

Sinikka Kilpikoski

The McKenzie Method in Assessing,  
Classifying and Treating Non-  
Specific Low Back Pain in Adults  
with Special Reference to the  
Centralization Phenomenon



STUDIES IN SPORT, PHYSICAL EDUCATION AND HEALTH 158

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# The McKenzie Method in Assessing, Classifying and Treating Non-Specific Low Back Pain in Adults with Special Reference to the Centralization Phenomenon

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*To Matti, Inna, Jonne and Juuso*

*"Every patient contains the  
truth." James Cyriax*

## ABSTRACT

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The McKenzie method in assessing, classifying and treating non-specific low back pain in adults with special reference to the centralization phenomenon.

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Finnish summary.

Diss.

In the McKenzie method of mechanical diagnosis and therapy clinical presentations are classified into mechanical syndromes based on patients' symptom response to standardized loading strategies. Pain centralization is a specific finding as a response to the loading when assessing patients with low back pain (LBP).

The aims of this study among Finnish adults (mean age 42 years, N= 173) with non-specific LBP were: (1) to assess inter-examiner agreement and reliability in classifying the subjects according to the McKenzie method with variability expressed by the kappa coefficient, and observed agreement; (2) to estimate utilizing magnetic resonance imaging (MRI) the association, expressed by sensitivity, specificity, positive and negative predictive values, likelihood ratios and diagnostic confidence value between pain centralization and lumbar disc morphology; (3) to compare treatment outcomes in subjects allocated randomly into orthopaedic manual therapy (OMT), McKenzie or "advice only" interventions with one-year follow-up; (4) to compare those with centralizing LBP treated by OMT, McKenzie or "advice only"; and (5) to investigate if centralization defined on the initial visit predicts treatment outcomes. The inclusion criteria of the randomized controlled trial were: male or female age 18 to 65 years, acute (more than seven days from onset) to chronic non-specific LBP with or without radiation to the lower limb(s). Exclusion criteria were pregnancy, serious pathology ("red flags") and back surgery within the past two months. Back and leg pain were assessed by the Visual Analogue Scale, disability with the Roland-Morris questionnaire and functional status with 7 daily activities on a 0-to 4-point scale at baseline, immediately after a treatment period, and at follow-up points of 3, 6 and 12 months. Intention-to-treat analysis was used. Inter-examiner reliability in sub-grouping patients according to the McKenzie classification was good. MRI showed that pain centralization was associated with abnormalities of lumbar discs. OMT and McKenzie seemed to be only marginally more effective in treating non-specific LBP compared to the one-session "advice only" treatment. However, those with centralizing LBP treated by McKenzie showed better and longer lasting recovery of symptoms compared with centralizers in the "advice only"-group. Furthermore, adults with centralizing LBP on the initial visit showed a tendency to better recovery of symptoms than those without, independently of the treatment used. To conclude, promising results were obtained for the McKenzie method in the pre-treatment assessment, classification and treatment of non-specific LBP in working-age adults. However, only tendency was found for better and longer lasting recovery among the sub-group of centralizers treated by the McKenzie method.

**Keywords:** McKenzie method, centralization phenomenon, low back pain, orthopaedic manual therapy, randomized controlled trial, MRI, reliability.

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Vaajakoski, 27<sup>th</sup> September 2010      Sinikka Kilpikoski

## LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following articles and manuscript, which will be referred to in the text by Roman numerals I-V:

- I Kilpikoski S, Airaksinen O, Kankaanpää M, Leminen P, Videman T, Alèn M: Inter-examiner reliability of low back pain assessment using the McKenzie method. *Spine* 2002;8:E207-14.
- II Kilpikoski S, Laslett M, Kankaanpää M, Airaksinen O, Alèn M: Pain centralization and lumbar disc MRI findings in chronic low back pain patients. Submitted.
- III Paatelma M, Kilpikoski S, Simonen R, Heinonen A, Alèn M, Videman T: Orthopaedic manual therapy, McKenzie method or advice only for low back pain in working adults: A randomized controlled trial with one year follow-up. *J Rehabil Med* 2008;40:858-63.\*
- IV Kilpikoski S, Alèn M, Paatelma M, Simonen R, Heinonen A, Videman T: Outcome comparison among working adults with centralizing low back pain: Secondary analysis of a randomized controlled trial with 1-year follow-up. *Adv Phys* 2009;11:210-17.
- V Kilpikoski S, Alèn M, Simonen R, Heinonen A, Videman T: Kann zentralisierender Schmerz bei der Erstuntersuchung den Behandlungserfolg bei Erwachsenen mit LWS-Beschwerden vorhersagen? Sekundäre Analyse einer randomisierten kontrollierten Studie mit 1-jährigem Follow-up. *Man Therapie* 2010;14:136-41.

In addition, unpublished data are presented.

\* The first two authors Paatelma M and Kilpikoski S had equal contribution.

## ABBREVIATIONS

ADL-index	Activities of daily living index
“Advice only”	Oral and written advice for LBP patient to stay physically active
ANOVA	Analysis of variance
CI	Confidence Interval
CLBP	Chronic low back pain
CT	Computed tomography
DP	Directional preference
IASP	International association for the study of pain
ICF	International classification of functioning, disability and health
ICD	International classification of diseases and related health problems
ITT -analysis	Intention-to-treat-analysis
$\kappa$	Kappa coefficient
LBP	Low back pain
MDT	Mechanical diagnosis and therapy
MRI	Magnetic resonance imaging
NSAIDs	Non-steroid anti-inflammatory drugs
OMT	Orthopaedic manual therapy
RMQ	Roland-Morris disability index
RCT	Randomized controlled trial
SD	Standard deviation
VAS	Visual analogue scale

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ABSTRACT

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# 1 INTRODUCTION

Low back pain (LBP) is one of the most common conditions that impair individuals' functional capacity in activities of daily living and at work, as well as their general health and quality of life. The high prevalence of back pain in the industrial countries is well known (Hestbaek et al. 2003). Approximately 80% of the population experience spinal pain at some point in life (Ijzelenberg and Burdorf 2005). In the Finnish population the life-time prevalence of LBP is approximately 76% irrespective of gender. Even in the youngest age-group (18 to 24 years) two-thirds of respondents reported suffering back pain at some time during their lives. The prevalence of back pain experienced during the past month was 28% in men and 33% in women (age-adjusted, 18+years) (Heistaro et al. 2007).

Low back trouble may radiate to the lower limb(s). The prevalence of leg pain, as a referred symptom associated with back pain, has been shown to be approximately 35%, while true prevalence of sciatica is 2 - 5% (Nachemson 2000). In the Finnish population the life-time cumulative occurrence of sciatic pain was 30% in men and 40% in women (Heistaro et al. 2007).

LBP is one of the commonest causes of disability in the working population. Self-rated disability at work was strongly associated with the presence of musculoskeletal disorders or other musculoskeletal diseases (Kaila-Kangas et al. 2007). Employees who are unable to work due to back pain spend a significant amount of time on sick leave, which impacts on productivity in the work place (Johanning 2000). Back pain caused loss of working time of 2% per month, 10% per year and 25-30% over the adult working years (Walsh et al. 1992).

In Finland, back problems are the most common reason for absence from work for men and the second-most common for women (Kaila-Kangas et al. 2007).

The costs to the national economy arising from back problems were € 400 million in disability pensions and € 93.5 million in sick leave (Kaila-Kangas et al. 2007). Although most episodes of back pain are considered mild in nature and usually resolve without medical intervention (Cassidy et al. 2005), the costs

for those who seek care are enormous. It has been shown that the minority of back pain sufferers use the majority of the resources earmarked for back pain management (Engel et al. 1996). Twenty percent of all people with back pain seek medical care (Ijzelenberg and Burdorf 2005) and up to 25% of this group of patients seek physical therapy services (Harreby et al. 1997).

Diagnosis is the foundation of management and is based on clinical assessment; however, a specific diagnosis has been shown to be possible in only 10-15% of cases (Spitzer et al. 1987, Nachemson 2000). Traditionally, many health providers such as physicians, surgeons, and radiologists use diagnostic codes of the ICD classification (International classification of diseases and related health, WHO), which is based on pathoanatomical structures and functional tests. The use of more specific differential diagnosis with the combination of radiological signs (CT, MRI, X -ray) and invasive methods (electromyography, contrast medium radiography, injections), has been suggested (Aprill and Bogduk 1992, Schellhas et al. 1996, Ito et al. 1998, Marras et al. 2001). However, diagnostic tools, such as imaging are mostly expensive and are neither available nor helpful to physical therapists in forming clinical decisions, as they can give confounding and inconclusive results (Videman et al. 2003).

It has been assumed that the large heterogeneous group of non-specific LBP patients would be treated more effectively if they could be assigned to more homogenous subgroups on the basis of valid criteria (Spitzer et al. 1987, Leboeuf-Yde et al. 1997, Borkan et al. 1998, Bouter et al. 1998). While many systems have been proposed for the classification and treatment of LBP (McKenzie 1981, Spizer et al. 1987, Delitto et al. 1995, Maluf et al. 2000, O'Sullivan et al. 2000, Petersen et al. 2003, van Tulder et al. 2004, Airaksinen et al. 2004), only some of them may have clinical value for physical therapists (McKenzie 1981, Delitto et al. 1995, Maluf et al. 2000, O'Sullivan et al. 2000, Petersen et al. 2003), and only a few of them have been investigated for their reliability and validity (Petersen et al. 1999, Fritz et al. 2000, Clare et al. 2003, Clare et al. 2004a, Clare et al. 2005, Fritz et al. 2006, May et al. 2006, Clare et al. 2007). Of these, the McKenzie method has been one of the most widely accepted physical therapy approaches both in the diagnosis and management of LBP in the UK and Ireland (Battie et al. 1994, Foster et al. 1999), and increasingly in Finland. Some of the above mentioned LBP clinical methods (McKenzie 1981, Delitto et al. 1995, Petersen et al. 2003) are based on the use of the centralization phenomenon and "directional preference" loading first designed by McKenzie (1981).

The present clinical report is a combination of a literature review and a critical summary of the five original articles focusing on the assessment, classification and treatment of non-specific LBP using the McKenzie method.



## 2 REVIEW OF THE LITERATURE

### 2.1 Low back pain

#### *Pain*

Pain is a normal protection mechanism and physiological reaction of the body to a dangerous stimulus and the main presenting symptom of patients with low back trouble. Although the symptoms of “pins and needles”, numbness, weakness, stiffness and instability are common, the most important symptom is pain. Pain is a complex experience which has sensory, affective, evaluative, cognitive and behavioural dimensions. Pain has been defined by the International Association for the Study of Pain (IASP) as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (Merskey and Bogduk 1994).

#### *Disability*

LBP is one of the commonest causes of disability in the working population. Disability due to LBP has been defined as restricted functioning, involving limitation of activities and restriction of participation in life situations. Disability often accompanies LBP, varies in extent and may be temporary or even permanent (Waddell 2004). In the International classification of functioning, disability and health (ICF), the emphasis was changed to activity and activity limitation meaning difficulty in the performance, accomplishment, or completion of an activity. Difficulties in performing activities occur when there is a qualitative or quantitative alteration in the way in which activities are carried out. Difficulty encompasses all the ways in which the doing of the activity may be affected (WHO 2001). It is widely accepted that LBP and disability can only be understood and managed in the light of a bio-psycho-social model (i.e. a model which includes physical, psychological and social elements), which describes the key psychological and behavioural factors that

may help to understand current levels of pain and disability (Waddell 1987, Turk et al. 1988). Such a model is one of human illness, rather than of disease or pain. Pain is both a physical sensation and an emotional experience. Illness behaviour and the sick-role reflect psychological events, but are also social events. These various elements not only interact, they develop together over the time-course of the illness (Waddell 1987, Turk et al. 1988).

#### *Anatomical site of low back pain*

LBP can be defined as specific pain of known origin or as non-specific pain of imprecisely known origin. Specific LBP may arise from either the lumbar or sacral spinal areas or from a combination of both. 'Lumbar spinal pain' has been defined as pain perceived as arising from anatomical areas of the region bounded laterally by the lateral borders of the erector spinae, superiorly by an imaginary transverse line through the T12 spinous process, and inferiorly by a line through the S1 spinous process (Merskey and Bogduk 1994). 'Sacral spinal pain' is defined as pain perceived within a region overlying the sacrum, bounded laterally by imaginary vertical lines through the posterior superior and posterior inferior iliac spines, superiorly by a transverse line through the S1 spinous process, and inferiorly by a transverse line through the posterior sacrococcygial joints (Merskey and Bogduk 1994). LBP is specific if its cause can be shown (e.g. infection, tumour, osteoporosis, ankylosing spondylitis, fracture, inflammatory process, radicular syndrome or cauda equina syndrome), and non-specific LBP if not attributed to recognisable, known specific pathology (van Tulder et al. 2004).

#### *Referred low back pain*

LBP may or may not refer to the lower limb(s) and into the groin or perineum. Referred pain means that the pain experienced in a part of the body by the patient may be situated far away from the diseased or injured area. Pain in the lower limb associated with LBP is either somatic referred pain or radicular pain. Pain extending across a relatively wide region and felt deeply, in a relatively constant or fixed location is somatic referred pain. Pain that travels along the length of the lower limb, along a narrow band, is radicular (sciatic) pain. Pain in the buttock or proximal thigh extending below the knee is not necessarily radicular pain. A patient does not necessarily have to exhibit neurological features to be suffering from radicular pain, but the presence of neurological features (motor weakness, sensory deficit, or numbness) favours the diagnosis of radicular (sciatic) pain. Deep aching pain indicates somatic referred pain. Lancinating or shooting pain is radicular of nature (Merskey and Bogduk 1994).

#### *Duration of low back pain*

Conventionally research protocols have defined low back troubles by duration of pain from the onset of the episode: acute, sub-acute and chronic.

Distinguishing pain on the basis of duration is said to be important, because the biological basis, natural history and response to therapy are different for each category and because persistent pain has strong association with higher levels of disability, psychosocial distress and costs to society (Waddell 2004). Pain is usually transitory, lasting only until the noxious stimulus is removed or the underlying damage or pathology has healed, but some painful conditions may persist for years (Turk and Okifuji 1999). There are differences between the LBP classifications in the definition of duration. According to the IASP, acute pain lasts for less than 3 months while chronic pain persists for longer than 3 months, whereas sub-acute pain lasts more than 6 weeks, but less than 3 months (Merskey and Bogduk 1994). The Quebec Task Force (QTF) report classified the duration of LBP according to tissue healing: acute pain lasts up to 7 days, sub-acute pain more than 7 days, but less than 7 weeks and chronic pain lasts more than 7 weeks (Spitzer et al. 1987). As the key feature of adult back pain has typical lifetime patterns of fluctuating symptoms of varying severity, a patient who suffers recurrent episodes of pain, each of which is separated by a pain-free period of at least 3 months, each new episode satisfies the definition of acute LBP (Bogduk and McGuirk 2002).

However, researchers investigated recently the validity of the distinction between acute and chronic duration of pain in LBP subgroups. They found that patients treated with directional specific exercises reported significant improvement in every outcome measured, independent of LBP duration, although the subjects with acute pain (> 7 days) reported the greatest improvement in pain and disability while in the chronic cases (< 7 weeks) the improvement was somewhat slower (Long et al. 2007).

### **2.1.1 Pain mechanism of low back pain**

There are several ways to categorize pain. It is common to distinguish pain by its aetiology as somatogenic / somatic pain (arising from a perturbation of the body) and psychogenic / idiopathic pain (arising from a perturbation of the mind when a thorough physical examination, imaging and laboratory tests fail to detect the cause of pain, it is assumed to be the product of psychic conflict or psychopathology) (Turk and Okifuji 1999).

#### *Nociceptive pain*

Somatogenic / somatic pain has been divided into nociceptive pain caused by activation of nociceptors and neuropathic pain caused by damage to or malfunctions of the nervous system (Keay et al. 2000). A nociceptor is a sensory receptor that reacts to potentially damaging stimuli by sending nerve signals to the spinal cord and brain (Woolf 1998). Only three mechanisms are known to activate nociceptors: thermal, chemical and mechanical stimulation (Woolf 1998). The latter two are the concern in subjects with LBP and sciatica.

*Chemical nociceptive pain*, which is constant in nature, is produced by irritation of free nerve endings in the presence of certain substances, e.g.,

histamine, serotonin, hydrogen ions, substance P, bradykinin and interleukin(s). These chemicals are released as a result of inflammatory or infective diseases and certain degenerative conditions (Woolf 2009).

*Mechanical nociceptors* respond to excess pressure or mechanical deformation. Thus activity-related pain (mechanical pain) may be produced in the absence of actual tissue damage by excessive mechanical strain or tension upon collagen fibres. The explanation for this is thought to be the result of the deformation of collagen networks so that nerve endings are squeezed between the collagen fibres, with the excessive pressure perceived as pain. No damage to the tissues needs to have occurred, and when the stress is removed the pain abates (Woolf 2009). The duration of mechanical pain might be acute to chronic. The pain is mostly intermittent in nature. There are no drugs available that can inhibit the transduction of mechanical nociceptive pain. It is therefore futile to attempt to treat mechanical nociceptive pain with peripherally-acting drugs. Mechanical transduction can only be treated by correcting the mechanical abnormality triggering nociception (Merskey and Bogduk 1994).

Visceral pain (e.g., because of urinary tract disorders), categorised as somatogenic pain, may also produce and refer pain to the lower back felt in the loin and inguinal region (Bogduk and McGuirk 2002).

#### *Neuropathic pain*

Neuropathic pain is divided into peripheral, originating in the peripheral nervous system and central, originating in the brain or spinal cord (Merskey and Bogduk 1994). Peripheral neuropathic pain (radicular) is often described as “burning”, “tingling”, “electrical stabbing” or “pins and needles” (Paice 2003).

#### *Sources of low back pain*

Any of the structures of the lumbar spine that receives innervations could be a source of LBP. Thus pain could arise from the ligaments, muscles, tendons, fasciae, joints, vertebral bodies, nerves, dura, or discs of the lumbar spine (Bogduk and McGuirk 2002). The leading source of chronic LBP has shown to be discogenic, which accounts for some 39% to 57% of all LBP cases (Schwarzer et al. 1995a, Donelson et al. 1997). In discogenic LBP the inflammatory factors travel into the fissure of the end plate or outer third of the annulus fibrosus and stimulate the pain receptors (nociceptors) (Zhang et al. 2009). An internal disc disruption appears to be the cardinal pathological basis for lumbar discogenic pain; another is discitis, in both cases of which the external contour of the disc is essentially normal, for the pathology lies within the substance of the disc. In patients with lower back and/or limb pain the central posterior annulus of the lumbar disc and posterior longitudinal ligament has been shown to produce central LBP (Kuslich 1991). A prolapsed disc, where the mixture of nuclear and annular material has displaced beyond the normal perimeter of the disc, may be symptomatic if it compromises a spinal nerve-root or its roots, producing sciatic pain. Sciatic radicular (*peripheral neuropathic*) pain is caused by inflammation of

the affected nerve roots, typically in the L4-S2 region, by compression of the dorsal root ganglion or its blood supply, or by microscopic damage to the nerve roots. Burke et al. (2002) found that patients with chronic LBP have significantly higher levels of released inflammatory factors compared to patients with prolapsed discs. Prolapsed discs can be totally asymptomatic (Boden et al. 1990, Jensen et al. 1994).

Although the cardinal complaint in sciatica is pain or/and symptoms in the lower limb with or without LBP, caused by inflammation of the affected nerve roots (Karppinen 2007), full thickness annular tears with or without disc bulging or herniation (= prolapsed disc) may reproduce concordant lower limb pain (sciatica) in patients with chronic LBP. Thus, annulus fibrosus and nucleus pulposus may contribute similarly to the development of sciatica and back pain (Ohnmeiss et al. 1999).

Kuslich (1991) reported that sometimes the "facet" (zygapophysial joint) capsule might be painful referring pain into lower back, very rarely to the buttocks, but never down to the lower limb. LBP caused by the "facet" joint accounts for pain in some 10-15% of younger injured workers, or elderly subjects (Schwarzer et al. 1995b). Sacroiliac-joint accounts for pain in some 20% of patients with low back trouble, but its pathology has remained unknown (Schwarzer et al. 1995c). Spondylolysis, which arises most commonly as a result of fatigue failure of the pars inter-articularis, usually at the level of L4 and L5 following repeated extension or flexion or in twisting movements of the lumbar spine, may cause back pain in athletes. Most often this is asymptomatic, and thus its radiographic presence therefore is not diagnostic of the cause of pain (Spratt et al. 1993, Sales de Gayzy et al. 2000). Degenerative osteophytes (Lee et al. 1988), muscles and nerve roots (Sihvonen 1992) are also capable of producing LBP. In addition, LBP could be produced by aortic atherosclerosis and stenosis of the feeding arteries of the lumbar spine (Kauppila 2009). Furthermore, the "red flags" i.e. fractures, tumours, infectious or metabolic diseases are capable of producing LBP, but are very rare (Bigos et al. 1994, Henschke et al. 2008).

### **2.1.2 Risk factors for low back pain**

There are numerous risk factors assumed to be related to LBP. Epidemiological studies have generally divided these factors into three dimensions: individual and lifestyle factors, physical or biomechanical factors and psychosocial factors (Bombardier et al. 1994, Frank et al. 1996, Ferguson and Marras 1997). Individual factors such as age, gender and anthropometric measures, and muscle strength and flexibility have been considered as possible risk factors for LBP. Hamberg-van Reenen et al. (2007) found strong evidence that there is no relationship between trunk muscle endurance and the risk for LBP. They found inconclusive evidence for relationship between trunk muscle strength or mobility of lumbar spine and the risk for LBP. However, factors related to lifestyle such as smoking and obesity have been shown to be risk factors for LBP (Shiri et al. 2010a, Shiri et al. 2010b). Shiri et al. (2007) also found an

increased risk of lumbar radicular pain (sciatica) among subjects with overweight or long smoking history and high physical activity.

The risk for having a recurrent back pain episode was twice as high once a history of the condition had been established (Hestbaek 2003). The functionally disabling recurrence rate is more than one episode in a year (Heliövaara et al. 1989, Klenerman et al. 1995, van den Hoogen 1997, Linton et al. 1998, Carey et al. 1999, Pengel et al. 2003). A history of previous back pain episodes is said to be more recurrent and persistent in older adults (Leboeuf and Kyvik 1998, Boos et al. 2002, Cassidy et al. 2005) and are more commonly reported by women (Hartvigsen et al. 2004).

Physical and biomechanical factors including postural stresses (high spinal load or awkward postures), whole body vibration, heavy work, frequent lifting and prolonged or repeated bending, driving, sitting and twisting have been considered to be associated with back pain and disc prolapses (Videman et al. 1984, Bombardier et al. 1994, Frank et al. 1996, Ferguson and Marras 1997, Vingard et al. 2000). Hoogendoorn et al. (1999) also found strong evidence for handling manual materials, bending, twisting and whole body vibration, and moderate evidence for heavy physical work as risk factors for LBP, while Bakker et al. (2009) in turn found conflicting evidence. Standing or walking, sitting, sports or total leisure-time physical activities were no risk factors for LBP (Bakker et al. 2009). Chen et al. (2009) confirmed that sedentary lifestyle by itself is not associated with LBP.

In addition, people dissatisfied with work are more likely to report LBP (Papageorgiou 1997). In addition, low social support (Hoogendoorn et al. 2000), low job control and low supervisor support in workplace have shown to be risk factors for LBP (Kaila-Kangas et al. 2004).

## 2.2 Diagnosis of low back pain

Despite the technological advances that have been made in recent years, specialists are still unable to identify the specific origin of acute back pain in the majority of patients. It has been argued that less than 15% of back pain sufferers can be given a clinically relevant specific diagnosis based on LBP history, clinical examination, neurophysiological and radiological studies (Nachemson 2000). However, Bogduk and McGuirk (2002) suggested that by using invasive diagnostic tests, such as diagnostic blocks, we can increase the number of specific diagnoses. This concept is not, however, commonly approved and consequently such tests are rarely used. Still today, the specific causes of chronic LBP are rarely found when examining individuals presenting with chronic LBP. Degenerative changes during aging can occur with and without pain and with no relation to radiological findings. Chronic pain also alters pain modulation and pain behaviour that presents difficulties in the classification and diagnosis of LBP. For example zygapophysial joint ("facet") pain, cannot be precisely localized or diagnosed by any clinical test, or combination of tests or



by CT scanning (Hancock et al. 2007). The same may be true with the sacroiliac (SI) joint as a cause of LBP. Studies using diagnostic blocks of the SI-joint showed that it can be the cause of chronic LBP (Bogduk and McGuirk 2002), and the study by Laslett et al. (2006) provides suggestive evidence that SI- joint pain provocation tests used according to a specific clinical reasoning process can enable the clinician to differentiate between symptomatic and asymptomatic sacroiliac joints in the majority of cases.

### **2.2.1 Radiological diagnosis**

Features of discs observed on MRI and most closely associated with pain include disc prolapse (Jensen et al. 1994), disc narrowing (Hassett et al. 2003, Videman et al. 2003), radial fissures (Moneta et al. 1994, Videman et al. 2003) especially when they reach the disc exterior and leak (Videman et al. 2004), and internal disc disruptions (Peng et al. 2006), including inward collapse of the annulus (Schwarzer et al. 1995a). More variability related to pain has been observed for end-plate fractures, Schmorl's nodes (Beattie et al. 1994), Modic changes (Jensen et al. 2008) and disc bulging (Beattie et al. 1994, Jensen et al. 1994, Videman et al. 2003, Boos et al. 1995). Disc signal intensity on MRI has little if any relationship to pain (Videman et al. 2003).

The mainstay for diagnosing discogenic pain is disc stimulation and discography. It has been stated that discogenic pain cannot be diagnosed clinically with any degree of certainty (Schwarzer et al. 1995a). However, the pain centralization phenomenon (Donelson et al. 1997, Young et al. 2003, Laslett et al. 2005a) and the vibration-induced bone pain methods (Yrjama et al. 1994) can be used to determine the diagnosis clinically, and have shown moderate sensitivity and specificity among patients with chronic discogenic LBP without severe psychological disabilities (Yrjama et al. 1994, Laslett et al. 2005b). However, invasive discography investigations have been shown to cause accelerated progression of degenerative changes in lumbar discs (Carragee 2009).

Diagnostic imaging tests (including X-rays, CT and MRI) are not routinely indicated for acute non-specific LBP (van Tulder et al. 2004). In contrast to acute LBP, European guidelines recommended radiographic imaging (plain radiography, CT or MRI) for non-specific chronic LBP only if a specific cause is strongly suspected (Airaksinen et al. 2004). Although MRI is said to be the best imaging procedure for use in diagnosing patients with radicular symptoms, or for those with suspected discitis or neoplasm (Airaksinen et al. 2004), the key limitation of spinal imaging is the inability to relate pathology to symptoms (Beattie et al. 1994, Hamanishi et al. 2004). Many high-quality studies have not found meaningful differences in MRI findings between patients and healthy subjects (Boden et al. 1990, Jensen et al. 1994, Beattie et al. 1994, Milette et al. 1999, Hamanishi et al. 2004). Abnormal morphology may be found in individuals who have no symptoms and vice versa (Beattie et al. 1994, Milette et al. 1999, Hamanishi et al. 2004). Imaging as such has been shown to have little value in identifying symptom-related abnormal morphology among LBP patients and thus has been proposed to be used for diagnosis or treatment

planning only in the context of clinical presentation (Beattie et al. 1994, Milette et al. 1999, Hamanishi et al. 2004).

### 2.2.2 Clinical diagnosis and classifications

Physicians referring patients for physical therapy typically assign a diagnosis (a form of classification). It has been stated that identifying and establishing valid LBP diagnoses (subgroups) has to be the first priority, as valid subgroups will improve clinical decision-making, accuracy of outcome prediction, treatment outcomes, understanding of disease process, quality and focus of research and cost of low back care (Borkan et al. 1998). This interest is due to the fact that LBP is most often not attributed to pathologies known to cause pain. Many authors agree that LBP can rarely be diagnosed accurately based on a single structural pathology (Delitto et al. 1995, Nachemson 2000, McKenzie and May 2003, Waddell and Burton 2005). Thus the pathoanatomical model is of limited value for managing LBP. However, these methods are valuable in excluding the “red flags” (contraindications for mechanical therapy) - severe conditions such as cancer, infections (tuberculosis) and neurological or muscular diseases (Bigos et al. 1994, Henschke et al. 2008).

The European guidelines (van Tulder et al. 2004, Airaksinen et al. 2004) for the management of LBP propose the use of the ‘diagnostic triage’ in which patients are classified as having (1) possible serious pathology: the “red flags” and (2) nerve root pain, which both are based on ICD-coding system used by physicians when diagnosing patients’ diseases. This system, the purpose of which is to provide health care providers and ancillary personnel with a common classification, uses pathoanatomical signs, symptoms, injuries, diseases and conditions as criteria (Espine and Wagner 2009). However, the inter-examiner reliability of the anatomically-based ICD-9 codes has not been determined in diagnosing patients with back pain, specifically concerning differentiation between disc or non-disc origin (Dionne et al. 2009).

The proposed third category of the ‘diagnostic triage’, the non-specific LBP (van Tulder et al. 2004, Airaksinen et al. 2004), has been shown to be the largest, accounting for 85-90% of the population of spinal disorders. However, the label of non-specific LBP is said not to be a useful diagnosis (Waddell and Burton 2005). It has been stated that the term non-specific LBP ‘betrays our ignorance and leads to failure of communication, and to confusion and lack of confidence’ (Waddell and Burton 2005). As many as 93% of family physicians believe that there are different types of pain in the group with non-specific LBP (Kent and Keating 2004).

There is growing evidence that the use of a classification approach to physical therapy results in better clinical outcomes than not using such approaches (Cook et al. 2005, Brennan et al. 2006, Browder et al. 2007). However, only little agreement exists on establishing a “gold standard” for the classification of LBP.

In a survey among physical therapists in the USA, Spoto and Collins (2008) found that 38% utilised a pathoanatomically-based classification system,



32% a mechanically-based classification , 9% a treatment-based classification and 7% the ICF movement impairment classification (WHO 2001).

Only a few classification methods (McKenzie 1981, Delitto et al. 1995, Maluf et al. 2000), have been shown to have benefits in guiding the identification and treatment of symptom provoking movements and postures, and have been investigated for their reliability and validity (Petersen et al. 1999). Delitto, Erhard and Bowling (1995) proposed a treatment-based classification system for use patients with acute LBP. Patients are classified into seven sub-groups: immobilization, lumbar mobilization, sacroiliac mobilization, extension and flexion syndrome, lateral shift and traction. Maluf, Sahrman and van Dillen (2000) developed a classification system comprising five categories based on assessment of muscular stability, alignment, asymmetry and flexibility of lumbar spine, pelvis and hip joints. The recording of movements and activities in daily functioning that provoke the patient's familiar symptoms is of particular interest in this system (van Dillen et al. 1998). Interestingly, both of the above described physical therapy methods include principles drawn from the mechanical-based, i.e. symptom response method of classification first described by McKenzie (1981), and both methods showed excellent inter-examiner agreement when pain response evaluation was included, but substantially lower agreement when examination was based on visual evaluation only (van Dillen et al. 1998).

A systematic review, which measured the quality of design of physical therapy exercise interventions based on the symptom response classification, found that only five studies met the standards for high quality (Cook et al. 2005). Four demonstrated superior outcomes using exercise therapy based on the patient symptom response method of classification (Delitto et al. 1995, Fritz et al. 2003, Schenk et al. 2003, Long et al. 2004). Exercise led to improved outcomes in patients with the centralization phenomenon as a classification criterion. The authors concluded that this form of classification reliably differentiates discogenic from non-discogenic symptoms (Cook et al. 2005).

### **2.2.2.1 The McKenzie classification**

The McKenzie approach is a mechanical-based method of classification and therapy for musculoskeletal disorders (McKenzie 1981, McKenzie and May 2003). The assessment and classifying protocol does not aim to identify a specific anatomical structure, but classifies the clinical presentations into mechanical syndromes (FIGURE 1, Appendix 1) based on patients' symptom response to standardized mechanical loading strategies (McKenzie 1981, McKenzie and May 2003). The aims of mechanical assessment are diagnostic, prognostic, therapeutic and prophylactic. Examination by standardized loading strategies will, early in the process of conservative care, eliminate patients whose pathology is unsuitable for mechanical treatment ("red flags"). If, during examination, no position or movement can be found to reduce, centralize or abolish the symptoms, mechanical therapy may be of no value, at least at that stage. If the symptoms are only increased or peripheralized, it is likely that a

more advanced pathology exists, such as an extruded disc fragment, fracture or other condition, and mechanical therapy is contraindicated. If the symptoms are not affected at all by mechanical measures (i.e. movements or positions, rest or activity, loading or unloading of the spine) or respond atypically to their application the underlying cause may not be mechanical, and further investigation is indicated (McKenzie and May 2003).

#### *Centralization and peripheralization phenomena*

Three clinical phenomena: the centralization phenomenon, the peripheralization phenomenon and the directional preferences, may be commonly observed during the evaluation of subjects with the derangement syndrome (Appendix 1), which has been shown to be the largest (80%) group of the mechanical syndromes (May et al. 2008, Hefford et al. 2008). The centralization phenomenon occurs when distal limb pain emanating from the spine, although not necessarily felt in it, is immediately or eventually abolished in response to the deliberate application of loading strategies. Such loading causes the abolition of peripheral pain that appears to retreat progressively in a proximal direction. As this occurs there may be a simultaneous development or increase in proximal pain (McKenzie and May 2003). The peripheralization phenomenon exists, when pain emanating from the spine, although not necessarily felt in it, spreads distally into, or further down, the limb. This is the reverse of centralization. In response to repeated movements or a sustained posture, if pain is produced and remains in the limb, spreads distally or increases distally, that particular loading strategy should be avoided (McKenzie and May 2003). The explanation for these phenomena may lie in the connectional model of disc displacement (peripheralization) and replacement (centralization) of annular / nuclear complex, which occur under defined circumstances as a result of movements and positions of the vertebral column (Schnebel et al. 1988, Fennell et al. 1996, Fredericson et al. 2001, Fazey et al. 2006, Kolber et al. 2009, Tsantizos et al. 2009).

Directional preference is closely related to pain centralization, and indicates the direction of force required to centralize the pain (McKenzie and May 2003).

The centralization and peripheralization of symptoms occur only in patients suffering from the derangement syndrome. Changes of pain location, pain intensity, and the range of motion are not likely to result from a single movement but can readily be observed during or after one to five sequences of 5 - to 15-movement repetitions (Kopp et al. 1986, Werneke et al. 1999, Fritz et al. 2000, Bybee et al. 2005). In certain conditions it may be necessary to repeat one or more movements many times, possibly over a 24-hour period, before centralization or peripheralization becomes apparent and the classification confirmed (Werneke et al. 1999). Donelson et al. (1991) found that 47% of LBP patients with or without referred pain displayed a directional preference for end range sagittal spinal movement: 40% preferred lumbar extension, and 7% lumbar flexion (Donelson et al. 1991).

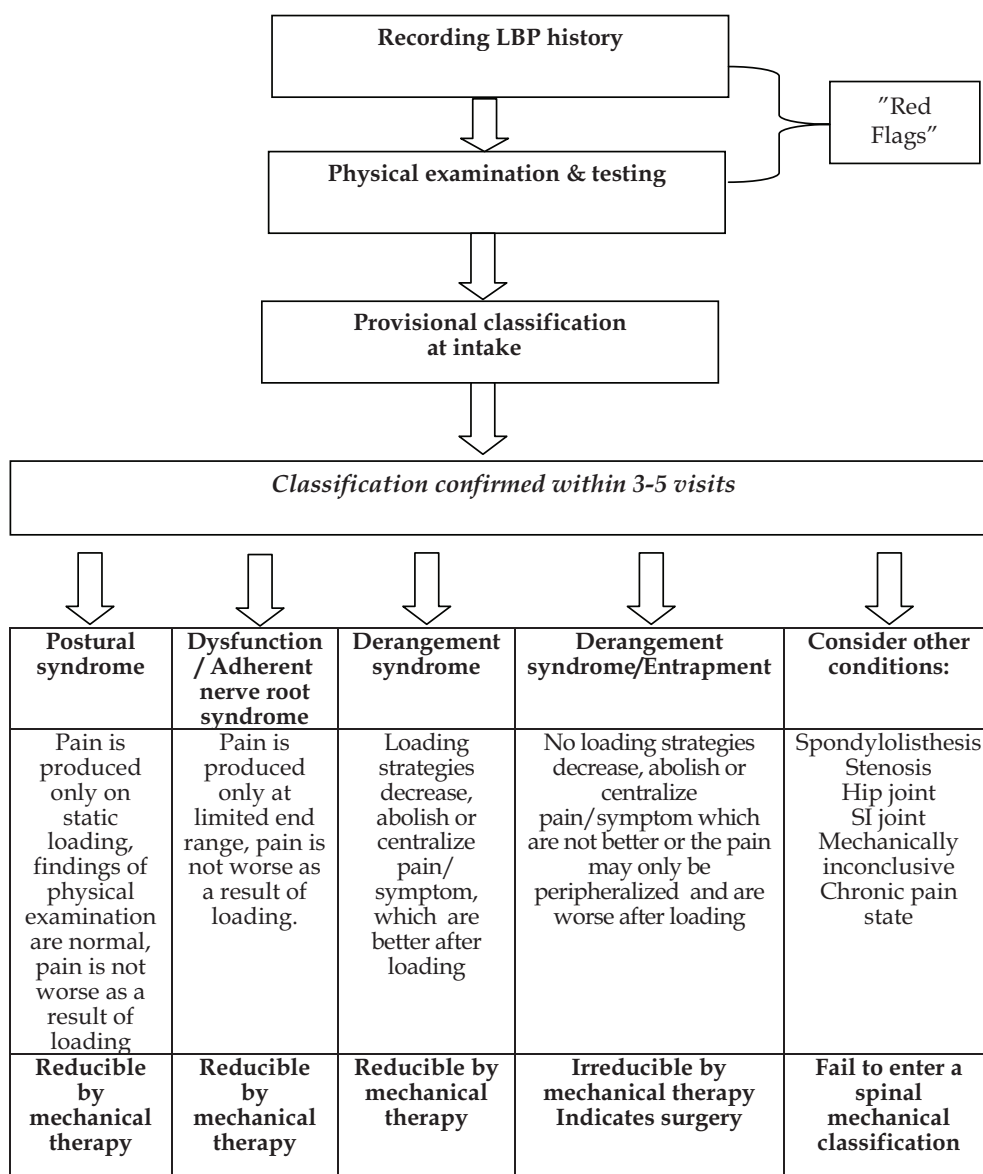


FIGURE 1 Classification algorithm of the McKenzie method.

#### 2.2.2.1.1 Reliability and validity of the McKenzie method

There are two separate determinants of how well a diagnostic test works: reliability and validity. A diagnostic test must be both reliable and valid (Sackett et al. 1991, Sim and Waterfield 1997). Conversely, the test cannot work if it lacks either reliability or validity (Sackett et al. 1991, Sim and Waterfield 1997).

Reliability is the extent to which two observers obtain the same results when using the same diagnostic test on the same sample of patients. It is determined by having the same patients, and recording the results in a contingency table (Sackett et al. 1991, Sim and Waterfield 1997). Reliability is expressed by Cohen's Kappa, which is the extent to which the observed agreement (discounted for chance) fills the range of possible agreement available (also discounted for chance) (Cohen 1960).

Validity refers to the degree to which a study accurately reflects or assesses the specific concept that the researcher is attempting to measure. While reliability is concerned with the accuracy of the actual measuring instrument or procedure, validity is concerned with the study's success as measuring what the researcher sets out to measure (Sackett et al. 1991, Sim and Waterfield 1997). Criterion-related validity, expressed by sensitivity, specificity, positive and negative predictive values, likelihood ratios (+ /-) and diagnostic confidence, measures of how well a diagnostic test actually establishes both the presence and the absence of a condition that it is intended to detect. It is determined by comparing the results of the diagnostic test with those of another test, called the criterion standard, which provides more direct evidence of the presence and absence of the condition. For diagnostic tests based on physical examination, the criterion standard could be the results of discography or MRI imaging findings (Sackett et al. 1991, Sim and Waterfield 1997). Predictive validity refers to the degree to which the operationalization of the test can predict or correlate with other measures of the same construct that are measured at some time in the future. It is the degree to which a measurement successfully predicts an outcome of interest (Sackett et al. 1991, Sim and Waterfield 1997). Discriminate validity is the lack of a relationship among measures which theoretically should not be related (Sackett et al. 1991, Sim and Waterfield 1997).

A systematic review on the reliability of McKenzie classification system yielded contradictory results as out of 3 high quality studies, two demonstrated reliability and one did not (May et al. 2006). The study demonstrating lack of reliability appeared to use inexperienced therapists with limited or no training in mechanical classification (Riddle et al. 1993). The very first study analyzing the reliability of the McKenzie's classification system (Kilby et al. 1990) found moderate inter-observer reliability between two therapists with some training in the use of the "McKenzie algorithm" in examination of pain behaviour and pain response with repeated movements. Total agreement was 59%, but the method was unable reliably to detect end-range pain, presence of kyphotic or flat lumbar spine and relevant lateral shift (sciatic scoliosis) (TABLE 1). Subsequently, a reliability study in which patients were classified into mechanical subgroups using the prefilled McKenzie patient assessment forms provided an adequate, but not ideal, clinical simulation, as the level of reliability was less (agreement 91%, classification into main syndromes  $\kappa = 0.56$ ; 95% CI 0.46-0.66 and into sub-syndromes 76%,  $\kappa = 0.68$ , 95% CI 0.67-0.69) than that obtained from inspection of real patients (Clare et al. 2004). In addition, the lateral shift (sciatic scoliosis) judgements had only moderate reliability, even

when trained observers judged stable stimuli by visual observation only (Clare et al. 2003). However, during the last ten years inter-observer reliability between clinicians trained in the McKenzie method has been found to be good to excellent (agreement from 70% to 100% and  $\kappa$ -values from 0.6 to 1.0) in classifying patients with lumbar pain (Sufka et al. 1998, Wilson et al. 1999, Werneke et al. 1999, Raztmjou et al. 2000, Fritz et al. 2000, Clare et al. 2005, Fritz et al. 2006) (TABLE 1).

TABLE 1 Reliability studies of pain response testing by the McKenzie method.

First author(s) and reference	Participants	Design/methods	Results	Conclusions
Spratt et al. 1990	42 patients with LBP. Assigned to one of three rater pairs trained in the examination methods.	A test-retest paradigm of 17 organic and 4 non-organic tests.	The reliability of organic and non-organic pain behavior composites was 0.78 and 0.82, respectively	The physical exam produced useful examiner-based outcome measures to supplement or complement traditional patient self-report measures of outcome.
Kilby et al. 1990	41 patients with LBP	Patients examined by two therapists according to an algorithm of McKenzie assessment	The algorithm was reliable in examination of pain behavior and pain response with repeated movement, but unreliable for the presence of kyphotic or flat lumbar spine and relevant lateral shift.	The algorithm's primary use is as a research tool for examination of inter-therapist agreement. The total agreement was 58,5%. The examiners had some training in MDT.
Riddle and Rothstein 1993	363 patients with LBP. Examined by randomly paired PTs in 8 clinics.	Patients were examined separately by two randomly assigned PTs with little or no training in the McKenzie method. Kappa coefficient values were determined.	Agreement was 39%, K-value 0.26, for PT's with some post-graduate training in the McKenzie method vs. 27% agreement, and K-value 0.15 among those with no McKenzie training.	Poor inter-tester reliability reported using examiners with little or no training in the McKenzie method.
Sufka et al. 1998	36 patients with LBP	All patients evaluated with McKenzie method. Treatment was based on McKenzie assessment findings	Inter-rater agreement 94%.	PTs trained in the classification system demonstrated good inter-tester reliability
Wilson et al. 1999	204 patients with LBP referred to 10 clinics	Paired PTs performed separate exams consisting of movement testing and pain response monitoring. Agreement and K-value were determined	Agreement in classification was 78,9%, K-value 0.61	PTs trained in the classification system demonstrated good inter-tester reliability

Werneke et al. 1999	289 consecutive patients with acute neck pain and LBP with and without radicular symptoms referred for PT.	Subjects were assessed and classified into three pain pattern groups using the McKenzie method.	Inter-tester reliability was excellent for classification into groups and distal pain location.	PTs trained in the classification system demonstrated high inter-tester reliability
Fritz et al. 2000	Patients with LBP were videotaped.	40 licensed PTs and 40 PT students viewed videotapes of PT examination. Agreement and K-value were determined	Inter-rater reliability was excellent for all (K=0.793; for licensed PTs it was (K= 0.823) and for PT students it was (K=0.763)	Clinical experience did not substantially improve reliability with the use of precise operational definitions.
Razmjou et al. 2000	45 patients with LBP	Each patient was examined simultaneously by two PTs both trained in the McKenzie method. One PT was the assessor and the other an observer. Agreement and K-value were determined	Agreement for syndromes K=0.70; sub-groups K=0.96. Presence of lateral shift K=0.52, relevance of lateral shift K=0.85, relevance of lateral component K=0.95, and deformity in sagittal plane K= 1.00.	Low back evaluation using pattern of pain response to repeated end-range test movement was highly reliable when performed by two well-trained PTs.
Clare et al. 2004	50 completed patient assessment forms were sent to 50 credentialed McKenzie therapist for classification.	Agreement and K-value were determined	K=0.56 for main syndromes and K=0.68 for sub-syndromes	Inter-rater reliability was moderate to good.
Clare et al. 2005	25 patients with LBP and 25 with cervical pain.	Patients were assessed simultaneously by 2 PTs (14 in total) trained in the McKenzie method. Agreement was expressed by multi-rater Kappa coefficient and percent agreement for classification into syndromes and sub-syndromes	For total main syndrome classification: 96% agreement, K= 0.84. For lumbar: 100% agreement, K=1.00; For cervical: 92% agreement, K=0.63. For total sub-syndrome classification: 90% agreement, K= 0.87. For lumbar: 92% agreement, K=0.89; For cervical: 88% agreement, K=0.64.	The McKenzie assessment performed by clinicians trained in the McKenzie method may allow for reliable classification of patients with lumbar or cervical pain.
Fritz et al. 2006	60 patients with LBP less than 90 days duration.	Patients examined on separate days by different examiners. Kappa coefficients and intra-class correlation coefficients were determined.	Overall agreement on classification was 76%, Kappa=0.60, 95% confidence interval 0.56,0.64), with no significant differences based on level of experience.	Reliability of the classification algorithm was good.



So far two criterion-related validity studies on the role of the centralization phenomenon as a predictor of provocation discography among chronic LBP patients have been published (Donelson et al. 1997, Laslett et al. 2005a). Both studies found a positive correlation between centralization and discogenic pain (Donelson et al. 1997, Laslett et al. 2005a). In the former study high sensitivity but low specificity was observed, while in the latter the results were opposite and the diagnostic confidence value was 95%. The discrepancy between the results was explained by the different definition of centralization used (Laslett et al. 2005a).

Furthermore, the centralization phenomenon and directional specific exercises have shown to be strong predictors of good treatment outcomes in several studies (Aina et al. 2004, Long et al. 2004, Werneke and Hart 1999, Skytte et al. 2005, May et al. 2008, Broetz et al. 2010) (TABLE 2). In contrast, non-centralization phenomenon, i.e. loading in the opposite direction worsening or peripheralizing pain and making movement more difficult, predicted poor conservative treatment outcomes and/or chronic low back trouble (Werneke and Hart 2001, Long 2004, Niemistö et al. 2004).

Further, Werneke and Hart (2004) evaluated predictive and discriminate validity in their patients, who completed pain and psychosocial questionnaires at study entry, and at discharge. At study entry physiotherapists classified patients according to the QTF (Spitzer 1987) and McKenzie pain pattern classifications. Both classifications could be used to differentiate patients by pain intensity or disability at study entry. However, the McKenzie pain pattern classification predicted pain intensity, disability and work status at discharge, whereas QTF classification did not (Werneke and Hart 2004) (TABLE 2).

TABLE 2 Outcome prediction studies (predictive validity) of the McKenzie method.

First author(s), reference	Participants	Design/methods	Results	Conclusions
Kopp et al. 1986	67 patients with LBP radiating to the calf or foot with at least one significant sign of nerve root irritation and at least 6 weeks of failed non-operative therapy.	All patients underwent an initial trial of extension exercises. Those who did not have worsening symptoms were prescribed an extension exercise program for several days while still hospitalized.	52% (n=34) experienced no symptoms worsening during the extension tests. All 34 performed extension exercise program and 100% regained a full extension range and symptoms recovered in 2-5 days. The other 32 had surgery. There were no significant differences in pre-operative demographics.	"The patients responded so dramatically to extension therapy that the use of extension exercises as a therapeutic modality is recommended."
Donelson et al. 1990	87 patients with LBP and radiating leg pain presenting to a orthopedic practice.	Patients assessed with the McKenzie method. Presence and absence of centralization were recorded.	77% to 98% of the centralizers and 17% to 50% of the non-centralizers had good to excellent outcomes. Only 4 patients were operated, all were non-centralizers.	Centralization was common (87%) and its presence or absence was a strong predictor of treatment outcome.

Long A. 1995	223 chronic LBP patients presenting to an interdisciplinary rehabilitation unit, all receiving compensation.	Patients assessed with the McKenzie method. Presence and absence of centralization was recorded. Treatment 5 days/week for 11 weeks of work hardening, work simulation, exercise, PT, psychological support.	Centralizers had greater decrease in pain intensity ( $p=0.05$ ) and higher return to work rate ( $p=0.034$ ) No difference in Oswestry scores or lift capacity	Centralizers had better treatment outcomes than non-centralizers.
Karas et al. 1997	171 consecutive LBP patients, with or without leg pain at 5 clinics. Duration: 14 days to 2 years	All assessed with the McKenzie method and with Waddell non-organic signs. Classified and treated for more than 30 days. Follow-up by phone at 6-months.	Centralization occurred in 73%. Waddell tests were positive in 83%. Centralizers returned to work more frequently than non-centralizers ( $p=.038$ ). High Waddell score overrode centralization as a predictor.	The probability of return to work is greater in centralizers.  Waddell tests should be performed even for centralizers.
Sufka et al. 1998	36 patients with LBP	All patients evaluated with the McKenzie method. Treatment based on McKenzie assessment	Inter-rater agreement 94%	LBP sufferers show greater improvement (functional outcomes) when there was evidence of complete centralization.
Werneke et al. 1999	289 consecutive patients with acute neck and LBP with and without radicular symptoms referred for PT.	Subjects were assessed and classified into three pain pattern groups using the McKenzie method.	Inter-tester reliability was excellent for classification and distal pain location.	Categorization by changes in pain location to mechanical assessment allowed identification of patients with good prognosis and facilitated treatment planning. Lack of changes indicated need for more investigations.
Werneke et al. 2001	225 consecutive patients with acute neck and LBP with or without radicular symptoms.	Subjects were assessed and classified according to centralization. Treatment was based on the McKenzie method. Outcomes assessed at 12 months.	Pain centralization or non-centralization were predictors of future pain, return to work, activity interference and continued use of health care.	Outcomes of this study support that physical factors are important predictors of chronic LBP and disability. Identifying those whose pain does not centralize is an important predictor of future disability and healthcare usage.
Werneke et al. 2004	171 patients with acute work-related LBP	Patients completed pain and psychosocial questionnaires at initial examination and at discharge and pain drawings throughout	QTF and McKenzie pain classification data could be used to differentiate patients by pain intensity or disability at intake.	Evidence of the predictive validity of the McKenzie method.



		intervention. Patients were classified by QTF and McKenzie pain pattern classifications at intake.	McKenzie-type pain classification predicted pain intensity, disability and work status also at discharge, but QTF classification did not.	
Skytte et al. 2005	104 consecutive patients referred because of possible disc herniation.	60 patients underwent a standardized McKenzie evaluation. 25 were centralizers. All patients were treated in the same way and followed for one year.	Results at 2 months favored centralizers in leg pain $p < 0.007$ , disability $p < 0.001$ and Nottingham Health Profile $p < 0.001$ . At 1-year disability was less in centralizers $p = 0.029$ . Three of the centralizers and sixteen of the non-centralizers received surgery ( $p < 0.001$ ).	Patients with sciatica and suspected disc herniation who have a centralization response have better conservative care outcomes. Non-centralizers are 6-fold more likely to undergo surgery.

### 2.3 Effectiveness of treatments in low back pain

LBP is considered to be a benign and self-limiting condition in most cases. The majority (80-90%) of acute LBP episodes have shown recovery within a 6-week period irrespective of the administration or the type of treatment (Waddell 1987, Pengel et al. 2003). However, long-term studies show that most patients with acute LBP actually continue to have long-term pain and disability (Croft et al. 1998, Hestbaek et al. 2003, Pengel et al. 2003). Most of the patients seen by medical practitioners within three months still had substantial pain and related disability, and only 25% of these patients had fully recovered 12 months later (Croft et al. 1998).

A large number of clinical trials investigating the effectiveness of conservative interventions for the management of LBP have been reported in the literature (Koes et al. 2006). Due to conflicting evidence on the outcomes of supporting treatment interventions for non-specific LBP, clinical practice guidelines based on the best available evidence have been developed in various countries around the world. Comparison of these clinical guidelines showed that diagnostic and therapeutic recommendations were generally similar (Koes et al. 2001).

#### *Advice to stay active*

All the guidelines agree, that patients with acute LBP should be advised to avoid bed rest if possible (certainly for more than a few days), to stay active, and to get on with their ordinary activities as normally as possible (Hilde et al. 2007). The evidence suggests that advice to stay active alone has little beneficial effect for patients with acute, simple LBP, and little or no effect for patients with sciatica. However, there is no evidence that advice to stay active is harmful either for acute LBP or sciatica. Because there is no substantial difference

between advice to stay active and advice on avoiding bed rest, and because prolonged bed rest is known to have potential harmful effects it is reasonable to advise people with acute LBP and sciatica to stay active (Hagen et al. 2004). Advice to stay active in conjunction with an educational booklet seemed to be better than unspecific exercises in an acute LBP population (Malmivaara et al. 1995) and as beneficial as manipulation or physical therapy using the McKenzie approach when treating sub-acute (more than seven days from episode onset) LBP (Cherkin et al. 1998).

#### *Pharmacological treatments*

For pain relief from acute LBP, the guidelines recommend paracetamol as a first choice and NSAIDs (non-steroidal anti-inflammatory drugs) as a second choice. If paracetamol or NSAIDs fail to reduce pain a short course of muscle relaxants alone or in addition to NSAIDs can be considered (van Tulder et al. 2004). Although paracetamol has been widely recommended as an analgesic for acute LBP little direct evidence has been shown for its efficacy. NSAIDs have been shown to be minimally more effective than placebo, if at all, for acute back pain (Bogduk and McGuirk 2002). For chronic LBP short-term use of NSAIDs and weak opioids, and noradrenergic or noradrenergic-serotonergic antidepressants and muscle relaxants has been recommended for consideration for pain relief (Airaksinen et al. 2004).

#### *Physical therapy*

Based on the results of the systematic reviews the guidelines generally recommend only minimal physical therapy intervention and conscious waiting with some advice during the 4-6-weeks after the LBP onset (Koes et al. 2001). The use of passive physical therapies such as heat/cold, traction, laser, ultrasound, short wave, interferential, corsets and TENS (transcutaneous nerve stimulation) cannot be recommended for non-specific chronic LPB (Airaksinen et al. 2004). Comparing physical therapy to inactive treatment or other conservative care for patients with acute sciatica, no differences regarding pain and disability, in overall improvement or return to work were found between the study groups at short and intermediate follow-up (Luijsterburg et al. 2007).

#### *Manual therapy (mobilization and manipulation)*

The European guidelines proposed considering referral for spinal manipulation (a small-amplitude high-velocity single-thrust passive movement up to the end of the available range of motion) for patients who fail to return to normal activities as non-surgical management for acute and chronic LBP (van Tulder et al. 2004, Airaksinen et al. 2004).

The Finnish national guidelines (Malmivaara et al. 2008) recommend considering LBP patients who need manipulation for referral for example to physical therapists specialized into OMT. OMT is a specialized area of physical

therapy designed, on the basis of clinical reasoning, for management of neuromusculoskeletal conditions by means of highly specific treatment approaches, including manual techniques (mobilization and manipulation) and therapeutic exercises (muscle stretching, spinal mobilization and stabilization). OMT also encompasses, and is driven by the available scientific and clinical evidence and the bio-psycho-social framework (IFOMT 2009).

However, a meta-analysis concluded that there is no evidence that spinal manipulative therapy is superior to other standard treatments for patients with acute or chronic LBP (Chaitow et al. 2004). Cherkin et al. (2003) also found that spinal manipulation has small clinical benefits equivalent to those of other commonly used therapies. Both studies indicated that spinal manipulation is superior to sham treatment and at least equivalent to other established interventions (Cherkin et al. 2003, Chaitow et al. 2004).

However, manipulation followed by exercises achieved a moderate benefit at 3 months and a small benefit at 12 months, while spinal manipulation or exercises alone achieved only a small to moderate benefit at 3 months, and small to none at 12 months (UK BEAM Trial Team 2004).

#### *Exercise therapy*

A meta-analysis of exercise therapy for non-specific LBP concluded that in acute LBP populations, exercise therapy is as effective as either no treatment or other conservative treatments (Hayden et al. 2005). In sub-acute LBP populations some evidence suggested that a graded activity program reduces work absenteeism, but evidence for other types of exercise is unclear. In adults with chronic LBP, exercise therapy seemed to be slightly effective in decreasing pain and improving function, particularly in primary care populations (Hayden et al. 2005). A recent study examined systematic reviews of which only three were of high quality, and provided strong evidence that exercise programs reduced sick-leave and improved pain and disability in people with non-acute non-specific LBP (Swinkels et al. 2009). The clinical value of the conclusion was impaired by the diversity of the exercise interventions (Swinkels et al. 2009). Choi et al. (2010) found moderate quality evidence that post-treatment exercises were more effective than no intervention for reducing the rate of recurrences at one year. The number of recurrences was significantly reduced at the two-year follow-up, but the review found low quality evidence that the number of days on sick leave was reduced by post-treatment exercises and conflicting evidence for the effectiveness of exercise treatment in reducing the number of recurrences or recurrence rate (Choi et al. 2010).

#### *Cognitive-behavioral therapy*

The cognitive-behavioral therapy approach to pain has been conceptualized as a way of enhancing treatment by addressing pertinent negative (emotions and thoughts) and behavioral (altered activity and medication-taking) aspects. It offers an educational concept whereby positive coping strategies are taught to

enhance recovery (Linton 2001). A group comparison indicated that the cognitive-behavioral group had better results with regard to fear-avoidance belief, number of pain-free and sick-leave days and in addition produced preventive effect with regard to disability compared to the control group (Linton 2001). Furthermore, the approach seemed to be an effective treatment for patients with chronic LBP, but it is unknown what type of patients benefit from what type of behavioral treatment (van Tulder et al. 2001).

### *Invasive methods*

The summary of the evidence on the Cochrane database of systematic reviews 2005 on surgery and other invasive procedures for managing acute or chronic non-specific LBP concluded that facet joint, epidural, trigger point and sclerosant injections have not clearly been shown to be effective (van Tulder et al. 2006). Similarly, there was scientific evidence on the effectiveness of spinal stenosis surgery (van Tulder et al. 2006). Discectomy may be considered for selected patients with sciatica due to lumbar disc prolapses that fail to resolve with conservative management (van Tulder et al. 2006). Cognitive intervention combined with exercises is recommended for chronic LBP, and fusion surgery may be considered only in carefully selected patients if active rehabilitation programmes have failed over a period of two years (van Tulder et al. 2006). Demanding surgical fusion techniques are not better than the traditional posterolateral fusion without internal fixation (van Tulder et al. 2006). However, neurosurgeons and orthopedic surgeons have offered an alternative to lumbar spinal fusion techniques. In the United States and in some European countries artificial disc replacements have been increasingly used for treating pain related to the intervertebral discs. A systematic review concluded that no study has shown total disc replacement to be superior to spinal fusion in terms of clinical outcome (van Tulder et al. 2006). The long-term benefits of total disc replacement in preventing adjacent level disc degeneration have yet to be realized. Complications arising from total disc replacement may not be known for many years (Freeman and Davenport 2006).

### **2.3.1 McKenzie method**

In the McKenzie method of mechanical therapy each distinct mechanical syndrome (Appendix 1) is a unique and separate disorder addressed according to its unique nature. The therapy of LBP patients consists of (1) an educational component, supported with advice from the book "Treat Your Own Back" (McKenzie 1985), and (2) an active therapy component along with instructions in postural control and directional specific exercises repeated several times a day according to the principle of the syndrome in question (McKenzie 1981, McKenzie and May 2003). The mechanical therapy itself can be defined briefly as a prophylactic empowerment concept, which begins on day one. Self-treatment plays a major role, but for some patients this is not sufficiently forceful or localized. On occasions, if improvements are not sustained or are too

slow in coming, patient-generated forces are supplemented by clinician-generated forces: over-pressure or mobilisation or both by the therapist within the same treatment direction principle of management (manipulation is rarely needed or used). The therapist should apply the technique in such a way that the patient is able to self-treat more effectively, thus self-treatment and therapist techniques are inter-related. The main aim is to avoid therapist-dependence and thus teach to the patient to cope with possible recurrences of LBP episodes (McKenzie 1981, McKenzie and May 2003).

Previously, only a few high quality prospective randomized controlled trials (RCTs) (Cherkin et al. 1998, Long et al. 1995) (TABLE 3) and several lower quality studies (Ponte et al. 1984, Nwuga and Nwuga 1985, Stancovic et al. 1990, Stancovic et al. 1995) existed on the effectiveness of the “pure” McKenzie method. A subsequent systematic review (Clare et al. 2004b) showed that McKenzie therapy resulted in a greater improvement in LBP and back-related disability in the short term than other standard therapies (TABLE 3). In the study by Long et al. (2004) all patients who demonstrated directional preference (DP) for centralizing pain were randomized to receive exercises matched to DP (group 1), exercises opposite to DP (group 2) or guidelines recommended “advice to stay active”(group 3). Over 30% of the patients in groups 2 and 3 withdrew from the study because of failure to improve or worsening of symptoms, compared to none in the group 1. Over 90% of the subjects in group 1 rated themselves better or resolved at 2 weeks, compared to approximately 20% in group 2 and 40% in group 3 (Long et al. 2004) (TABLE 3).

In another study (Moffet et al. 2006), 315 patients were randomized to either the McKenzie therapy or cognitive behavioural approach. The patients were followed for 12 months with the Tampa Scale of Kinesiophobia (TSK) as the main outcome. Both groups reported modest but clinically important functional improvements, but at 6 months the results in the TSK activity-avoidance, patients’ satisfaction and one aspect of health locus of control favoured the McKenzie method. In an economic analysis of the same trial the McKenzie therapy was cost-effective with regard to Quality Adjusted Life Years despite the fact that it was more expensive (Manca et al. 2007).

The advice on passive prone lumbar extension and ergonomics, inherent to the McKenzie method prevented LBP episodes and the use of health care services during the military service (Larsen et al. 2002). In a systematic review on the prevention of low back problems in working age adults, effective exercises in prevention included extension exercises and the educational session based on the book *Treat Your Own Back* by McKenzie (Bigos et al. 2009). In the clinical study by Broetz et al. (2008) LBP sciatic patients with weakness and sensory loss and with prolapsed discs confirmed by MRI were treated by the McKenzie method. Most patients’ pain centralized, all patients showed improvement in signs and symptoms, but there was no change in the features of the MRI. Centralization predicted good long-term outcome in the majority of the patients measured at the 5-year follow-up (Broetz et al. 2010). Machado et al. (2010) compared trained GPs’ (physicians’) first-line care (advice,

reassurance and paracetamol) with trained GPs' first-line care in conjunction with McKenzie care delivered by McKenzie trained therapists for acute LBP patients for a period of three weeks. The treatment program based on the McKenzie method did not produce appreciable improvements in pain, disability, function, global perceived effect or risk for developing persistent symptoms in these acute LBP patients receiving recommended first-line care. However, the patients with acute LBP receiving only the recommended first-line care sought more additional health care than the patients receiving the McKenzie method (Machado et al. 2010).

In an observational study (Rasmussen et al. 2005) the rates of lumbar disc surgery before and after implementation of two spine rehabilitation programs focused on the McKenzie method were compared to the rates elsewhere in Denmark among sciatica patients. The annual rate of all lumbar discectomies decreased by approximately 50% and elective first time discectomies by two thirds in the catchment area of the McKenzie clinics, while the surgery rates remained unchanged during the same period in the rest of Denmark.

TABLE 3 Effectiveness of symptom response RCTs of the McKenzie method.

Study, first author, year	Participants	Design/methods	Results	Conclusions
Delitto et al. 1993	39 LBP patients. 24 were classified as centralizers and as having symptoms indicating treatment with an extension-mobilization approach. The remaining subjects were dismissed from the study.	24 patients were randomly assigned to either mobilization and extension treatment category/matched (14) or a flexion treatment category / unmatched (10). Outcomes: LBP, Oswestry index,	Patients treated by using the matched/extension and mobilization responded positively at a faster rate than did the unmatched/flexion treatment category.	A priori classification of selected patients into a matched treatment category of extension and mobilization and subsequently treating the patients with specific interventions can be an effective approach to conservative management of selected patients.
Larsen et al. 2002	314 males with or without LBP.	Randomized in two groups: Group 1 received theory session based on book Treat Your Own Back, disc model, tape support to back and instructed to do 15 repetitions of extension in supine lying 2 times a day for the period of military duty. The other group was control group.	214 (68%) completed follow-up at 12 months. 1-year prevalence LBP in group 1 was 33%, and 51% in control group. Numbers seeking medical help for LBP was also significantly less 9% vs. 25%). In those who reported LBP at baseline 1-year prevalence was 45 vs. 80% in controls.	It is possible to reduce the prevalence of LBP and the use of health care services during military service using passive prone lumbar extension exercises based on the theory of the disc as a pain generator and ergonomic instructions. Prevention for subjects with prior LBP history was significant vs. those with no history.



Fritz et al. 2003	78 patients with work-related LBP of less than 3 weeks duration. Evaluated and classified into Delitto categories, including centralization phenomenon.	Patients randomized to receive therapy determined by their baseline classification or therapy based on the Agency for Health Care Policy and Research guidelines. Follow-up for one year. Outcomes: Impair index, Oswestry index, SF-36 component scores.	Patients receiving classification-based therapy showed greater change on the Oswestry (p=0.023) and SF-36 physical component (p=0.029), patient satisfaction (p=0.006) and return to full-time work (p=0.017). After one year there was a trend toward reduced Oswestry index in classification-based group (p=0.63). Median total medical costs for 1 year were lower in classification-based group (p=0.013).	For patients with acute work-related LBP the use of classification -based approach resulted improvement in disability and return to work after 1 month, as compared with therapy based on clinical practice guidelines.
Schenk et al. 2003	25 Low back patients, classified as a McKenzie "derangement syndrome" upon initial examination.	Patients randomized into spinal mobilization or therapeutic exercises according to McKenzie method. All seen for 3 physiotherapy visits: Pain and Oswestry index were measured at baseline and at discharge.	Therapeutic exercises produced significantly greater decrease in pain level (p<0.01) and greater improvement in function (p<0.03) compared to the mobilization group.	Exercises selected by repeated movement testing created greater pain reduction and recovery of function than joint mobilization in acute lumbar derangements.
Long et al. 2004	312 consecutive LBP patients with or without leg pain, with no or one neurologic sign, acute to chronic pain referred to eleven physiotherapy clinics. All assessed by the McKenzie MDT method and those with directional preferences identified by McKenzie trained therapists.	Patients randomized to exercise that matched the directional preference (DP), or opposite to the directional preference (Opp) or were non-directional (ND). Primary outcomes: Back and leg pain intensity. Secondary outcomes: patient satisfaction, QTF classification, use of medication, the Beck depression inventory, interference with work and leisure activity and the Roland-Morris questionnaire.	Of the matched DP group 95% reported either better or resolved symptoms, and no one was worse; whereas only 23% of the Opp group and 42% of the ND group was better or resolved. In both Opp and ND groups 15% reported they were worse. All outcomes were significantly better in the matched DP group than either the Opp or ND groups.	It matters which exercises are done in the large directional preference subgroup of LBP. In this study, effective, ineffective and even counter-productive exercises were identified. Improving or eliminating patients' pain significantly decreased patients' medication use and improved all six secondary outcome measures. Due to attrition in Opp and ND groups, this study could not continue past 2 weeks of follow-up.
Brennan et al. 2006	123 LBP patients with and without referred pain. Excluded :lateral and kyphotic deformity, signs of nerve-root compression. Patients were classified into one of the tree treatment categories based on treatment expected to be beneficial.	Randomized controlled trial comparing manipulation, stabilization and directional preference exercises, but also analyzing results according to whether patients were treated by classification sub-groups or not.	Patients receiving treatments matching their category experienced greater short and long-term reductions in disability than those receiving unmatched treatments.	Non-specific LBP should not be viewed as a homogenous condition. Outcomes can be improved when sub-grouping is used to guide treatment decision-making.

Browder et al. 2007	Acute LBP patients (63) with referred pain below buttocks and centralization phenomenon with 10 repeated extension in standing or lying supine identified at baseline assessment.	Patients were randomized to either extension-oriented treatment or stabilization exercises. Outcomes: pain intensity, Oswestry index.	Extension-oriented treatment significantly better at one week, 4 weeks and 6 months for Oswestry scores, but pain-wise only at one week. Significant difference in centralization of symptoms favoring the extension protocol group.	Developing treatment-based sub-grouping procedures for patients with LBP is an important priority. Directional preference and centralization appear to be important sub-grouping criteria.
Machado et al. 2010	148 acute LBP patients, 31 general practitioner, 15 McKenzie trained physical therapists	Patients were randomized either in GPs' first-line care or in GPs' first-line care plus McKenzie treatment groups. Pain, disability, function, global perceived effect or risk of developing persistent symptoms and care seeking were measured.	Patients with acute LBP receiving only the recommended first-line care seek more additional health care than patients receiving the McKenzie method. No other differences in outcomes between the groups.	Patients with GP advice in conjunction with McKenzie treatment needed not to seek additional health care, due to they learnt to treat their own low back trouble and prevent recurrences.

## 2.4 Predictors of the outcome of low back pain

Predictive factors that cause acute pain to become chronic are clearly complex, multiple and heterogeneous between individuals. Factors of the outcomes of LBP relate to three dimensions: individual factors, physical or biomechanical factors and psychosocial factors (Bombardier et al. 1994, Frank et al. 1996, Ferguson and Marras, 1997).

Individual history of previous LBP is both a risk factor for future pain and a prognostic factor for prolonged symptoms. Leg pain at onset is associated with poor outcomes and greater likelihood of developing chronic symptoms (Lanier and Stockton 1988; Goertz 1990, Cherkin et al. 1996, Thomas et al. 1999, Carey et al. 2000). However, centralization of leg pain has been shown to be a predictor of good outcomes (Aina et al. 2004). Even in patients with sciatica and suspected disc herniation who have a centralization response have been found to have good conservative care outcomes (Aina et al. 2004). Identifying those whose pain does not centralize is an important predictor of chronic LBP, future disability and healthcare usage (Aina et al. 2004). Non-centralizers are 6-fold more likely to undergo surgery than centralizers (Skytte et al. 2005). The inability to centralize was found to be the strongest predictor of chronicity compared with a range of psychosocial, clinical and demographic factors in the study by Werneke and Hart (2001). In a recent systematic review, only the changes in pain location and pain intensity with repeated movements or in response to treatment were associated with outcomes (Chorti et al. 2009).

A systematic review of socio-demographic, physical and psychological predictors of multidisciplinary rehabilitation or back school treatment outcome in patients with chronic LBP (van der Hurst et al. 2005) found that the more



pain patients had, i.e. the higher intensity of pain, the worse the outcomes. Another review of factors as predictors of LBP chronicity and disability (Pincus et al. 2002) suggested that psychological factors play an important role, equal to that of clinical factors, in the transition to chronicity in LBP. Abnormal psychological distress, anxiety, fear-avoidance, beliefs and attitudes have been associated with severity of back pain, resulting in poorer clinical outcomes (Kinney et al. 1993, Fritz and George 2002, Laslett et al. 2005a). Substantial evidence was established for the role of distress and depressive mood, and to lesser extent: somatisation (Pincus et al. 2002). In summary, several studies suggested that chronic back pain disability and persistent symptoms are associated with a combination of clinical, psychological and social factors.

### 3 PURPOSE OF THE STUDY

The purpose of this clinical study was first to investigate if non-specific LBP in adults could be classified reliably by using the standardized loading strategies developed by R.A. McKenzie. Secondly, the purpose was to compare treatment outcomes in a randomized three-armed RCT with 1-year follow-up.

In detail, the specific questions were:

1. What is the inter-examiner agreement in classifying non-specific LBP patients into mechanical syndromes, in defining the centralization phenomenon and directional preferences by using the McKenzie method? (*Article I*)
2. What is the association of clinically defined pain centralization with lumbar disc findings as assessed by MRI in chronic LBP patients? (*Article II*)
3. How effective is the McKenzie method or OMT in relieving LBP and disability in comparison to “advice to stay active”? (*Article III*)
4. How effective is the McKenzie method in relieving LBP and disability among sub-grouped subjects with centralizing pain in comparison to orthopaedic manual therapy or to “advice to stay active”? (*Article IV*)
5. Does pain centralization on the initial visit predict outcomes among adults with LBP? (*Article V*)

## **4 MATERIAL AND METHODS**

### **4.1 Subjects and study designs**

This study consists of two separate populations both of which comprised working-age adult men and women with acute to chronic non-specific LBP.

#### **4.1.1 Study I (Articles I and II)**

The participants (N=39) were recruited in 1997 through the Kuopio Occupational Health Centre, Kuopio, Finland where they had sought medical attention for LBP. Patients fulfilling the inclusion criteria were randomly selected to participate in this study. The inclusion criteria were: male or female gender, age 18 to 65years, non-specific LBP with symptom duration longer than three months and moderate functional disability. The patients with radicular symptoms (radiating pain below the knee, loss of sensation, muscle dysfunction, or loss of reflexes), disc prolapses, severe scoliosis, spondyloarthrosis, previous back surgery and other specific and serious causes of back pain were excluded from the study (*Articles I and II*). The detailed descriptive characteristics of the patients are shown in TABLE 4.

TABLE 4 Characteristics of population of the study I on clinical assessment day (N=39).

Characteristics	Non-specific LBP patients
<b>Age</b> (mean years, range)	40 (24 - 55)
<b>Gender</b> (number of females / males)	15 / 24
<b>Duration of low back trouble</b> (mean years, range)	14 (1-38)
<b>Number of previous episodes:</b> 1-5episodes, n (%) 6-10episodes, n (%) > 10episodes, n (%)	16 (41) 7 (18) 16 (41)
<b>Duration of current episode of LBP:</b> (on the day of McKenzie clinical assessment) Symptom-free, n (%) Acute: < 7 days, n (%) Sub-acute: > 7 days < 7 weeks, n (%) Chronic: > 7 weeks, n (%)	2 (5) 5 (13) 9 (23) 23 (59)
<b>Symptom location:</b> Symptom-free n (%) Low back pain only n (%) Radiating pain to thigh n (%) Radiating pain below the knee n (%) Radiating pain below the knee with neurological signs n (%)	2 (5) 7 (17) 21 (55) 3 (8) 6 (15)

*Study I design (Articles I and II)*

The patients were originally randomized into active and passive rehabilitation groups in a larger RCT by drawing lots before attending the rehabilitation clinic for the baseline measurements (Kankaanpää et al. 1999). In study I, an informative welcoming letter of invitation to participate was sent to these patients (N=59). Before entering the study, the patients were assessed medically, first by a general practitioner, and subsequently by a specialist in physical and rehabilitation medicine. Patients fulfilling the inclusion criteria were randomly selected to participate in the clinical assessment. Thirty-three volunteer participants randomly assigned from the total sample were examined independently by two physical therapists in succession (the duration of an assessment session was approximately 1 ½ hours). The examiners were randomly assigned to the first examiner in half of cases and the second examiner in the other half of cases. The examiners possessed a high level of training, averaging 5 years of clinical experience in the McKenzie method.

Magnetic resonance imaging in *Article II* was performed 1 to 5 times with a three-month intervals during the years 1997 and 1998 using a Siemens

Magnetom SP4000 with a 1,5 Tesla superconducting magnet (Magnetom Vision Siemens AG, Germany). The flow-chart of study I is shown in FIGURE 2.

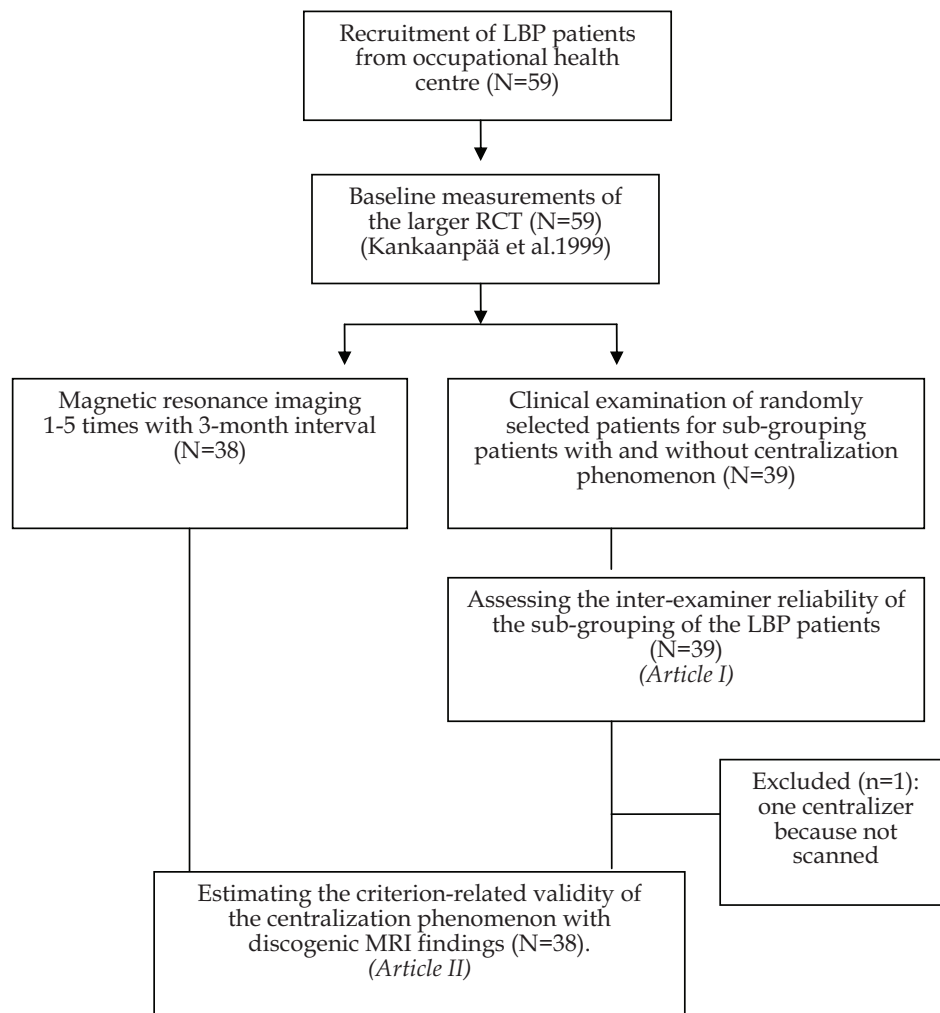


FIGURE 2 Flow-chart of study I (Articles I and II).

#### 4.1.2 Study II (Articles III, IV and V)

The intention was to investigate 180 participants from the beginning of 1998 to the end of 2000 for this study, but during the three-year period it proved possible to recruit only 136 subjects from four occupational health care centres in Jyväskylä, Finland. Occupational physicians were instructed to identify eligible subjects. Two subjects were excluded because they did not fulfil the inclusion criteria. The inclusion criteria were: being employed, age 18 to 65 years and current non-specific LBP with or without radiating pain to one or both lower

limbs. Exclusion criteria were: pregnancy, low back surgery during the past 2 months, and 'red flags' indicating serious spinal pathology. The descriptive characteristics of the participants at study entry are shown in TABLE 5.

TABLE 5 Characteristics of the population of study II at intake (N=134).

	OMT (n=45)	McKenzie (n=52)	Advice only (n=37)	Total	P-value
<b>Age</b> (years, mean, sd)	44(10)	44(9)	44(15)	44(11)	<b>0.93</b>
<b>Gender</b> (females/males)	16/29	10/42	13/24	39/95	
<b>History of previous LBP</b>					<b>0.70</b>
First episode (%)	9	6	5	7	
1-5 episodes (%)	55	46	54	51	
≥ 6 episodes (%)	36	48	41	42	
<b>Type of previous LBP</b>					
Sciatica, yes (%)	56	47	46	50	<b>0.62</b>
Lumbago, yes (%)	22	29	41	30	<b>0.19</b>
Other low back disorder, yes (%)	22	23	14	20	<b>0.49</b>
<b>Previous low back surgery, yes (n)</b>	1	0	2	3	<b>0.24</b>
<b>Symptom location</b>					<b>0.24</b>
Low back pain only (%)	29	17	31	25	
Radiating pain to the thigh (%)	29	50	36	39	
Radiating pain below the knee (%)	42	33	33	36	
<b>Duration of the current episode</b>					<b>0.82</b>
Acute: < 7 days	9	12	6	9	
Sub-acute: > 7 days < 7 weeks	40	46	44	44	
Chronic: > 7 weeks	51	42	50	47	
<b>Physical work load</b>					<b>0.96</b>
sedentary (%)	38	33	54	40	
light (%)	51	61	32	50	
heavy (%)	11	6	14	10	
<b>On sick-leave because of LBP (%)</b>	18	15	8	14	<b>0.44</b>

#### *Study II design (Articles III, IV and V)*

For study II (*Articles III, IV and V*) every patient who visited the occupational health care centre because of low back trouble and fulfilled the inclusion criteria was recruited into the study. After more than seven days from the onset of their present LBP episode, the participants (N=136) completed the questionnaires, were examined clinically (Appendix 3), classified and were randomized into one of study groups: OMT (n=45), the McKenzie method (n=52) and "advice to stay active" (n=37). Two subjects were excluded because they did not fulfil the inclusion criteria.

The clinical examination and classification (Appendix 1) was carried out by a physiotherapist, certified in the McKenzie method, prior to the randomization. The participants were randomized into the treatment groups by means of a stack of sealed envelopes numbered by an order from a random number table. The measurements were all performed by the same research assistant and coded by another, and both were blinded to the patient's group assignment. Outcome variables were assessed at study entry, immediately after the treatment period of 1-7 visits, and at 3-, 6-, and at 12-month visits. A flow-chart comparing the treatment outcomes in adults with non-specific LBP (*Article III*) is presented in FIGURE 3.

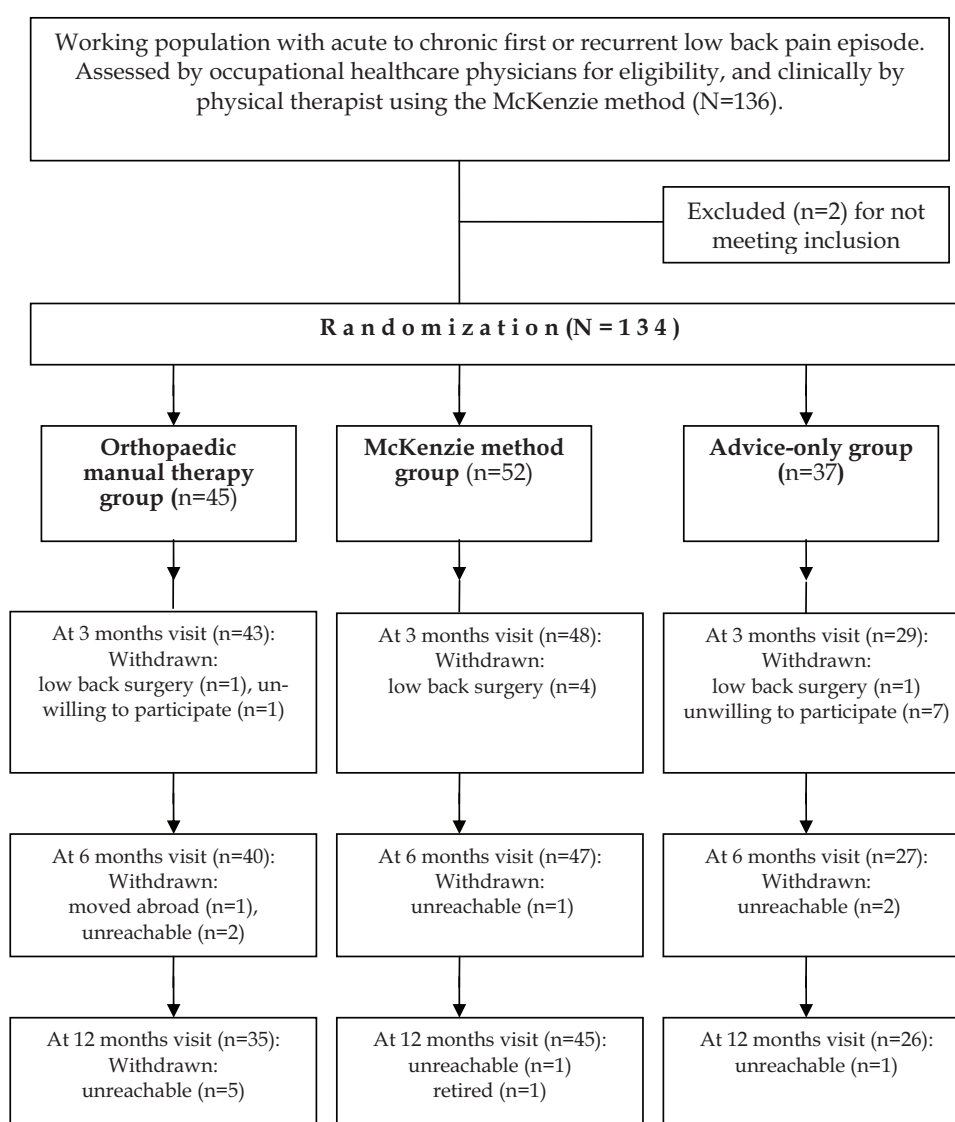


FIGURE 3 Flow-chart comparing treatment outcomes in adults with non-specific LBP.



OMT group: Participants (n=45) in the OMT group were first examined and then treated by specific mobilization and with muscle-stretching techniques (Kaltenborn et al. 2003, Evjenth et al. 1989). Additionally, the patients underwent spinal manipulation if indicated (Krauss et al. 2006). The following mobilization or/and high velocity, low-force manipulation techniques were performed: (1) translatoric thrust manipulation or mobilization of the thoracic-lumbar junction performed with the patient supine or lying on side, (2) translatoric thrust manipulation or mobilization of L1 to L5 performed with the patient prone or lying on side and (3) sacroiliac manipulation/mobilization, which in this study was a ventral or dorsal gliding of the ileum on the sacrum with the patient prone. In addition, these patients were taught to perform self-mobilization and stretching exercises at home once a day. Usually 3 to 5 individually selected home-exercises were prescribed to actively mobilize the low back, with 2 to 3 sets of 15 to 20 repetitions for each exercise, along with lumbar stabilization exercises with 10 repetitions of 10 seconds, and stretching exercises to be performed once a day for 45 to 60 seconds.

The McKenzie group: The participants (n=52) in the McKenzie group were first assessed clinically (Appendix 3) and classified into mechanical syndromes (Appendix 1). If a non-mechanical syndrome was present, the subjects were transferred from conservative care for further investigation. If a mechanical syndrome was present, then one of the treatment principles of mechanical therapy was selected as the management strategy. This consisted of (1) an educational component, supported with the book "Treat Your Own Back" (McKenzie, 1985) and (2) an active therapy component providing individual instructions for exercises. These were repeated on a regular basis several times a day according to the principles of the approach: 10-15 repetitions every 1 to 2 hours (with or without a sustained end-range position according to symptom response of direction-specific exercises). If improvements in symptom response were not sustained or were too slow in coming, patient-generated forces were supplemented by clinician-generated forces: over-pressure or mobilisation or both by the therapist within the same treatment direction principle of management. "High velocity, low-force" manipulation techniques were not used in this group during this trial (McKenzie and May 2003).

"Advice to stay active" group: Participants in the advice to stay active ("advice only") group received 30-45 min physiotherapist counselling by physiotherapist about the good prognosis of LBP, pain tolerance, medication and early return to work. The participants in the group were told to avoid bed rest and advised to continue their routines as actively as possible, including exercise activities, within the limits permitted by their back pain. They were also instructed to contact their physician if the symptoms got worse. A two-page summary booklet (Burton et al. 1999) in Finnish related to these items was also given to the patients (Takala 1995; Appendix 5).

In both therapy groups, the physical therapists treated their patients independently by the method in which they were certified. All treatments were provided to each individual participant by the same therapist. The OMT was

carried out by a physical therapist (Markku Paatelma) with 20 years of clinical experience in this field at the time of the study. The McKenzie method was carried out by a physical therapist (Sinikka Kilpikoski) with 10 years of experience in this therapy method. The physical therapist (Riitta Simonen) who advised the subjects to stay active and continue normal daily living had 5 years of clinical experience in treating patients with LBP.

## 4.2 Ethical aspects

The studies were conducted according to good clinical and scientific practice. All subjects were carefully informed both orally and in writing about the study design and the potential risks involved. Every subject was provided with a written informed consent before the study, and the study protocols were approved by the local ethics committee of the Kuopio University Hospital, Kuopio, Finland (Study I) and of the University of Jyväskylä, Jyväskylä Finland (Study II).

## 4.3 Evaluation of subjects and outcome measures

### 4.3.1 Clinical evaluation

The clinical assessment for *Articles I and II* consisted of taking disease history and physical examination including observational visual assessment of range and quality of motion, recording anatomical location of dominant pain, nerve tension tests, key muscle strength tests, light touch sensitivity, and the standardized test of single and repeated end range movements and/or sustained end range positions as described by McKenzie (1981).

In testing the centralization phenomenon during the mechanical assessment the exact site and change in the location of low back and referred pain was recorded. The patient was classified as a centralizer if the pain was found to move from the periphery towards the spinal midline and remained more central in response to a specific direction of testing. If there was midline spine pain only and it was abolished and remained so this too was classified as centralization. Patients who were symptom-free, or in whom no change in the location of pain was observed, or whose pain was found to move only towards periphery (peripheralization) during the assessment were classified as non-centralizers.

The movements and positions used to determine centralization are highly standardized and consist of standing flexion, standing extension, side gliding in standing to the left and right (a form of lateral flexion), supine flexion, prone extension, asymmetric prone lumbar extension, and lumbar rotation performed in the supine position (Appendix 2). In study I the physical examination was

performed twice, once by each examiner; and once in the study II before randomization. The participants were asked to stand in their normal relaxed position, with their feet approximately 20 cm apart, on a marked line. A plumb-line passing through C7 to S1 assisted in identifying the presence and direction of a lateral shift. The examiners completed the lumbar spine assessment forms and data collection forms, based on the original McKenzie form (Appendix 3). The syndrome categories were expanded to form subgroups, and the category "other" included inconclusive mechanical pain patterns and non-mechanical conditions in which pain was not presumed to originate from the spine (cf. FIGURE 1; Appendix 1). After completing the forms, the examiners sealed them in envelopes for storage pending data analysis.

### **4.3.2 Questionnaires**

The intensity of leg and low back pain was measured with a visual analogue scale (VAS) which allowed the subject to rate his or her current intensity of leg and low back pain from 0 (no pain/symptoms) to 100 (worst imaginable pain/symptoms) (Scott et al. 1978).

The Roland-Morris Disability questionnaire (RMQ) (0 to 24-point scale) was used to measure disability in daily activities in relation to low back trouble during the previous 3 months (Roland et al. 2000). Functional status in relation to low back trouble during the previous three months was evaluated with a seven-item ADL (activities of daily living) index on a scale from 0 (no problem) to 4 (unable to perform). The seven daily activities were forward bending, dressing, driving a car, rising from sitting, walking more than 1 km, sleeping, and carrying a load.

### **4.3.3 Radiological assessment**

The patients were imaged between 1 to 5 times (mean 3) with three-month intervals during the years 1997 and 1998 (mean interval 56 days, range 0 - 195 days) before the clinical assessment. Magnetic resonance images were acquired with patients lying supine with knees slightly bent, the position maintained with a cushion. The spinal levels from L1 to L5 were imaged axially and sagittally with T1- and T2-weighting. Images were recorded and analyzed by a radiologist at Kuopio University Hospital, Kuopio, Finland. Possible MRI findings of discs associated with pain such as bulging disc, disc protrusions, disc prolapses / extrusions, disc space narrowing and high intensity zones (HIZ) were recorded as discogenic source of pain (Appendix 4). The examiners conducting the clinical assessment in test-retest manner were blinded from each other and to the results of imaging findings. The radiologist was blinded to the results of the clinical examination and classifications.

#### 4.3.4 Statistical methods

The demographic characteristics of the study reported in *Article I* were summarized for descriptive purposes with means and standard deviations for continuous measures, and frequencies and percentages for categorical measures. Variability between the two examiners in binary decisions was expressed by the kappa coefficient ( $\kappa$ ) and by the proportion of observed agreement (%). The kappa statistics provides an index of chance-corrected agreement. Together, these indexes offer a single expression that summarizes the results from the 2 x 2 contingency table of concordance. The verbal translations of the kappa scores are as follows: 0 to 0.20 (poor agreement), 0.21 to 0.40 (slight agreement), 0.41 to 0.60 (moderate agreement), 0.61 to 0.80 (good agreement) and 0.81 to 1.0 (very good/excellent agreement) (Cohen 1960).

For *Article II*, the inter-examiner reliability statistics were re-calculated using the DAG Stat Excel spreadsheet. The criterion-related validity was analyzed in 2 x 2 contingency table using Confidence Interval Analysis Software (© Trevor Bryant 2000-2004, University of Southampton, UK. 2.1.2. Build 50) (MacKinnon 2000), and was expressed as sensitivity, specificity, positive (PPV) and negative predictive values (NPV), positive and negative likelihood ratios (LR +/-) with confidence intervals, and with diagnostic confidence statistics (Sackett et al. 1991, Sim and Waterfield 1997). Changes in features associated with discogenic pain on MRI performed from 1 to 5 times in 3-month intervals during the years 1997 and 1998 were analyzed by MANOVA (multivariate analysis of variance).

The baseline characteristics of the study II were summarized for descriptive purposes using medians and quartiles for continuous measures and percentages for categorical measures. The outcome comparisons were analyzed firstly between participants with non-specific LBP treated either with "advice only" or with OMT or the McKenzie method (*Article III*), secondly between participants with centralizing LBP treated either with advice to stay active only, OMT or the McKenzie method (*Article IV*), and finally between participants with and without centralizing LBP. Both of these groups (centralizers and non-centralizers) included participants who were treated by "advice only", or by OMT or by the McKenzie method (*Article V*). The data were analysed by the intention-to-treat principle with post hoc tests using ANOVA (analysis of variance). Post hoc between-groups comparisons were performed using Sheffe's adjustment for multiple comparisons. An alternative analysis was conducted that accounted for drop-outs at follow-up, whereby missing values were replaced with imputed values generated by a series of estimated marginal means of measuring two-tailed equations, i.e. subjects' previous scores were used to determine a predicted value that reduced the variance of the value for each variable. For all comparisons, a probability of < 0.05 was considered statistically significant (two-tailed) (Hicks 2000, Sim and Wright 2000).

## 5 RESULTS

### 5.1 Descriptive characteristics of the study population

Study I. Thirty-nine (39) volunteers with non-specific LBP, mean age 40 years (range, 24-55 years) with or without radiation to the lower limb(s) participated in study I (*Articles I and II*). Twenty-four (62%) were men. Fifty-nine per cent of the patients had experienced six or more recurrent LBP episodes during their lives. The descriptive data of the patients in study I are presented in TABLE 4. One centralizer was excluded from the diagnostic validity calculation, because he was not scanned. Thirty-three patients were agreed to be centralizers, two patients were symptom-free and one had non-centralizing pain. The examiners disagreed in classifying two patients. One classified them as centralizers and the other as non-centralizers. The MRI findings on the eligible thirty-three centralizers were compared in this study (*Article II*). Most patients, 61% (n = 20) were scanned less than two weeks prior to the clinical assessment (mean 6 days before, range 0-13 days). No statistically significant changes were observed in MRI findings when analyzed with repeated measures of MANOVA (multivariate analysis of variance).

Study II. One hundred and thirty-four (N=134) participants mean age 44 years, with acute to chronic non-specific LBP, with or without radiation to the lower limb(s) participated in study II. At the beginning of the study, centralizing pain was found in 119 (88%) participants. The non-centralizing group included: one (1%) with postural syndrome, five (4%) with dysfunction syndrome, four (3%) with irreducible derangement with "peripheralization only" and five (4%) "other" (FIGURE 1, Appendix 1). There were no significant differences in descriptive characteristics between the intervention groups at baseline in age, gender, or other clinical features (*Articles III and IV*). It was only when patients with and without centralizing LBP were analyzed for *Article V* that some statistically significant differences were found between the two groups. The non-centralizers (n=15) reported in questionnaires more previous attacks of lumbagos (p=0.022) than the centralizers, who instead had

experienced more attacks of episodes of non-radiating LBP ( $p=0.012$ ) than the non-centralizers recorded by clinical examination. The distribution of mechanical syndromes classified on the initial visit is shown in TABLE 6.

TABLE 6 Distribution of mechanical syndromes in the population in study II (N=134).

Mechanical syndromes*	OMT (N=45)	McKenzie(N=52)	Advice(N=37)
Reducible derangement with centralizing LBP	n = 42	n= 48	n=29
Irreducible derangement with non-centralizing LBP		n=2	n=2
Dysfunction	n = 1	n=1	n =3
Postural			n =1
"Other" condition	n = 2	n=1	n= 2

\* Mechanical syndromes are described in detail in FIGURE 1 and in Appendix 1.

## 5.2 Inter-examiner reliability in McKenzie clinical assessment (Article I)

The inter-examiner reliability of the McKenzie lumbar spine assessment during the performance of clinical tests was poor to moderate in visually defining the presence and direction of lateral shift (sciatic scoliosis). However the agreement on the relevance of lateral shift (sciatic scoliosis) according to symptom responses was good ( $\kappa = 0.7$ ;  $p < 0.000$ ). In sub-grouping these non-specific LBP patients (N=39) was found that 87% (n=34) demonstrated centralizing pain, and the agreement was excellent, 95% ( $\kappa = 0.72$ ; CI 95% 0.41, 1.0; SE of  $\kappa$  0.192). Agreement of directional preferences of these centralizers was also excellent, 90% ( $\kappa = 0.9$ ;  $p < 0.001$ ). The agreed-on specific directions were lumbar extension, compromising asymmetrical extension (67%), side-gliding (27%) and rotation in flexion (6%) (Appendix 2, TABLE 7). In classifying patients into the main syndromes, agreement was good ( $\kappa = 0.6$ ;  $p < 0.001$ ) and classifying them into specific sub-groups slightly better ( $\kappa = 0.7$ ;  $p < 0.001$ ).

## 5.3 Association of pain centralization with lumbar discogenic MRI findings (Article II).

The centralization phenomenon was associated with specific abnormalities in intervertebral discs as determined by MRI. The prevalence of discogenic MRI findings was 82% in total sample (N=38) and 94% among the agreed-on centralizers (N=33). Assumed features of discs most closely associated with pain on MRI were alterations in disc shape contour and disc narrowing, High



Intensity Zone lesions and endplate changes, which were concatenated into a single variable. Twenty-nine (88%) agreed-on centralizers had alteration of disc shape contour at least at one spinal level in conjunction with disc space narrowing mostly at levels L3 to L5. Only one centralizer with referred pain below the knee had no visible structural abnormalities on MRI. Almost half (n=16) of the centralizers also had other imaging abnormalities such as stenosis, anterolisthesis, retrolisthesis, and/or zygapophyseal joint osteoarthritis (TABLE 7). The criterion-related validity of centralization in relation to the assumed discogenic MRI findings was: sensitivity 0.91 (95%CI 0.8-0.96), specificity 0.5 (95%CI 0.018-0.82), PPV 0.94 (95%CI 0.83-0.98), NPV 0.40(95%CI 0.14-0.73), positive LR+1.8 (95%CI 0.8-4.2) and negative LR-0.18 (95%CI 0.05-0.6). The diagnostic confidence value was 94% (TABLE 8).

TABLE 7 Directions of loading producing the centralization phenomenon and the MRI findings at different level from L1 to L5 among agreed centralizers (N=33)

Direction of loading:	Discogenic finding* in MRI	Other abnormalities* in MRI
Lumbar extension (n=7):	<b>L1:</b> <b>L2:</b> Narrowing (2). <b>L3:</b> Extr (1), Narrowing (2). <b>L4:</b> Bulge (1), Extr (2), Narrowing (3). <b>L5:</b> Bulge (2), Prot (1), Extr (1), Narrowing (5).	<b>L1:</b> Retro (1). <b>L2:</b> Retro (1). <b>L3:</b> Retro (1), Stenosis (1). <b>L4:</b> Retro (1), Facet (1). <b>L5:</b> Antero (1), Retro (1), Facet (1).
Lumbar extension with hips off centre and side-gliding forces (n=24).	<b>L1:</b> Bulge (1), Extr (1), HZ (1), Narrowing (4). <b>L2:</b> Bulge (2), Narrowing (3). <b>L3:</b> Bulge (3), Prot (2), Extr (2), Narrowing (7). <b>L4:</b> Bulge (3), Prot (7), Extr (3), Narrowing (14). <b>L5:</b> Bulge (5), Prot (2), Extr (4), Narrowing (14).	<b>L1:</b> Facet (1). <b>L2:</b> <b>L3:</b> Stenosis (1), Facet (1). <b>L4:</b> Retro(2), Stenosis(6), Facet (4). <b>L5:</b> Antero(2),Stenosis(2),Facet (3).
Rotation in flexion (n=2).	<b>L1:</b> <b>L2:</b> Bulge (1). <b>L3:</b> <b>L4:</b> Bulge (1), Extr (1), Narrowing (2). <b>L5:</b> Prot (1), Narrowing (1).	<b>L1:</b> <b>L2:</b> <b>L3:</b> <b>L4:</b> Retro (1),Stenosis (1),Facet (1). <b>L5:</b>

\* Bulge = a bulging disc, Prot = protruded disc, Extr = extruded disc, Narrowing = disc space narrowing, HZ = high intensity zone, Retro = retrolisthesis, Antero= anterolisthesis, Stenosis = foraminal or spinal stenosis, Facet = zygapophysial joint arthritis.  
 $\beta$  Number in brackets means numbers of the finding in question.



TABLE 8 The 2x2 contingency table comparing “centralizing or non-centralizing pain” with features of discogenic pain such as bulged, protruded, prolapsed / extruded discs, disc space narrowing and disc disruptions (HIZ) on MRI among LBP patients (N=38).

Centralizing pain	Features of discogenic pain on MRI	Features of discogenic pain on MRI	Totals
	Yes ( + )	No ( - )	
Yes ( + )	31	2	33
No ( - )	3	2	5
Total	34	4	38

#### 5.4 Comparison of the three treatment interventions studied (Articles III, IV, and V).

At study commencement lower limb and low back pain, disability and functional status were similar across the three groups. Immediately after the treatment period of 1-7 (mean 6) visits a significant improvement ( $p < 0.001$  for all improvements) occurred in each group, although LBP decreased significantly more among centralizers ( $p = 0.001$ ) in the McKenzie group (Article IV) than in the “advice to stay active” group. At 3 months, leg pain had decreased more among centralizers in the McKenzie group than in the OMT group ( $p = 0.011$ ) and LBP more in the McKenzie than in the “advice to stay active” group ( $p = 0.037$ ; Article IV), but statistically significant differences between the intervention groups were observed neither between the non-specific LBP groups (Article III) nor between the centralizers and non-centralizers (Article V). However at 6 months, centralizers’ leg pain and LBP had decreased and functional status increased significantly more in both active therapy groups than in the “advice to stay active” group. This was also found in Article III between the McKenzie and the “advice to stay active” groups, but not between the therapy groups. In addition, centralizers’ disability had decreased somewhat more in the McKenzie group than in the OMT and the “advice only” groups (Article IV). At 12 months, improvements among centralizers in leg pain, disability and functional status indexes remained at a lower level in the McKenzie group than in the “advice only” group, but the differences were not clinically significant (Article IV). However, LBP and disability remained at a lower level among centralizers than non-centralizers. There were no significant differences in any outcomes between the OMT and McKenzie groups in the

pain and disability scores at any follow-up point in the non-specific LBP group. However, the participants with centralizing LBP treated with the McKenzie method had somewhat larger decrease in leg pain at 3 months and in disability at 6 months than those treated with OMT, but the differences might not have been clinically meaningful. In addition, no between-group differences emerged during the follow-up in visits to physicians or other health care professionals or in use of painkillers.

At the one-year follow-up, 71% (n=94) of the participants of the study II reported that their LBP was better or much better than at baseline. Twenty of these participants (15%) reported that they were fully recovered. Four (3%) participants had got worse and nine (7%) reported their LBP was unchanged compared with the symptom intensity at study entry. Of the rest (n=27) six had been operated and 21 were dropped out for multiple reasons, mostly from the "advice to stay active" group due to dissatisfaction with non-individualized spinal care (FIGURE 3).

During the follow-up year the drop-out rate ranged from 14% in the McKenzie group to 22% in the OMT group to 30% in the "advice only" group (*Article III*). Among those with centralizing pain (N=119), the drop-out rates were 6% (n=3), 17% (n=7) and 24% (n=7) respectively (*Article IV*). Of the six participants who had low back surgery during the follow-up, one was randomized into the OMT and one into the "advice only" groups (both subjects were classified as having centralizing LBP at study entry) and four into the McKenzie group. Two of the four subjects in the McKenzie group were classified at study entry as having centralizing LBP, but after testing one of these after a couple of visits was found him to have non-centralizing LBP while the other one's pain centralized during the intervention. This subject had surgery because of radiating leg pain due to underlying foraminal stenosis. The other two participants had non-centralizing pain with "only peripheralizing pain".

The number of treatment visits was one per subject in the "advice only" group, and ranged from three to seven in the McKenzie and the OMT groups (mean = six treatments in each group).

## 6 DISCUSSION

### 6.1 Methodological considerations

Study I: Study I was an inter-examiner observer cross-sectional analysis for which voluntary LBP patients were drawn randomly from a larger RCT (Kankaanpää et al. 1999). The examiners conducted the clinical assessment according to test-retest procedure and the clinical findings were compared with the discogenic findings on MRI. The test-retest procedure might have influenced on the inter-examiner agreement when classifying the mechanical subgroups on the basis of changes in pain location. However, the reliability in determining the mechanical subgroups was found to be good ( $\kappa = 0.7$ ), which is in line with the findings of earlier studies among trained observers (Werneke et al. 1999, Ratzmjou et al. 2000, Clare et al. 2005). The observation that most patients fell into the derangement category accords with McKenzie's original description of this mechanical syndrome (Appendix 1, McKenzie 1981) as occurring most frequently among those who seek care. It also is consistent with the findings of the previously published surveys (May 2008, Hefford 2008) where the derangement syndrome (includes centralization and peripheralization phenomena) group accounted for the largest share, approximately 80% of the mechanical syndrome groups. However, too homogenous sample may overinflate the  $\kappa$  values (Cincchetti and Feinstein 1990, Feinstein and Cincchetti 1990).

A good test is one which carries few, if any false positive and false negative results (Sackett 1991). In *Article II* there were a few false positives numerically, but there were also some cases without MRI changes, resulting in specificity equivalent to random guessing. This does not mean that these centralizers did not have discogenic pain. It may be possible that the morphological features of disc mechanics, associated with centralization, were not demonstrated by MRI in these cases. The false negative value, which "describes how often patients without the measured condition are positive for the test in question"

(Sackett 1991) was quite low in the present study. The examiners disagreed in classifying two patients with alterations of disc shape contour on MRI, and only one centralizer had no visible imaging findings. Abnormal imaging findings may be found also in asymptomatic individuals (Boden et al. 1990, Beattie et al. 1994, Weishaupt et al. 1998, Jarvik et al 2001), but in our study only one patient, who was totally symptom-free at the time of clinical assessment, had a bulging disc at the L5 spinal level. This compares with the average rates in the asymptomatic population (from 36% to 65%) (Boden et al. 1990, Beattie et al. 1994, Weishaupt et al. 1998, Jarvik et al. 2001). In addition, the prevalence of the discogenic findings (94%) among centralizers in our study was higher than shown on the average among asymptomatic subjects, i.e. from 24% to 65%, depending on the population in question (Boden et al. 1990, Weishaupt et al. 1998, Jarvik et al 2001).

Generalization of these outcomes is tentative for several reasons. First, the study included a rather small number of volunteers complaining of back pain. Also the study population might have been too homogenous with a high prevalence of centralizers. This might overinflate the kappa value and hinder the statistical analysis of validity (Cincchetti and Feinstein 1990, Feinstein and Cincchetti 1990). Further, the use of MRI as a reference standard for defining discogenic pain may be questionable. In addition, the use of only one pair of examiners might limit the generalizability of the results, although the findings are strengthened by them being in line with the results of earlier published studies among trained clinicians (Aina et al. 2004). The results are also strengthened by the fact that the patients were randomly drawn from a larger RCT (Kankaanpää et al. 1999). Furthermore, the McKenzie-trained examiners were blinded to each other and to the results of the imaging findings. However, the small groups of non-centralizers (n=5) and those with no discogenic MRI findings (n=4), resulted in wide confidence intervals for specificity, NPV and the likelihood ratios (Sackett 1991). Consequently only tentative conclusions are reasonable. In addition, the relatively long time period between the imaging and the clinical assessment might compromise the results. However, one strength of the study reported in *Article II* was the fact that multiple imaging (mean 3 times) was conducted during the larger study (Kankaanpää et al. 1999) and no significant changes were found between the findings on the successive imaging occasions. The radiologist was blinded to the results of the clinical examination and classifications. However the radiologist's determination of the MRI morphology was not subjected to inter-examiner reliability assessment. On the other hand, the examiners trained in the McKenzie method had high experience of the clinical method used. All these issues strengthen the conclusions drawn on the basis of study I (*Articles I and II*).

Study II: The aim of our RCT was to investigate 180 patients over a 3-year period. However the final number of participants available was 136, which explains the imbalance in the number of subjects between the treatment groups. The distribution of centralizers and non-centralizers (88% vs. 12%, respectively) (*Article V*) caused additional variability. However, the uneven distribution

between centralizers and non-centralizers equals the findings of earlier published surveys (May 2008, Hefford 2008). Unfortunately, we did not calculate sample size before the analysis, but the power analysis showed that the F - test will detect between-group differences equal to those implied by the sample difference. In addition, the fact that the classification into centralizers and non-centralizers were predefined and done before randomization strengthens the study protocol. Furthermore, the participants, after filling in the questionnaires, undergoing the clinical assessment and signing the informed consent, were randomly assigned to the treatment groups by the use of a stack of sealed envelopes numbered in an order prepared beforehand from a random number table.

The number of subjects in the non-centralizer group was rather small, and was thus liable to produce type II errors (Hicks 2000, Sim and Wright 2000). This group was abnormally distributed with large confidence intervals (95% CI) of the measured variables. This restricted the statistical comparison and generalization of the results. However, the data were analysed by the intention-to-treat principle, which strengthens the results. In addition, an alternative analysis was conducted that accounted for drop-outs at the follow-up. The missing values were replaced with imputed values generated by a series of estimated marginal means of measuring two-tailed equations. Subjects' previous scores were used to determine a predicted value that reduced the variance of the value for each variable, as described earlier, which strengthened the statistical analysis.

One limitation might have been the fact that centralization was determined only once at the baseline whereas in the earlier studies (Werneke et al. 2001, Fritz et al. 2003, Long, 2004, Cook et al. 2005, Skytte et al. 2005) centralization was tested over multiple visits. However, we had planned to classify the participants into centralizers and non-centralizers by using the McKenzie evaluation protocol at the initial visit prior to randomization. Only a few participants had to be re-assessed for centralization at multiple visits, which strengthens the classification used. Further, the prevalence of centralization at entry to our study was rather high (88%), yet at the same level as reported by Donelson et al. (1990) and Bybee et al. (2005). To avoid bias and to increase validity, the research assistant who evaluated and sub-grouped the participants during the initial visit had prior expertise in classification as a co-examiner in our earlier study (*Article I*). We used exactly the same protocol in these two studies with high inter-examiner agreement in determining the centralizers and non-centralizers. A high level of reliability in identifying centralization has also been found in previous studies (Fritz et al. 2000, Ratzmjou et al. 2000).

One crucial limitation might be the difference in the amount of time spent with the subjects in the different treatment groups. Those in the "advice to stay active" group had only 45 to 60 minutes of counselling compared with the members of the other groups who had 1 to 7 (mean 6) visits each lasting 30-45

minutes. Thus it could be speculated that the improvements in the two active treatment groups were due to extra therapeutic in-put.

In addition, the rather high drop-out rate in the “advice only” group might impair the generalizability of these results. The main reason for this high drop-out rate was dissatisfaction with non-individualized care. However, the use of the intention-to-treat principle with the alternative analysis strengthens the validity of the results.

Despite these limitations, the present study has a number of strengths. Since our participants were referred routinely from occupational health care services, and the interventions included commonly delivered treatments, our results might have high generalizability. The baseline characteristics of the participants in the different treatment arms were similar. Patients were also recruited in accordance with a limited number of inclusion and exclusion criteria, which led to a high level of recruitment from the pool of potential candidates. In addition, we used a randomized controlled design and the therapists in the OMT and McKenzie groups had over 20 and 10 years experience, respectively, in the field. The validity of the measurement tools used (VAS and RMQ) was good. The VAS for intensity of pain has been demonstrated to be reliable, generalizable, internally consistent measure of clinical and experimental pain sensation intensity (Price 1983, Rocchi et al. 2005). The RMQ disability questionnaire is simple, quick and easy to use. It is sensitive to changes (Kuijer 2005), and is a good measure of early and acute disability and recovery (Waddell and Burton 2001).

## **6.2 Main findings**

### **6.2.1 Inter-examiner reliability of McKenzie method.**

In this current study the classification to clinically meaningful sub-groups according to the McKenzie method showed good to excellent inter-examiner reliability. We found that the two examiners reliably agreed in performing the relevant clinical tests, in classifying patients into mechanical syndromes, and in defining the centralization phenomenon and directional preferences. Reliability was best in defining the relevance of lateral shift (sciatic scoliosis) ( $\kappa = 0.7$ ), the centralization phenomenon ( $\kappa = 0.7$ ) and the directional preferences ( $\kappa = 0.9$ ) in centralizers. Agreement was poorer in defining the presence and the direction of lateral shift ( $\kappa = 0.2$  and  $\kappa = 0.4$ , respectively), both of which are based solely on visual observation. These findings are in line with the earlier studies, in which the determination of lateral shift (sciatic scoliosis) by visual observation alone was found to be very unreliable (Kilby et al. 1990, Donahue et al. 1996, Clare et al. 2003). However, the determination of positive side-gliding test (Appendix 2), based on alteration of a patient’s reported pain, was found to be highly reliable in the study by Donahue et al. (1996) as well as in our study.



The centralization phenomenon is a common feature in assessing spinal pain. The examiners in our study I agreed that 33 patients (85%) had centralizing LBP, whereas in study II 86% of subjects were classified as centralizers. High prevalence of the phenomenon has also been noticed in earlier studies: the prevalence has varied from 58% to 91% depending on the population in question (Aina et al. 2004, Bybee et al. 2005). We found good reliability in defining the centralization phenomenon ( $\kappa = 0.7$ ). A high level of reliability in identifying centralization has also been recognized in other inter-examiner studies among McKenzie-trained clinicians (Werneke et al. 1999, Fritz et al. 2000, Ratzmjou et al. 2000, Aina et al. 2004), while it has been poor among those with low or none training (Riddle et al. 1993). The present study is to our knowledge the first to report inter-examiner agreement on “directional preferences”, which are closely related to centralization phenomenon. The agreement between our observers was found to be excellent ( $\kappa = 0.9$ ) among centralizers. This study is among those that describe the proportion of those responding to extension, flexion and/or lateral forces of the standardized mechanical loading strategies. Donelson et al. (1991) found that 40% of their study group had a directional preference of extension and 7% of flexion. We found that 67% of the patients responded to extension. This includes those requiring asymmetrical extension (= extension with hips off-center or side-gliding force before extension), whereas only 18% were “pure” sagittal extension responders (TABLE 7). We had no flexion responders, but two patients needed rotational force in flexion to initiate the centralization. The reason for these abovementioned differences might be that Donelson et al. (1991) reported only the sagittal force responders, but not those who centralized with lateral forces.

However, on the basis of these responses, patients were classified into the mechanical syndromes with a moderate to good level of agreement, which is in line with the results of earlier studies of (Fritz et al. 2000, Ratzmjou et al. 2000, Clare et al. 2004b and Clare et al. 2005).

### **6.2.2 Pain centralization and MRI findings**

In study I, we further estimated the association (criterion-related validity) of the centralization phenomenon in relation to the MRI features of discs most closely associated with pain as the criterion standard. We found that the majority of the patients (agreed by both observers) with centralizing LBP had disc abnormalities on MRI more (94%) than the average prevalence of 24% to 64% in asymptomatic populations (Boden et al. 1990, Weishaupt et al. 1998, Jarvik et al. 2001).

Centralization as a predictor of discogenic pain has previously been shown to be highly specific correlating with positive discography (Donelson et al. 1997, Laslett et al. 2005). In our study we had higher sensitivity (0.91), but lower specificity (0.50) than in the study by Donelson et al. (1997). However, the results of our study are not directly comparable to these previous studies



because the reference standards are very different. The aim in discography is specifically to identify symptomatic discs whereas MRI imaging identifies anatomical and morphologic features only, and thus does not directly test whether they are the source of pain. Thus MRI findings as a reference standard are questionable for defining the source of LBP. However, the high sensitivity of pain centralization effectively enables pain-related MRI findings among LBP population to be ruled out (Sackett et al. 1991). A McKenzie assessment of repeated movements is an inexpensive and efficient screening tool in selecting patients with MRI findings related to discogenic pain.

### **6.2.3 Effect of McKenzie treatment in low back pain**

The purpose of our RCT was first to compare the outcomes of three therapy interventions: the “advice to stay active” and OMT both recommended by the Finnish national guidelines, and the McKenzie method for treating adults with non-specific LBP. A second aim was to test the effectiveness of these treatments among those with centralizing pain diagnosed at the initial visit. The short-term outcomes of this study are in accordance with those of earlier studies (Waddell and Burton 2001, Burton et al. 2004) showing that the majority of acute LBP disorders are resolved within a 4- to 6-week-period. Our results in the “heterogeneous” non-specific LBP group are in line with those of the earlier studies as we also found significant improvement in pain and disability in all groups with no differences between the groups at the 3-months visit. This may be due to good spontaneous LBP recovery in the short term despite the fact that recurrences of LBP is frequent (Croft 1998). Differences in back pain and disability favoured the McKenzie group only at the 6-month follow-up assessment. In addition, at the 12-month follow-up the disability index had decreased in both the active therapy groups but somewhat more in the McKenzie group. At the 12-month visit two-thirds of the participants felt that their back pain was better or much better than at study entry. Only twenty subjects reported that they had fully recovered, which is less than in the study by Croft et al. (1998). However, only a few participants felt that their LBP was worse.

Previous studies (Burton et al. 1999, Little et al. 2001, Hancock et al. 2007) have suggested that advice in form of a booklet is a useful intervention when compared with the usual care given by a general practitioner, but only if the information is reinforced by all the therapists involved in the patient’s care. In addition, our results in this non-specific population are similar to the study in which “routine” physiotherapy seemed to be no more effective than one session of assessment and advice from a physiotherapist (Frost et al. 2004). “Advice to stay active” in conjunction with an educational booklet was more effective than McKenzie-type repeated movements in the study by Malmivaara et al. (1995), whereas this “advice only” group was not better than the active therapy groups in our study. Our results resemble those of Cherkin et al. (1998), where “advice to stay active” in conjunction with an educational booklet was as beneficial as manipulation or physical therapy using the McKenzie approach when treating sub-acute (more than seven days but less than 7 weeks) non-specific LBP.

Although the differences between the OMT or McKenzie groups and the “advice only” group favoured the active therapy groups to some extent, this finding was not clinically meaningful at any time point during the follow-up. However, in each group, the reduction in pain and disability was clinically significant only at the 12-month visit, if estimated according to the proposal of Ostelo et al. (2005). They estimated that the minimum clinically significant change in the VAS pain score is 20mm (Ostelo et al. 2005). On the average, patients with greater pain require a greater change in the VAS score to achieve clinically significant pain relief (Bird et al. 2001, Kovacs et al. 2007). Salaffi et al. (2004) also found that patients with a high baseline level of pain (> 70 mm) reported greater changes in pain than did patients with lower baseline scores (less than 40 mm). Furthermore, Farrar et al. (2001) found that clinically important change in chronic pain was approximately two points or a reduction of 30%, whereas improvement less than 15 mm is meaningless among sub-acute and chronic LBP patients (Kovacs et al 2007). As the mean baseline scores of low back and leg pain intensity among our patients were in average less than 40 mm, it could be assumed that the decrease in the pain intensity scores was also lower.

The minimum clinically significant change, when measuring disability with the Roland-Morris questionnaire (RMQ), has been estimated to be at least 3.5 points or a reduction of 30% from the baseline value (Jordan et al. 2006). In sub-acute and chronic patients, improvements in disability due to LBP of less than 2.5 points should be seen meaningless (Kovacs et al. 2007). At the 6-month follow-up, low back and leg pain and disability showed a tendency for improvement in both the active therapy groups compared with the “advice only” group. The reduction in LBP was approximately 30% (30 mm) on a VAS and five points or 50% on the RMQ index, which both represent a clinically significant change (Ostelo et al.2005, Jordan et al. 2006). The decrease in the intensity of LBP in the treatment groups was in line with earlier findings (Wand et al. 2004, Niemistö et al. 2005, Pengel et al. 2004), showing similar improvements in LBP (56-63% at 3- to 12-month follow-ups) to those in our study. The disability improved in each group to the same extent as in the studies of Frost et al. (2004) and Wand et al. (2004).

It is assumed that the large non-specific heterogeneous group of patients with LBP would be treated more effectively if patients could be assigned to more homogeneous subgroups (Spitzer et al. 1987, Leboeuf-Yde et al.1997, Borkan et al. 1998, Bouter et al. 1998). The purpose of the secondary analysis of our RCT was to find out whether patients with centralizing LBP might achieve better outcomes when treated by individually tailored advice in conjunction with directional-specific exercises as compared to “advice only”. The findings of this analysis suggest that a more homogeneous subgroup in terms of pain response (centralization), defined at the initial visit, showed a tendency to better pain recovery and a longer lasting treatment outcome than those provided with “advice to stay active” only. The present findings resemble the results of earlier studies, where the centralization phenomenon has been shown to be associated

with good treatment outcomes (Fritz et al. 2003, Aina et al. 2004, Long et al. 2004, Cook et al. 2005, Skytte et al. 2005, Werneke et al. 2008). Although low back and leg pain decreased significantly more in the McKenzie group than in the other two groups, the differences were not clinically meaningful. However at the 6-month follow-up, low back and leg pain and disability showed a tendency to significant improvement in both the active therapy groups compared with the “advice to stay active” group, and was clinically significant between the McKenzie and “advice only” groups. At 12 months, the outcomes in the McKenzie group remained at a decreased level. One reason for this difference might be that in our study at the 12-month visit most of the centralizers (more than 80%) in the active therapy groups reported that they had learnt to manage their own back pain by themselves compared to only 24% of those in the “advice to stay active” group, which could have decreased the likelihood of LBP recurrences. The tendency for longer lasting recovery in the McKenzie group in this study does not totally accord with the earlier published outcomes of RCTs, in which advice alone in combination with an educational booklet was more effective in managing LBP than other physical modalities (Cherkin et al. 1998, Frost et al. 2004, Wand et al. 2004). However, it should be borne in mind that our study was a secondary analysis of a RCT. Therefore these results are only tentative. However, this secondary analysis of data originating from our RCT (*Article IV*) suggests that centralizers have tendency to achieve better treatment outcomes when treated by individually tailored advice with directional-specific exercises than “advice to stay active” only.

The other secondary analysis of our RCT (*Article V*) demonstrated that centralizing pain defined at the initial visit might be a sign of a better prognosis in comparison to non-centralizing pain, independent of the intervention used, among working-age adults with LBP. Repeated determination of centralization has been shown to increase the reliability of this prognostic sign (Werneke and Hart 2003).

Our findings are in line with the results of earlier studies (Fritz et al. 2003, Aina et al. 2004, Long 2004, Cook et al. 2005, Skytte et al. 2005, Werneke et al. 2008), in which LBP and disability improved more among centralizers than among non-centralizers. Although the changes between these two groups in the present analysis differed statistically significantly only at some follow-up points, a clinically significant change was found immediately after the treatment period among centralizers in LBP (mean improvement in VAS of 21 mm) and in disability (mean improvement in RMQ of 6 points). Yet, the differences tended to remain at a decreased level throughout the follow-up period in this group. One explanation for these discrepancies with the results of earlier studies might be the fact that in our study centralization was determined only once at study entry, whereas in the earlier studies (Fritz et al. 2003, Aina et al. 2004, Long, 2004, Cook et al. 2005, Skytte et al. 2005, Werneke et al. 2008), the phenomenon was evaluated during subsequent treatment visits. Another explanation could be that unlike in previous studies (Fritz et al. 2003, Aina et al. 2004, Long, 2004, Cook et al. 2005, Skytte et al. 2005, Werneke et al. 2008), the

present group of non-centralizers also included subjects with other types of activity-related LBP, not only subjects with “peripheralizing” pain (Werneke et al. 2003), but also those with pain at the end of the range of restricted motion, or pain of “other” than mechanical origin (FIGURE 1, Appendix 1).

## 7 PRIMARY FINDINGS AND CONCLUSIONS

The main findings of the present study can be summarized as follows:

1. Examiners trained in the McKenzie method were able to agree in defining the clinically meaningful tests and sub-groups relevant to the mechanical diagnosis and therapy approach.
2. The clinical phenomenon of pain centralization and structural MRI changes gave preliminary evidence of a relationship between clinical signs and discogenic MRI findings, a result which could be useful when differentiating discogenic from non-discogenic LBP in clinical settings without MRI equipment.
3. Adults with non-specific LBP improved in leg and low back pain and in disability irrespective of the nature of intervention used in our study. However the OMT (including high velocity, low-force manipulation techniques) and the McKenzie (excluding high velocity, low-force manipulation techniques) groups showed no consistent treatment effect compared with the “advice to stay active” group during the 12-month follow-up. However, the OMT and the McKenzie groups showed slight positive treatment effect when compared with the advice-only group.
4. The subgroup of centralizers had a tendency to achieve better treatment outcomes when treated by the directional-specific exercises used in the McKenzie method compared to “advice to stay active”.
5. Centralizing LBP, identified at the initial visit tended to predict better treatment outcomes compared to non-centralizing pain independently of the intervention used.

## YHTEENVETO

### **McKenzien mekaaninen diagnostisointi- ja terapiamenetelmä tutkittaessa, luokiteltaessa ja hoidettaessa aikuisten epäspesifiä alaselkäkipua.**

McKenzien mekaanisessa diagnostisointi- ja terapiamenetelmässä potilaat luokitellaan oireyhtymiin vakioidulla kuormitusmenetelmällä oireiden mukaisesti. Kivun sentralisaatio-ilmiö on keskeinen löydös tutkittaessa alaselän kipua. Kivun sentralisaatio-ilmiöllä tarkoitetaan alaraajaan säteilevän kivun vähenemistä tai poistumista raajan ääreisosista. Kivun tuntemus siirtyy eli kipu sentralisoi- tuu raajan yläosiin tai keskelle alaselkää. Sentralisaation tapahtuessa selän liike- laajuus lisääntyy ja henkilön toimintakyky paranee. Ilmiön on todettu olevan yhteydessä välilevyperäiseen kipuun, ja kun sentralisaatio tapahtuu, sillä on todettu olevan hyvä konservatiivisen hoidon ennuste.

Tämän viidestä osajulkaisusta koostuvan kliinisen tutkimuskokonaisuuden tarkoituksena oli selvittää voidaanko epäspesifi alaselkäkipu luokitella aikuisilla luotettavasti käyttämällä McKenzien kehittämää diagnostisointi- ja luokittelumenetelmää. Toisena tavoitteena oli verrata kolmella eri konservatiivisella menetelmällä kuntoutettujen potilaiden hoidon tuloksia satunnaistetussa tutkimusasetelmassa vuoden seurannassa.

Tutkimus koostui kahdesta erillisestä tutkimusjoukosta (N=173), joiden keski-ikä oli 42 vuotta. Ensimmäisessä tutkimusjoukossa oli 39 kroonista alaselkäpotilasta, joilla oli ollut selkävaiavaa keskimäärin 14 vuoden ajan (1-38 vuotta). Heidät tutkittiin kliinisesti toistomittausperiaatteella. MRI -tutkimukset toteutettiin pitkittäistutkimusasetelmalla kolmen kuukauden välein 1-5 kertaa.

Aluksi selvitettiin kahden McKenzien menetelmään koulutetun tutkijan välistä luotettavuutta luokiteltaessa alaselkäkipupotilaat mekaanisen terapian kannalta oleellisiin alaryhmiin ja oireyhtymiin. Tutkijoiden välinen luotettavuus ilmaistiin prosentuaalisesti ja Cohenin kappa-kertoimella. Toiseksi arvioitiin sentralisaatio-ilmiön ja alaselän välilevyperäisten MRI löydösten yhteys (kriteeripohjainen validiteetti), mikä ilmaistiin herkkyytenä, tarkkuutena, positiivisena ja negatiivisena ennustearvoina sekä uskottavuusosamäärinä, sekä lisäksi diagnostisena toteutumismahdollisuutena.

Toisessa tutkimusjoukossa oli 134 selkäkipua potevaa 18 - 65-vuotiasta (keskiarvo 44 vuotta) työssäkäyvää miestä (n=95) ja naista (n=39), joiden alaselkäkipu ja siihen liittyvä(t) alaraajan oireet olivat kestäneet vähintään 7 päivää ennen terapian aloittamista. Henkilöt jotka olivat raskaana, tai joilla oli vakavia muita sairauksia tai joiden alaselän leikkauksesta oli vähemmän kuin 2 kuukautta suljettiin pois tutkimuksesta.

Tavoitteena oli verrata kahdella eri konservatiivisella terapiamenetelmällä sekä käypähoitosuosituksen ohjeella ”pysyä normaalisti aktiivisena” kuntoutettujen aikuisten hoitotuloksia. Osallistujat arvottiin sattumanvaraisesti kolmeen eri ryhmään, jotka olivat ortopedinen manuaalinen terapia-ryhmä (OMT) (n=45), McKenzie-ryhmä (n=52) ja ”ohjeella pysyä aktiivisena” -ryhmä (n=37).

Tuloksia verrattiin ensin kaikkien erityyppistä selkävaivaa potevien välillä (N=134), ja toiseksi niiden välillä, joiden oireet sentralisoituivat alkututkimuksessa (n=119). Lopuksi tutkittiin ennustaako alkututkimuksessa määritelty sentralisaatio-ilmio terapian tuloksia.

Hoidon vaikuttavuutta mitattiin alaselän ja jalkakivun voimakkuudella ns. kipujanaa käyttäen (VAS), haitta-asteella (Roland-Morris -indeksi) ja toimintakykyisyyttä seitsemällä eri päivittäisellä toiminnalla alkututkimuksessa, välittömästi hoitojakson jälkeen, sekä 3, 6 ja 12 kuukauden kuluttua. Tuloksia käsiteltiin tilastollisesti hoitoaikeen mukaista tarkastelua käyttäen (ITT-analyysi).

Tutkijoiden välinen luotettavuus oli hyvä luokiteltaessa alaselkäpotilaat McKenzién menetelmälle oleellisiin alaryhmiin sekä oireyhtymiin. Sentralisaatio oli yhteydessä välilevyperäisiin MRI - löydöksiin. OMT- ja McKenzién menetelmät olivat vain lievästi parempia hoidettaessa epäspesifisestä alaselkävasta kärsiviä potilaita verrattuna käypähoito-suosituksen ohjeeseen pysyä aktiivisena. Tutkittavat, joiden oireet sentralisoituivat ja jotka kuntoutettiin McKenzién menetelmällä, näyttivät toipuvan paremmin ja oireet pysyivät pidempään parempina verrattuna heihin, joita vain neuvottiin pysymään aktiivisena. Lisäksi, ne joiden oireet sentralisoituivat alkumittauksessa, näyttivät toipuvan paremmin ja heidän oireensa pysyivät parempina pidempään verrattuna heihin, joiden oireet eivät sentralisoituneet riippumatta siitä millä menetelmällä heidät oli hoidettu.

Johtopäätöksenä voidaan todeta, että tämä tutkimus antaa lupaavan kuvan McKenzién mekaanisesta tutkimus- ja hoitomenetelmästä luokiteltaessa ja kuntoutettaessa potilaita, joilla on epäspesifi alaselkävaiva. Kuitenkin tulokset ovat ainoastaan suuntaa-antavia. Sen tähden laaja-alaisempi tutkimus luokituilla alaselkävasta potilasryhmillä olisi tarpeen tulosten varmistamiseksi.



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## Appendix 1 The mechanical syndromes (McKenzie 1981) 1/1

**Syndrome:** A syndrome is a characteristic group of symptoms and pattern of happenings typical of a particular problem (The Chambers Dictionary).

**Postural Syndrome:** Pain is caused by mechanical deformation of normal soft tissues or vascular insufficiency arising from prolonged positional or postural stresses, affecting any articular or contractile structures.

### Clinical presentation

Age: usually not over 30 years  
 Poor posture; no movement loss  
 Intermittent pain, local pain  
 Better when on the move

### Test movements

Repeated movements do not reproduce the pain originating from postural syndrome  
 Pain can be reproduced only by sustained positions or posture  
 Not progressively worse; no rapid changes in symptom

**Dysfunction Syndrome:** Pain caused by mechanical deformation of structurally impaired soft tissues. These abnormal tissues may be the product of previous trauma, or inflammatory or degenerative processes. These events cause contraction, scarring, adherence, or adaptive shortening. Pain is felt when the abnormal tissue is loaded. Dysfunction may be located in articular or contractile tissue.

### Clinical presentation of Flexion dysfunction syndrome

Age: Usually over 30 years, unless trauma or derangement is a causative factor  
 May present with poor posture, and the patient always has a loss of movement or function  
 Intermittent pain, only at the end of the range of flexion  
 No pain during movement; no radiation

### Test movements

Repeated movements reproduce pain at the end-range of flexion, but pain remains not worse as a result of repeated flexion  
 Not progressively worse; no rapid changes in symptoms

### Clinical presentation of Extension dysfunction syndrome

Age: Usually exceeds 30 years, unless trauma or derangement is a causative factor  
 May present with poor posture, and the patient always has a loss of movement or function  
 Intermittent pain, only at the end of the range of extension  
 No pain during movement; no radiation  
 Difficulties while sleeping in prone position

**Test movements**

1/2

Repeated movements reproduce pain at the end-range of extension, but pain remains not worse as a result of repeated extension  
 Not progressively worse; no rapid changes in symptoms

**Clinical presentation of Side-glide dysfunction syndrome**

Age: Usually exceeds 30 years, unless trauma or derangement is a causative factor  
 May present with poor posture, and the patient always has a loss of movement or function  
 Intermittent pain, only at the end of the range of side-glide  
 No pain during movement; no radiation

**Test movements**

Repeated movements reproduce pain at the end-range of side-glide, but pain remains not worse as a result of repeated side-glide  
 Not progressively worse; no rapid changes in symptoms

**Clinical presentation of Multidirectional dysfunction syndrome**

Clinical presentation and principles of treatment dependent on the direction of dysfunction (see single -plane dysfunction sub-syndromes)

**Adherent Nerve Root Syndrome****Clinical presentation**

Intermittent sciatica

**Test movements**

Flexion in standing produces leg pain, which stops on return to the upright position  
 Flexion in lying has no effect on symptoms  
 Repeated extension has no effect on symptoms  
 Leg symptoms are produced at end-range of flexion in standing  
 Symptoms do not remain worse after the test movements are stopped

**Derangement Syndrome:** Internal dislocation of articular tissue, of whatever origin, that causes a disturbance in normal resting position of the affected joint surfaces. This deforms the capsule and periarticular supportive ligaments resulting in pain, which will remain until such time as the displacement is reduced or adaptive changes have remodelled the displaced tissues. Internal dislocation of articular tissue obstructs movement attempted towards the direction of displacement. In spinal column derangement syndrome is caused by internal disruption and displacement of the fluid nucleus/annulus complex of the outer innervated annulus fibroses and/or adjacent soft tissues resulting in back pain alone or back pain and referred pain depending on the degree of internal displacement and whether or not this causes compression of the nerve root.

**Derangement 1 (posterior displacement)****Clinical presentation**

Central/symmetrical pain, rarely buttock or thigh pain  
 No postural deformity

**Test movements**

Repeated flexion usually increases; peripheralizes pain  
 Pain often remains worse as a result of repeated flexion  
 Repeated extension usually reduces, centralizes and abolishes pain  
 Pain usually remains better as a result of repeated extension

**Derangement 2 (posterior displacement with relevant deformity of lumbar kyphosis )****Clinical presentation**

Usually constant central or symmetrical pain, with or without buttock or thigh pain  
 Deformity of lumbar kyphosis

**Test movements**

Repeated flexion progressively increases and peripheralizes the pain  
 Pain usually remains worse as a result of repeated flexion  
 Time factor is important in Derangement 2 (correction of blockage in extension requires time for a successful reduction)  
 Repeated extension, therefore, may not be possible initially  
 Sustained positioning is attempted if a major deformity of kyphosis exists  
 Pain initially decreases with prone lying in flexed position; derangement reduces gradually by increasing the extension in unloaded position.

**Derangement 3 (posterior/-lateral displacement)****Clinical presentation**

Unilateral or asymmetrical pain, with or without buttock or thigh pain  
 No postural deformity

**Test movements**

Repeated flexion usually increases; peripheralizes pain  
 Pain may remain worse as a result of repeated flexion  
 Repeated extension usually reduces, centralizes and abolishes pain; if pain does not decrease or centralize with extension, then side-glide with extension decreases the pain.

**Derangement 4 (posterior-lateral displacement with relevant deformity of sciatic skoliosis)****Clinical presentation**

Usually constant unilateral or asymmetrical pain, with or without buttock or thigh pain  
 Deformity of sciatic scoliosis (lateral shift)

**Test movements**

Repeated flexion and extension usually increases and peripheralizes the pain  
 Symptoms usually remain worse as a result of sagittal movements (flexion and extension) because of lateral shift deformity  
 Correction of lateral shift decreases and centralizes the pain  
 If the lateral shift can be successfully corrected, extension procedures often complete the reduction of the hypothesized derangement.

**Derangement 5 (posterior /-lateral displacement)****Clinical presentation**

Unilateral or asymmetrical pain, with or without buttock or thigh pain  
 No postural deformity  
 Leg pain extending below knee joint (constant or intermittent sciatica)

**Test movements**

1/4

Repeated flexion usually increases; peripheralizes pain

Symptoms may remain worse as a result of repeated flexion

Repeated extension usually reduces, centralizes and abolishes pain; if unsuccessful, then side-glide or rotation techniques decrease the pain.

**Derangement 6 (posterior-lateral displacement with relevant deformity of sciatic scoliosis)****Clinical presentation**

Unilateral or asymmetrical pain, with or without buttock or thigh pain

Leg pain extending below the knee ( usually constant sciatica)

Deformity of sciatic scoliosis (lateral shift)

**Test movements**

Repeated flexion and extension usually increases and peripheralizes the symptoms

Symptoms usually remain worse as a result of sagittal movements (flexion and extension) because of lateral shift deformity

Correction of lateral shift decreases and centralizes the pain

If the lateral shift can be successfully corrected, extension procedures often complete the reduction of the hypothesized derangement.

**Derangement 7 (anterior displacement with relevant accentuated lumbar lordosis)****Clinical presentation**

Symmetrical or asymmetrical pain, with or without buttock or thigh pain

Deformity of accentuated lordosis

**Test movements**

Repeated extension usually increases and may peripheralize the pain

Symptoms remain worse as a result of repeated extension

Repeated flexion decreases and centralizes the pain.

Symptoms remain better as a result of repeated flexion.

**“Other”:****Irreducible derangement/ Nerve Root Entrapment****Clinical presentation**

Long standing, constant radicular-type pain or/and paraesthesia

**Test Movements**

Repeated flexion may reduce the pain temporarily, but the patient is no better as a result

Range increases temporarily

Repeated extension may increase symptoms temporarily, but the patient does not remain worse after testing.

**Inconclusive mechanical pain pattern**

Behaviour of mechanical presentation, for instance movement loss, in response to particular loading strategy, but conclusion of syndrome classification is still unclear or inconclusive.

**Non-mechanical low back pain**

As infections, inflammations, fractures, cancer etc. and other than pain of spinal origin.

## Appendix 2 ( McKenzie 1981, McKenzie and May, 2003).

**Lumbar extension:** In standing by bending the trunk backwards; and in prone lying by passively raising the trunk, using the arms instead of the back muscles and at the same time keeping the pelvis down. Both manoeuvres cause extension of the lumbar spine from above downwards.

**Lumbar extension with hips off centre:** Extension in lying with hips off centre is needed if testing is inconclusive and pain unilateral asymmetrical. Hips are placed off centre, away from the side of pain and then extension in lying is repeated.

**Lumbar flexion:** In standing by bending the trunk forwards and in supine lying by using the hands to passively bend the knees onto the chest. In flexion in lying the flexion takes place from below upwards, the L5-S1 joint moving first followed by flexion in turn of each successively higher segment. In flexion in standing the flexion occurs from above downwards.

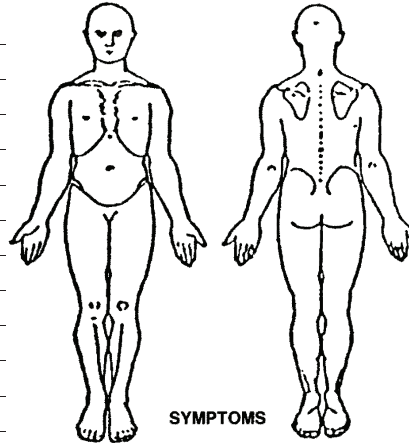
**Side-gliding:** This movement takes place when the patient laterally displaces his or hers shoulders, relative to the pelvis. This movement is different from side-bending because the shoulders remain parallel to the ground. While the patient is in the standing position side-gliding to right takes place when patient's shoulders are gliding to right in relation to the pelvis in the frontal plane viewed from behind (C7-S1).

**Rotation in flexion:** When rotation of the lumbar spine is achieved by using the legs of the patient as a lever or fulcrum of movement, confusion arises as to the direction in which the lumbar spine rotates. This is judged by the movement of the upper vertebrae in relation to the lower- for example if the patient is lying supine and the legs are taken to the right, then the lumbar spine rotates to the left.



**THE MCKENZIE INSTITUTE  
LUMBAR SPINE ASSESSMENT**

Date \_\_\_\_\_  
 Name \_\_\_\_\_ Sex M / F  
 Address \_\_\_\_\_  
 Telephone \_\_\_\_\_  
 Date of Birth \_\_\_\_\_ Age \_\_\_\_\_  
 Referral: GP / Orth / Self / Other \_\_\_\_\_  
 Work / Leisure \_\_\_\_\_  
 \_\_\_\_\_  
 Postures / Stresses \_\_\_\_\_  
 Functional Disability from present episode \_\_\_\_\_  
 Functional Disability score \_\_\_\_\_  
 VAS Score (0-10) \_\_\_\_\_



**HISTORY**

Present Symptoms \_\_\_\_\_  
 Present since \_\_\_\_\_ Improving / Unchanging / Worsening  
 Commenced as a result of \_\_\_\_\_ Or no apparent reason  
 Symptoms at onset: back / thigh / leg \_\_\_\_\_  
 Constant symptoms: back / thigh / leg \_\_\_\_\_ Intermittent symptoms: back / thigh / leg \_\_\_\_\_  
 Worse           bending           sitting / rising           standing           walking           lying  
                   am / as the day progresses / pm                                   when still / on the move  
                   other \_\_\_\_\_  
 Better           bending           sitting           standing           walking           lying  
                   am / as the day progresses / pm                                   when still / on the move  
                   other \_\_\_\_\_  
 Disturbed Sleep Yes / No           Sleeping postures: prone / sup / side R L           Surface: firm / soft / sag  
 Previous Episodes 0 1-5 6-10 11+           Year of first episode \_\_\_\_\_  
 Previous History \_\_\_\_\_  
 \_\_\_\_\_  
 Previous Treatments \_\_\_\_\_  
 \_\_\_\_\_

**SPECIFIC QUESTIONS**

Cough / Sneeze / Strain / +ve / -ve           Bladder: normal / abnormal           Gait: normal / abnormal  
 Medications: Nil / NSAIDS / Analg / Steroids / Anticoag / Other \_\_\_\_\_  
 General Health: Good / Fair / Poor \_\_\_\_\_  
 Imaging: Yes / No \_\_\_\_\_  
 Recent or major surgery: Yes / No \_\_\_\_\_ Night Pain: Yes / No \_\_\_\_\_  
 Accidents: Yes / No \_\_\_\_\_ Unexplained weight loss: Yes / No \_\_\_\_\_  
 Other: \_\_\_\_\_



**EXAMINATION**

**POSTURE**

Sitting: *Good / Fair / Poor*    Standing: *Good / Fair / Poor*    Lordosis: *Red / Acc / Normal*    Lateral Shift: *Right / Left / Nil*  
 Correction of Posture: *Better / Worse / No effect* \_\_\_\_\_ Relevant: *Yes / No*  
 Other Observations: \_\_\_\_\_

**NEUROLOGICAL**

Motor Deficit \_\_\_\_\_ Reflexes \_\_\_\_\_  
 Sensory Deficit \_\_\_\_\_ Dural Signs \_\_\_\_\_

**MOVEMENT LOSS**

	Maj	Mod	Min	Nil	Pain
Flexion					
Extension					
Side Gliding R					
Side Gliding L					

**TEST MOVEMENTS**    Describe effect on present pain – **During:** produces, abolishes, increases, decreases, no effect, centralising, peripheralising. **After:** better, worse, no better, no worse, no effect, centralised, peripheralised.

	Symptoms During Testing	Symptoms After Testing	Mechanical Response		
			↑Rom	↓Rom	No Effect
<b>Pretest symptoms standing:</b>					
FIS					
Rep FIS					
EIS					
Rep EIS					
<b>Pretest symptoms lying:</b>					
FIL					
Rep FIL					
EIL					
Rep EIL					
<b>If required pretest symptoms:</b>					
SGIS R					
Rep SGIS R					
SGIS L					
Rep SGIS L					

**STATIC TESTS**

Sitting slouched \_\_\_\_\_ Sitting erect \_\_\_\_\_  
 Standing slouched \_\_\_\_\_ Standing erect \_\_\_\_\_  
 Lying prone in extension \_\_\_\_\_ Long sitting \_\_\_\_\_

**OTHER TESTS** \_\_\_\_\_

**PROVISIONAL CLASSIFICATION**

Derangement \_\_\_\_\_ Dysfunction \_\_\_\_\_ Posture \_\_\_\_\_ Other \_\_\_\_\_  
 Subclassification \_\_\_\_\_

**PRINCIPLE OF MANAGEMENT**

Education \_\_\_\_\_ Equipment Provided \_\_\_\_\_  
 Mechanical Therapy \_\_\_\_\_  
 Extension Principle \_\_\_\_\_ Lateral Principle \_\_\_\_\_ Flexion Principle \_\_\_\_\_  
 Other \_\_\_\_\_  
 Treatment Goals \_\_\_\_\_

## Appendix 4

### KLIININEN FYSIATRIA, SELKÄPROJEKTI

NIMI: \_\_\_\_\_

NRO: \_\_\_\_\_

**-välilevyt:** 0 = normaali, 1 = pullottava annulus, 2 = protruusio, 3 = prolapsi:

a) sentraalinen

b) oikea,

c) vasen

L1	
L2	
L3	
L4	
L5	

**-stenoosi:** 0 = ei ole, 1 = sentraalinen, 2 = lateraalinen, 3 = foraminaalinen:

a. oikea

a. oikea

b. vasen

b. vasen

L1	
L2	
L3	
L4	
L5	

**-nikamavälit:** 0 = normaali, 1 = välilevyn signaalikato, 2 = päätelevyn signaali muutos,

3 = nikamavälin madaltuminen

L1	
L2	
L3	
L4	
L5	

**-olisteesi (mm)**

L1	
L2	
L3	
L4	
L5	

**-fasettinivelet:** 0 = normaali, 1 = arthroosi, joka ei ahtautta juuriaukkoa, 2 = juuriaukkoa ahtauttava arthroosi

a) oikea

b) vasen

L1	
L2	
L3	
L4	
L5	

## **ÄLÄ SUOTTA KÄRSI SELKÄKIVUSTA**

Opas pohjautuu englantilaisen selkätutkimuskeskuksen käyttämään malliin  
(The University of Huddersfield, Spinal Research Unit: Back pain. Don't suffer needlessly)  
Suomennos E-P Takala ja MUSKELI-projektiryhmä, Työterveyslaitos 1995

## Appendix 5

5/2

**Tosiasioita selkäkivusta**

- Lähes kaikilla ihmisillä on selkäkipua elämänsä jossakin vaiheessa.
- Yleensä on kysymys ohimenevästä kivusta, joka paranee parhaiten omia aikojaan.
- Lepo ei tavallisesti nopeuta paranemista.
- Kivusta ja tulevaisuudesta huolestuminen yleensä pahentaa asioita.
- Kipu ei välttämättä ole vakava oire.
- Ihminen on luotu liikkumaan ja tekemään työtä. Lian vähäinen selän kuormittaminen on todennäköisesti yhtä haitallista kuin ylikuormitus.
- Selkäkivusta ei todennäköisesti tule pysyvää ongelmaa - varsinkin jos toimit oikein.
- Kipuun liittyvien ongelmien määrään voi vaikuttaa se, kuinka ylipäätään suhtaudut kipuun.

## ☹ "Luovuttaja"

- pelkää kipua
- lepää paljon kivun vuoksi, ottaa jatkuvasti lääkkeitä ja huolestuu tulevaisuudesta
- uskoo, että kipu on aina elimistön varoitusmerkki ja kivun tunntuminen tarkoittaa lisääntyvää selän vauriota ja vammautumista – näin ei ole!

## ☺ "Selviytyjä"

- ymmärtää, että kipu on ohimenevää ja pyrkii toimimaan mahdollisimman normaalisti kivusta huolimatta
- uskoo, että selkäkipu paranee pian eikä huolestu tulevaisuudestaan
- elää kipunsa kanssa myönteisesti ja aktiivisesti sekä pyrkii olemaan työssä

**Kuka kärsii eniten?**

- "Luovuttajat" kärsivät eniten. Heidän kipunsa kestää muita pitempään, he ovat muita useammin työkyvyttömänä ja selkäkipu voi helpommin johtaa vajaakuntoisuuteen.
- "Selviytyjät" kärsivät vähemmän. Pitemmän päälle he ovat myös terveempiä.

... siis kuinka tulla "selviytyjäksi" ja välttää turhaa kärsimystä?

**Toimi näin**

- Elä mahdollisimman normaalia elämää. Se auttaa paremmin kuin vuodelepo.
- Pyri tekemään se mitä muutoinkin teet päivittäin. Arkiaskareista ei ole haittaa selälle. Vältä ainoastaan todella rasittavia ponnisteluja.
- Pyri pitämään yleiskuntosi hyvänä. Kävely, murtomaahiihto ja uinti ovat hyvää harjoitusta selälle.
- Pyri joka päivä tekemään hieman enemmän kuin edellisenä päivänä. Siten näet paranemisesi edistymisen päivittäin.
- Pyri pysymään työssä tai palaa takaisin työhön niin pian kuin mahdollista. Kysy tarvittaessa esimieheltäsi, voidaanko työtäsi tilapäisesti keventää.
- Ole kärsivällinen. Ajoittaiset selkävaivat ovat osa ihmisen normaalia elämää.

**Älä tee näin**

- Älä usko, että pelkät lääkkeet parantavat selkävaivasi. Pyri itse hallitsemaan kipusi!
- Älä huolestu. Selkäkipu ei tarkoita sitä, että Sinusta on tulossa invalidi.
- Älä selkävaivan vuoksi jää kotiin tai lopeta niitä toimintoja, joista olet elämässäsi nauttinut.

Jos uusiutuva selkäkipu jatkuu useiden päivien ajan kovana tai säteilee jalkaterään asti, ota yhteys lääkäriin. Ota pikaisesti yhteyttä lääkäriin, jos selkäkipuun liittyy virtsan tai ulosteen karkaamista, pakaroiden ja peräaukon alueen tunnottomuutta tai nopeasti etenevä alaraajan lihasvoiman heikentyminen.

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