according to the patient's prognosis (low, medium, or high risk). They compared the clinical effectiveness and cost-effectiveness of stratified primary care (intervention) with non-stratified current best practice (control). 851 patients were assigned to the intervention (n = 568) and control groups (n = 283). Overall, adjusted mean changes in RMDQ scores were significantly higher in the intervention group than in the control group at 4 months and at 12 months. At 12 months, stratified care was associated with a mean increase in generic health benefit cost savings compared with the control group. The results suggest that a stratified approach, by use of prognostic screening with matched pathways, may have important implications for the future management of back pain in primary care. (138)

5.1.4 Movement control

The importance of sub-classification has been highlighted in several studies. When sitting postures are compared between pain free subjects and patients with LBP, there are no significant differences (71-73). However, when the patients are sub-classified into flexion and active extension control impairments, then the differences are significant. The direction of the movement control defines the way patients sit (73) and the activity in their back muscles; the flexion group has less back muscle activity and the active extension group more (72).

The MD is a clear subgroup of non-specific LBP. Pathokinesiologic movement patterns in the lumbar spine have been investigated and described in several studies (68; 74-78).
Scholtes et al. (80) compared two groups of people who played rotation-related sports and their capability to control lumbar spine movement during knee flexion lateral hip rotation. The interpretation of that study was that patients with LPB have poorer control of their lumbopelvic movements, and because of this, might be moving in their daily activities and sports more on their lumbar spine which may cause pain. A significant difference in the ability to actively control the movements of low back between patients with low back pain and subjects without back pain has been demonstrated by Luomajoki et al. (81). The effect size between patients with LBP and healthy controls in movement control is large.

The reliability of tests to diagnose MCI has been shown to be acceptable. Dankaerts et al. (21) reported an almost perfect agreement (k = 0.96 and percentage agreement 97%) between two expert examiners rating a motor control impairment classification. Van Dillen et al. (83) used a battery of physical examination items in order to categorize the patients in an impairment dysfunction subgroup. They found a very high agreement for the assessment of symptoms among the examiners (k > 0.89 and percentage agreement > 98%). Luomajoki et al. (23) examined ten movement control tests for the back. Four blinded physiotherapists evaluated subjects through observation of videos. For the intraobserver reliability, five tests out of ten showed an excellent reliability (k > 0.80). Four further tests had a substantial reliability (k = 0.6-0.8) and one was moderate (0.51). Five out of ten tests showed a substantial inter-observer reliability (k > 0.6), four tests had Kappa values between 0.4 and 0.6 (good) and one test was under 0.4 (fair). The percentage agreement varied between 65% - 97.5%.

White and Thomas (84) investigated the reliability (N = 37) of 16 tests of the Movement System Balance approach developed by Sahrmann (68), finding a satisfactory reliability between raters. Harris-Hayes and van Dillen found overall percent agreement on the classification assigned to be 83% with kappa = 0.75 (95% confidence interval = 0.51-0.99; P < .0001) and concluded that inter-tester reliability of classification of patients with LBP when therapists use a standardized clinical examination based on the Movement System Impairment classification system is substantial (85). Trudelle-Jackson et al. (2008) showed that interrater reliability between two physical therapists classifying patients with CLBP into 1 of 5 lumbar spine movement impairment categories had substantial agreement (86).

One recent study analysed the reproducibility of five different quantitative tests for those commonly used in daily clinical practice. These five tests for lumbar movement control displayed excellent reproducibility. There is no gold standard for movement control, therefore there are no diagnostic accuracy statistics available for these tests. The diagnostic accuracy of these tests needs to be addressed in larger cohorts of subjects, establishing values for the normal population. Also cut off points between subjects with and without LBP must be determined, taking into account age, level of activity, degree of impairment and participation in sports (87).

We are using the model presented by O’Sullivan (20). In this classification of chronic LBP pain disorders, sub-groups, based on the mechanism underlying the disorder, are considered critical to ensure appropriate management. It is proposed that three broad sub-groups of chronic LBP disorders exist. In the first group of disorder patients present underlying pathological processes driving the pain, and the patients’ motor responses in the disorder are adaptive. A second group disorders patients show psychological and/or social factors representing the primary
mechanism underlying the disorder that centrally drives pain, and where the patient’s coping and motor control strategies are mal-adaptive in nature. Finally, it is proposed that there is a large group of chronic LBP disorders where patients present with either movement impairments (characterized by pain avoidance behaviour) or control impairments (characterized by pain provocation behaviour). These pain disorders are predominantly mechanically induced and patients typically undertake mal-adaptive primary physical and secondary cognitive compensations for their disorders that become a mechanism for ongoing pain. These subjects present either with an excess or deficit in spinal stability, which underlies their pain disorder (21).

5.1.5 Specific movement control exercises
The underlying hypothesis is that, due to poor MD of the back, the person is unknowingly damaging him- or herself through faulty movement patterns. O’ Sullivan (20) describes these back pain patients not as pain avoiders, but, as pain provocateur. Relative flexibility theory (68) suggests that movement occurs through the pathway of least effort, e.g. if the hip movement is relatively stiff compared to that of the low back, then the movement is more likely to happen in the back, leading to a back pain problem related to the direction of that particular movement.

The directions or symptoms of the movement control are called flexion, extension and sideflexion/rotation.

To rehabilitate this type of MD, specific movement control exercises (SMCE) have been suggested (68). These are exercises in which one joint (or region) is maintained in a neutral position with conscious control, either while an adjacent joint (or region) is independently moved, or while performing part of a functional movement, with normal breathing. The exercises require more sensory motor awareness and neurocognitive function to perform than general exercise. They are generally performed with slow, low force repetitive movements. They can be performed with high load or with speed, however it is recommended that this is included in the description of the exercise protocol.

Evidence is gradually accumulating for the use of SMCE. A recent systematic review identified six randomized controlled trials, one prospective cohort study, one case control study, one case series and seven case studies that used SMCE. Based on four high quality RCT, the following levels of evidence were found: there is moderate evidence from one study for a long term (12 months) benefit of disability, pain and fear for the use of SMCE when combined with another form of active treatment and education for chronic LBP; there is moderate evidence from two studies for a short term (6 weeks) benefit of pain, pain interference and disability, for the use of SMCE when combined with active and passive treatments for chronic LBP; there is moderate evidence from one study for medium term (6 months) benefit of pain, disability and quality of life for the use of SMCE when combined with active and passive treatments for a mixed group of sub-acute and chronic LBP.

The clinical trials in this review used subjects with mostly chronic LBP. There is a need for knowledge of this type of intervention in sub-acute LBP.
5.1.5 The aim of the study
The purpose of this study is to compare individually tailored SMCE to general exercise for reducing disability in patients with recurrent, sub-acute non-specific LBP after they have been sub-classified with MD.

5.2 METHODS/DESIGN

The study protocol was registered on 18th January 2012, registration number ISRCTN48684087 and approved by the Ethics Committee of Carea (Kymenlaakso Hospital District, Finland) in 17th May 2010.

5.2.1 Participants
Recruitment

Participants are 70 patients seeking treatment for sub-acute non-specific LBP from one physical therapy clinic in Kotka, Finland, between October 2010 and November 2012 (estimation).

Inclusion criteria

To be eligible for inclusion patients had to have non-specific LBP for at least 6 weeks, be aged between 16 and 65 years, and give written informed consent. Participants should have had at least one episode of LPB prior to the study. The aim of the rest inclusion regimen is to sub-classify those patients who have MD.

The participant should score Roland-Morris Disability Questionnaire (94) to be ≥ 5 points, DEPS (139) < 12 points, Tampa Scale for Kinesiophobia (140)< 38 points and Motor Control Abilities Questionnaire < 80 points. The Motor Control Abilities Questionnaire (MCAQ) is a self report tool that was developed to screen people for their ability to learn specific motor control stability exercise and specific movement control exercise. Reliability and validity have been established. A cut off point of 80 has a specificity of 0.98 and a sensitivity of 0.88 (141). The MCAQ should be used to exclude those subjects who are unable to learn the exercises and thus not benefit from the treatment (142).

Within the physical examination the participant should have ≥ 2/6 positive MD test described by Luomajoki et al. (23); should not have Straight Leg Raise (SLR) under 50° or any positive sacroiliac-joint pain provocation tests (143) to be eligible to participate in the study. Clinical assessment should indicate that the subject is suitable for active exercise, which is asked within a questionnaire.

Exclusion criteria

Potential participants are screened for evidence of serious low back pathology and for contraindications to exercise therapy by a physical therapist. They are excluded prior to randomization if they had neurological signs (leg weakness), specific spinal pathology (e.g. malignancy, or inflammatory joint or bone disease) or if they had undergone back surgery.
aim of the measurement of DEPS, TSK and MCAQ is to rule out those patients with LBP of non-mechanical origin, e.g. depression, fear-avoidance and a poor ability to learn exercises. The aim of physical examination of SLR and sacroiliac-joint provocation tests is to rule out those patients with mechanical movement impairment (143).

5.2.2 Randomization
Each participant is randomized to a general exercise group or a SMCE group. Randomization will be done with the Randomizer 17.0 program. The randomization schedule is known only to one investigator who is not involved in recruiting participants, and it is concealed from patients and the other investigators using consecutively numbered, sealed, opaque envelopes. The physiotherapists treating the participants are not involved in the randomization process.

Baseline assessment of each group will be taken to ensure they are not different.

5.2.3 Interventions
Participants attend for up to five treatment sessions over an eight week period. The treatment is carried out by two different physiotherapists. The treatments are implemented as follows.

Initial assessment
A physical therapist carries out an initial assessment of each participant allocated to the exercise group to determine how physically active the participant is, how troublesome the back problem is, and the ability of the participant to perform the exercises. These are measured by the treating physiotherapist by asking the participant.

General exercise
Participants are taught the exercises and advised of the intensity at which they should exercise. The exercises are performed under supervision of a physical therapist. The intensity of the exercises is progressed over the 5 treatments with participants being encouraged to improve their own performance. Each session lasts 45 min and includes a short session (10-15 minutes) of manual therapy. Home exercises are taught and the ability to perform them is controlled in each treatment session. The participant performs the previously taught exercises and the physiotherapist corrects the performance if necessary. Home exercises are instructed to be performed three times a week.

The main aims of the program are to improve physical function and confidence in using the spine. The program targeting at abdominal and paraspinal muscles without the involvement of the deep muscles activation was described by McGill (45) and was investigated by Koumantakis et al. (2005) (42).

Specific movement control exercise
Participants are taught the SMCE and advise of the intensity at which they should exercise. The exercises are performed under supervision of a physical therapist. The participant performs the previously taught exercises and the physiotherapist corrects the performance if necessary. In addition the movement control is taught with sitting position exercises, four point kneeling and standing exercises according to the decision of the physical therapist to be performed once or
twice daily. The intensity of the exercises is progressed over the 5 treatments with participants being encouraged to improve their own performance. Each session lasts 45 min and includes a short session (10-15 minutes) of manual therapy. Home exercises are taught and the ability to perform them is controlled in each treatment session. Home exercises are taught to be performed three times a week and the sitting, four point kneeling and standing exercises are taught to be performed once or twice daily.

The main aims of the program are to improve the individual direction specific movement control of the lumbar spine, physical function and confidence in using the spine.

The main difference between the two exercise groups is individual and also cognitive learning, because in SMCE group the participants also learn how to move and use their back. Figure 17.

5.2.4 Outcome measures
Baseline measures are taken of the one primary outcome (RMDQ), and four secondary outcomes (PSFS and Oswestry Disability Index, Movement control tests by Luomajoki, general health questions) prior to randomization.

TABLE 4. Outcome measures of the trial.

<table>
<thead>
<tr>
<th>Main outcome measure:</th>
<th>Roland-Morris Disability Questionnaire (RMDQ) (94)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary outcome measures:</td>
<td></td>
</tr>
<tr>
<td>Patient-Specific Functional Scale (PSFS) (100)</td>
<td></td>
</tr>
<tr>
<td>Oswestry Disability Index (95)</td>
<td></td>
</tr>
<tr>
<td>Movement control tests described by Luomajoki et al. (23)</td>
<td></td>
</tr>
<tr>
<td>The amount of absence from work with a questionnaire#</td>
<td></td>
</tr>
<tr>
<td>The need for other treatment modalities with a questionnaire#</td>
<td></td>
</tr>
<tr>
<td>The need for pain medication with a questionnaire#</td>
<td></td>
</tr>
<tr>
<td>Patient satisfactory with global assessment with a questionnaire#</td>
<td></td>
</tr>
</tbody>
</table>

# A questionnaire with three claims (less than usual, equal, more than usual)

5.2.5 Statistical analysis
A sample size of 70 participants, determined a priori, provides 80% power by α 0.05 to detect an effect of change in disability based on three-point difference with RMDQ, which we regard as minimal important difference for this outcome. (137)

The comparability of the groups on prognostic and outcome variables at baseline will be analyzed using the two-sample t-tests for parametric and Wilcoxon test for non-parametric
distribution as well as Chi-Square test for nominal data. Differences between the groups over time are measured with Mann Whitney \( U \) test. A regression analysis for predictive factors will be conducted on covariates at baseline. Statistical significance is set on \( \alpha < 0.05 \). Statistical analyses will be done with SPSS for Windows release 17.0.

5.3 DISCUSSION

The aim of this study is to compare SMCE and general exercises within the sub-group of patients with MD in the sub-acute stage of LBP. The main study question is which of the two exercise programs is more effective in reducing the disability associated with LBP. European clinical guideline for management of chronic LBP recommends that more research is required to develop tools to improve the classification and identification of specific clinical sub-groups of chronic LBP patients (4). Good quality RCTs are then needed to determine the effectiveness of specific interventions aimed at these specific risk/target groups. There is a need to evaluate sub-acute non-specific LBP and need to study interventions aimed at subgroup of patients with MD.

This RCT aims to test the hypothesis whether patients within a sub-group of MD benefit more through a specific individually tailored exercise program than through general exercise. The participants in this trial are unique population; a sub-classification of MD or movement control impairment in non-specific LBP patients will show that the findings of this trial can confidently be applied to similar populations. The comparison is between two exercise programs and therefore the data should not be used to make inferences about the effectiveness, compared to no intervention, of any of the treatments. The findings can assist care providers, therapists and people with sub-acute LBP to make rational decisions about treatment. Care providers will need to take into account how the interventions are administered. The study protocol of investigating patients with sub-acute LBP is important. If there are effective ways of preventing LBP to become chronic, the high costs of treating patients could be avoided.

This study has several limitations. The treating physiotherapist or subjects cannot be blinded, however because there is no accepted standard therapy, it is not truly known which therapy is better. The amount of the home exercises is totally dependent the motivation of the subject to perform the given exercise program which could influence the outcome of this study. Core stability represents a spectrum of exercises (145). The comparison group includes a group of core stability exercises, core stiffness exercises, that involves an element of control of the spine. This means that both groups have an intervention that is cognitively attempting to control the position of the spine, although they also have fundamental differences in their application and potential benefits. This study includes subjects with recurrent, sub-acute LBP. Some of these individuals may spontaneously recover (36). With a small sample size, the results would have to be interpreted with caution. There are several aspects of the study which influence the external validity. The application of the interventions within the study relies on the skills of the
treated by physiotherapist. Physiotherapists could learn to teach general exercise program, but the assessment and rehabilitation of MD is not taught in all undergraduate courses and post graduate training is required. This study will use five treatment sessions, however it may take longer for some patients to learn the SMCE well enough to change the movement patterns and decrease disability. In practice, greater than five sessions is likely possible, however if the SMCE are not effective in reducing disability, it is not known what would happen with a longer rehabilitation time frame with more sessions. In clinical practice, time and costs often limit the time that a physiotherapist can spend with a patient. It may not be appropriate to physiotherapists to spend forty-five minutes with patients as was done in this study. This could influence the application of learning the SMCE.

The main study question is which of the two exercise programs is more effective in reducing the disability associated with LBP.
Sub-classification based specific movement control exercises are superior to general exercise in sub-acute low back pain when both are combined with manual therapy: A randomized controlled trial.

Abstract

Background: Clinical guidelines recommend research on sub-groups of patients with low back pain (LBP) but, to date, only few studies have been published. One sub-group of LBP is movement control impairment (MCI) and clinical tests to identify this sub-group have been developed. Also, exercises appear to be beneficial for the management of chronic LBP (CLBP), but very little is known about the management of sub-acute LBP.

Methods: A randomized controlled trial (RCT) was conducted to compare the effects of general exercise versus specific movement control exercise (SMCE) on disability and function in patients with MCI within the recurrent sub-acute LBP group. Participants having a MCI attended five treatment sessions of either specific or general exercises. In both groups a short application of manual therapy was applied. The primary outcome was disability, assessed by the Roland-Morris Disability Questionnaire (RMDQ). The measurements were taken at baseline, immediately after the three months intervention and at twelve-month follow-up.

Results: 70 patients met the inclusion criteria and were eligible for the trial. Measurements of 61 patients (SMCE n= 30 and general exercise n= 31) were completed at twelve months. (Drop-out rate 12.9 %). Patients in both groups reported significantly less disability (RMDQ) at twelve months follow-up. The mean change on the RMDQ between baseline and the twelve-month measurement showed statistically significantly superior improvement for the SMCE group -1.7 points (95% CI -3.9 to -0.5). However, the result did not reach the clinically significant three point difference. There was no statistical difference between the groups measured with Oswestry Disability Index (ODI).

Conclusion: For subjects with non-specific recurrent sub-acute LBP and MCI an intervention consisting of SMCE and manual therapy combined may be superior to general exercise combined with manual therapy.

The study protocol registration number is ISRCTN48684087. It was registered retrospectively 18th Jan 2012.

Figure 17. Flow chart. LBP: low back pain; RMDQ: Roland-Morris Disability Questionnaire; MD: movement control dysfunction; TSK: Tampa Scale for Kinesiophobia; DEPS: a depression questionnaire; MCAQ: Motor Control Abilities Questionnaire; SMCE: specific movement control exercise; MC: movement control; ManTher: manual therapy.
6 Sub-classification based specific movement control exercises are superior to general exercise in sub-acute low back pain when both are combined with manual therapy: A randomized controlled trial.

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6.1 BACKGROUND

Exercise is a common intervention for sub-acute LBP although it’s effect size seems to be modest. This is supported by systematic reviews (1;2) and meta-analysis (3) which has lead to exercise being recommended in guidelines (4-7). Little is known about the relative effectiveness of general versus specific exercise on sub-acute LBP (8).

LBP has been viewed as a multi-factorial biopsychosocial pain syndrome (9). In spite of the large number of potentially pain generating structures and pathological conditions that can give rise to LBP in most cases approximately eighty-five (10) to ninety percent (11) have no identifiable cause. The heterogeneity of patients with non-specific low back pain (NSLBP) has been a challenging issue. Two systematic reviews support treatment targeted at sub-groups of patients with NSLBP to improve patient outcomes (12;13). Three randomized controlled trials show positive outcome for patients with chronic LBP when movement patterns are cognitively altered or controlled (14-16). The application of rehabilitation concepts from chronic LBP to recurrent sub-acute NSLBP pain has face validity since altered movement control may occur at any stage of rehabilitation (17). Altered movement patterns within a mixed group of acute, sub-acute and chronic LBP subjects was not related to their symptom duration (18). In another mixed population the improvement of the movement pattern could improve the majority of subjects’ symptoms (19). Recent research has demonstrated that spinal manipulative therapy is effective for subgroups of patients and as a component of a comprehensive treatment plan rather than in isolation. The benefits of manual therapy include pain relief and function improvement. (7)

In this trial we used the sub-classification model presented by O’Sullivan in which sub-groups are based on the mechanism underlying the disorder and which are considered critical in ensuring appropriate management (20). In this model, patients with MCI provoke the pain through maladaptive physical and also cognitive compensation for their disorders, which then cause ongoing pain. These subjects present with a deficit in movement control which underlies their pain disorder (21). Because these patients cannot control their movement properly they might themselves unknowingly be increasing their pain (20). The sub-grouping system of O’Sullivan shows high reliability (22). For the movement control subgroup a test battery has been proposed which demonstrates adequate discriminative validity (23).

The purpose of this study, following sub-classification for MCI of patients with recurrent sub-acute non-specific LBP, was to compare the effect of individually tailored SMCE combined with manual therapy to combined general exercise and manual therapy on disability reduction.

6.2 METHODS

The study protocol registration number is ISRCTN48684087 and it was approved by the Ethics Committee of Carea (Kymenlaakso Hospital District, Finland) in 17th May 2010. The protocol of
the study design has been published in BMC Musculoskeletal Disorders (146). The study was performed according to Helsinki declaration.

6.2.1 Participants

Inclusion criteria was non-specific low back pain for at least 6 weeks, age between 16 and 65 years, a written informed consent, at least one episode of low back pain prior to the study, physically suitable for active exercise, score greater than 4 on the Roland-Morris Disability Questionnaire (RMDQ) (94), less than 12 points on the Finnish validated depression scale (DEPS), less than 38 on the Tampa Scale for Kinesiophobia (TSK) and less than 80 on the Motor Control Abilities Questionnaire (MCAQ). A DEPS score above the cut off implies that the patient has at least mild depression. A TSK score above 38 is associated with poor outcome (147). The MCAQ is a self-report tool which was developed to screen people for their ability to learn specific motor control stability exercise and specific movement control exercise. A score above 80 accurately predicts patients who cannot learn the specific movement control exercises. The MCAQ was used to exclude those subjects who are unable to learn the exercises and thus not likely benefit from the treatment (141).

The further inclusion regimen aimed to sub-classify patients with movement control impairment. Within the physical examination the participant should have ≥2/6 positive movement control impairment test described by Luomajoki (23). Three of the tests are for flexion control (waiter’s bow, rocking backwards and sitting knee extension), three for extension control (posterior pelvic tilt, rocking forwards and prone knee flexion) and one for rotation/sideflexion control (one leg standing). Reliability of the movement control test battery has been shown to be at least k>0.6 (23) for all the six tests and the battery discriminates patients with LBP from healthy controls very well (81).

Exclusion criteria (prior to randomization): evidence of serious low back pathology; contraindications to exercise therapy; neurological signs (leg weakness); specific spinal pathology (e.g. malignancy, or inflammatory joint or bone disease); and prior back surgery. The DEPS, TSK and MCAQ were measured in order to rule out patients with negative behavioral factors, e.g. depression, fear-avoidance and a poor ability to learn specific movement control exercises. Participants should not have a Straight Leg Raise (SLR) under 50°, or any positive sacroiliac-joint pain provocation tests. The aim of physical examination of SLR and sacroiliac-joint provocation tests was to exclude those patients with mechanical movement impairment of the lumbar spine.

Randomization

Each participant was randomized to general exercise group or to specific movement control group (SMCE) by the Randomizer 17.0 program and an independent investigator. This independent investigator was not involved in recruiting or treating the patients, was concealed from patients and the other investigators and used consecutively numbered, sealed, opaque envelopes. The envelopes were held in a locked box during the trial.

6.2.2 Interventions

Participants attended five treatment sessions over a three-month period. The number of treatment sessions was chosen to mimic clinical physiotherapy practice. The treatment was
carried out by two different physical therapists in one private physiotherapy clinic in Finland. Each therapist was designated to implement one of the two interventions, i.e. therapist #1: intervention #1; therapist #2: intervention #2. Physical therapists preferences in relation to the interventions were neutral: both physical therapists were specifically trained and enthusiastic about both intervention methods. Both therapists were experienced manual therapists and instructors and had over 25 years experience in clinical physiotherapy practice. The treatments were implemented as follows.

**Initial assessment**

A physical therapist carried out an initial assessment of each patient to determine how physically active the participant was, how troublesome the back problem and his/her ability to perform the exercises. The method was to interview the subject with five questions regarding their physical activity. The questions were part of Finnish translation of SF-36 (148). The assessor was blinded to the allocation of subjects.

**General exercise**

Participants were taught the exercises and advised on the intensity of performance. The exercises were performed under supervision of a physical therapist. The intensity of the exercises was progressed over the 5 treatments sessions, with participants being encouraged to improve their own performance. Each session lasted 45 minutes and included a short session of manual therapy (10-15 minutes). Manual therapy was based on individual findings (segmental hypomobility or restricted motion) and consisted of any spinal, myofascial or neurodynamic technique the physical therapist found necessary. Home exercises were taught and the ability to perform them was controlled at each treatment session. The participant performed the previously taught exercises and the physical therapist corrected the performance when necessary. The typical individual exercise program comprised three sets of 15 repetitions. At the last session of the intervention, the participant had an exercise program of 10 to 12 different exercises and the complete program lasted 30 to 40 minutes. Home exercises were to be performed three times a week during the intervention and follow-up period.

The main aims of the program were to improve physical function and self-confidence in using the spine. The program targeted abdominal and paraspinal muscles without the involvement of specific deep muscle activation (42). (Appendix 2)

**Specific movement control exercise**

Participants were taught the specific movement control exercises and advised on the intensity at which they should exercise. The exercises were performed under supervision of a physical therapist. The participant performed the previously taught exercises and the physical therapist corrected the performance when necessary. The intensity of the exercises was similar to general exercise, i.e. the typical individual exercise program was three sets of 15 repetitions. In addition, movement control was taught in the positions of sitting, four-point kneeling and standing, according to the decision of the physical therapist. The intensity of the exercises was progressed over the 5 treatments with participants being encouraged to improve their own performance. Each session lasted 45 minutes and included a short session of manual therapy (10-15 minutes)
as described above. At the last session of the intervention, the participant had an exercise program of 10 to 12 different exercises and the complete program lasted 30 to 40 minutes. Home exercises were to be performed three times a week and, additionally, the sitting, four-point kneeling and standing exercises once or twice daily.

The main aims of the program were to improve the individual direction-specific movement control of the lumbar spine, physical function and confidence in using the spine. (Appendix 3)

**Contrast between the exercise methods**

The main difference between the two exercise groups was individual, sensorimotor and cognitive learning of the precision of the exercise. In the SMCE group, the participants also learned how to move and control their lumbar spine in relation to their hips and thoracic spine. The working hypothesis is, that this specific control requires the participant to have constant awareness of the position of their lumbar spine to maintain the precision required throughout the exercise. This may be through proprioception and general body awareness. If this is not accurate enough, sensorimotor function can be complimented by tactility (e.g. placing a hand on the spine). These exercises require a high degree of skill and expertise on the part of the treating therapist (142). Two key points make this exercise fundamentally different from the other intervention: the level of sensorimotor function and neurocognitive function required to continuously monitor the precision of the lumbar spine position for constant control to maintain accuracy throughout the movement; and the exercise approach specifically targets a direction of trunk movement in which the lack of control is believed to be the underlying mechanism contributing to the patient's low back pain.

In both groups, the exercises were integrated into participants’ other physical exercises, according to the UKK Institute’s Weekly Physical Activity Pie (http://www.ukkinstiitutti.fi/en/products/physical_activity_pie). These written instructions were given to participants during the last intervention session. Participants were instructed and taught how to record a practice diary.

**6.2.3 Outcome measures**

The main outcome measure was the RMDQ (94). Secondary outcome measures were: the Patient-Specific Functional Scale (PSFS) (149); Oswestry Disability Index (ODI) (95); and movement control tests (23). Baseline measures were taken of these prior to randomization, three months measurements after the intervention and follow-up at twelve months after the randomization. The quantity of absence from work, need for other treatment modalities, pain medication and patient satisfaction were recorded using a 1-5 scale.

**6.2.4 Statistical analysis**

A sample size of 70 participants, determined a priori, provides 80% power with an α of 0.05 to detect an effect of change in disability with the RMDQ. This was based on three points minimally important difference between the groups for this outcome measure.

The comparability of the groups on outcome variables at baseline were analyzed using the two-sample t-tests for parametric, the Wilcoxon test for non-parametric distribution, as well as Chi-Square test for nominal data. Differences between the groups over time were measured with
Students t-test (absolute change scores) for parametric and the Mann Whitney U test for non-parametric distribution. The Numbers Needed to Treat (NNT) was calculated based on the absolute risk reduction for a change in disability. The reduction of 50 per cent in RMDQ was chosen because of the sub-acute stage and it’s possible spontaneous recovery (36). An Intention-to-Treat Analyses: Missing data for this analysis were replaced by the each group’s mean value.

Statistical significance was set as α of <0.05. Statistical analyses were performed with SPSS for Windows version 19.0.

6.3 RESULTS

6.3.1 Recruitment
Initially 223 subjects seeking treatment for sub-acute non-specific low back pain at a physical therapy clinic in Kotka, Finland, were assessed for eligibility between October 2010 and November 2012. Participants were recruited from local general practitioners, occupational health clinics and three advertisements published in the local newspaper. Seventy patients met the inclusion criteria and were found eligible for the trial, while 129 patients were excluded at the first examination stage (Table 5). Twenty-four patients were excluded at the physical examination: they either, did not have two or more positive movement control impairment tests or had SLR under 50 degrees or had positive sacroiliac joint provocation tests.

TABLE 5. The reasons for exclusion in the first examination stage (N=129).

- Patients were at the acute stage of their LBP 19 (14.7%)
- Patients were at the chronic stage of their LBP 86 (66.8%)
- Patients had too low score (0-4) in RMDQ 87 (67.4%)
- Patients had too high score (over 38) in TSK 39 (30.2%)
- Patients had too high score (over 12) in DEPS 12 (9.3%)
- Patients had too high score (over 80) in MCAQ 23 (17.8%)

After randomization, 35 patients were assigned to the specific movement control exercise group and 35 patients to the general exercise group. Sixty-four subjects (SMCE n= 31 and general exercises n= 33) concluded their three-month interventions, resulting in a drop-out rate 8.6 %. Drop-outs were caused by: prolapsed disc during the intervention period (2); lack of motivation (2); serious acute illness of a subject’s child (1); and radical change in work duties (1). In the baseline characteristics, the two groups were comparable. (Table 6).
Students t-test (absolute change scores) for parametric and the Mann Whitney U test for non-parametric distribution. The Numbers Needed to Treat (NNT) was calculated based on the absolute risk reduction for a change in disability. The reduction of 50 per cent in RMDQ was chosen because of the sub-acute stage and its possible spontaneous recovery (36). An Intention-to-Treat Analyses: Missing data for this analysis were replaced by the each group’s mean value.

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<table>
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<tr>
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<table>
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<tr>
<th>TABLE 6</th>
<th>Comparability of the treatment groups at baseline. (RMDQ is roland-morris score, ODI is oswestry disability index and MC is movement control).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Movement Control Group n=35</td>
<td>General Exercises Group n=35</td>
</tr>
<tr>
<td>Sex female</td>
<td>20 (57.1%)</td>
</tr>
<tr>
<td>Height</td>
<td>172 (12)</td>
</tr>
<tr>
<td>Weight</td>
<td>78 (18)</td>
</tr>
<tr>
<td>Age</td>
<td>51 (11)</td>
</tr>
<tr>
<td>RMDQ baseline</td>
<td>8,3 (3,2)</td>
</tr>
<tr>
<td>PSFS baseline</td>
<td>13,9 (5,0)</td>
</tr>
<tr>
<td>ODI baseline</td>
<td>22,5 (7,3)</td>
</tr>
<tr>
<td>MC tests baseline</td>
<td>3,0 (0,6)</td>
</tr>
</tbody>
</table>

Sixty-one subjects (SMCE n= 30 and general exercises n= 31) attended the twelve-month follow-up measurement, resulting in a final drop-out rate of 12.9 %. (Figure 17)
6.3.2 Main outcome measure
The data were normally distributed and, therefore, parametric tests were used.

Three-month results:
In the between-group comparison, the mean change in the RMDQ from baseline to the three-month measurement showed a significantly superior improvement for the SMCE group; (p<0.01) -1.9 (95% CI -4.5 to -1.1) (Table 7 and figure 18). Categorical data analysis showed that 87.1% (27 out of 31) of the SMCE group and 54.5% (18 out of 33) of the general exercise group reduced their disability (measured with RMDQ) by more than 50%. The NNT was 3 for the SMCE.
Figure 17. The flow chart of the participants through the evaluation process, intervention and measurements. RMDQ is Roland-Morris Disability Questionnaire, TSK is Tampa Scale for Kinesiophobia, DEPS is Depression scale, MCAQ is Motor Control Abilities Questionnaire, MCI is Movement Control Impairment, SLR is Straight Leg Raise and SMCE is Specific Movement Control Exercises group.

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<table>
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<th>Mean change in score (95% CI)</th>
<th>Between group difference (95% CI)</th>
<th>p</th>
<th>Mean scores (95% CI)</th>
<th></th>
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<tr>
<td></td>
<td>SMCE (n=31)</td>
<td>General Exercises</td>
<td></td>
<td>SMCE (n=31) Baseline</td>
<td></td>
<td>SMCE three months</td>
<td>General Exercises</td>
<td></td>
<td>General Exercises three months</td>
</tr>
<tr>
<td>RMDQ</td>
<td>-6.5 (-7.9 to -5.0)</td>
<td>4.6 (-4.7 to -2.6)</td>
<td>-1.9 (-4.5 to -1.1)</td>
<td>&lt;0.01</td>
<td>8.3 (7.1 to 9.4)</td>
<td>1.8 (1.2 to 2.5)</td>
<td>7.5 (6.4 to 8.6)</td>
<td>3.4 (2.4 to 4.4)</td>
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<tr>
<td>PSFS</td>
<td>8.0 (5.1 to 9.3)</td>
<td>5.3 (3.2 to 6.7)</td>
<td>2.7 (0.4 to 5.9)</td>
<td>0.15</td>
<td>13.9 (12.1 to 15.6)</td>
<td>21.9 (20.3 to 23.4)</td>
<td>15.0 (13.5 to 16.4)</td>
<td>20.3 (18.9 to 21.7)</td>
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<tr>
<td>ODI</td>
<td>-13.2 (-15.2 to -9.3)</td>
<td>10.5 (-13.6 to -7.0)</td>
<td>-2.7 (-6.3 to -2.3)</td>
<td>0.35</td>
<td>22.5 (20.0 to 25.0)</td>
<td>9.3 (6.9 to 11.6)</td>
<td>24.4 (21.7 to 27.2)</td>
<td>13.9 (10.3 to 17.5)</td>
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</tr>
</tbody>
</table>

RMDQ is Roland-Morris Disability Questionnaire, PSFS is Patient-Specific Functional Scale and ODI is Oswestry Disability Index.

At the twelve-month follow-up, the between-group difference measured by the mean change in the RMDQ from baseline to the twelve-month measurement showed a significantly superior improvement for the SMCE group; (p<0.01) -1.7 (95% CI -3.9 to -0.5) (Table 8). Categorical data analysis showed that 93.3% (28 out of 30) of the SMCE group and 77.4% (24 out of 31) of the general exercise group reduced their disability (measured with RMDQ) more than 50%. The NNT was 6 for SMCE.

<table>
<thead>
<tr>
<th></th>
<th>Mean change in score (95% CI)</th>
<th>Between group difference (95% CI)</th>
<th>p</th>
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<th></th>
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<td>SMCE (n=30)</td>
<td>General Exercises</td>
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<td>SMCE (n=30) Baseline</td>
<td></td>
<td>SMCE twelve months</td>
<td>General Exercises</td>
<td></td>
<td>General Exercises twelve months</td>
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<td>RMDQ</td>
<td>-6.9 (-8.4 to -5.4)</td>
<td>5.2 (-5.6 to -3.9)</td>
<td>-1.7 (-3.9 to -0.5)</td>
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<td>ODI</td>
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TABLE 7. Mean Change (SD) in disability and function at three month for treatment groups.

TABLE 8. Mean Change (SD) in disability and function at twelve month follow-up for treatment groups.
6.3.2 Secondary outcome measures

The secondary outcome measures PSFS and ODI demonstrated that both groups significantly improved but that there was no statistical difference between the groups in the measurements at three months. At the twelve-month follow-up SMCE showed a significantly better result in the self-reported function (measured with PSFS) (table 8). The average (standard deviation, sd) amount of positive movement control tests at baseline were 3.0 (0.6) in the SMCE group and 2.8 (0.8) in the general exercise group. At the three-month measurement the number of positive tests were 0.8 (sd 0.8) and 1.8 (sd 1.2), respectively. The scores 0 and 1 are considered as normal values. Within the inclusion criteria of this trial subjects had to have at least two (2 out of 6) positive tests. At the three-month measurement 83.9 % of subjects in the SMCE group had a normal result (0 or 1) compared to 45.5 % of subjects in the general exercise group. The NNT was 3 (2.6) in favor of the SMCE group.

The need for pain medication at the twelve-month measurement was statistically significantly lower in favor of the SMCE group. There was no statistically significant difference between the groups in need for other treatment modalities, the quantity of absence from work or patient satisfaction.
6.4 DISCUSSION

The aim of this study was to compare the effect of individually tailored SMCE combined with manual therapy to combined general exercise and manual therapy on disability reduction. This was following sub-classification for MCI of patients with recurrent sub-acute NSLBP. The findings suggest that both interventions reduce disability and improve function. However, patients undergoing a combination of specific exercises and manual therapy had a significantly greater reduction in disability (as measured by the RMDQ) at both the three-month and twelve-month measurements. The effect size of SMCE in our study was 0.77, which is favorable compared to studies with heterogeneous patients (1;2). There was a significant change in self-reported function between the groups in favor of SMCE at the twelve-month follow-up, but not at three months after intervention.

This was a level 1 clinical trial. The RMDQ and the ODI significantly improved in both groups but there were no statistical difference between the groups as measured with the ODI. This may be because the RMDQ has been shown to be more sensitive for patients with mild to moderate disability while the ODI is more effective for persistent, severe disability (150). The disability was less than moderate in this trial, hence the statistically different results. The effect on the RMDQ did not reach the threshold of clinical importance of three points difference, but was still statistically significant. It has to be acknowledged, that the difference found in this study may not be clinical important.

Patients in both groups improved significantly. At twelve months 93% of patients in the SMCE group and 77% in the general exercise group improved more than 50% on the RMDQ. This finding underlines and strengthens the earlier findings on LBP that exercises are an effective intervention. Whether there is a specific sub-group within these patients with MCI who benefit more from specific treatment needs to be further investigated. We did not calculate cost-effectiveness of the study intervention, but it should be noted that the patients had only five sessions of therapy and showed these promising effects within a year. 66.7 per cent of the SMCE group and 60.0 per cent of the general exercises group had conducted their exercises less than planned. Thus, one year after randomisation, approximately one third of the patients in both groups reported that they still did their exercises in accordance with the recommended three times per week or daily. This result has to be interpreted with caution because at the last session of intervention the treating PT gave the subjects UKK Institute’s Weekly Physical Activity Pie. In practice, participants were instructed to undertake two cardiovascular exercises in a week in addition to the intervention-based exercises. Some of the subjects may have answered this question according to total amount of weekly exercises and the others from the perspective of intervention-based exercises only. The question should have had a more specific wording (e.g. “Have you done the exercises your physical therapist taught you during treatment session?”).

A similar sub-classification study compared cognitive functional therapy with combined traditional manual therapy and general exercise in chronic NSLBP (15) and produced superior outcomes for the specific therapy. While a direct comparison to this study is difficult both
control groups included different types of motor control exercises, and the specific intervention of cognitively altering movement patterns was shown to be superior. An almost identical study on sub-acute and chronic LBP but conducted in a multicenter setting, found no additional benefit of specific exercises targeting MCI compared with general exercises (151). Key differences to the current study were that they did not use the MCAQ (141) to exclude patients with motor learning difficulties and they excluded patients with high psychosocial risk factors (measured with Örebro questionnaire). These factors could explain the difference in the results between these two studies. This study is one of the first studies to show that one specific type of exercise may be more beneficial than general exercise in patients with sub-acute NSLBP. In patients with chronic low back pain a similar intervention was superior compared to a strengthening program for function (16). Exercise therapy is recommended in various guidelines (4-7), but it is not clear if one exercise type is superior. Findings of the current study may start a discussion both for guidelines and policymakers, because general exercise is currently the most common recommendation contained in the guidelines.

The heterogeneity of patients with NSLBP has been a challenging issue, with the sub-grouping of patients declared to be one of the main focus areas of research. The MCI is a clear sub-group of non-specific low back pain. Pathokinesiological movement patterns in the lumbar spine have been investigated and described (71-75;78)]. A significant difference between subjects with and without LBP in the ability to actively control the movements of the low back has been demonstrated by Luomajoki et al. (2008) (81). The reliability of tests to diagnose MCI has been shown to be acceptable in several studies (23;85-86). The participants in this trial are not a unique population, which contributes to the external validity. A sub-classification of MCI in NSLBP patients indicates that the findings of this trial can confidently be applied to similar populations. However, it should also be acknowledged that a large proportion of people had to be screened to be eligible. The inclusion criteria were designed to exclude patients with fear-avoidance, depression, poor ability to learn the exercises, and those patients predominantly with MCI. According to a systematic review, there is cautious evidence to support the notion that treatment targeted at sub-groups of patients with NSLBP may improve patient outcomes (12). A recent paper recommended SMCE for LBP patients with moderate pain and disability status (152).

This study has several limitations. The study was registered retrospectively. The subjects and clinicians could not be blinded to the intervention. However, there is no accepted standard therapy for any type of NSLBP or it was unknown which therapy would be better. This may help to reduce the performance bias. In addition, the sitting, four-point kneeling and standing exercises were to be performed by patients in the SMCE group once or twice daily. This frequency is higher than that for the home exercise program of the general exercise group and could potentially be an alternative explanation for the reported effect. The general exercise group included a group of core stability exercises (core stiffness exercises), which involved an element of spinal control. This means that both groups received interventions that were attempting to cognitively control the position of the spine, although they also had fundamental differences in their application and potential benefits. This was a level 1 clinical trial. With a sub-acute study group it is possible some of the patients may have spontaneously recovered. Therefore the results have to be interpreted cautiously with the small sample size used. The ITT
method used in this trial was to replace the missing values with the mean values of each group. When drop-out rates are less than 20% (which is the case in our study) this method keeps statistical power at higher levels compared to the last-observation-carried-forward method (153). The mean changes of control group may have been a more valid method. Additionally, longer follow-up is needed to evaluate the sustainability of the treatment effect. Another limitation of this study is that no information on pain intensity levels in the groups was measured. It has to be acknowledged that there is no data available that shows MCI is a treatment effect modifier. More research of the causality of control impairment and disability is needed.

As discussed in the protocol (146) there are several aspects of the study which influence the external validity. These include: the skills of the treating physical therapist, the number of sessions used (five), and the time spent with each patient (forty-five minutes). As well, since there are many other exercises that could be considered as general exercise, it is unknown whether SMCE would show the same benefit when compared to other types of general exercise. Further, the data should not be used to make inferences about the effectiveness of other types of interventions compared to SMCE. Ideally, to be able to recommend a specific intervention for one sub-group of patients we would also need to know the effectiveness of the same intervention on those who do not belong to this sub-group. Further research of this kind of study design is recommended.

6.5 CONCLUSIONS

Although the result did not reach the clinically significant three points difference this study suggests that a combination of SMCE and manual therapy may be more effective in reducing disability and improving function than combined general exercise and manual therapy in subjects with non-specific recurrent sub-acute LBP and MCI.
General discussion

7.1 ROLE OF THE PATIENT-SPECIFIC FUNCTIONAL SCALE

Increasing emphasis has been placed on evidence-based practice in physiotherapy, leading to the need for specific, valid, reliable, and sensitive outcome measures. These measures are used to assess the change in a patient's condition and subsequently monitor the benefits achieved by a treatment plan. Traditionally, physiotherapists have relied on physical impairment measures, such as joint range of motion or muscle strength, to monitor the progress of a patient's rehabilitation. Current outcome measures may not adequately capture the specific problems and consequences that patients describe, and there is sometimes a discrepancy between patients' scores and their feedback. Important domains in LBP, such as functioning and disability, are implicitly defined based on the content of the different instruments used in different studies (89-93). In addition to research applications, health care professionals require appropriate measures that are feasible for use in clinical practice. Disability and functioning are core issues in the assessment and treatment of patients with LBP, and items comprising outcome measures must reflect these important domains. In order to assess the impact of a given condition on a patient's ability to achieve their desired activities in their particular environment, outcome measures have moved towards functional limitations. Consequently, a wide range of different outcome measures have been assessed and validated (96). The PSFS was developed to provide a method for eliciting, measuring, and recording descriptions of patients' disabilities (101). The results can be used to guide treatment and assess patient outcomes. The PSFS intended to complement the findings of generic or condition-specific measures. The shortcoming of such measures is that they are limited in detecting small, but important, disabilities and changes in disability over time (101). When put in the framework of ICF domains, the activity component is most commonly represented by patient-nominated PSFS items, the participation component moderately represented, and impairment least represented. Thus, the PSFS would complement impairment-based clinical outcome measures (116). The PSFS focuses on the patient's opinion of their function and requires the physiotherapist to ask the patient to list three activities that are limited by the condition for which they are seeking treatment. The overall PSFS score is an average of all three activity scores. As the PSFS score is patient-specific, it addresses issues that may often be missed in other outcome measures with set content. The PSFS relies on subjective data without fixed content, which has raised questions regarding the meaning of a mean score or comparisons of scores across different patients. Consequently, the PSFS is not used as an absolute measure of disability, but as a measure to assess change over time, giving weight to absolute and relative changes from baseline (101).
7 General discussion

7.1 ROLE OF THE PATIENT-SPECIFIC FUNCTIONAL SCALE

Increasing emphasis has been placed on evidence-based practice in physiotherapy, leading to the need for specific, valid, reliable, and sensitive outcome measures. These measures are used to assess the change in a patient’s condition and subsequently monitor the benefits achieved by a treatment plan. Traditionally, physiotherapists have relied on physical impairment measures, such as joint range of motion or muscle strength, to monitor the progress of a patient’s rehabilitation. Current outcome measures may not adequately capture the specific problems and consequences that patients describe, and there is sometimes a discrepancy between patients’ scores and their feedback. Important domains in LBP, such as functioning and disability, are implicitly defined based on the content of the different instruments used in different studies (89-93). In addition to research applications, health care professionals require appropriate measures that are feasible for use in clinical practice. Disability and functioning are core issues in the assessment and treatment of patients with LBP, and items comprising outcome measures must reflect these important domains. In order to assess the impact of a given condition on a patient’s ability to achieve their desired activities in their particular environment, outcome measures have moved towards functional limitations. Consequently, a wide range of different outcome measures have been assessed and validated (96).

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RCTs usually report the significance of changes in scores from outcome measures, reflecting both the magnitude and variability of the treatment effects, as well as the sample size. Significance does not indicate the proportion of individuals in the treatment group who achieved a MCIC from the treatment intervention. The MCIC of the PSFS has been evaluated for certain conditions and found to be 3 for LBP, one point per question (113). The increasing use of the PSFS in research as a tool for assessing the efficacy of treatments demonstrates the scale’s growing popularity (117-123).

Our first goal in this study was to adapt the questionnaire following the recommendations from the guidelines for the process of cross-cultural adaptation of self-reported measures. We followed the procedure exactly as the Brazilian-Portuguese validation research group did previously (112). To conclude the procedure, no difficulties with the linguistic items were found. Volunteers from two different provinces read the questionnaire through. Despite different dialects in different provinces in Finland, it is safe to assume that the entire population can understand the written standard language in this short questionnaire. The expert team had the same opinion of the wording on the translated form of the questionnaire as the professional translator.

To the best of our knowledge, no previous studies have validated the PSFS in the Finnish language. Our results show that the Finnish translation of the PSFS questionnaire performs as the original, has adequate content validity and responsiveness, and can be recommended as the assessment tool for clinical and research use. The results of our study are in line with the literature review of previous validation studies (108-114). After the publication of this result in 2013, the Finnish version of the PSFS has become a clinical assessment tool in various clinics all over Finland, and many students have used the PSFS as an outcome measure in their theses.

### 7.2 Impact of Subclassification of the Subjects in LBP Intervention

The main finding of our study was that both general exercises and SMCEs combined with manual therapy are effective in reducing disability and improving function following the intervention period in subjects with non-specific recurrent subacute LBP and MCI. In the subacute study group, it is possible that some of the patients may have spontaneously recovered (36). Therefore, the results have to be interpreted cautiously with the small sample size used. One possibility for the study design could have been a control group without any therapeutic intervention. That solution would have led to an ethical consideration; with a 12-month follow-up, patients in this passive group would have had deteriorated physical performance and the current literature shows that this passive way of managing subacute LBP is a risk factor for chronic pain (10).
Physiotherapists use exercise-based interventions in the management of patients with LBP, but effect sizes for exercise treatments of NSLBP are modest (0.07 to 0.61) (63). This result is attributed to a failure to recognize heterogeneity within NSLBP and a failure to individualize treatments. Promising results have emerged when patients and treatments are matched using subgrouping (12,13,15). Another viewpoint is that, although exercise is recognized to be effective in treating subacute LBP and CLBP, which kind of exercise best suits a certain subgroup of LBP patients is unknown.

The results of our study showed an effect size of 0.77 for SMCE. This result was analyzed using the formula \[ d = \frac{\bar{x}_1 - \bar{x}_2}{\sqrt{(\sigma_1^2 + \sigma_2^2)/2}} \] with Cohen’s d. Two main outcome measures, disability measured by the RMDQ and function measured by the PSFS, demonstrated significantly better results in favor of SMCE. The power calculation in this trial was based on three points difference in RMDQ. Another important element of a questionnaire’s responsiveness is the smallest clinically significant effect. Individual authors have suggested that the smallest change likely to be clinically significant is between 2.5 and 5 points. However, this may vary depending on the level of disability among the patients. Stratford et al. (101) suggested that the minimum clinically important change in scores is 1–2 points for patients with little disability, 7–8 points for patients reporting high levels of disability, and 5 points in unselected patients. Patrick et al. (102) suggested 2–3 points as the minimum clinically important difference for a 23-item version of the RMDQ. These are minimum changes in score that should be regarded as clinically significant in individual patients. In this trial, patients in the SMCE group decreased their score by 6.9 points and those in the general exercise group by 5.2 points. The NNT score was 6 in favor of the SMCE group when the threshold was set to a 50% decrease in the RMDQ score between baseline and follow-up. Thus, the present study adds to current knowledge by showing that there is a significant difference between specific and general exercises. However, an almost identical study on subacute LBP and CLBP conducted in a multicenter setting in Switzerland found no additional benefit of specific exercises targeting MCI compared to general exercises (151). The factors explaining this difference should be recognized after post-hoc analyses of both studies. Excluding criteria made little difference; in our study design we excluded volunteers with motor learning difficulties, and in the other study the motor control abilities questionnaire was not used.

For forthcoming studies on NSLBP, the sub-classification of patients using a valid method is strongly recommended.

The study protocol had several limitations. The subjects and clinicians could not be blinded to the intervention. However, since there is no accepted standard therapy for MCI it was unknown which therapy would be more beneficial, which reduced the performance bias. In addition, the SMCE group had higher frequency in their exercises than that for the home exercise program of the general exercise group and could potentially be an alternative explanation for the reported treatment outcome. The general exercise group included a group of core stiffness exercises, which could have had an element of lumbar
control. With a sub-acute study protocol it is possible some of the patients may have spontaneously recovered. Therefore the results have to be interpreted cautiously with the relatively small sample size used. In this study the ITT method involved replacing the missing values with the mean values of each group. Later on the research group was informed of more valid ITT method; The mean changes of control group could have been used instead of the current method (153). Additionally, longer follow-up is needed to evaluate the sustainability of the treatment effect. In fact, the research group has conducted an extra three-year follow-up in September 2016.

As discussed in the protocol (146) there are several aspects of the study which influence the external validity. These include: the skills of the treating physical therapist, the number of sessions used (five), and the time spent with each patient (forty-five minutes). After this trial it is unknown whether SMCE would show the same benefit when compared to some other general exercise, yoga or pilates for example. Ideally, to be able to recommend a specific intervention for one sub-group of patients the effectiveness of the same intervention should be tested on those patients who do not belong to this sub-group. Further research of this kind of study design is recommended.

### 7.3 MOVEMENT CONTROL IMPAIRMENT AMONG LBP PATIENTS

This study points out that there are effective methods for treating disability and self-reported functional limitations caused by MCI. Impairments or coordination impairments have been shown to have a causal effect on LBP. The results of a recent observational, cross-sectional study indicate the changes in movement control in people suffering from LBP (154). Whether recurrence and determinism of lumbar movement patterns strengthen LBP intensity or are a consequence of increased LBP intensity should be addressed in a future prospective study. Three RCTs have reported positive outcomes for patients with CLBP when movement patterns are cognitively altered or controlled (14-16). The application of rehabilitation concepts from CLBP to recurrent subacute NSLBP, as in this study, has face validity; altered movement control may occur at any stage of rehabilitation for LBP (acute, subacute, or chronic).

However, there is no gold standard for movement control. The diagnostic accuracy of MCI tests needs to be addressed in larger cohorts and values established for the normal population and LBP patients. Especially important are the cut-off points between subjects with and without LBP, taking into account age, level of physical activity, degree of impairment, and participation in sports. In addition, a recent longitudinal cohort study claimed that an active life resulting in higher physical fitness is related to better spinal control in middle-aged men and women (82). Thus, altered spinal control is linked to pain and, maybe even more so, to the level of physical activity. These conclusions challenge future studies concerning the cause-effect relationship of MCI in the lower back.
Exercise therapy is a central component in the management of subacute NSLBP, but in practice a biomedical approach has been established mainly to improve physical fitness and may work as an obstacle to enhance the long-term effects of LBP. The results of our study underline the efficacy of exercise and point out that the control of movement is very important.

In this trial, participants were taught the SMCEs and advised on the intensity at which they should exercise. The exercises were performed under the supervision of a physical therapist. The intensity of the exercises was similar to that of general exercise (i.e., the typical individual exercise program was three sets of 15 repetitions). In addition, movement control was taught in the positions of sitting, four-point kneeling, and standing according to the decision of the physical therapist. The intensity of the exercises progressed over five treatments, with participants being encouraged to improve their own performance. According to the current theory, the main difference between these two exercise groups was individual sensorimotor and cognitive learning of the exercise. Specific control requires the participant to be constantly aware of the position of the lumbar spine to maintain the precision required throughout the exercise. This can be reflected through proprioception and general body awareness. Two key features make specific exercise fundamentally different from general exercise: the level of sensorimotor function and neurocognitive function required to continuously monitor the precision of the lumbar spine position for constant control and the maintenance of accuracy throughout the movement (142). Furthermore, the exercise approach specifically targets a direction of trunk movement in which the lack of control is thought to be the underlying mechanism contributing to the patient’s LBP (142). In general exercises the focus is mainly muscle-centric (42).

The benefits of SMCEs in this trial included decreased disability, improved self-reported problematic function, and improved movement control of the lumbar spine compared to general exercises. In addition, patients who performed SMCEs reported significantly less need for pain medication. Post hoc analyses will reveal the possible subgroups of patients who benefit more from specific exercises than general exercises. Many of the secondary outcomes were equal, e.g., there was no significant differences with the need for other treatment modalities, sick leave, or patient satisfaction with treatment. Adherence, the percent of subjects who did their home exercises, was also equal between the two treatment groups. Adherence in this trial was in line with previous trials on managing LBP with home exercises (151,155).

When evaluated by effect size analyses, the results of both treatment groups were much more effective than previously described for the management of subacute LBP and CLBP, and SMCEs especially exhibited good effectiveness. Comparison to acute LBP is not essential, as exercise therapy is not recommended as a treatment modality for the management of acute LBP.
However, the growing empirical evidence of the importance of psychosocial factors in the development of CLBP is addressed and highlighted in the research field and clinical practice. Subacute LBP is a crucial point at which to change the direction of patient outcomes. The weak relationship between changes in physical function measures in LBP after exercise therapy requires a behavioral approach. One of the key factors is spine movement control.

Conclusions

I The Finnish translation of the Patient-Specific Functional Scale questionnaire performs as the original, is proven to have adequate content validity and responsiveness and could be recommended as the assessment tool for clinical and research use.

II Both general exercise and specific movement control exercise, combined with manual therapy, are effective in reducing disability and improving function following the intervention period in subjects with non-specific recurrent sub-acute low back pain and movement control impairment.

III This study suggests that a combination of specific movement control exercise and manual therapy is likely to be more effective in reducing disability and improving function than combined general exercise and manual therapy.
8 Conclusions

I

The Finnish translation of the Patient-Specific Functional Scale questionnaire performs as the original, is proven to have adequate content validity and responsiveness and could be recommended as the assessment tool for clinical and research use.

II

Both general exercise and specific movement control exercise, combined with manual therapy, are effective in reducing disability and improving function following the intervention period in subjects with non-specific recurrent sub-acute low back pain and movement control impairment.

III

This study suggests that a combination of specific movement control exercise and manual therapy is likely to be more effective in reducing disability and improving function than combined general exercise and manual therapy.
References


9 References


Development of a reliable and sensitive measure of disability in low back pain.


Appendix 1. The Patient-Specific Functional Scale in Finnish language.

Potilaskohtainen toiminnallinen asteikko (PTA)

Nimi _____________________________________________ Päiväys ____________________

Mutkä ovat 3 toimintoa elämässäsi, joita et pysty tekemään tai joissa sinulla on eniten vaikeuksia pääasiallisen ongelmasi seurauksena.

Luettele 3 toimintoa

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Allekirjoitus ja päiväys
Appendix 1. The Patient-Specific Functional Scale in Finnish language.

Potilaskohtainen toiminnallinen asteikko (PTA)

Nimi _____________________________________________ Päiväys ____________________

Mitkä ovat 3 toimintoa elämässäsi, joita et pysty tekemään tai joissa sinulla on eniten vaikeuksia pääasiallisen ongelmasi se urauksena.

Luettele 3 toimintoa

1. ___________________________________________________________________
2. ___________________________________________________________________
3. ___________________________________________________________________

Ole hyvä ja pisteytä jokainen 3 toiminnosta

Ole hyvä ja ympyröi YKSI numero kutakin toimintoa kohden, joka on tarkin vastaus

Toiminto # 1

0          1          2          3          4          5          6          7          8          9          10

Kykenemätön                Kykenee suorittamaan
suorittamaan                 toiminnon samalla
toimintoa                tasolla kuin ennen
vammaa tai ongelmaa

Toiminto # 2

0          1          2          3          4          5          6          7          8          9          10

Kykenemätön                Kykenee suorittamaan
suorittamaan                 toiminnon samalla
toimintoa                tasolla kuin ennen
vammaa tai ongelmaa

Toiminto # 3

0          1          2          3          4          5          6          7          8          9          10

Kykenemätön                Kykenee suorittamaan
suorittamaan                 toiminnon samalla
toimintoa                tasolla kuin ennen
vammaa tai ongelmaa

________________________________________

Allekirjoitus ja päiväys

Appendix 2. Example of the general exercises program

![General exercises program images]
Appendix 3. Example of the specific movement control exercises program.
Movement Control Impairment is one subgroup of Non-Specific Low Back Pain. In this PhD thesis the efficacy of two different exercise methods is throughout investigated in order to find out which method is more efficient in improving disability and patient-specific functional limitations caused by Movement Control Impairment. The patients are in sub-acute stage of their Low Back Pain.