## Light mobilization treatment of subacute, non-specific low back pain

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## Light mobilization treatment of subacute, non-specific low back pain

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2006

We must seek the basic science that helps to explain our clinical findings, instead of trying to force our patients to fit basic science.

(Gordon Waddell)

#### PREFACE

This project started in 1994. The Norwegian Parliament had demanded efforts for back pain patients, and thus made it possible for me to receive financial support to establish a spine clinic at Sykehuset Innlandet HF in Ottestad. For many years I had a special interest in back pain problems and I was concerned about the lack of organised offers within the health care system for this group of patients. I was convinced that a spine clinic would be beneficial for these patients by offering treatment by health care providers with a special competence in this field. The political decision opened possibilities for improvements, but the condition for receiving financial support was to evaluate whether the assumptions of the treatment at a spine clinic reduced sick leave for low back pain patients. I had no experience about research, how to do randomised trials, and I felt relieved when the Ministry of Health and Social Affairs appointed professor Holger Ursin at the Department of Biological and Medical Psychology, University of Bergen, to research supervisor. From his staff, Hege R. Eriksen became my personal adviser, and she visited me several times at the clinic to discuss study design and to start the process for me to acquire good knowledge of science and research. At that time I had no plans or ambitions to make a doctor's degree. My main goal was to establish a spine clinic. I was delighted by all the positive support I received from Hege and Holger, and as the study proceeded and the results showed positive effects in reduction of sick leave in the group of patients treated at the spine clinic, I became more and more interested in research. Two papers were published when Hege and Holger in May 2003 managed to persuade me to apply for entrance for the doctoral program at the Faculty of Medicine at the University of Bergen.

Stange / Bergen, September 2005

Eli Molde Hagen

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#### Abstract

**Background:** During the last decades there has been a major rise in sick leave due to low back pain, emphasising the need for interventions preventing chronicity and long term sick leave. Early intervention with information, advice, reassurance, and encouragement to stay active may be a cost-effective method for returning patients quickly to normal activity.

**Aims:** 1) To study if an early intervention at a spine clinic with information, reassurance, and encouragement to stay active may reduce sick leave for subacute low back pain (sick listed 8-12 weeks). 2) To evaluate short- and long-term clinical and cost-benefit effects. 3) To identify predictors and modifiers of treatment effect influencing sick leave. 4) To investigate if low back pain complaints are specific or part of a more general unspecific condition comparable to subjective health complaints in the normal population.

**Material and methods:** 457 patients sick listed 8-12 weeks for low back pain with or without radiating pain and age between 18-60 years were included. The patients were randomised into an intervention group (n=237) and a control group (n=220). The intervention group was examined at a spine clinic by a treatment team consisting of a physician (specialist in physical medicine and rehabilitation) and a physiotherapist. The main purpose of the intervention was to provide the patients with coping skills to manage their back pain through information for better understanding why the pain was not dangerous, and why activity was important despite the pain. The patients were given time to express their concerns and explain how the back problem affected their life and daily activities. They were given practical advice in how to resume normal activity, and they were encouraged to stay active. The control group was treated within the primary health care. All subjects filled out questionnaires. Data on sick leave, disability, and other social benefits were collected register data from the National Insurance Offices. Finally, the subjective health complaints scored by all the subjects in the study group at inclusion time were compared to reference values from a Norwegian normal population, consisting of 1240 adults.

**Results:** The intervention program had significant effect in reducing sick leave. At 3-months follow up 51.9% of the patients in the intervention group had returned to full-duty work, as compared with 35.9% in the control group. At six months 61.2% in the intervention group vs 45% in the control group had returned to work, and at 12 months 68.4% in the intervention group vs 56.4% in the control group had returned to work. (Paper 1).

Over the 3 years of observation, the intervention group had significantly fewer days of sickness compensation (average 125.7 d/person) than the control group (169.6 d/person). The difference was mainly caused by a more rapid return to work during the first year. The intervention had economic gains for the society. Net benefits accumulated over 3 years of treating the 237 patients in the intervention group amount to approximately NOK 6 049 649 (\$ 828 719). (Paper 2).

At three months follow up predictors for non-return to work, both subgroups (intervention and control group) combined, were other illnesses, the belief that work would aggravate the condition, pain when performing daily activities, and age below 41. The strongest modifying effect of the intervention on return to work was the perception of constant back strain when working and beliefs about reduced ability to work. At 12 months follow up predictors for non-return to work, both subgroups (intervention and control group) combined, were other illnesses, less than 12 years of education, low belief that back pain would disappear, and being a female. The strongest modifier for the effect of the intervention on return to work was gastrointestinal complaints. (Paper 3).

Compared to the normal reference population, the low back pain patients had significantly more low back pain, neck pain, upper back pain, pain in the feet during exercise, headache, migraine, sleep problems, flushes/heat sensations, anxiety, and sadness/depression. The prevalence of pain in arms, pain in shoulders, and tiredness was also high, but not significantly higher than in the reference population. (Paper 4).

**Conclusion:** Early intervention with examination, information, reassurance, and encouragement to engage in physical activity as normal as possible reduced sick leave for subacute low back pain and had economic gains for the society. The effect occurred during the first year after intervention. There was no increased risk for reoccurrence of sick leave due to low back pain over the next 2 years in patients returning early. The intervention was short and simple and seemed to have a main effect on work absenteeism via interacting with concerns of being unable to work. Patients suffering from low back pain also have other complaints, and these comorbid conditions may influence the prognosis, in particular the trust and ability to return to work. The intervention may have its main effect via the perception and interpretation of the condition, and the concerns underlying the decision to return to work.

**Key words:** subacute low back pain, randomised controlled study, return to work, comorbidity, subjective health complaints, predictive factors, light mobilization.

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My colleague and friend Aage Indahl had started his back project "Rygg i revers" at the Central Hospital in Østfold when I was about to establish the spine clinic at Sykehuset Innlandet HF. His experience and advice were of particular interest and value to me in my planning, and his conception of a spine clinic intervention influenced my design. Thank you for all the discussions, support, and fun.

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#### List of papers

- Paper 1 Hagen EM, Eriksen HR, Ursin H. Does early intervention with a light mobilization program reduce long-term sick leave for low back pain? Spine 2000;25:1973-1976.
- Paper 2 Hagen EM, Grasdal A, Eriksen HR. Does early intervention with a light mobilization program reduce long-term sick leave for low back pain? A 3-year follow-up study. Spine 2003;28:2309-2316.
- Paper 3 Hagen EM, Svensen E, Eriksen HR. Predictors and modifiers of treatment effect influencing sick leave in subacute low back pain patients. Spine 2005;30:2717-2723.
- Paper 4 Hagen EM, Svensen E, Eriksen HR, Ihlebæk C, Ursin H. Comorbid subjective health complaints in low back pain. Spine, in press.

#### Abbreviations

- ADS Activity Discomfort Scale
- CI Confidence Interval
- CNS Central Nervous System
- CODE Coping and Defence
- GP General Practitioner
- GRWA Graded Reduced Work Ability Scale
- ICPC International Classification of Primary Care
- LBP Low Back Pain
- MHLC Multidimensional Health Locus of Control
- NIO National Insurance Offices
- NOK Norwegian Kroner
- OR Odds Ratios
- RR Relative Risk
- SD Standard Deviation
- SHC Subjective Health Complaints
- SPSS Statistical Package for the Social Sciences
- WHO World Health Organisation

#### **INTRODUCTION**

#### 1. AIMS OF THE STUDY.

**1.0.** The main aim of this thesis was to evaluate if an early intervention at a spine clinic with information, reassurance, and encouragement to stay active could reduce sick leave for subacute low back pain, and, if so, would this also yield any cost-benefit effects. Additionally, questionnaires were used to identify predictors and modifiers of treatment effect influencing sick leave. Finally, are low back pain complaints specific or part of a more general unspecific condition comparable to subjective health complaints (pain, mood changes, tiredness, and gastrointestinal problems) in the normal population.

The thesis consists of four papers, addressing the following four research questions ("Aims"):

Aim 1: To study if an early intervention at a spine clinic with information, reassurance, and encouragement to stay active may reduce sick leave for subacute low back pain (sick listed 8-12 weeks).

Aim 2: To evaluate short- and long-term clinical and cost-benefit effects.

Aim 3: To identify predictors and modifiers of treatment effect influencing sick leave.

Aim 4: To investigate if low back pain complaints are specific or part of a more general unspecific condition comparable to subjective health complaints in the normal population.

**1.1. Early intervention and new treatment principles for low back pain. (Aims 1 and 2)** Low back pain (LBP) is common and one of the most frequent reasons for visits to a General Practitioner (GP) (Hart et al., 1995; Carey et al., 1995), sick listing and disablement benefits (The Clinical Standards Advisory Group, 1994; Brage et al., 1998a; Picavet et al., 1999). Although there is no evidence of any change in the prevalence of back pain (Leboeuf-Yde & Lauritsen, 1995; Leino et al., 1994; Ihlebaek et al., 2002), nor any evidence of any change in the pathology basis of non-specific back ache (Waddell, 2004d), there has been a major rise in sickness benefits due to LBP during the last decades, in Norway as in other welfare states (NOU, 2000; Nyman et al., 2002; Frymoyer & Cats-Baril, 1991). Uncertainty related to the understanding of pain mechanisms in the back, treatment strategies and management of back pain, may have contributed to this negative development.

Treatment recommendations for back pain in the 19<sup>th</sup> and 20<sup>th</sup> century were based on the ideas that back pain comes from the spine, involves the nervous system, is due to injury, and should be treated with rest and inactivity until the "injury" was resolved and the pain abated (Waddell, 1989; Hadler, 1987). A common advice was to be careful and to keep the back straight during activity (Brown, 1972; Zachrisson-Forsell, 1980). During the last decades at the end of the 20<sup>th</sup> century there has been a "back pain revolution" based on increasing evidence against traditional treatment by rest and for a more active approach (Deyo et al., 1986a; Waddell, 1987; Manniche et al., 1988; Malmivaara et al., 1995; Indahl et al., 1995; Waddell et al., 1997). This new active approach with more focus on resources to improve function instead of restrictions and disability made clinical sense to me as a specialist in

physical medicine and rehabilitation, and the trend of rising disability and sick leave due to LBP challenged me in the begin of the 1990's. In the literature there was no indication that normal activity could cause any injury. The need for better medical management was obvious, and it was necessary to put the growing new evidence and understanding of back pain into clinical practice. To improve health care for LBP patients I wanted to establish a spine clinic based on the assumption that unnecessary inactivity and long sick leave might be prevented by providing information for better understanding that back pain was not dangerous, and that activity did no harm to the back, to give practical advice and reassurance, combined with encouragement to stay active even though the back hurts. The first two papers in this thesis address these issues. Does an early intervention based on these new principles have any effect on sick leave (Aim 1), and, if so, what are the clinical and cost-benefit effects of the treatment? (Aim 2)

#### 1.2. Disability and pain, clinical effects. (Aims 1 and 2)

Clinical effects of a treatment may be measured by reduction of pain as well as increased abilities to function in working and social life.

Parallel to the paradigm shift in back pain management, there has been a similar change in WHO's interpretation of the term disability, moving focus from the restricted, limited function (disabilities and handicaps) in 1980 ("International Classification of Impairments, Disabilities, and Handicaps") to possibilities and the more positive terms (activities and participation) in the later revised definitions (1997: "International Classification of Impairments, Activities and Participation" / 1999: "International Classification of Functioning and Disability" / 2001: "International Classification of Functioning, Disability and Health").

Back pain does not always lead to disability and sick leave, and the amount of disability is not always proportionate to the severity of pain (Waddell, 1987). Many patients manage to live a normal life despite serious spinal pathology or severe pain, while others are totally and permanently disabled, even when they have little objective pathology (Waddell, 1987). Limitations in activity and work restrictions due to LBP can not only be explained by pain. Waddell (2004c) points out that pain and disability are not the same. Many patients, doctors and therapists assume that the pain is causing disability, and if we treat the pain, disability will disappear. This is not necessarily true. Pain is not a clinical sign, diagnosis or disease. Disability refers to restricted function.

Our knowledge of the causes of LBP and why some people develop chronic pain and disability is limited and thus makes it difficult to target the treatment. Fear of pain and avoidance behaviours are present in patients with acute LBP, and may be important factors in explaining the transition from acute to chronic conditions (Waddell et al., 1993). Fear of movement and reinjury induce inactivity and, therefore, contribute to risks of chronic disability. The longer a patient is off work because of LBP, the greater the risk of chronic pain and the lower the chance of ever returning to work (Hildebrandt et al., 1996). Back pain starts with a physical problem in the back, but in the development of chronic disability, psychosocial variables and patient's beliefs and coping behaviours play central roles (Burton et al., 1995). This is a dynamic process, and the first 6-12 weeks are probably the critical period (Gatchel et al., 1995).

#### **1.3.** Cost-benefit effects of a brief intervention. (Aim 2)

Due to the growing socio-economic problem for the society and for the individuals suffering from back pain, the Norwegian Parliament demanded in 1993 efforts for back pain patients, to reduce the waiting time to be seen by a specialist and to improve treatment and research (Ref. Stortingsmeldingen). In his pioneer study, Indahl (1995) had already shown that a brief

intervention with information, fear reduction and light activity lead to a significant reduction of sick leave at 6 months follow-up (Indahl et al., 1995). Later studies showed a remarkable long term effect of his treatment (Indahl et al., 1998). The political decision focussing on back pain made it possible for me to receive financial support from the Norwegian Ministry of Health and Social Affairs to establish an outpatient spine clinic at Sykehuset Innlandet HF, Ottestad, Norway. The old beliefs about treatment of LBP were still strong and additional data were needed for the evaluation and acceptance of the new treatment principles. The condition for the financial support from the Ministry of Health and Social Affairs was to evaluate whether the assumptions and the practice at the spine clinic reduced sickness absence for low back pain patients. Based on this condition a collaboration with the University of Bergen (Eriksen, Ursin) was established for a randomised controlled clinical study of subacute low back pain patients sick listed 8-12 weeks. In addition to the clinical effects we also investigated the cost-benefit effects of the treatment in collaboration with the Department of economics at the University of Bergen (Grasdal).

#### 1.4. Predictors of prognosis and effects of the treatment. (Aim 3)

Since the intervention was directed at changing the patient's perception and interpretation of the pain, reducing the stress and worries, and through this changing the behaviour to activity, it appeared important to evaluate prognostic factors particularly in the psychosocial area. A set of standard questionnaires used in previous international and in Norwegian research (Nasjonalt ryggnettverk) was used for this purpose

#### 1.5. Unspecific complaints and sensitisation. (Aim 4)

Finally, from theoretical and empirical data, long lasting pain conditions are known to be accompanied by a psychobiological sensitisation, reducing the threshold for perception and tolerance of pain as well as other somatic complaints. It has been suggested (Eriksen & Ursin, 2004) that several conditions involving chronic muscle pain may have neurobiological or cognitive loops that when sustained may lead to biological changes in the nervous system. Since this may affect other sensory systems as well, the level of all such "subjective" health complaints was evaluated by a standard form used for this purpose (Eriksen et al., 1999). This would elucidate how specific the back complaints are in a typical spine clinic population. (Aim 4)

#### 1.6. The thesis.

The thesis consists of the four papers addressing these aims, and an introduction giving the background for the papers and the problems addressed. This introduction also serves the purpose of demonstrating the coherence and connections between these papers, as required by the rules for a thesis.

#### 2. BACKGROUND

#### 2.1. Low back pain

LBP is defined as pain and discomfort localised below the costal margin and above the inferior gluteal folds, with or without referred leg pain (www.backpaineurope.org).

The exact cause of pain for the majority of LBP patients remains unknown. It is frequently reported that low back pain symptoms, pathology and radiological findings are poorly correlated (Espeland et al., 2001; Jarvik & Deyo, 2000; Van Tulder et al., 1997). In 80 to 90% of back pain cases there are no evident objective findings, and therefore difficult to establish a

pathological basis of pain (Deyo, 1988; Pope & Novotny, 1993; Waddell, 2004d). An approach to diagnosis is Waddell's diagnostic triage (Waddell, 2004b):

- non-specific (ordinary) backache
- nerve root pain
- possible serious spinal pathology

- Most back pain is non-specific, defined as mechanical pain of musculoskeletal origin in which symptoms vary with physical activities and includes a variety of different conditions (Waddel, 2004b).

- Nerve root pain, also called sciatica, can arise from a disk prolapse or spinal stenosis. It is a sharp, well-localised pain down the leg that at least approximates to a dermatom pattern. It radiates below the knee and often into the foot or toes. There is a lack of epidemiological studies examining the prevalence of lumbar radiculopathy, but it is assumed that less than 5% is true nerve root pain (Waddell, 2004b).

-Serious spinal pathology is often referred to as "red flags" and includes diseases such as spinal tumor and infection, and inflammatory disease such as ankylosing spondylitis. About 1% of people seen with LBP in primary care have a neoplasm (Deyo, 1992), and 4% have compression fractures (Deyo, 1992). Spinal infections are rare (www.backpaineurope.org). Less than 1% is due to inflammatory disease that needs rheumatologic investigation and treatment (Waddell, 2004b).

Many factors influence the development of disability due to LBP. Frank et al. (1996) described three stages in the development of chronic disability:

- In the *acute stage* (< 4 weeks) the prognosis is good and 90% settle within 6 weeks, at least sufficient to return to work.
- The *subacute stage* (4-12 weeks) is the critical stage for intervention. Psychosocial issues become more important.
- In the *chronic stage* (> 12 weeks) psychosocial issues are important with major impact on every aspect of the individual's life, family, and work. The prognosis is poor. Likelihood of return to work diminishes with time. Medical treatment, rehabilitation, and vocational rehabilitation are difficult and success rate is low.

In all stages diagnostic concerns related to possible serious spinal pathology as well as psychosocial influences have to be taken into consideration.

Psychosocial concerns, expectations, and behaviour are different at the acute, subacute, and chronic stages. Social, employment, and economic status changes from the acute to the chronic stage. The outcome of any intervention may be quite different in each phase, so the timing of health care or rehabilitation interventions is critical. To avoid development of chronic LBP, early intervention might be crucial, and active interventions to control pain and improve activity levels might reduce disability.

#### 2.2. Prevalence of low back pain / economic consequences

A large number of international studies show that 12-33% of people report back complaints on the day of the interview; 22-65% report back pain in the previous 12 months, and 11-84% report back pain at some time in their life (www.backpaineurope.org ). Norwegian studies have found one month prevalence of 22% (Hagen et al., 1997) and 40% (Ihlebæk et al., 2002), and one year prevalence of 53% (Natvig et al., 1995). Studies of adult populations have tended to show an increase in the prevalence of low back pain until mid to late forties, with rates stabilising after that age until the mid sixties (Walsh et al., 1992; Skovron et al., 1994). Despite the high prevalence of LBP in the general population, it has been estimated that in a 12-month period, fewer than 10% of those episodes will lead to a consultation with a health care practitioner (Papageorgiou et al., 1995). The proportion of the population with work loss due to low back pain is estimated to about 2-5% per year (Mason, 1994; Nachemson et al., 2000; Waddell, 2004d).

In Norway musculoskeletal complaints account for 47% (Rikstrygdeverket, 2004) of sickness absence (back pain 14.7%), and 33% of disablement benefits (back pain 14%). In Norway, direct and indirect costs due to LBP are estimated to be NOK 13 billions every year (Eriksen & Brage, 2000) which is 1.3% of the Gross National Product. Similar amounts are reported from other European countries (Nyman et al., 2002).

Most acute LBP episodes resolve within a few weeks regardless of treatment (Deyo, 1998), but residual symptoms and recurrences are common, occurring in 40-80% of patients (Battie & Bigos, 1991; Von Korff et al., 1993), which may influence health and quality of life of the individuals. A minority (6%) develops chronic disabling back pain (Croft et al., 1997), and this minority is responsible for the largest part of the costs due to LBP (Frymoyer & Cats-Baril, 1991; Goossens, 2002; Brage et al., 1998). Interventions directed to reduce development of chronic disability due to LBP might be cost-effective.

#### 2.3. Sickness benefits in Norway

Sickness certification is a declaration issued by a physician when a person is found to be temporally incapacitated for work because of disease, injury or illness (Tellnes, 1989). In 1988 the National Insurance Offices (NIO) introduced a special continuation certificate (sickness certificate II) issued by the general practitioner when a patient had been sick-listed 8 weeks or longer. This sickness certification system was changed in 1999, with introduction of new schemes and withdrawal of certificate II.

All employees receive 100% compensation from the first day of absence from work. Employers pay for the first 2 weeks of certified sickness absence, and the NIO covers further absence, to a total of maximum 365 calendar days. After a sickness benefit period of one year, the patients can apply for medical or vocational rehabilitation benefits, or disability pension. Due to the increasing number of persons receiving sickness benefits and disability pension for musculoskeletal complaints, there is a need for efforts reversing this trend.

#### 2.4. Functional anatomy of the lumbar spine

The coactivity of trunk muscles plays a vital role in the stability and functional movement of the vertebral column. The lumbar multifidus, which is thought to be particularly important for stability (Kaigle et al., 1995; Crisco & Panjabi, 1991; Wilke et al., 1995), is the largest and most medial of the lumbar back muscles. It consists of five separate bands which receive their own innervation (Macintosh et al., 1986). These bands are polysegmental, spreading caudolaterally from the midline, each originating from one lumbar vertebra and attaching to mamillary processes, the iliac crest, and the sacrum. The deep abdominal muscle, the transversus abdominis, also performs an important role in spinal stabilisation (Richardson et al., 1990; Hodges & Richardson, 1996) through its role in the generation of intra-abdominal pressure (Cresswell et al., 1992) and tension in the thoracolumbar fascia (Tesh et al., 1987). The muscle fibers of transversus abdominis run horizontally around the abdomen, attaching via the thoracolumbar fascia to the transverse processes of each of the lumbar vertebrae (Williams et al., 1989).

All muscles that traverse the lumbar region have potential to impart stability to the lumbar spine, but they also interact with other muscle groups. Hip, pelvic, and leg muscles interact with arm and spinal muscles via the thoracolumbar fascia. The posterior layer of the thoracolumbar fascia covers the back muscles from the sacral region through the thoracic region as far as the fascia nuchae and is a part of a "corset" that surrounds the trunk. This allows for effective load transfer between spine, pelvis, legs, and arms. The tension of the posterior layer of the thoracolumbar fascia can be influenced by contraction or stretching of a variety of muscles (Vleeming et al., 1995). The fascia has rich innervation for both proprioception and nociception.

Effective dynamic stability of the lumbar spine requires not only adequate force generated by muscular tension, but also appropriate muscle response and normal proprioception with exact balance between agonist and antagonistic muscle groups. Several studies have identified neuromuscular dysfunction in the presence of LBP (Hides et al., 1996; Hodges & Richardson, 1996; Mannion & Dolan, 1994). LBP patients have less refined position sense (Gill & Callaghan, 1998; Parkhurst & Burnett, 1994; Taimela et al., 1999), poorer postural control (Byl & Sinnott, 1991; Luoto et al., 1996; Radebold et al., 2001), delayed muscle response to sudden trunk loading (Hodges & Richardson, 1996; 1998; Radebold et al., 2000), and an overall longer psychomotor speed (Luoto et al., 1996; 1999; Taimela et al., 1993). Paquet et al., (1994) and Grabiner et al. (1992) found that individuals with LBP had a different motor control strategy when compared with individuals without back pain. Isokinetic studies show that patients with LBP have reduced strength compared with normal, asymptomatic subjects (Newton et al., 1993). EMG findings of the back muscles reflect this disturbed muscle function showing higher activity in patients with back pain (Sihvonen et al., 1991; Ahern et al., 1988; Watson et al., 1997). The abnormal patterns of movement and muscle activity reflect physical dysfunction, starting as a reflex response to pain, but may be self-sustaining if symptoms persist. Physical inactivity may worsen the situation by producing muscle deficiency and atrophy, and treatment directed towards resuming light normal activity may help restore normal function.

#### 2.5. Pain perception

According to the definition of the International Association for the Study of Pain (IASP), "Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (Merskey, 1979). However, pain is more than just a signal of tissue damage. The experience of pain is a subjective event which is influenced not only by anatomical, physiological and biochemical factors in response to tissue damage, but also by a number of psychological and social factors (Gamsa, 1994; Linton & Ryberg, 2001; Hoogendorn et al., 2000).

LBP causes much suffering, distress and incapacitation to the individual. For each individual the pain experience is different, due not only to physiological characteristics but also to psychosocial factors. Biomechanical problems affect the spine, but factors such as depression, anxiety and emotional distress affect the CNS control of posture and movement with resultant physiological symptoms such as muscle dysfunction and disorders of posture and gait (Adams, 1997a). Therefore, although physical impairment may be ameliorated by physical intervention, it is also necessary to address psychological factors in treatment strategies.

Loeser (1980) described four aspects or dimensions of pain:

- 1. *Nociception* refers to mechanical or other stimuli that could cause tissue damage. These stimuli act on peripheral pain receptors to produce activity in nerve fibres.
- 2. *Pain* is the perception of the sensation of pain. This has two important implications. First, we must perceive nociception before it is pain. Second, it is possible to perceive pain even when no tissue damage is occurring.
- 3. *Suffering* is the unpleasant emotional response generated in higher nervous centres by pain and other emotional situations. Suffering is not unique to pain, but also occurs with grief, stress, anxiety, or depression. Indeed, we often use the language of pain to describe our suffering in these situations. But pain and suffering are different. We can have pain without suffering and suffering without pain.
- 4. *Pain behaviour* includes all acts and conduct that we commonly understand to suggest the presence of pain. Pain behaviours include talking, moaning, facial expressions, and limping, taking painkillers, seeking health care and stopping work. Pain behaviour is a form of communication. This does not necessarily mean it is conscious or intended. Most pain behaviour is unconscious.

Pain and disability often involve all these aspects of pain. To understand the pain experience we must look at emotions, psychology, and human behaviour (Villemure & Bushnell, 2002). The nociceptive system is normally inactive. It becomes active if nociceptive nerve fibres are depolarised by stress, damage, deforming mechanical stimuli or exposure to sufficient quantities of irritating chemical substances (Melzack & Wall, 1989; Iggo, 1973). The lumbosacral nociceptor receptor system are found in skin, subcutaneous and adipose tissue, muscles and fascia, vertebral bodies, capsule of the facet and sacroiliac joints, ligaments (Wyke, 1987), the vertebral periosteum, dura mater , the walls of the blood vessels (Wyke, 1987), and the outer fibres of the annulus fibrosus (Coppes et al., 1997).

Pain perception is a complex, integrated, neural network or neuromatrix (Melzack, 1999). It is genetically determined, but modified by learning. It allows multiple stress, endocrine, autonomic and immune system inputs, and mental functions, as well as the traditional sensory inputs, to interact and modulate pain (Casey & Bushnell, 2000; Devor, 2001). Therefore, the experience of pain is not simply in direct relationship to the amount of peripheral nociceptive input. There are considerable psychosocial components which affect a person's perception of and response to pain. These include factors such as social background and environment and people's own beliefs, attitudes and expectations of their pain, the professional and their treatment. Emotional factors such as anxiety, state of mind and past experience all affect perception of the experience and response to pain. The interaction of the patient and practitioner may have a powerful therapeutic effect and the attitudes and behaviours of health professionals influence a patient's response to treatment (Bush et al., 1993).

Chronic pain patients often feel that their pain has control over them rather than being able to control their pain (Adams, 1997b). Such feelings of loss of control and of hopelessness and helplessness can lead to anxiety and depression, and the experience of pain and concomitant symptoms tend to be magnified (Adams, 1997b).

There is evidence that anxious persons have a cognitive processing priority for information that is related to their fears (Brosschot, 2002). Anxious persons will detect fear-related information earlier than other persons. Their normal cognitive performance is interrupted, and their cognitive capacity is absorbed in enhanced processing of information that is related to their concerns (Brosschot, 2002). People who are anxious are more sensitive to pain than

people who are not (French, 1992). The intensity of pain has been found to decrease if anxiety is reduced by giving subjects control of the situation. The anticipation of pain, and uncertainty regarding its cause, tend to raise anxiety which in turn increases its perceived intensity (Adams, 1997b). Anxiety may be reduced by giving patients information about their condition and providing details of their treatment. If people understand that the pain is not dangerous, they are less likely to be anxious about it. Similarly, pain can be better tolerated and probably perceived as less intense if the person believes it to be temporary or "normal".

Sensitivity to pain is also increased if the person is depressed (Adams, 1997b). This may be due to certain neurotransmitters, e.g. serotonin, in the body which are associated with chronic pain and also depression (Cesselin et al., 1993; Adams, 1997b). It may be due to the psychological effects of having pain which imposes inactivity, perhaps a loss in work status, and limits social activities. The person becomes more focused on the pain and feels increasingly helpless, hopeless, and socially alienated and isolated. Depression may be relieved by use of antidepressant drugs, treating the pain, and the patient feeling in control of the pain with the reassurance and empathy of the practitioner. Increasing physical activity may improve mood and self-esteem (Martinsen, 2000).

A biopsychosocial model including psychological and behavioural factors has been constructed to understand current levels of pain and disability (Engel, 1977; Waddell, 1987; 2002; Turk et al., 1988). To understand chronic pain and disability Gordon Waddell emphasises the importance of social issues: "Psychological issues may be more important for understanding chronic pain. When it comes to understanding disability and especially incapacity for work, then social issues are probably even more important" (Waddell, 2004e). He claims that society fails to make allowance and arrangements that would enable people with disabilities to fulfil the potential they retain, and that disability becomes a political rather than a medical issue.

Treatment has become multimodal and increasingly multidisciplinary (Adams & Taylor, 1997), in recognition of the number of factors involved in the aetiology and perpetuation of LBP, in particular chronic LBP, suggesting that a treatment program to reduce pain and dysfunction should be concerned with developing patient' abilities to manage their pain, rather than become pain victims, by utilising both physical and psychological methods. The two main psychological approaches are *behavioural* and *cognitive approaches*. Behavioural approaches focus on changing patients' pain behaviour. Cognitive approaches focus on mental events – changing how patients think about and cope with their pain. Most pain management use a combined cognitive-behavioural approache.

Because pain perception is multicausal and complex, the potential for these patients to respond to a wide variety of treatments can be great. However, whatever the source of back pain, it may be anticipated that in all treatment strategies it is important to focus on how patients react to pain, their worries and concerns, distress, and beliefs of doing any harm to the back. To prevent unnecessary inactivity and long sick leave, and to help the patients developing a better understanding why the pain is not dangerous and why activity is important despite the pain, it may be important to provide information, practical advice and reassurance, to encourage mobilisation, and to intervene at an early stage.

#### 2.6. Sensitisation

When nociceptors are stimulated repeatedly or the tissue they innervate is damaged, they show sensitisation to further cutaneous stimulation (Wells et al., 1988). Sensitised receptor units are more easily activated by a given stimulus than would otherwise be the case in uninjured skin. Following the injury there also develops a much larger area of hyperalgesia and allodynia that surrounds the site of injury (secondary hyperalgesia). Endogenous biochemical agents travelling along afferent nerve fibres coming from damaged or inflamed tissues may also sensitise wide dynamic range central cells in the spinal cord so that they respond to almost any peripheral stimulus with a "pain-type" discharge pattern (Bowsher, 1988). That is, they respond abnormally to input from normally innocuous primary afferent messages. Long-term potentiation has been demonstrated for nociceptive pathways in the superficial dorsal horn of the spinal cord (Rygh et al., 2002). A continuous afferent input of signals will gradually sensitise dorsal horn neurones of the spinal cord, making them more receptive for transmission of pain messages to the brain cortex, and may lead to persistent morphological changes in the central nervous system, resulting in chronic pain refractory to treatment.

Peripheral as well as central sensitisation can explain development of fibromyalgia symptoms (Staud & Smitherman, 2002; Værøy et al., 1988; Ursin et al., 1993) whereas pain arising from muscles starts with sensitisation in the peripheral nociceptors and subsequently leads to sensitisation in central nociceptive systems. Sensitisation has been suggested as the underlying mechanism for subjective health complaints reaching a level not tolerated by the patient (Eriksen & Ursin, 2004). Sensitisation of central nervous loops has also been suggested as an explanatory concept for comorbid psychiatric disorders in somatisation patients like major depression, panic disorder, mania, phobic disorder, and anxiety (Ursin & Eriksen, 2001). All these conditions may depend on kindling of limbic structures (Bell et al., 1992). According to this hypothesis, subconvulsive kindling of limbic structures (Goddard, 1987) may explain why some subjects get more sensitive than others do to a variety of stimuli. This could explain the high comorbidity of these subjective states, and would offer a model for cross-sensitisation from one source of stimuli to another (Bell et al., 1992; Eriksen & Ursin, 2002).

Sensitisation produce lower thresholds for self-reports of stress, and lower thresholds for reporting and seeking medical assistance for complaints (Eriksen & Ursin, 2004). It follows from the theoretical position of sensitisation that with longer duration of complaints, the chance of sensitisation and chronification increases. With prolonged inactivity, pathology may increases to involve other structures, with resultant loss of function and increase in pain. To avoid development of a vicious circle and to help the patients to understand and react adequately, it may be crucial to understand pain perception mechanisms and to intervene at an early stage.

#### 2.7. Subjective health complaints

Subjective health complaints (SHC) are common conditions where complaints are not explained or go beyond objective findings (Ihlebaek & Eriksen, 2002). "Unexplained medical symptoms" is preferred by some (Wessely et al., 1990) for these conditions. General medical examination, laboratory tests, and referrals to specialists do not reveal any pathological findings in most cases. Subjective health complaints have a high level of prevalence in the normal population, but only in a minority do they reach a level where function is seriously impaired (Tveito et al., 2002).

In a survey of 1240 individuals from the Norwegian population 96% reported that they had experienced at least one type of complaints during the preceding 30 days. Musculoskeletal pain was reported by 80%, pseudoneurological complaints by 65%, and gastrointestinal problems by 60%. Although the prevalence of having any complaints was high for most subscales, the prevalence of substantial complaints was much lower with 13% musculoskeletal, 5% pseudoneurological, and 4% gastrointestinal complaints (Ihlebaek et al., 2002). The intensity of SHC formed a continuum with no obvious cut-off point indicating what are normal complaints and what is illness. The transition from "normal" complaints to a serious condition seemed to be a continuous process, with no clear or objective thresholds.

Most of us do not seek medical assistance for these complaints. However, the conditions are still the most frequent sources of long-term sickness compensation, permanent inability to work, and the most frequent reason for encounter and for repeated visits in general practice (Eriksen et al., 1998). In some cases SHC may signal somatic disease, in most cases not. Eriksen and Ursin (2004) suggest that SHC are based on sensations from what in most people are normal physiological processes, but for some individuals become intolerable. They conclude that SHC are particularly common in individuals with low coping and high levels of helplessness and hopelessness, and that the psychobiological mechanisms for this is sensitisation in neural loops maintained by sustained attention and arousal (Eriksen & Ursin, 2004).

Because SHC as well as back pain are common bodily symptoms, it can be questioned if back pain is specific or part of a more general unspecific condition like SHC.

#### 2.8. Comorbidity.

Patients with long-lasting and non-specific LBP often have other complaints as well (Taylor & Curran, 1985; Bergenudd, 1989; Hestbaek et al., 2003; Von Korff et al., 2005; Raspe et al., 2003), and this comorbidity raises serious questions for specific biomechanical models for LBP. The comorbidity may be more in line with the biopsychosocial model, focusing on the complex interactions between pain and disability. Gilchrist reported in 1976 that people suffering from backache were more likely to manifest features of anxiety (Gilchrist, 1976). In 1985 the Nuprin Pain report (Taylor & Curran, 1985) found that 90% of those with frequent back pain had multiple pains, though half of them said that back pain was the "most troublesome". A Swedish study from 1989 (Bergenudd, 1989) found that back pain often was associated with other pains. Other epidemiologic studies have also found that chronic back pain often is comorbid with other pain conditions (Raspe et al., 2003), with chronic physical disorders (Hestbaek et al., 2003), and with mental disorders (Currie & Wang, 2004; Gureje et al., 1998). Many patients with LBP also report sleep problems (Ursin R et al., 1999). In a cross-sectional survey of 12- to 22- year-olds, LBP was positively associated with headache, cardiovascular disease, respiratory disorders, neck pain, gynecological disease, asthma, hay fever and other allergies, as well as with general poor health (Hestbaek et al., 2003). In a Norwegian study among 40-42 year-olds with chronic LBP, only 1/3 of the men and 1/6 of the women had localised LBP; the rest reported pain from at least one additional body area. Divorced and those with low education reported more widespread pain (Hoddevik & Selmer, 1999).

A recent survey of US adults found that a vast majority (87%) of chronic back pain patients report at least one other comorbid condition, including other chronic pain conditions (69%), chronic physical disorders (55%), and mental disorders (35%) (Von Korff et al., 2005). Von Korff et al. (2005) concluded in their study that the high comorbidity with other pain conditions, chronic diseases, and mental disorders, plays a significant role in role disability

associated with chronic spinal pain. This agrees with findings from a Dutch study (IJzelenberg & Burdorf, 2004), that among workers with low back pain, subjects with high pain intensity or disabling low back pain were more likely to have musculoskeletal comorbidity. They found that LBP was associated with pain in the neck, shoulder, elbow-wrist-hand, and any upper extremity complaints. In comparison to the subjects who reported back pain only, subjects with comorbidity showed worse general health and health related quality of life. In a Swedish study of acute LBP patients (Seferlis et al., 1999) they found that LBP patients compared to a matched control group had a fourfold increase in sick leave episodes for reasons other than spinal morbidity during the preceding 2 years.

It is assumed that because back pain is a common complaint as well as headache, tiredness, psychological and stress-related symptoms, and work-related or other social problems, it is not surprising that people with back pain often report other symptoms (Waddell, 2004d). It might therefore be hypothesised that sensitisation may lead to a high level of comorbidity of other SHC in non-specific LBP patients. If so, it might be expected to find a high level of SHC in an ordinary, help seeking population of LBP patients.

#### **3. MATERIALS AND METHODS**

In the acute stage of LBP the prognosis is good and most patients return to work. A randomised study at this stage would be very expensive and resource consuming, since the sample size must be increased substantially to have satisfactory power in the study. Patients not returning to work in the acute stage are candidates for being chronic disabled, and the longer the length of absence from work due to LBP, the lower the chance of ever returning to work (Waddell & Burton, 2001). It is argued that the subacute stage is the critical stage for intervention in preventing chronicity, and inclusion criteria thus were limited to 8 - 12 weeks duration of sick leave. 8 weeks as a lower limit was appropriate for collaboration with the National Insurance Offices in Hedmark county with referral of patients via sickness certificate II (sick listed more than 8 weeks).

#### 3.1. Design

*Paper I* Randomised controlled clinical trial investigating how an early intervention at a spine clinic with information, reassurance, and encouragement to stay active could reduce sickness absence for subacute low back pain patients. Patients in the intervention group (n=237) were compared to a control group (n=220) treated within the primary health care. *Paper II* Randomised controlled clinical trial evaluating long-term (3 years) clinical and economical effects of the intervention referred to in Paper I.

*Paper III* Prospective observational study of a randomised controlled trial, referred to in paper I, identifying predictors and modifiers of treatment effect for return to work in the two groups at 3 and 12 months follow up.

*Paper IV* Cross-sectional study comparing subjective health complaints in subacute LBP patients (n=457) with reference values from a Norwegian normal population (n=1240).

#### 3.2. Patients

The study group consisted of 457 patients sick-listed 8-12 weeks for LBP with or without radiating pain and age between 18-60 years. Mean age at entry was 41 years (range 20-60), 52 % men and 48% women. The intervention group consisted of 237 patients, 123 men and 114

women with mean age of 40.8 years (SD=10.1). The control group consisted of 220 patients, 115 men and 105 women with mean age of 41.1 years (SD=9.8).

There were no significant differences between the two groups on baseline characteristics such as age, gender, civil status, education, job security, blue collar/white collar job, previous sick leave for LBP, or diagnoses given from the primary care physician at sickness certificate II. International Classification of Primary Care (ICPC) diagnoses required for inclusion were: L02 (back pain), L03 (low back pain), L14 (leg and thigh pain), L84 (back pain without sciatica), and L86 (sciatica). Exclusion criteria were pregnancy, recent low back trauma, cauda equina symptoms, cancer, osteoporosis, rheumatic low back disease, and ongoing treatment for LBP by another specialist. Sickness certificates were sent to the spine clinic from 22 National Insurance Offices (NIO) in Hedmark County in Norway for evaluation to be included in the study. In Norway the NIO received a special continuation certificate (sickness certificate II) issued by the general practitioner when a patient had been sick-listed 8 weeks or longer. ICPC-diagnosis for LBP given by the physicians on sickness certificates II were used for patient selection. The sickness certificates, a one page form, contained only information on name, address, ICPC-diagnosis, and a brief anamnestic report from the physician. The specialist at the spine clinic selected patients suitable to be included in the study, but was not involved in the randomisation procedure.

Patients were included over a two year period between January 1995 and December 1996. The enrolled subjects should be representative for the source population. Everyone from Hedmark County (187 000 inhabitants) sick listed 8-12 weeks for LBP with or without radiating pain and age between 18-60 years was equally to end up as a study subject, except exclusion criteria. Patients included in the study were referred from the whole county of Hedmark. As far as known, there was no selection bias or other systematic differences in the referral pattern. Type and size of employment in the study group were comparable to Hedmark County, and unemployment rate in Hedmark County was comparable to the whole country.

#### 3.3. Randomisation

In all, 510 patients met the inclusion criteria and were randomised before they were invited to participate in the study. 254 were randomised to the intervention group and 256 to the control group. All patients were informed about the study according to the Declaration of Helsinki, and informed consent was obtained after randomisation. In the control group, 220 patients (86%) accepted to participate in the study, in the intervention group 237 patients (93%) accepted. The high number of volunteers in both groups is a strength of this study. The total number of patients referred to the spine clinic from the NIO and the excluded part has not been registered. The post-consent randomisation used in this study was accepted at that time. However, today the Data Inspectorate would demand to inform and ask the patients for permission to participate in a study before collecting sickness certificates and perform randomising. The post-consent randomisation might have biased the results in favour of the intervention. If the patients knew which group they were randomised to, patients assigned to the control group who did not agree to participate might have tended to have a less favourable prognosis. To eliminate this possible bias it had been necessary to determine whether there was any difference in severity or prognostic indicators between the refusers in the two groups, but those data are not available. According to the Data Inspectorate, the participation in a clinical study is voluntary, and hence not permitted to ask for the reason for refusal.

The actual randomising procedures at the spine clinic minimised possibilities for biases. A randomisation list was generated in advance from the University of Bergen (Norwegian Back Pain Network, Research Unit), using a table of random numbers, and the randomisation results were kept in sealed numbered envelopes, one for each patient. The randomisation list was generated using a table of random numbers to avoid rearrangements of the order. Blocks of 20 patients were used to produce the list (Pocock, 1983), to ensure equal treatment numbers. The clinician was not aware of the random block size, and therefore, could not predict the group assignments. The secretaries performing this work were independent persons responsible for patients' registration only, and thus were not involved in the treatment of the patients.

#### 3.4. Intervention group

The patients in the intervention group were invited to the spine clinic within 12<sup>th</sup> week of sick leave. They were interviewed and examined by a treatment team consisting of a physician (specialist in physical medicine and rehabilitation) and a physiotherapist. Special attention was given to the description of daily activities and the restrictions caused by LBP, in addition to psychosocial conditions at home and at work. The main purpose of the intervention was to provide the patients with coping skills to manage their back pain through information, practical advice and reassurance, and to motivate and encourage them to stay active despite the pain. It is important for treatment compliance that the patients feel secure of being taken serious and that the physician understands and listens (Verbeek et al., 2004). At the spine clinic the patients were given time to express their concerns and explain how the back problem affected their life and daily activity. As a part of the process to take away unnecessary fear, the patients were examined by the physician. Any somatic findings were explained, and information was given about their importance. Positive comments were given about normal findings such as normal nerve function in legs. If the patient moved in a tense way, attention was called to this, to make the patient aware of how muscles became involved and maintained and worsened the condition. Radiographs were shown and explained. The patients were informed that looking for the source of pain on radiographs had limited importance, and that degenerative changes in the spine most often were a normal ageing process and not necessarily painful. Unless symptoms and clinical findings indicated some serious spinal disease, the patients were informed about the good prognosis, and the importance of staving active to avoid development of muscle dysfunction. They were encouraged to do daily walks and given assurance that light activity would not do any harm to their backs, on the contrary more likely would improve their complaints. The physiotherapist gave individual instruction in how to train and stretch at home and practical advice in coping with daily activities at home and at work and how to resume normal activities. The patients performed exercises supervised by the physiotherapist to make sure and to be confident that it did no harm to the back, and to make them confident to manage on their own. Advice given at the spine clinic and the instructed exercises were mainly focused on gradually retaining normal activity-level, not necessarily focused on regular training. The patients were encouraged to contact the spine clinic whenever they wanted, especially if they had concerns about training activities.

The visit at the spine clinic lasted  $2\frac{1}{2}$  - 3 hours ( $\frac{1}{2}$  hour to sign the consent and answer questionnaires, 1 hour with the physician and 1 -  $1\frac{1}{2}$  hour with the physiotherapist). According to the protocol, all patients visited the spine clinic once. However, the patients were encouraged to contact the spine clinic whenever they wanted. Of the 237 patients in the intervention group, 58 patients (24.5%) contacted the spine clinic for one or more follow-up

evaluations by the physiotherapist. 13 patients (5.5%) were referred to other specialists (10 patients to an orthopaedic surgeon, 2 patients to a rheumatologist, and 1 patients to a neurologist).

Reports from the examination were sent to the patient's primary care physician and to the NIO with diagnoses, recommendations concerning need of further diagnostic tests, treatment, job, and if possible recommendations regarding need of further sick leave.

#### **3.5.** Control group

The control group patients were invited to their local insurance office within 12<sup>th</sup> week of sick leave to answer the same questionnaires as in the intervention group. They were not examined at the spine clinic, but were treated within the primary health care. Patients in the control group had at least one visit to a general practitioner, since this is required in order to obtain sick leave. Over the three years of observation patients in the control group reported more GP visits and more chiropractor treatment, but not statistically significant.

During the first year after inclusion, 6 patients in the control group were given appointment for examination at the spine clinic. During the second year additional 11 patients and during the third year additional one patient were examined at the spine clinic. The reason was pressure from the patients' primary care physicians. Those 18 patients (8%) still maintain registered in the control group.

#### 3.6. Questionnaires

Questionnaires were used to identify predictors and modifiers of treatment effect influencing sick leave, and to register amount of SHC among LBP patients. The patients in the intervention group and the control group answered the same standard validated Norwegian versions of questionnaires 3, 6, 12, and 24 months after sick leave, concerning sociodemographic and psychosocial factors, physical activity, job stress and perceived work ability, amount of pain, and subjective health complaints.

Patients in the intervention group answered the 3-month questionnaires at their first visit at the spine clinic, before seeing the doctor and the physiotherapist. In the control group the patients answered the same questionnaires at their local insurance office within  $12^{th}$  week of sick leave, and the completed questionnaires were immediately put into a pre-stamped envelope, sealed and send by mail to the spine clinic. All patients (100%) in both groups answered the questionnaires at inclusion time. Follow up questionnaires were sent to the patients. At 6 months 310 patients (68%) answered the questionnaires (intervention group 71% / control group 64%). At 12 months 264 patients (58%) answered the questionnaires (intervention group 61% / control group 55%). At 24 months response rate was very low, less than 40%, and thus not useful.

<u>Job security</u> was measured by the question: "Do you have a job to return to?" <u>Perceived physical workload</u> was measured by 4 questions about the frequency work involved repetitive movements, positions with constant strain on the back, hands above shoulder heights, and lifting more than 20 kg (alpha = .57).

<u>Psychological work load</u> was measured by a Norwegian version of the Cooper job stress questionnaire (Cooper, 1981; Endresen et al., 1991). The scale consists of 22 items rated on a six-point scale ranging from 0 (no stress) to 5 (high experience of stress).

<u>Subjective health complaints</u> were measured by 29 items from the Subjective Health Complaint Inventory, SHC (Eriksen et al., 1999). Subjective somatic and psychological complaints experienced during the last 30 days were measured. Severity was scored on a four-point scale (no complaints/a little/some/serious). The SHC inventory yields five subscales: *musculoskeletal pain* (headache, neck pain, upper back pain, low back pain, arm pain, shoulder pain, migraine, and leg pain) (alpha=.67), *"pseudoneurology"* (palpitation, heat flushes, sleep problems, tiredness, dizziness, anxiety, and, sadness/depression), (alpha=.72), *gastrointestinal complaints* (gas discomfort, stomach discomfort, diarrhoea, obstipation, gastritis/ulcer, heartburn, and stomach pain) (alpha=.64), *allergy* (allergies, breathing difficulties, eczema, and asthma) (alpha=.54), and *flu* (cold/flu and coughing) (alpha=.61).

<u>Perceived work ability</u> was measured by the Graded Reduced Work Ability Scale (GRWA) (Haldorsen et al., 1998), and consists of 6 items grading the self reported working capacity of the patient in relation to the complaints they were sick listed for (alpha=.73). Three of these items (reduced ability to work, the belief work will aggravate condition and other complaints) are analysed here.

<u>Health Locus of Control</u> was measured by 18 items from the Multidimensional Health Locus of Control questionnaire (Form A) (Wallston et al., 1978; Aarø, 1986), scored on a 6-point scale (alpha=.74). The MHLC consists of three subscales; Internality, or the extent to which the respondent believes that power to affect his state of health lies within his own control (alpha=.70), Chance (alpha=.59), and Powerful others (alpha=.67).

Activity Discomfort Scale (ADS) (Turner et al., 1983) measure the amount of pain caused by each of 18 common daily activities, such as walking, bending, sitting, standing, driving and the like (alpha=.89).

<u>State and Trait Anxiety</u> were measured by 20 items, scored on a 4-point scale, from the State-Trait Anxiety Inventory (Håseth et al., 1990). The questionnaire yields 2 subscales: State anxiety (alpha=.83) and trait anxiety (alpha=.84). State anxiety is an emotional state associated with a particular situation, may fluctuate over time and can vary in intensity. Trait anxiety is a characteristic of the individual and is a stable personality state referring to a general tendency to respond with anxiety to perceived threats in the environment.

<u>Coping and defense</u> were measured by the CODE (Eriksen et al., 1997). CODE consists of the Utrecht Coping List (Schreurs et al., 1993) and a reduced Defence Mechanism Inventory (Gleser & Ihilevich 1969).

<u>Physical activity</u> was measured by a brief questionnaire on physical activity (type and frequency).

#### 3.7. Statistical analyses

Sick leave data (total length of leave, frequency of sick leave periods) were collected from both groups 3, 6, 12, 24, and 36 months after the initial sick leave. The data on sick leave, disability, and other social benefits were collected register data from the NIO. In the randomised study referred to in paper I, II, and III, these data were analysed according to the "Intention to treat" principle. Data from 2 patients in the intervention group (1 man and 1 woman) were missing at two years follow up. At three years follow up data were missing from 11 patients (4 men and 7 women) in the intervention group, and 5 patients (2 men and 3 women) in the control group. They were all regarded as failures in the data analysis. At the two years follow up, two patients were dead, at three years follow up a total of five patients were dead. These patients are regarded as missing, since the cause of death was assumed to be unrelated to their low back pain problem, and are not treated according to the intention to treat principle.

In **Paper I** the effect of the intervention at the spine clinic on the duration of sick leave at one year follow up was analysed. Relative Risk (RR) and 95% Confidence Interval (95 % CI), were used to determine the effect of intervention and control on return to work. 100% return to work (full duty work) was the main outcome. RR was calculated at three different times; 3 months, 6 months, and 12 months after the sickness compensation date used for inclusion in the study. Simple ANOVA in SPSS 7.5.1 for Windows was used to test the difference between the intervention group and the control group on number of days on sickness compensation (full time and part time). In the ANOVA analysis number of days on Disability Pension and Rehabilitation Program were calculated as sickness compensation. Descriptive statistics are reported with standard deviation (SD) when RR or other statistical comparisons were used, 95% confidence intervals (CI) were reported to facilitate comparisons.

In **Paper II** the results from 3 years follow up on clinical effects, duration of sick leave and economic consequences were analysed. The same procedures as in paper I concerning Relative Risk (RR) and 95% Confidence Interval (95% CI) were used for 24 and 36 months follow ups. Odds ratios (OR) adjusted for gender, age, education, and marital status were also calculated. To control for age, gender, education, and marital status Univariate Analysis of Variance was used. Descriptive statistics were reported with standard deviation when RR or other statistical comparisons were involved, and 95% CI was reported to facilitate comparisons.

Economic returns of the intervention with 43.9 days reduction of days of sickness compensation accumulated over the three years follow up, were calculated in terms of increases in the net present value of production for the society because of the reduction in number of days on sick leave. Differences in costs of treatment at the spine clinic and in primary health care were accounted for. Information about type and amount of treatment outside the spine clinic was collected from participants in both groups from standard follow up questionnaires. On average, controls and participants in the intervention group received approximately the same amount of physiotherapy. Differences between the groups in chiropractic treatment and visits to the GP (control group higher) were not statistically significant, and were therefore not taken into account in the calculation of treatment costs. The treatment costs in the intervention program were not monitored at the patient level and were therefore approximated based on personnel costs related to treatment. Based on experience from a Norwegian outpatient clinic for rehabilitation of musculoskeletal patients where operating expenses amounted to 50% of the clinics total costs, the estimate of personnel costs were multiplied by a factor of two in order to account for operating expenses in the study. This may overstate the total costs of treatment when based inside a hospital, hence suggesting that the calculation is based on a conservative cost estimate.

In **Paper III** logistic regression and tests for interaction were used to identify prognostic factors and modifiers for return to work in the intervention group and the control group at 3 and 12 months follow up. SPSS 12.0 were used for all analyses. Data for the intervention group (n=237) and the control group (n=220) were split into the patients who had returned to work and those who had not three and 12 months after consultation. Returnees and non-returnees were compared at baseline to decide which variables had predictive value for the outcome for each of the two groups.

All variables were dichotomised using the median score as the split point. The exception was belief in recovery where the variables were divided between "to a small extent" and "some and large extent". In phase 1 all potential predictors were tested with logistic regression. To test for potential modifiers in the two subgroups, the interaction (Pocock et al., 2002) was

added. Return vs non-return at 3 and 12 months follow up was dependent variable. Statistical significance was defined as p < .05. In phase 2 all significant variables were included in a multiple logistic regression model where gender, age, education and group were used as control variables. The variables were then entered into the model, one by one, starting with the most significant variables. If p < .20, the variables were included in further analysis.

In **Paper IV** the subjective health complaints scored by all the subjects in the study group (n=457, 48% females, mean age 41 years) at inclusion time were compared to reference values from a Norwegian normal population, consisting of 1240 adults (53% females, mean age 41 years) included in a cross-sectional survey in Norway during 1996 (Ihlebæk et al., 2002). SPSS 12.0 was used for all analyses. The LBP patients were compared to the reference population using logistic regression analysis.

#### **3.8.** Ethical aspects.

Written information according to the Declaration of Helsinki was sent to all patients invited to participate in the study. The patients gave their written consent at inclusion. The study was approved by the Regional Ethics Committee for Medical Research and the Norwegian Data Inspectorate.

#### 4. RESULTS

# 4.1. (Paper 1): Does early intervention at a spine clinic with information, reassurance, and encouragement to stay active reduce sick leave for subacute low back pain? One year follow up.

Patients sick listed 8 - 12 weeks were randomised into an intervention group and a control group. Patients in the intervention group were invited to the spine clinic offering consultation with examination, information, reassurance, and encouragement to engage in physical activity as normal as possible. Patients in the control group were treated within the conventional primary health care.

The intervention showed significant effects in reducing sick leave. At three months follow up 52 % of the patients in the intervention group had returned to full duty work compared to 36 % in the control group (RR=1.45), (95% CI: 1.17-1.79). At six months follow up 61 % in the intervention group had returned to full duty work compared to 45 % in the control group (RR=1.36), (95% CI: 1.14-1.62). At twelve months follow up 68% in the intervention group had returned to 56% in the control group (RR=1.21), (95% CI: 1.05-1.40).

## **4.2.** (Paper 2): Did the initial effect last? Three years follow up – clinical and economical effects of the intervention program.

Low back pain: Although as many as 95.3% in the intervention group and 93.1% in the control group still reported LBP at 6 months follow up, there were more patients in the intervention group (60%) than in the control group (51%) reporting that their LBP had improved. At one year follow up only 46.8% of the patients in the intervention group reported improvement, while there was no change in the control group (51.7%) compared to 6 months follow up. There were a few significant differences between the intervention group and the control group in use of different strategies to cope with LBP. At 6 months follow up, patients in the intervention group were less likely to use bed rest and more likely to use walking and

stretching to cope with their back pain compared to the control group. This effect diminished. At 12-months follow up the only significant difference between the groups was in the use of stretching. No significant differences were found between the two groups in the use of analgesics or contacting the physician.

<u>Return to work:</u> Over the 3 years of observation, the intervention group had significantly fewer days of sickness compensation (average 125.7 d/person) than the control group (169.6 d/person). This difference was mainly due to a more rapid return to work during the first year (Figure 1). There was no significant difference for the second or third year. In particular, there were no significant differences between groups regarding risk for new episodes of sick leave because of LBP. However, both groups had rather high prevalence of such episodes, 62% (n=147) in the intervention group and 61.4% (n=135) in the control group.

There were no significant gender differences between the number of men and women reported off sick leave in the intervention group at one, two, or three years follow up. In the control group there were no gender differences at one and two years follow up, but significantly more men than women were reported off sick leave at 3-year follow up.

<u>Cost-Benefit Analysis:</u> Economic returns of the intervention were calculated in terms of increases in the net present value of production for the society due to the reduction in number of days on sick leave. The total discounted benefit accumulated over 3 years of treating the 237 patients in the intervention group amounts to NOK 6 574 349 (\$ 900 596). Total costs of the treatment were estimated to NOK 524 658 (\$ 71 877). Net benefits for the society amounting to NOK 6 049 649 (\$ 828 719).

Hypothetical, if this treatment had been implemented in the whole country, the potential saving for the first year had been NOK 643 000 000 (\$ 90 000 000) (Gjelsvik 2004).

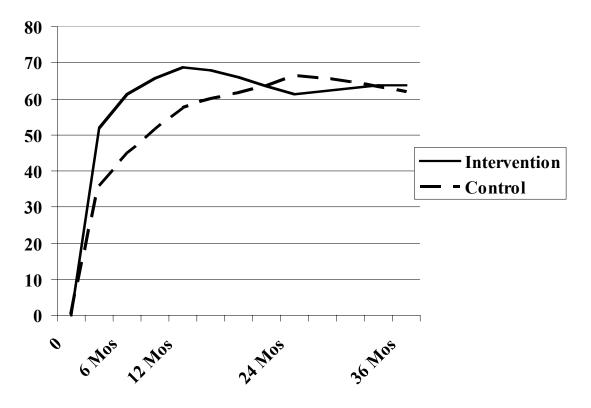


Figure 1. Percent of patients reported off the sick list.

#### 4.3. (Paper 3): Predictors and modifiers of treatment effect influencing sick leave.

In this paper predictors for non-return and prognostic factors for the effect of a brief intervention ("modifiers") at the spine clinic on return to work were evaluated. At 3 months follow up predictors for non-return to work, both subgroups (intervention and control group) combined, were other illnesses, the belief that work would aggravate the condition, pain when performing daily activities, and age below 41. The strongest modifying effect on return to work was the perception of constant back strain when working and beliefs about reduced ability to work. Of those patients reporting work with constant back strain more than 50% of the working time, 65% of the patients in the control group and 36% of the intervention group were sick-listed at the 3 months follow up. Of those patients that believed their ability to work was largely reduced, 76% of the patients in the control group and 55% of the patients in the intervention group were sick-listed at 3 months follow up. Among patients that scored low on chance (health locus of control), 72% of the patients in the control group and 45% of the patients in the intervention group were sick-listed at 3 months follow up. At *1 year follow up* predictors for non-return to work, both subgroups (intervention and control group) combined, were other illnesses, chance externality (health locus of control), less than 12 years of education, low belief that the back pain would disappear, and being a female. Heavy lifting or perceived constant back strain did not predict non-return to work. The strongest modifier for the effect of the intervention on return to work was gastrointestinal complaints. 55% of the patients in the control group and 22% of the patients in the intervention group were sick-listed at 1 year follow up, if they were high on gastrointestinal complaints at baseline. Scoring low on chance (health locus of control), elevated the probability of being sick listed at 1 year follow up for the patients in the control group, while the reversed effect was true for the intervention group.

# 4.4. (Paper 4): Subacute low back pain patients – what sort of other complaints did they have? Are their complaints specific or part of a more general unspecific condition comparable to subjective health complaints in the normal population?

Compared to the subjective health complaints of the normal reference population, the low back pain patients had significantly more low back pain, neck pain, upper back pain, pain in the feet during exercise, headache, migraine, sleep problems, flushes/heat sensations, anxiety, and sadness/depression (table 1). The prevalence of pain in arms, pain in shoulders, and tiredness was also high, but not significantly higher than in the reference population. Most of the patients reported more than one complaint, median was 5. Only 7 patients (1.6%) reported LBP as their only complaint. The more widespread musculoskeletal pain in addition to the LBP, the more other subjective health complaints were reported (table 2).

The twelve most frequent complaints among the LBP patients were compared with "normals". The figure below (Figure 2) shows percentage of LBP patients and "normals" that reports up to 12 complaints within the LBP "syndrome".

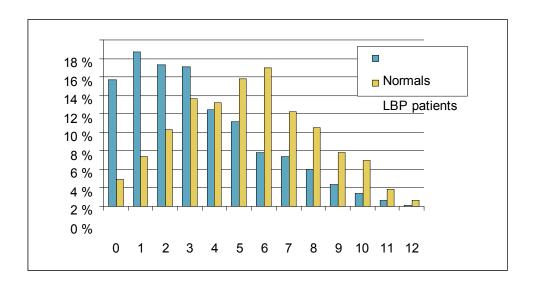


Figure 2

	Patients with LBP n=457		Normals n=1243		Statistics (OR* with 95%CI) LBP versus Normals		
Variable	Any	Substantial		Substantial	Any	Substantial	
Cold, flue	33	17	49	23	.5(.46)	.7 (.5-1.0)	
Cough, bronchitis	21	8	24	8	0.8 (.6-1.1)	.9 (.6-1.4)	
Asthma	4	2	5	2	.7 (.4-1.2)	.8 (.4-1.6)	
Headache	52	27	51	19	1.1 (.9-1.3)	1.6 (1.2-2.1)	
Neck pain	54	29	38	19	2.1 (1.7-2.6)	1.9 (1.5-2.4)	
Pain upper part of back	45	22	18	10	3.9 (3.1-5.0)	2.7 (1.9-3.6)	
Pain lower part of back	95	88	40	19	35.1 (21.7-56.6)	33.6 (24.2-46.7)	
Pains in arms	30	14	23	12	1.3 (1.0-1.6)§	1.1 (.8-1.6)	
Pains in shoulders	40	18	38	20	1.0 (.8-1.3)	.8 (.6-1.1)	
Migraine	11	6	8	5	1.6 (1.1-2.3)	1.4(.9-2.2)	
Extra heart beats	11	2	13	5	.7 (.5-1.1)	.4 (.28)	
Chest pain	13	3	13	4	.9 (.6-1.2)	.9 (.5-1.7)	
Breathing difficulties	7	2	8	3	.7 (.5-1.2)	.5 (.2-1.1)	
Pain in the feet during exercise	44	26	22	10	2.8 (2.2-3.6)	3.1 (2.2-4.3)	
Heart-burn	25	9	25	9	.9 (.7-1.2)	.9 (.6-1.4)	
Stomach discomfort	15	6	17	6	.9 (.6-1.2)	1.1 (.7-1.9)	
Gastritis, ulcus-ulceration	3	1	4	2	.7 (.4-1.3)	.4 (.2-1.2)	
Stomach pains	15	5	20	6	.7 (.5-1.0)	.8 (.5-1.3)	
«Wind»	23	9	35	13	.6 (.47)	.6 (.49)	
Diarrhoea	24	9	21	7	1.2 (.9-1.5)	1.2 (.8-1.9)	
Obstipation	6	2	8	2	.7 (.5-1.1)	1.1 (.5-2.3)	
Eczema	8	4	14	5	.6 (.49)	.7 (.4-1.2)	
Allergic skin problems	13	6	12	5	1.2 (.8-1.6)	1.2 (.7-1.8)	
«Flushes», heat sensations	18	7	8	3	2.2 (1.5-3.1)	2.6 (1.6-4.5)	
Sleep problems	54	29	28	11	3.1 (2.5-4.0)	3.4 (2.6-4.6)	
Tiredness	54	24	50	22	1.2 (.9-1.4)	1.2 (.9-1.6)	
Dizziness	17	5	17	5	.8 (.6-1.1)	1.1 (.6-1.7)	
Anxiety	19	8	10	3	1.7 (1.2-2.4)	2.2 (1.3-3.6)	
Sad, depressed	40	14	24	9	2.1 (1.6-2.6)	1.7 (1.2-2.4)	

Table 1: Percentage of any (score 1 or more) and substantial (score 2 or more) subjective health complaints in patients with LBP and in a Norwegian reference population (Normals)

\*Adjusted for gender, age and education. Significant differences (p<.05) are in bold. § p=.08

Number of subjective health complaints	1 or 2 musculoskeletal complaints (n=122)	3 or 4 musculoskeletal complaints (n=155)	5 or 6 musculoskeletal complaints (n=118)	7 or 8 musculoskeletal complaints (n=34)	F	р
Pseudoneurology (mean/sd)	1.4 (1.4)	2.0(1.6)	2.6(1.7)	3.9(1.6)	27.07	<.001
Gastrointestinal complaints	.9(1.2)	1.0(1.3)	1.3(1.5)	2.1(1.4)	7.92	<.001
(mean/sd)						
Allergy (mean/sd)	.2(.5)	.3(.6)	.7(1.1)	1.3(1.2)	20.83	<.001
Flu (mean/sd)	.5(.7)	.4(.7)	.6(.7)	.9(.9)	2.96	.032

 Table 2.

 Number of musculoskeletal complaints on 4 factors between 4 groups of patients

#### **5. DISCUSSION**

**5.1. Does an early intervention at a spine clinic with information, reassurance, and encouragement to stay active reduce sick leave for subacute low back pain? (Aim 1)** The treatment offered in this study provided information, practical advice and reassurance aiming at encouraging activity. The intervention was initiated at the beginning of the paradigm shift in back pain management, and old beliefs and attitudes about treatment of LBP were still strong. Thus it was an opportunity to compare if the new active approach was more effective than the standard treatment in primary health care, and to evaluate if the results from this study agreed with results from other similar studies. The main result is that patients receiving this brief intervention at the spine clinic did return to work sooner compared with the treatment offered by conventional primary health care.

The results from this study agree with results from similar studies accomplished at the same time and later (Indahl et al., 1995; 1998; Malmivaara et al., 1995; Waddell et al., 1997; Karjalainen et al., 2003a). Today there is consensus in the evidence backed literature that LBP patients benefit from maintaining activity as normal as possible, and that providing information on how to manage the back pain, and giving advice on how to resume normal activities reduce discomfort and functional disability (www.backpaineurope.org 2004).

The data do not allow conclusions as to whether all the components of the intervention were necessary. It seems likely that the whole integrated "package" is important. The advice is given by experts; the examination is thorough; and the team at the clinic is enthusiastic and optimistic about treatment results. The comfort (placebo) and fear-reducing effects of being taken seriously by an enthusiastic treatment team should not be underestimated (Bush et al., 1993), and seem to facilitate resumption of normal activities. Some of the slower progress in the control group may be caused by the disappointment of not being included in the treatment group and thus might have biased the responses. However, as many as 86% of the patients randomised to the control group agreed to participate in the study and answered the questionnaires.

#### 5.2. Short and long-term clinical effects, and cost benefit evaluation. (Aim 2)

The information about the complaints and the practical advice about how to resume normal activity was meant to provide the patients with coping skills to better manage their back pain, in particular by being active. At 6 months follow-up, patients in the intervention group reported to be more physical active than the control group. They were significantly more likely to use walking and significantly less likely to use bed rest as coping strategies as compared to the control group. This effect diminished at 12-months follow-up. A gradual loss of effect has been found also in other studies of behavioural treatment for patients with LBP and other non-specific conditions (Becker et al., 2000; Harkapaa et al., 1989; Lindstrom et al., 1992; Loisel et al., 1997; Moore et al., 2000). The Indahl study, the model for the present intervention, had a much more dramatic and long-lasting effect (Indahl et al., 1998). Our patients in the intervention group visited the spine clinic only once, but were encouraged to contact the spine clinic whenever they wished. Only 25% used this opportunity. The intervention in the study by Indahl et al. (1998) contained follow up visits at the spine clinic 2 weeks, 3 months, and one year after the first consultation. This may account for the excellent results obtained, where only 19% of the patients in the intervention group, compared to 34% in the control group, were still on sick leave at five years follow-up (Indahl et al., 1998). However, a change in attitudes among GP's to a more active treatment strategy in back pain visits may also influence duration of sick leave.

All significant differences between the two groups on sick leave occurred during the first year. Rapid return to work did not represent any increased risk for new episodes of sick leave due to LBP, which is one of the concerns patients, general public, and some therapists share. The intervention represented economic gains for the society, since costs in terms of production loss caused by sick leave and costs due to sickness compensation are substantial. The modest treatment costs for this intervention are less than the economic returns for the society in general and for our insurance system in particular.

#### 5.3. Predictors and modifiers of treatment effect influencing sick leave. (Aim 3)

In both the intervention group and the control group potential predictors for prolonged sick leave were high psychological work load, perceived large reduced ability to work, belief that work would aggravate the condition, other illnesses, and other subjective health complaints.

Which patients may benefit from the treatment given at the spine clinic? The interaction analyses of the prognostic factors revealed that the low back pain patients that appeared to benefit most from treatment given at the spine clinic were those that initially believed that their ability to work was largely reduced, that their work was straining for the back, and that the reason for their health complaint was not attributed to chance. Much of the brief intervention was directed to these factors. A significant part of the difference in return to work between the intervention group and the control group is carried by these items in the interaction analyses. This might suggest that the treatment may be particularly efficient in changing these attitudes that in themselves predict poor prognosis.

The interaction with a low score on the "chance" dimension of external locus of control of health is interesting. Patients with a low score on this dimension do not believe that health problems are due to chance and luck. They believe that their main health problem is the back, and this problem is not related to chance, but to their work. Therefore, they have to avoid work in order to alleviate their problem. It is generally accepted that this type of beliefs are particularly important factors for prolonged absence from work (Waddell & Burton, 2001).

These attitudes are what the brief intervention was aiming to change, but there are no available data to analyse whether the attitudes really changed.

At the 1 year follow up the strongest modifying effect of treatment results was for patients with high score on gastrointestinal complaints from the Subjective Health Complaints inventory (Eriksen et al., 1999). This inventory records only subjective complaints. The gastrointestinal complaints may be a part of more generalised health complaints. In extreme degrees this represents a somatisation syndrome. A possible explanation for why this may modify treatment effect may be that since the treatment focused on distress reduction for LBP, this may also influence distress about other complaints.

Work postures and compression load on the spine have been claimed to be predictors for prolonged sick leave for LBP (Hagen et al., 2002; Karjalainen et al., 2003; Shaw et al., 2001; McIntosh et al., 2000). In this study, heavy lifting or perceived constant back strain did not predict not returning to work, which is in accordance to the findings by Lindstrom (Lindstrom et al., 1994). Our data are more in line with claims that psychosocial or psychological factors are important. Returning to work and coping at the worksite are often difficult (Hoogendorn et al., 2000; Overmier, 2002). Work-related psychosocial factors may play an important role in persisting symptoms and disability, and influence response to treatment and rehabilitation (Waddell & Burton, 2001). Significant prognostic factors include workplace support and modification of duties (Shaw et al., 2001). Health care professionals may facilitate return to work by establishing what the patient's worries really are, to identify the reasons for avoidance of physical activity and the fear of pain at an early stage, in order to tailor advice and reassurance appropriately (Karjalainen et al., 2003; Indahl et al., 1995; 1998).

5.4. Are low back pain complaints specific or part of a more general unspecific condition comparable to subjective health complaints in the normal population? (Aim 4) In this material with subacute LBP only 7 patients (1.6%) reported pain localised only to the lumbar part of the back. Although the level of comorbidity was high in the material, the complaints of the LBP patients seemed to be more specific than a general sensitisation to all somatic complaints for example as seen in patients with irritable bowel syndrome. These patients have high scores on most other subjective health complaints, including musculoskeletal pain (Vandvik et al., 2004; Whitehead et al., 2002), while LBP patients in the study group did not report any higher levels of gastrointestinal complaints than the general population. The subacute LBP patient, therefore, does not seem to qualify for a general somatisation diagnosis. Their complaints may rather be referred to as a "syndrome", consisting of muscle pain located to the whole spine as well as to legs and head, and accompanying sleep problems, anxiety, and sadness/depression. The reported anxiety and depression in this study may be psychological consequences of a state which interferes with social and work related functions in the patient. The prevalence data on the sleep problems and the tiredness problems raise an interesting question on why it was not a significant change in tiredness. However, the prevalence of tiredness in the general population is also very high, but this group does not report sleep problems to the same degree. The findings from the present study are similar to reports of comorbidity from other sources (Hestback et al., 2003; Raspe et al., 2003; Von Korff et al., 2005; IJzelenberg & Burdorf, 2004).

The relationships between the various complaints appear to make sense clinically. From a pathophysiological point of view the generalised muscle pain may be agree with the assumption of neurophysiological and psychological sensitisation to muscle pain (Eriksen &

Ursin, 2002). In many LBP patients, the precise nociceptive mechanism is uncertain, and central neuromodulation might play an important role in the development of chronic back pain as well as in other chronic pain syndromes. However, the widespread pain located at the entire spine, legs and head, also might be connected with muscular dysfunction starting in the lumbar region, and interact via the thoracolumbar fascia to a variety of muscles along the spine, shoulders and pelvis.

The findings indicate that duration of sick leave may be more likely influenced by other illnesses and cognitive factors, a finding also noted by Waddell and Burton (2001). Cognitive factors are important in how the patients experience pain, how they cope with pain, and in the transition from acute to chronic pain (Jensen et al., 1999; Severeijns et al., 2004; Jensen et al., 1994; Turner et al., 2000; Waddell et al., 1993; Fritz et al., 2001). Comorbidity is important for the functional disability and must be taken into account in the interpretation and the selection of treatment.

## 5.5. Clinical course of low back pain – a multicausal event. How can a brief and simple intervention reduce sick leave?

Results from other studies before, parallel, and after carrying out this trial reveal that many factors influence the development of disability due to LBP. Even if psychological and psychosocial factors are important for the prognosis and for the results of intervention of low back pain, the pain does not appear without a somatic background. Electromyographic studies in back pain patients have shown increased tension of the lumbar muscles compared with normal (Flor et al., 1990; Flor & Birkbaumer, 1994; Sihvonen et al., 1991). Increased muscle tension influences proprioception and the motor control of lumbar spine stability (Matre et al., 1998; Zedka et al., 1999; Gill & Callaghan, 1998), may alter spinal kinematics (Gill & Callaghan, 1998; Luoto et al., 1995; 1996; 1998) and normal walking (Arendt-Nielsen et al., 1996). The association, however, between increased muscle tension and muscle pain is still not well understood.

Since muscle spasm is a common clinical observation associated with pain, a pain-spasm-pain cycle has been hypothesised (Roland, 1986). There is, however, little evidence that static muscle tension plays a direct role in LBP (Roland, 1986; Lund et al., 1991; Orbach & McCall, 1996). Pain is a complex sensory and emotional experience involving both neurophysiology and psychology. The emotional pain reactions also influence muscle tension and degree of pain perception, and psychosocial variables related to future disability, like fear-avoidance beliefs, have been detectable during an acute episode of LBP (Klenermann et al., 1995; Fritz et al., 2001; Gatchel et al., 1995; Burton et al., 1995; Boersma & Linton, 2005).

Neurophysiologic changes with sensitisation may aggravate and perpetuate pain. Normal afferent input from mechanoreceptors may be interpreted as pain, and normal movements may become painful. Pain therefore might be connected to disturbed function without any structural damage, which means that symptoms can persist for as long as dysfunction continues.

A cascade of sensory and emotional events influences how an acute episode of LBP can turn into a disabling process. Somatoform symptoms have biological components that have an important role in creating a vicious circle together with cognitive, behavioural, and emotional features (Brosschot, 2002). It follows from the theoretical position of sensitisation that with longer duration of complaints, the chance of sensitisation and chronification increases. With prolonged inactivity, pathology increases to involve other structures, with resultant loss of function and increase in pain. At this stage, patients often report feelings of frustration and depression as they perceive a loss of control and an increase in feeling of hopelessness about their condition. To avoid development of a vicious circle and to help the patients to understand and react adequately, it is crucial to understand pain perception mechanisms and to intervene at an early stage.

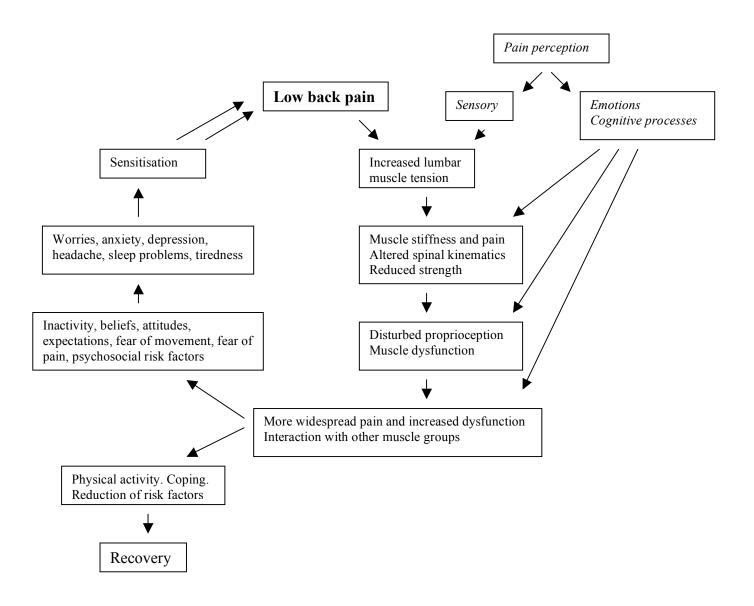


Figure 3. Cycle of low back pain

Treatment should aim at interrupting the pain cycle (see Figure 3). Different treatments may interrupt the cycle at different points, and therefore the potential for these patients to respond to a wide variety of interventions is great. However, taken into consideration that whatever the source of back pain may be, back muscles will be affected to different degrees, and it follows that the chance of developing problems with muscle dysfunction is great if the condition continuous over time. Patients' distress and beliefs of doing any harm to the back

also influence pain perception and muscle tension, and contribute to maintain muscle dysfunction. Therefore, it seems reasonable to assume that for all treatment strategies it is important to provide information, practical advice and reassurance, to encourage mobilisation, and to intervene at an early stage.

The intervention was short and simple and had a significant effect on patients susceptible to this treatment. Although the treatment was given at a spine clinic, the focus on activity and how patients react to pain, their worries and concerns, distress, and beliefs of doing any harm to the back, may be used equally well in primary health care. Patients that believe that they will not recover from their back pain may need more time and more information both to reduce the fear of not recovering, and to reduce the fear of pain. They may also need more encouragement to stay active. It is possible that patients with more severe and complex problems are in the need for more complex intervention with more special attention given to reduce anxiety and to improve coping skills (Linton & Ryberg, 2001; Haldorsen et al., 2002).

### 6. CONCLUSIONS

- Early intervention at a spine clinic with examination, information, and recommendations to stay active showed significant effect in reducing sick leave for patients with subacute low back pain and had economic gains for the society.
- The effect occurred during the first year after intervention. The initial gain obtained during the first year did not lead to any increased costs or increased risks for reoccurrence of sick leave due to low back pain over the next 2 years in patients returning early.
- Potential predictors for prolonged sick leave in both the intervention group and the control group were high psychological work load, perceived large reduced ability to work, belief that work would aggravate the condition, other illnesses, and other subjective health complaints.
- The strongest modifying effects on the treatment results in the intervention group were for patients with perceived large reduced ability to work and constant back pain when working, and a high score on gastrointestinal complaints.
- Most patients with low back pain also have pain related to the whole spine, legs and head, in addition to sleep problems, anxiety and sadness/depression. These findings appear more like a special LBP "syndrome" than a somatisation phenomenon.

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