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Tiina Kuukkanen

Therapeutic Exercise Programs and Subjects with Low Back Pain

A Controlled Study of Changes in Function, Activity and Participation

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JYVÄSKYLÄN YLIOPISTO

JYVÄSKYLÄ 2000

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ABSTRACT

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Therapeutic exercise programs and subjects with low back pain. A controlled study of changes in function, activity and participation.
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The purpose of this prospective, clinical trial of twelve months was to investigate the changes in impairments, activity and participation among subacute and chronic low back pain population after a three months therapeutic exercise program using a controlled study design.

Initially, 49 male and 41 female attended their local occupational health care services because of low back pain. Finally, the 29 subjects were placed into the three months intensive training group and the 57 subjects were randomly allocated into a home exercise and a control group. Measurements at different levels of ICIDH-2 classification were made at the baseline and after the three months interventions. Follow-up measurements were performed three and nine months after the completion of the interventions. Measurements of low back pain, muscular performance, spinal and muscle flexibility, psychomotor performance, postural sway, activity and participation were included.

Low back pain and the Oswestry Index decreased while muscular performance increased following three months of intensive training or home exercises. These positive changes were still present at the twelve months follow-up measurement. Spinal rotation and flexibility of hamstring and erector spinae muscles increased with therapeutic exercise programs. No significant changes occurred in psychomotor performance. The postural sway velocity of the subjects in the home exercise group increased. Restrictions at work decreased slightly in the home exercise and control groups and the number of sick leaves decreased in all subjects. Restrictions in recreational hobbies did not change.

In conclusion, positive changes in low back pain, muscular performance, flexibility and at the level of activity can be achieved with progressive, supervised, continuous, three months therapeutic exercise programs either in a gym or at home. The improvement of psychomotor performance and postural sway may require more specific and customised exercises. The changes at the level of participation may require more time to occur or different kinds of interventions.

Keywords: Prospective clinical trial, low back pain, therapeutic exercise, muscle strength, flexibility, psychomotor performance, postural sway, activity, participation

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Jyväskylä, September 2000

Tiina Kuukkanen

CONTENTS

LIST OF ORIGINAL ARTICLES

This thesis is based on the following papers, which are referred to in the text by their Roman numerals:

I Kuukkanen T, Mälkiä E. Muscular performance after a 3-month progressive physical exercise program and 9-month follow-up in subjects with low back pain. A controlled study. Scandinavian Journal of Medicine and Science in Sports 6:112-121,1996.

II Kuukkanen T, Mälkiä E. Effects of a three-month therapeutic exercise programme on flexibility in subjects with low back pain. Physiotherapy Research International 5:46-61, 2000.

III Kuukkanen T, Mälkiä E. Effects of a three month active rehabilitation program on psychomotor performance of lower limbs in subjects with low back pain: a controlled study with a nine month follow-up. Perceptual and Motor Skills 87:739-753, 1998.

IV Kuukkanen T, Mälkiä E. An experimental, controlled study on postural sway and therapeutic exercise in subjects with low back pain. Clinical Rehabilitation 14:204-214, 2000.

V Kuukkanen T, Mälkiä E. A new method for measurements of psychomotor times in lower extremity: feasibility, reliability and association with anthropometric measures. XVth Congress of the International Society of Biomechanics. Book of Abstracts. Jyväskylä, Finland 516-517, 1995.

In addition, this thesis contains unpublished data.

1 INTRODUCTION

Therapeutic exercise, which can be defined as the scientific supervision of exercise for the purpose of preventing impairment, functional limitation, disability and handicap (Thomas 1993) is recommended in most cases of subacute and chronic low back pain. There is large variability in the intensity of therapeutic exercises ranging from bed rest (Deyo et al. 1986) via functional restoration (Bendix et al.1996) to work hardening programs (Lechner 1994). In physiotherapy, historically an overall shift from the passive modalities to more active therapies can be seen (Jette & Delitto 1997). Further, the specificity of low back pain problems, and also the time duration from the onset of low back problems is reflected to the nature of therapies, which differ from pain control and coping to avoiding the recurrence and maintenance of a physically active lifestyle (Saal & Saal 1997).

The main aim of therapeutic exercise programs is to improve and optimise function at work, in the household and in leisure time (Saal & Saal 1997). In the case of low back pain, the aims of therapeutic exercise programs are, for example, to control pain, to improve flexibility and mobility, muscle strength and endurance, to increase balance, proprioception and co-ordination, and to improve cardiorespiratory capacity, as well as to execute ergonomic and psychosocial counselling (Hall & Brody 1999, Saal & Saal 1997).

Low back pain is recognised as a challenging, unchanged and very common problem, with a lifetime prevalence 60-70% in several countries. Individuals who suffer from low back pain use health services frequently (Heliövaara et al. 1989, Waddell 1998). The number of different kinds of therapies is great, but the quality of the therapies varies. It has been found that the quality is insufficient (Heliövaara et al. 1989) and the effects are uncertain (Spitzer et al. 1987).

The conceptual framework for this study arises from the original version of interdisciplinary disablement model of the WHO "International Classification of Impairments, Disabilities and Handicaps (ICIDH). The first version is from the year 1980 (WHO 1980) and it has been developed to be more practical in common use by health care providers and researchers. In 1999 a new revised and modified version " International Classification of Functioning and Disability" (ICIDH-2) was published (WHO 1999) (Figure 1). In physiotherapy, with this kind of modelling, it is possible to set goals, outcome measurements and physical therapy modalities for low back pain subjects. Although the specific course of low back pain is still unclear (Bouter et al. 1998), it is well known that low back pain has certain consequences, which can be identified with the ICIDH-2 model.

An individual with low back pain may have an impairment at the body level, in structure (" loss or abnormality of body structure"), for example, atrophy of type II muscle units (Mattila et al. 1986), or in function (" loss or abnormality of a physiological or psychological function"), for example, decreased muscle strength (Biering- Sörensen 1984). His or her individual activities may be limited in nature, duration and quality (WHO 1999), so he or she may have some kind of restrictions in activities of daily living (ADL) (Heliövaara et al. 1989). Also the individual's participation in social life activities may be restricted in nature, duration or quality, for example, work absenteeism may be increased (Ljunggren et al. 1997). Nevertheless, impairments may be present without any limitations in activity or participation. Also, a particular, clear pathology does not necessarily have any effect on an individual's activity or participation, and vice versa (Herno et al. 1999, WHO 1999).

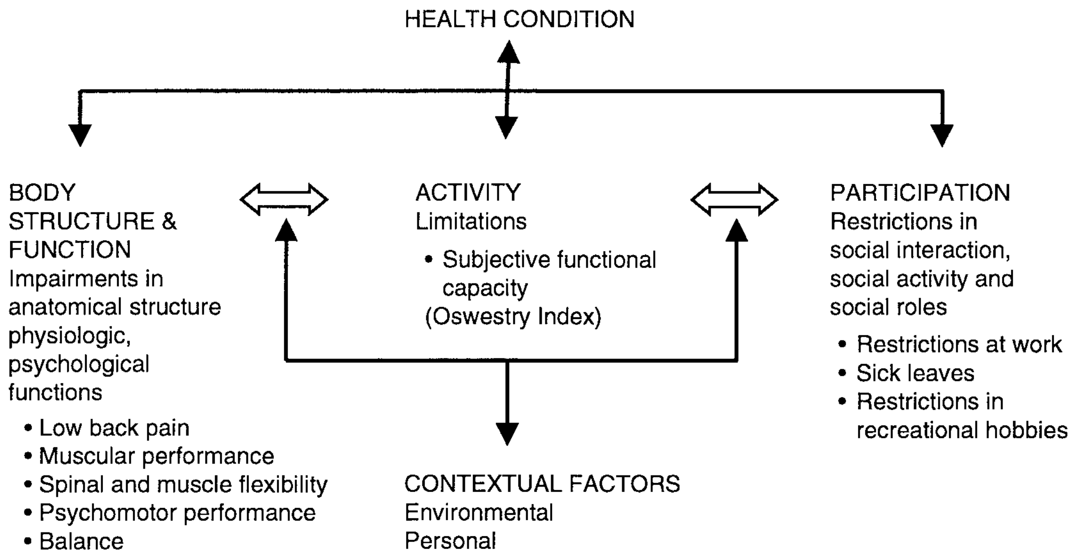


FIGURE 1 Framework of this study (modified from the International Classification of Functioning and Disability WHO 1999, Hall & Brody 1999)

With different kinds of interventions, changes (either positive or negative) in the consequences of low back pain can be achieved. In earlier studies therapeutic exercise programs have been demonstrated to be effective for obtaining physiological changes and decreasing impairments in structure (Hides et al. 1996, Lindström et al. 1992a, Torstensen et al. 1998) and in function (Cooper et al. 1996, Lindström et al. 1992a, Lord et al. 1993, Magnusson et al. 1998, Torstensen et al. 1998). Also, the effect of therapeutic exercise on activity/disability is unquestionable (Cooper et al. 1996, Frost et al. 1995). Even the low back pain subjects´ levels of participation, functions at work increased, absenteeism decreased (Ljunggren et al. 1997) and return to work increased (Lindström et al. 1992a) after therapeutic exercise programs. Contradictory findings of the effects of physical exercise also exist, at least in acute low back pain (Koes et al. 1991, Malmivaara et al. 1995, Moffroid et al. 1994).

Evaluations of the outcomes after therapeutic exercise programs have to be assigned to the targets of therapeutic exercise programs. Earlier the tradition in physiotherapy research has been mainly focused on the outcomes pooled at the level of impairment, as well as the level of participation, for example, return to work. Nowadays, it is suggested that the outcome should be measured according to a broader framework, that is, at all levels of the ICIDH-2 model. The adequate assessment of outcome should include at least the measurement of pain, subjective improvement of symptoms, back pain specific functional status and return to work (van Tulder et al. 1997a). The associations between the variables at different levels of ICIDH-2 classification should also be analysed.

The measurement of change after therapeutic exercise programs should be analysed with longitudinal experimental control group designs and with suitable follow-up periods (Bouter et al. 1998, Koes et al. 1995, van Tulder 1997b). In several studies, which have been referred to this thesis, the control groups have not been true control groups. They have been exposed to different kinds of therapies, usually called conventional or traditional physiotherapy. The existence of a pure control group is fundamental because of the spontaneous recovery, which is undisputed. In addition, the content of therapeutic exercise programs or therapies that the control groups are exposed to, are mostly insufficiently and superficially described. Some criteria have been presented for assessing the quality of studies (Koes et al. 1991, Koes et al. 1995). The Cochrane Collaboration for systematic reviews (van Tulder et al. 1997b) has also established methodological guidelines, which may help in the evaluation of research methodology in clinical trials.

The general aim of this research work was to investigate the changes in body functions, activity and participation among a population of subacute and chronic low back pain subjects after a three-month therapeutic exercise program using a controlled study design. The ultimate aim for this kind of research work is to help in the customisation of the therapeutic exercise programs used in physiotherapy for low back pain subjects.

2 LOW BACK PAIN AND ITS CONSEQUENCES

2.1 Epidemiology and definition of low back pain

Low back pain is one of the most usually reported musculoskeletal disorder among working population. In the Finnish population, 70 percent of people aged 30 years or over have experienced at least one low back pain episode (Heliövaara et al. 1993). Low back pain has been shown to associate with physiological, physical and psychosocial work factors, as well as health behaviour, for example, smoking and physical activity (Lindström 1994, Waddell 1998) and further, on the whole, with urbanisation and rapid industrialisation (Volinn 1997).

In many cases, the pathology or the organic basis behind low back pain remains unclear (Bouter et al. 1998, Turk & Okifuji 1999) and the origin of low back pain has been explained in several ways. Pain may arise from the degeneration of intervertebral discs (Frymoer et al. 1984, Mooney 1989) or from abnormalities in other tissues, such as, facet joints, vertebral bodies, ligaments, muscles (Cavanaugh 1995, Siddall & Cousins 1997). The changes in different structures of the spine may produce spinal instability, which may cause the sensation of pain (Panjabi 1992). Pain may be associated with compression/mechanical load (for example, due to disc herniation), damage to the nerves (Mooney 1989, Siddall & Cousins 1997), or abnormal chemical events that occur with tissue damage, as well as the release of chemical mediators (Cavanaugh 1995, Mooney 1989). Psychological factors may also produce pain and the pain may then be of psychogenic origin (Liebenson 1992, Viikari-Juntura et al. 1991). Furthermore, the findings of objective diagnostic procedures do not always relate to the sensation of pain (Frymoyer et al. 1984, Mooney 1989) and, in many cases, the exact identification of the origin of low back pain can not be determined.

Low back pain starts quite spontaneously or during the performance of ordinary activities. Usually, it is an episodic, intermittent and recurrent problem, which classification to a certain category being difficult (Waddell 1998).

Low back pain has been defined in various ways, for example, according to the occurrence and duration of symptoms (Spitzer et al. 1987), the localisation of pain/symptoms (Abenhaim et al. 2000, Spitzer et al. 1987), the natural history of back pain (von Korff 1994), and the severity of pain in relation to functional disability (Delitto et al. 1995).

The classification of the Quebec Task Force on Spinal Disorders (Spitzer et al. 1987) of activity-related spinal disorders also contains the dimensions of back pain history; 1) acute (duration 1-7 days) 2) reinjury/exacerbation of a previous injury or 3) chronic pain syndrome (duration over three months). In addition to the above- mentioned phases, von Korff (1994) has added the flare-up phase, where the pain temporarily worsens in recurrent or chronic phases. Delitto´s et al. (1995) treatment based model also provides guidance for the goals in physiotherapy. In acute-pain situations the goal for physiotherapy is the relief of pain. In subacute phases, there is a need for quick return to normal activities, and in chronic situations a lack of physical conditioning can be seen and therapy modalities are planned accordingly.

Most of the subjects can be categorised into a so called non-specific low back pain group, which excludes severe pathologies such as fractures, tumors, infections, and cauda equina syndrome. Subject with non-specific low back pain has low back pain without radicular leg pain and without clinical or radiological features of lumbar spine pathology (McGregor et al. 1998). The prognosis for non-specific low back pain is good. Most of the patients will naturally recover within six weeks after an acute non-specific low back pain episode (Nordin & Campello 1999). But for those individuals who will not improve, the consequences at different levels of ICIDH- classification are evident.

2.2 Impairments in structure and function

In the ICIDH-2 classification (WHO 1999) the impairment means "a loss or abnormality of body structure or of a physiological or psychological function". A chronic pain situation itself may have an effect on physical functioning (Turk & Okifuji 1999). Low back pain subjects have several impairments in structure (Hultman et al. 1993, Mattila et al. 1986, Sihvonen et al.1993, Venna et al. 1994), as well as limitations in functions, such as in muscle strength (Biering-Sörensen 1984, Mayer et al. 1985), flexibility (Jull & Janda 1990, Mellin 1988, Triano & Schultz 1987) and in psychomotor performance (Hodges & Richardson 1996, Luoto et al. 1996, McGregor et al. 1995). (Tables 1,2).

TABLE 1 Impairments in structure

Impairments in structure	References
Atrophy of type II units in the trunk musculature	Mattila et al. 1986 Rissanen et al. 1995
Changes in type I units	Mattila et al. 1986
Decreased muscle density	Hultman et al. 1993
Muscle spasm	Hides et al. 1996
Sensory and neurological deficits	Venna et al. 1994
Abnormal EMG activity	Sihvonen et al. 1993

TABLE 2 Impairments in function

Impairment in function	References
Pain	Battie et al. 1994, Jette & Jette 1996
Decreased muscle strength	Biering-Sörensen 1984 Hultman et al. 1993 Kankaanpää 1999 Mayer et al. 1985
Decreased muscle endurance	Nicolaisen & Jörgensen 1985 Hultman et al. 1993
Increased muscle fatigue	Kankaanpää 1999
Restricted spinal and muscle flexibility	Alaranta et al. 1994a Battie et al. 1990 Burton et al. 1989 Hadjipaulov et al. 1996 Jull & Janda 1990 McGregor et al. 1995 Mellin 1988, 1990 Moffroid et al. 1994 Pope et al. 1985 Triano & Schultz 1987 Troup et al. 1987
Decreased aerobic fitness	McQuade et al. 1988
Changes in psychomotor performance	
slow reactions/psychomotor speed	Luoto et al. 1996 Taimela et al. 1993 Venna et al. 1994
impaired speed of spine movements	Marras & Wongsam 1986, McGregor et al. 1995
slow gait	Khodadadeh & Eisenstein 1993
impaired trunk control	Novy et al. 1999
Increased postural sway	Alexander & Kinney LaPier 1998 Byl & Sinnott 1991 Luoto et al. 1998
Dysfunction in the neuromuscular system	O´Sullivan et al. 1997, 1998
Deficit of motor control	Hodges & Richardson 1996
Changes in activity and relaxation of muscles	Triano & Schultz 1987
Deconditioning syndrome	Mayer et al. 1985 Mayer & Gatchel 1988

2.3 Activity limitations

ICIDH-2 (WHO 1999) defines activity as follows: "Activity is the performance of a task or action by an individual". Activity includes everything what a person does, from very basic movements (for example, grasping) to very complex activities (for example, driving a car or personal social skills). Activity limitations may be seen as altered way of doing things; the quality or quantity of the activity is affected. These limitations are obvious after the first three months (Waddell 1993). It has been reported that functional ability decreased in 75 percent of subjects with low back pain (Heliövaara et al. 1989). Table 3 shows the limitations in activity according to earlier studies.

TABLE 3 Limitations in activity and in participation

Limitations in activity	References
Decreased Oswestry Index	Hazard et al. 1994 Hupli 1998
Limitations in participation	
Decreased working capacity	Mayer et al. 1985
Increased sick leaves	Heliövaara et al. 1989
Decrease in every day duties	Heliövaara et al. 1989
Decreased recreational activities	Heliövaara et al. 1989 Mayer et al. 1985

The level of activity limitations is influenced by the characteristics of the individual (Haazen et al. 1994), but also the psychological, social and environmental factors interact with this personal level of low back pain disability (Waddell 1993).

In previous studies associations between impairments in functions and activity have been observed. Activity, measured by Oswestry Index, and low back pain had positive correlations (Cooper et al. 1996, Grönblad et al. 1996, Hupli 1998). Hupli (1998) also found low correlations between muscular performance and Oswestry Index. In Grönblad´s study (1996) subjective disability was also found to be associated with work-related factors.

2.4 Participation limitations

Participation (formerly disability or handicap) is "an individual´s involvement in life situations in relation to health conditions, body functions and structures, activities and contextual factors" (WHO 1999). It is the loss of function and role at the social level (WHO 1999), which is evident in many chronic pain situations (Ashburn & Staats 1999, Turk & Okifuji 1999). Low back pain has associations with decreased working capacity, work absenteeism and increased sick leaves (DiFabio et al. 1995, Hagen & Thune 1998, Kellett et al. 1991, Mayer et al. 1985). Social and recreational activities may also decrease (Mayer et al. 1985). Alterations in participation are strongly influenced, for example, by the psychological factors (for example distress, depression), cultural, national and financial policies, such as socio-economic compensations, (Waddell 1998, Wade 1998). Table 3 shows the limitations in participation due to low back pain.

3 THE CONTENT OF THERAPEUTIC EXERCISE AND CHANGES IN IMPAIRMENTS, ACTIVITY AND PARTICIPATION

Physical activity

Overall physical activity has different meanings at the different levels of the ICIDH-classification. Physical activity can rarely totally cure the disease, but it can be used to reduce functional limitations and to increase activity and participation (Mälkiä 1990). The group of low back pain subjects with high a level of physical activity during leisure time had lower pain level and better subjective function in ADL compared with the less active group (Bendix et al. 1997). Further, physical activity has a preventive role. Activity prevents the growth of disability (Koes et al. 1991, Lindström 1992b, Mayer & Gatchel 1988, Mälkiä & Ljunggren 1996, Waddell 1993) and it may also diminish the recurrence of low back pain (Soukup et al. 1999, Stankovic & Johnell 1990).

In physiotherapy there is a wide variety of treatment approaches for low back pain subjects. Pure manual therapies (Davies et al. 1979, Koes et al. 1992a, Koes 1992b,) or physical modalities (Jette et al. 1994, Manniche et al. 1988) are used. According to Jette et al. (1994) the most frequently used therapies were physical modalities, manual therapy and physical exercises. At least in chronic situations, however, physical exercises were superior compared to physical modalities, such as transcutaneus nervous stimulation (van Tulder 1996), heat or manual therapy (Maher et al. 1999).

Physical activity is a combination of activities at work, during commuting and at leisure time, and it can be defined as follows: "any bodily movement produced by skeletal muscles and resulting in energy expenditure" (Bouchard et al. 1990). Physical activity pattern can be analysed according to their type, frequency, duration and intensity (Bouchard et al. 1990). The physical activity of individuals can be increased in physiotherapy by guided physical exercises, for example with therapeutic exercise. Therapeutic exercise has been defined as "supervised bodily movements with or without the help of an external apparatus" (Thomas 1993). Therapeutic exercises can be considered to be non-specific interventions, if they do not treat specific areas of the spine, for example they can be general strengthening, endurance or flexibility exercises, and the program is the same for all subjects (DiFabio et al. 1996). Therapeutic exercises can also be considered to be specific treatment methods, for example, William's flexion program (Williams 1965), McKenzie´s approach (McKenzie 1981) or Medical Exercise Therapy (Torstensen et al. 1998). However, the therapeutic exercise programs are mostly combinations of different forms (Bendix et al. 1995, Evans et al. 1987, Linton et al. 1989) and even during the same physiotherapy session, a physiotherapist can use many kinds of treatment techniques (Battie et al. 1994, Jette & Jette 1996).

Aims, objectives of physiotherapy

Rothstein (1994) stated that "effective physiotherapy of low back pain has to cause changes in function, disability status and it has to improve quality of life". The restoration and optimisation of independent function is the most meaningful goal for physiotherapy among low back pain subjects (Beattie 1994, Nordin & Campello 1999, Rodriquez 1992, Saal & Saal 1997, Waddell 1995). In detail, the objectives of physiotherapy are to modulate and control pain, to improve muscle strength, endurance, balance, co-ordination, aerobic and anaerobic capacity, biomechanical and ergonomic counselling, and finally, the maintenance of a lifelong physically active lifestyle (DeRosa & Portefield 1992, Farrell et al. 1994, Ljunggren et al. 1997, Nordin & Campello 1999, Norris 1995, Saal & Saal 1991, Saal & Saal 1997, Waddell 1993).

Types of physical interventions

The strain of physical interventions varies from bed rest via normal activities of daily living to progressive physical exercises and work hardening programs (Deyo et al. 1986, Lindström et al. 1992b, Malmivaara et al. 1995). Functional restoration programs (Alaranta et al. 1994b) include active back rehabilitation without psychological or occupational counselling (DiFabio et al. 1995). However, so called multimodal interventions are comprised of multidisciplinary team work with psychological and vocational training (Gill et al. 1994, Mitchell & Garmen 1994). Gill et al. (1994) found better levels of coping and control of pain following multimodal treatment programs. At least in chronic low back pain situations, the combination of exercises for example physical exercise, education, psychosocial and ergonomic counselling, as well as behavioural techniques, can be effective (Maher et al. 1999, Nordin & Campello 1999, Soukup et al. 1999).

According to Saal & Saal (1997), during the initial phase, rehabilitation starts with pain control, for example with medication, physical agents, traction or extension or flexion exercises. In the second training phase, exercises to improve the muscle strength and endurance of the prime movers and stabilizers, as well as flexibility training, are recommended. Also, a total fitness program with aerobic and anaerobic training are planned for each subject.

Via muscle exercises the subjects are taught to utilise postural stability and dynamic muscle control and hence proper trunk positioning, while performing daily activities (Hall & Brody 1999, Saal & Saal 1997). The program starts with simple exercises on the floor with isometric contractions followed by isotonic contractions with free weights, bands or machines. Flexibility exercises include exercises for trunk, hip and lower limb area, especially for the hamstrings, iliopsoas and knee extensors. These stretching movements are executed slowly, 15-30 seconds per movement, but only after careful warm-up period (Saal & Saal 1997).

Dose and duration

If therapeutic exercise programs are started within six weeks (Waddell 1995), executed daily (Mayer et al. 1985), three times per week (McGill 1998) with 2-3 months training programs (Kellett et al. 1991, Manniche et al. 1988) and the progression in the training stimulus is high enough (number of repetitions and sessions, maximal resistance in muscle training) (Manniche 1996, Pollock et al. 1998, Saal & Saal 1991) and specific (Hall & Brody 1999, Pollock et al. 1998, Saal & Saal 1997), some effects can be expected, for example, in preventing chronicity and work loss (Waddell 1995).

The overall content of therapeutic exercise

In the analyses of exercise programs Faas (1996) expressed that intensive exercise programs had short-term (3-6 months) effects, but the positive findings were reversible within 12 months. After these intensified, supervised training periods subjects have to continue training in exercise groups or with controlled home exercises (Brody 1999, Gill et al. 1994). With active home exercises the positive effects may be maintained, but the effective home exercise programs will need frequent follow-ups by physiotherapists (Ljunggren et al. 1997). Also, personal responsibility for continued exercise has to be develop during the physiotherapy sessions (Waddell 1995). The level of compliance with the exercise programs and the supervisor of the program have an important and critical role for the outcomes of exercise programs (Reilly et al. 1989). With good level of compliance, better results have been obtained in terms of the Oswestry Index, spinal flexibility and return to work (DiFabio et al. 1995).

Some subjects may need encouragement and support from group sessions (Kellett et al. 1991), and group therapies are considered to be more economical compared to individual therapies (Frost et al. 1995). However, Rose et al. (1997) stated that there are no differences in the outcomes following multimodal therapy performed either in groups, or as individually supervised programs.

The outcome of therapeutic exercise programs also depends on patient´s status at the initial stage. For example, Cooper et al.(1996) explained that there will be no changes in the Oswestry Index if the initial Oswestry score is very low (<20), and Meade et al. (1990) stated that subjects with an Oswestry Index over 40 percent responded better to chiropractic treatments than those with scores under or equal to 40 percent. Bendix et al. (1998) assumed that subjects with high initial score were more likely to have better scores in the follow-ups. Good muscle endurance, physical activity, as well as low level of disability prior to participation in a functional restoration program correlated positively with a decrease in low back pain (Bendix et al. 1998).

The content of the therapeutic exercise program has to be changed by the course of progression from the passive modalities to active methods in the later stages (Jette & Delitto 1997) and there needs to be a state of overloading to enhance the positive changes in the physiologic functions (Pollock et al. 1998). Usually, the use of strengthening and endurance training increases in the later stages of rehabilitation (Jette & Delitto 1997). Examples of the content of therapeutic exercises are presented in the table 4.

TABLE 4 Some examples of the content of therapeutic exercise programs for low back pain subjects

Muscle strength training	Farrell et al. 1994, McGill 1998
- back muscles	Hall & Brody 1999,Ljunggren et al. 1997
- abdominal muscles	Hall & Brody 1999,Ljunggren et al. 1997
- hip muscles	Ljunggren et al. 1997
Muscle endurance training	McGill 1998
Spinal and muscle flexibility	Evans et al. 1987, Hall & Brody 1999, Martin et al. 1986, McGill 1998, Norris 1995, Sullivan et al. 1996
Kinaesthetic training	Farrell et al. 1994, Norris 1995, Saal & Saal 1991
Proprioceptive training	Farrell et al. 1994, Norris 1995
Balance and co-ordination training	Hall & Brody 1999
Active lumbar stabilisation and postural control	Hall & Brody 1999, Norris 1995, Richardson et al. 1999, Saal & Saal 1991
Aerobic exercises	Hall & Brody 1999, Sullivan et al. 1996, Mannion et al. 1999
Training with exercise devices	Mannion et al. 1999
Hydrotherapy	Sjogren et al. 1997
Walking	Sullivan et al. 1996

Changes according to the ICIDH-2 classification

If the structured, progressive and individually adjusted therapeutic exercise programs are planned and executed carefully, the exercises are evidently effective (DiFabio et al. 1996, Maher et al. 1999, Nordin & Campello 1999, van Tulder 1996), and the positive outcomes can be seen in the different levels of the ICIDH classification (table 5). Physiotherapy and therapeutic exercise have been found to be effective in decreasing pain (Ambrosius et al. 1995, DiFabio & Boissonnault 1998, Friedrich et al. 1998, Lindström 1994, Manniche et al. 1988, Torstensen et al. 1998) and physical impairments (Manniche et al. 1988), and in improving function (Ambrosius et al. 1995). Active rehabilitation programs have decreased subjective disability (Lindström 1994, Manniche et al. 1988, Torstensen et al. 1998). Friedrich et al. (1998) showed that the combination of physical exercises and motivation program was effective in decreasing the degree of disability. Lindström (1992a) and Ambrosius et al. (1995) observed that physical exercise programs lead to increases in return to work figures and decrease in sick-leave figures among low back pain subjects.

TABLE 5 The effects of exercise on impairments, activity and participation in healthy and low back pain subjects

	Subjects	References
BODY STRUCTURE		
Elastic stiffness in muscle tissue↑	Healthy	Kannus et al. 1992
Nutrition↑	Healthy	Kannus et al. 1992
Adaptive changes in cartilage tissue↑	Healthy	Kannus et al. 1992
Atrophy of type II fibres↓	LBP	Rissanen et al. 1995
Multifidus muscle recovery	LBP	Hides et al. 1996
Aerobic fitness↑	LBP	Lindström 1992a
	LBP	Reilly et al. 1989
FUNCTION		
Pain↓	Back injury	Cooper et al. 1996
	LBP	Frost et al. 1995
	LBP	Lindström 1994
	LBP	Reilly et al. 1989
	LBP	Torstensen et al. 1998
Muscular strength & endurance↑	LBP	Alaranta et al. 1994b Lindström 1992a
Spinal and muscle flexibility↑	LBP	Alaranta et al. 1994b Kankaanpää 1999 Lindström 1992a Magnusson et al. 1998
Neuromuscular performance↑	LBP	Lord et al. 1993
Co-ordination and balance↑	LBP	Lord et al. 1993
Movement velocity↑	LBP	Magnusson et al. 1998
Motor skills↑	LBP	Magnusson et al. 1998
ACTIVITY		
Oswestry Index↓	LBP	DiFabio et al. 1995
	LBP	Frost et al. 1995
	LBP	Torstensen et al. 1998
	Back injury	Cooper et al. 1996
Walking capacity↑	LBP	Frost et al. 1995
PARTICIPATION		
Absenteeism↓	LBP	Ljunggren et al. 1997
Sick leaves↓	LBP	Ambrosius et al. 1995
	LBP	Indahl et al. 1995
	LBP	Kellett et al. 1991
	LBP	Lindström 1992a
Return to work↑	LBP	Ambrosius et al.1995
	LBP	Lindström 1992a
	LBP	DiFabio et al. 1995

(continues)

TABLE 5 (continues)

	Subjects	References
Capacity to perform more strenuous leisure time activities ↑	LBP	Alaranta et al. 1994b
Use of medical services↓	LBP	Alaranta et al. 1994b
Occupational handicap↓	LBP	Alaranta et al. 1994b

↑= increase, ↓= decrease
LBP= Low Back Pain subjects

4 MEASUREMENT OF CHANGE

4.1 Study population

Randomised controlled trials (RCT) with relevant endpoint have been stated to be the best and most effective method for analysing the efficacy and effectiveness of physiotherapy interventions (Bouter et al. 1998, Hoffman et al. 1994, Koes et al. 1995, van Tulder et al. 1997b). On the other hand, because RCTs are often difficult to execute in natural settings, quasi-experimental studies can also be used (Kane 1994).

A representative study population has to be gathered with adequate sampling methods in relation to the study problem and without any selection bias (Koes et al. 1991). In clinical trials the convenience sample is quite common , but the representativeness of the subject group has to be secured for correct interpretation of results (Campbell & Machin 1995). In low back pain research, the generalizability of findings may also be influenced by the diagnose of low back pain and the standardisation of therapeutic exercises (Hoffman et al. 1994).

The exact definition and diagnose of low back pain is difficult (Bouter et al. 1998, Turk & Okifuji 1999) and therefore the homogeneity of study populations will issue a challenge to low back pain research (Bouter et al. 1998). In RCTs the equal distribution of confounding factors is defined by randomisation and then there is the comparability between study groups in relevant baseline characteristics (Koes et al. 1991). However, in small samples sizes the randomisation procedure may be unsuccessful (Koes et al. 1995).

In follow-up studies, some drop out will occur. During the study period, all the drop out cases need to be described for each of the study groups separately and low drop out rates are favoured (Koes et al. 1991, 1995). A small study population may increase the type II error. Therefore, a sample size over 50 subject per each study group is preferred (Koes 1996). Adequate sampling size can be determined a priori (Hoffman et al. 1994) with power analysis (Altman 1991) and separately for each outcome parameter (Tate et al. 1999). Power expresses the possibility of avoiding type II errors, and usually a power of 0.80 is sufficient (Campbell & Machin 1995, Hulley & Cummings 1988).

4.2 Interventions

Interventions, which are used in study designs, must be standardised and exactly described (Koes et al. 1995, van Tulder 1997c), but often the definition of treatment, its amount and content, is inadequate and insufficient (Kane 1994, Koes et al. 1995).

Physiotherapy research is threatened by the influence of co-treatments (Hoffman et al. 1994) and all kinds of co-interventions have to be avoided during the study period (Koes et al. 1991, van Tulder et al. 1997b). Co-treatments hinder the observation of pure cause effect relationship of the interventions included in the study design. The use of placebo or sham therapies in physiotherapy research is not always feasible (Koes et al. 1991, 1992a). In some situations, however, the use of real control group may be unethical (Hulley & Cummings 1988). Participation in therapeutic interventions requires some degree of compliance (Hoffman et al. 1994) and so the rate of adherence needs to be analysed and reported.

Therapeutic exercise program needs to correspond with the goals of physiotherapy, as well as with the outcome measurements. Evidence based exercise methods exist for the enhancement of muscular performance, muscle strength and endurance (Richardson et al. 1999) for the improvement of flexibility (Hall & Brody 1999), psychomotor speed (Kauranen 1999), balance performance (Hall & Brody 1999), as well as for increasing overall levels of activity (Cooper et al. 1996, Frost et al. 1995) and participation (Lindström 1994, Ljunggren et al. 1997). Therefore, the therapeutic exercise programs are expected to be effective.

4.3 Measurements

In the measurement of outcome, many factors, which have effects on the outcome need to be taken into account. Kane (1994) clarified this as follows: The outcome is a combination of the outcome measurements at the baseline, patient factors, environment, and treatment. Environmental factors such as, sosioeconomic background (Andersson et al. 1994, Kane 1994), make the comparability of results between different countries very difficult.

The use of blinding in the assessment of outcome will eliminate the effects of unintended interventions (Hulley & Cummings 1988, Koes et al. 1991) and Hoffman et al. (1994) presented double-blinded (=blinding subjects and assessments) randomised placebo-controlled trials as the gold standards for study designs. However, the blinding of subjects may be impossible in trials that evaluate the therapeutic exercises (Koes et al. 1995), and also the blinding of physiotherapists may be infeasible (Hoffman et al. 1994).

Both objective and subjective measurements of outcomes are important for the client, physiotherapist and the entire rehabilitation team (Koes et al. 1995, Nordin & Campello 1999). Outcome measurements should include pain, symptoms, overall improvement, spinal mobility, back specific functional status, course of dysfunction, activity limitations, well being, health-related quality of life, disability, work status and medical consumption (Andersson et al. 1994, Deyo et al. 1994, Hoffman et al. 1994, Koes et al. 1991, Koes et al. 1995, von Korff 1994, van Tulder et al. 1997b). In addition, Haazen et al. (1994) presented health-promoting variables such as, creativity, problem-solving, sense of humour if the goal is to predict the treatment outcome. The reality of a patient´s life has to be evaluated and this means the measurements of improvements in functions in patient´s own environment (Kane 1994). However, in these kind of assessments, the co-influence of motivation, depression and other socio-economical factors also needs to be taken into account (Kane 1994).

All outcome measurements should be relevant (Koes et al. 1991, van Tulder et al. 1997b) and these relevant outcome measurements have to be reliable, valid and clinically sensible to be able to detect small changes (Deyo et al. 1994, Koes et al. 1995). The reliability of measurements consists of internal consistency and reproducibility (Deyo et al. 1994). Internal validity is the equivalence between conclusions and what actually happened (Hulley & Cummings 1988) and it is influenced by treatment allocation, blinding (provider, patient, measurer), co-interventions, compliance, relevant outcomes, drop out rate, and timing of outcome assessment (van Tulder et al. 1997b).

Campbell & Machin (1995) suggested that reports of results should include an estimate of effect. Effect size defines the magnitude of the association between the predictor and the outcome (Hulley & Cummings 1988) and it can be decided beforehand. Effect size can also be calculated ex post facto by using the outcome variables and their standard deviations (Mannion et al. 1999).

Koes et al. (1991) presumed an adequate follow-up period in clinical trials. The optimal timing of outcome measurements may be difficult in follow-up studies (for example, natural recovery in acute phase) (Andersson et al. 1994), and therefore, the accommodation of measurements in relation to the natural history of low back pain is essential (Hoffman et al. 1994). Kane (1994) pointed out that follow-up measurements need to be repeated at several points of time. The results of physiotherapy are usually measured at the end of intervention period. With longer follow-up periods, the confounding variables may interfere, and it is supposed that there will be residual effects of physiotherapy, for example, after one-year- follow-up period (Kane 1994). In addition, recall bias can have effect on the outcome in retrospective reconstructions (Bouter et al. 1998). The background problem must be taken into account. For example, DiFabio et al. (1996) explained that subjects with mechanical low back pain had better short term outcomes than subjects with herniated discs.

Reliable and valid methods exist for the measurement of muscular performance, flexibility, balance and psychomotor performance, but the measurements of pain, activity/disability and participation are not easily executed in reliable, valid and sensitive ways (Bouter et al. 1998, Kopec & Esdaile 1995) and there are also no exact criterions for them (Stratford et al. 1994).

4.4 Data analysis and presentation

When presenting data, it is usual to report frequencies and standard deviations for the most important outcome variables for each study group (Koes et al. 1991, Koes et al. 1995). In addition, Campbell & Machin (1995) favoured the presentation of confidence intervals. A confidence interval defines the range of values within which the population mean is likely to be situated. From calculation (mean-1.96xsd(mean) to mean+1.96xsd(mean), a 95% confidence interval can be calculated. The changes in outcome variables during the study period can be interpreted in the light of confidence intervals. (Hicks 1995).

Experimental studies require tightly controlled situations and measurements of the subjects adherence to directions. Pragmatic studies need to be analysed on an intention to treat basis, which reflects the likely action of the subject (Campbell & Machin 1995). According to Koes et al. (1995) the main deficiency in clinical trials has been the lack of intention to treat analysis, at least when the drop out rate exceeds 10%.

Statistical significance is not related to the clinical significance of findings and with large study population, for example, statistically significant but unimportant results may be detected (Campbell & Machin 1995). The probability of accepting the null hypothesis has connections with the type I errors and false positive findings (Campbell & Machin 1995).

Even if the results are always combinations of the true situation and real effects, random and systematic errors, as well as variability, it can be guaranteed that the changes have not occurred by chance with the use of appropriate statistical methods (Campbell & Machin 1995).

5 PURPOSE OF THE STUDY

The main aim of this research work was to evaluate the changes and their permanence at the levels of impairment, activity and participation among low back pain subjects after a three months therapeutic exercise program, and also to determine the necessary, essential components and critical points of physiotherapy.

In detail, the aims and study questions were as follows:

1. Are there changes at the level of impairment and how permanent are the changes?
   - 1.1 in low back pain
   - 1.2 in muscle strength and endurance
   - 1.3 in spinal and muscle flexibility
   - 1.4 in psychomotor performance
   - 1.5 in postural sway
2. Is there change at the level of activity and how permanent is the change?
   - 2.1 in Oswestry Index
3. Are there changes at the level of participation and how permanent are the changes?
   - 3.1 in restrictions at work
   - 3.2 sick leaves
   - 3.3 in restrictions in recreational hobbies
4. Are there associations between the above mentioned outcome measurements?

6 MATERIAL AND METHODS

6.1 Subjects and design

The subjects selected for this study were 90 employed residents of the city of Jyväskylä in Central Finland who had non-specific, subacute or chronic low back pain. The subjects had visited their occupational health care system because of low back pain. They had had disabling back pain at least three months. For the majority of the subjects, the duration of the present episode of low back pain at the time of initial assessment was greater than three months. All subjects with a history of surgery or sciatica or comorbidity situations were excluded and none of the subjects had any other diseases that may have had an influence on the results of this study. The inclusion criteria are presented in appendix 1. The flow chart of the course of this study is illustrated in figure 2.

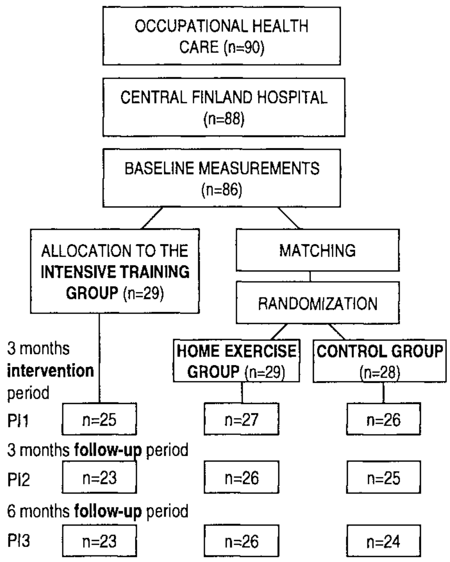


FIGURE 2 The flow chart of the study (PI1 = The first post-intervention measurement session, PI2 = The second post-intervention measurement session, PI3 = The third post-intervention measurement session)

The characteristics of the subjects during the phase of baseline measurements are presented in table 6.

TABLE 6 Characteristics of subjects (n=86) according to the baseline measurement

	Intensive training group	Home exercise group	Control group
Male (n)	11	15	13
Female (n)	18	14	15
Age (years)	39	41	40
Height (cm±sd)	167±7.3	171±11.3	168±9.0
Weight (kg±sd)	73±15	75±15	72±12
First onset of low back pain(years)	9.7±8.9	11.1±8.8	10.0±7.7
Duration of current symptoms (%)			
= 7 weeks	33%	22%	25%
> 7 weeks- 6 months	33%	22%	25%
> 6 months	34%	56%	50%
Work (MET)	4.0±1.9	3.9±2.0	4.7±2.5
Leisure (MET)	5.1±2.0	5.2±2.1	5.5±1.8
Educational level (%)*			
-no professional education	7	14	21
-school level	83	62	75
-polytechnic or university	10	24	4

There were no statistically significant differences between the three study groups in these basic characteristics at the baseline measurement, except for education level.
*Statistically significant difference between the three study groups ($p<.05$)
MET= Metabolic equivalent unit = O_2 consumption at rest 3.5ml/kg/min

Randomisation

After careful medical examinations at the Central Finland Hospital and the baseline measurements the subjects were divided into three groups. The purpose was to randomise the subjects into the different study groups. Due to the slow rate of obtaining subject numbers for this study, the 29 subjects were placed into the intensive (I) training group, because their training was required to commence at the same time. During the next phase, 57 subjects were matched with the subjects in the intensive training group according to age, gender and the level of physical activity at work and during leisure time, and they were then randomised by drawing of lots into the home (H) and control (C) groups. These subjects entered into the study in five clusters ranging from 6-10 subjects. The three study groups were homogenous in their basic characteristics at the initial stage of the study: age, gender, anthropometry, educational level, physical activity at work and in leisure time and in history of low back pain. In the beginning of this study, only a few differences existed between the three study groups in the outcome variables: the control group had significantly higher values in the dynamic endurance of trunk flexors (I), the intensive training group had less flexibility in erector spinae muscle (II) and the medio-lateral postural sway velocity in the eyes closed test was the highest in the intensive training group.

The duration of the intervention period was three months. The post-intervention measurements were performed three (PI1), six (PI2), and twelve (PI3) months after the baseline (BM) measurements. The study was approved by The Ethical Committee of the Central Finland Hospital and each subject signed a statement for this study. The subjects were also informed of the standardised instructions for the different measurements. All the measurements and interventions were performed by the same educated staff at the Research Laboratory of Sport and Health Sciences, University of Jyväskylä.

Dropouts

After visiting his local occupational health care services, one male subject did not arrive for his physician´s appointment at the Central Finland Hospital due to work commitments, and one woman was not able to be contacted.

After a medical examination by a physician, one male subject was referred for back operation and one female subject for further examinations. One male subject did not start the intensive training due to a prolapsed disc.

During the three months intervention period three subjects from the intensive training group interrupted their exercise program: One male had spinal stenosis and his need for an operation was determined just prior the start of the exercise program. Thus, he interrupted his exercise program right at the outset. In relation to two female subjects, one became pregnant and the other stated she was too busy at work to participate. The two drop-outs from the home and control groups also stated that they were too busy with their work.

During the follow-up period, two subjects from the intensive training group dropped out: one male participated also extra weight-lifting and suffered a back accident while lifting weights. The other male subject suffered a prolapsed disc while performing heavy gardening activities. In the home exercise group, one male subject had heart disorders. Two female subjects from the control group dropped out during the follow-up, one because of a gynaecological operation, and the other because of an infection due to an animal bite on her upper extremity. The total drop out rate was 19% during the study.

6.2 Measurements

The subjects completed a structured questionnaire during the baseline measurement phase of the study and then again during each of the three follow-up sessions. The questionnaire was comprised of a large variety of questions, for example, data about the initial onset of low back symptoms and the duration of the current low back pain symptoms was gathered. Physical activity at work and during the leisure time was graded according to the frequency and intensity of exercise. A corresponding MET value (metabolic unit = O_2 consumption at rest 3.5 ml x kg^{-1} x min^{-1}) was calculated from each activity level at work and during leisure time (Mälkiä et al. 1994). During the initial period of the study, there were separate questions on commuting activity. The changes in overall physical activity and in other co-interventions were controlled with questionnaires along the study.

6.2.1 Measurements of impairments

Low back pain (Study I)
In this study the low back pain intensity was evaluated with the Borg scale (0 to 11) (Borg 1982, 1998) during each measurement session. The Borg scale was also used to describe the symptoms during different test situations. (table 7)

Muscle strength and endurance (Study I)
The maximal isometric trunk extension and flexion were measured in a standing position and isometric knee extension, ankle extension and flexion strength were measured in a sitting position with dynamometers. The subjects performed three maximal isometric contractions with a 30 second rest period between each contraction. The best result was recorded and the absolute values of isometric muscle strength were used. The dynamic endurance of back, abdominal and lower limb muscles were tested according to the method of Alaranta et al. (1990, 1994c), with the exception that the subjects were allowed to perform a maximal amount of repetitions. The isometric endurance of trunk extensors was assessed with the Sörensen test (Biering-Sörensen 1984). Three sum indexes of strength were calculated 1) Index of isometric trunk strength (maximal isometric trunk extension and flexion) 2) Index of dynamic endurance of trunk (dynamic endurance of back and sit-up test)and 3) Index of isometric lower limb strength (isometric knee extension, ankle extension, and ankle flexion). (table 7)

Spinal and muscle flexibility (Study II)
The flexibility measurements consisted of active measures of spinal flexibility and passive measurements of muscle flexibility of the erector spinae, hamstring and iliopsoas muscles. The flexibility measurements were performed by two physiotherapists. (table 7)

Psychomotor performance (Study III, V)
Lower limbs psychomotor speed was determined with new equipment, which was planned and constructed at the Technical Department of Faculty of Sports and Health Sciences, University of Jyväskylä. Choice reaction time was the time that elapsed between random emission of one of the three light stimuli and the initiation of movement i.e. lifting the foot from the starting sensor plate. The time duration of moving the foot from the starting sensor plate to one of three smaller receiving sensor plates was recorded as the movement time. The sum of choice reaction time and movement time is termed total response time. Ten tests of both lower extremities were performed and the means of the last five tests were used for further calculations. The test-retest reliability of this method was tested with 19 healthy subjects (v).

Vertical static jump was used to evaluate the overall movement coordination and the explosive strength of the lower limbs. The subjects performed three maximal vertical jumps without preliminary countermovement from a contact platform. In the starting position, the subjects were positioned with 90° of knee flexion and were required to hold a stick on their shoulders in order to stabilise the movements of the upper trunk and extremities. The flight time in milliseconds was recorded and the maximal value was used. (table 7).

Postural sway (Study IV)
Measurement of postural sway was made with a force platform (Kistler 9861A). The use of this method has been well documented in an earlier study by Era et al. (1996). At every measurement session, postural sway measurements were made by the same tester in a quiet room, and the following conditions were present; normal standing with hands on the hips, looking ahead to a marked point at a distance of 4 meters, normal standing with eyes closed, and tandem standing. The duration of the tests was 40 seconds. The middle 20 seconds of each measurements was used in further analysis in order to avoid any possible errors resulting from initially attaining the erect standing position or from the possible effects of fatigue at the end of the test. The variables of mean velocity (in mm/s) in the antero-posterior direction and in the medio-lateral direction, as well as the amplitude of sway (maximal square side length in millimetres, 100% points in square) were calculated. (table 7)

6.2.2 Measurement of activity

In this study, the activity limitations were assessed with the Oswestry Low Back Pain Disability Questionnaire (Fairbank 1980), which has been found to be sensitive to changes over time (Stratford et al. 1994). (table 7)

6.2.3 Measurements of participation

Restrictions in participation were evaluated with the questionnaires at every measurement session. The questions were modified from several earlier Finnish studies (Lukinmaa 1990, Mälkiä et al. 1988) and they described subjective assessments of restrictions at work due to low back pain, the number of sick leaves, and restrictions in recreational hobbies due to low back pain (appendix II).

TABLE 7 Variables measured in the original studies and the methods used

Variables	Reference	Reliability
IMPAIRMENTS		
Low back pain (I-IV)	Borg 1982,1998	Borg 1998
Muscle strength (I)		
Maximal isometric trunk extension	Viitasalo et al. 1977	
Maximal isometric trunk flexion	Viljanen et al. 1990	
Isometric knee extension	Heikkinen et al. 1984	

(continues)

TABLE 7 (continues)

Variables	Reference	Reliability
Isometric ankle extension	Kuukkanen & Mälkiä 1994	Kuukkanen & Mälkiä 1994 test-retest r=.73 to .91
Isometric ankle flexion	Kuukkanen & Mälkiä 1994	Kuukkanen & Mälkiä 1994 r=.83 to .90
Muscle endurance		
Dynamic endurance of trunk extensors	Alaranta et al. 1990, 1994c	
Dynamic endurance of trunk flexors	"	
Dynamic endurance of lower limbs	"	
Isometric endurance of trunk extensors	Alaranta et al. 1990 Biering- Sörensen 1984	Biering-Sörensen 1984 CV 7% Jörgensen & Nicolaisen 1986 CV 19% Latimer et al. 1999 ICC 0.88
Spinal flexibility (II)		
Lumbar extension	Alaranta et al. 1994a	Mellin et al. 1991 test-retest r=.72 Williams et al. 1993 intertester ICC=.48 Alaranta et al. 1994a intratester r=.07
Lumbar flexion	Alaranta et al. 1994a	Williams et al. 1993 test-retest ICC = .13-.87 Alaranta et al. 1994a intertester r=.61 Alaranta et al. 1994a intratester r=.07
Spinal lateral flexion	Alaranta et al. 1994a, Mellin 1988	Alaranta et al. 1994a intertester r=.91 intratester r=.81
Spinal rotation	Alaranta et al. 1994a, Mellin 1988	Alaranta et al. 1994a intertester r=.79 intratester r=.48 Mellin 1988 intertester r=.77-.90 intratester r=.73-.87

(continues)

TABLE 7 (continues)

Variables	Reference	Reliability
Muscle flexibility (II)		
Erector spinae	Alaranta et al. 1990	
Hamstring	Chow et al. 1994 Keeley et al. 1986	Keeley et al. 1986 intertester r=.98 intratester r=.99 Chow et al. 1994 test-retest ICC=.95
Iliopsoas	Godges et al. 1993	Godges et al. 1993 test-retest ICC= .71-.95
Psychomotor performance (III, V)	V	V
Choice reaction time of lower limb		test-retest r=.74
Movement time of lower limb		test-retest r=.62
Total response time		test-retest r=.67
Flight time	Kujala et al. 1994 Viljanen et al. 1990	Suni 2000 intratester ICC=.98 test-retest CV%=2.4
Postural sway (IV)		
velocity of sway amplitude of sway	Era et al. 1996	
Activity (I-IV)		
Oswestry Index	Fairbank 1980	Daltroy et al. 1996[#] internal reliability Cronbach alpha=.93 test-retest reliability ICC= .97 Hupli 1998 ICC= .83
Participation		
Sick leaves	Lukinmaa 1990	
Restrictions at work due to low back pain	Mälkiä et al. 1988	
Restrictions in recreational hobbies		

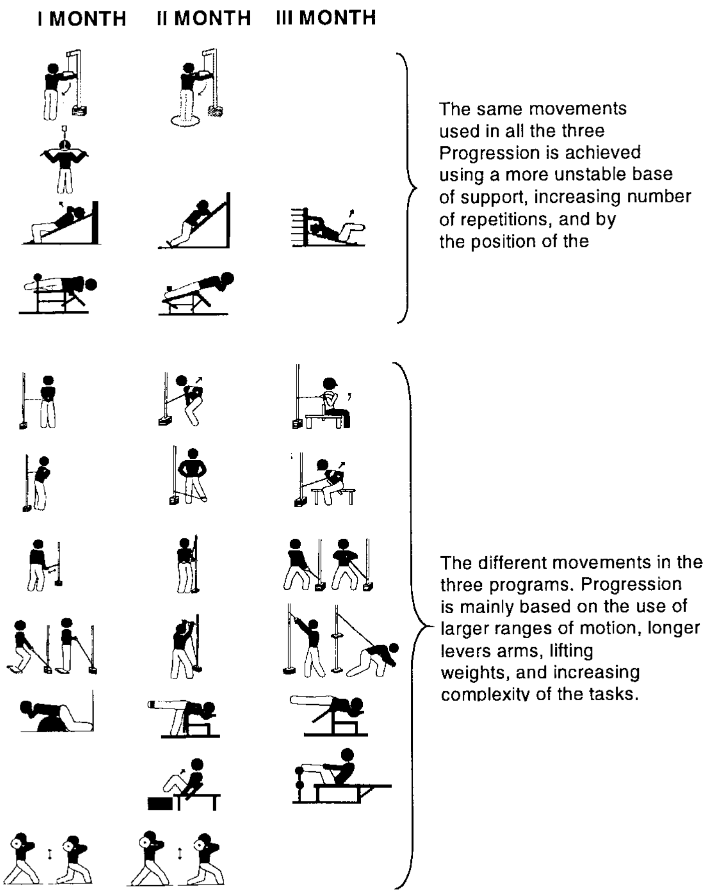
[#] = modified Oswestry Index
r = correlation coefficient
CV= coefficient of variation
ICC = intra class correlation

6.3 Therapeutic exercise program

The aims of the intensive and home training programs were to develop the strength, endurance and speed of the trunk and lower limb muscles, as well as to improve the overall body control and dynamic stability of trunk during the movements. All the subjects in the intensive and home exercise groups had first been educated in the ergonomics of back saving movements at work, and in the importance of leisure time physical activities as a complement or support to therapeutic training. Ten minutes warm-up and cool-down periods were included in both programs. The strength exercises were performed as 3-4 sets of 7-10 repetitions at 60-80% of 10 repetitions of maximum (RM), and the endurance exercises in 3-4 sets of 15-20 repetitions at 30-40% of 10RM. The progression of the programs for the intensive and home exercise groups was based on tests performed at weekly intervals. According to the results of the tests, the load of each exercise movement was individually adjusted.

Intensive training:

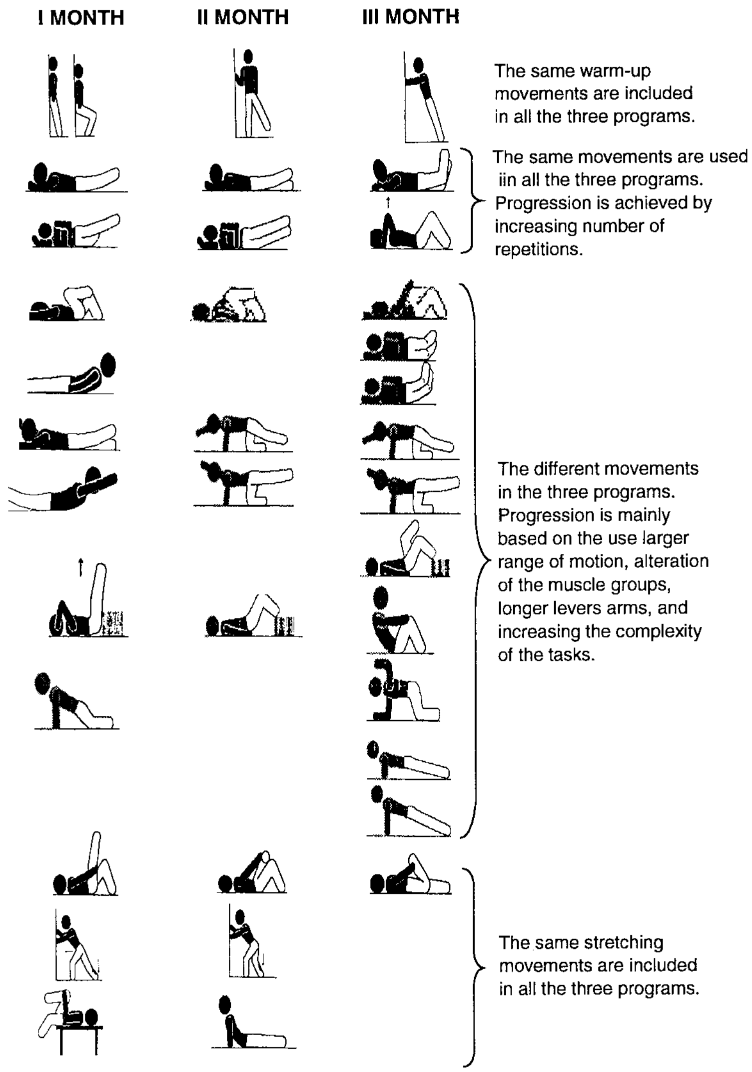
The program consisted of three different exercise programs, which included seven similar primary exercise movements performed in a gymnasium using pulleys (Saba), barbells, pillows and plinths. The tempo, load, duration, speed, and repetitions of each movement were controlled individually. The goal was to have gym-like exercises performed 3 times/week, and the home exercises every day. Both the training and weekly tests were controlled by a physiotherapist. (figure 3)



	I MONTH	II MONTH	III MONTH
1.	18.4	28.7	42.1
2.	1260	1474	1307
3.	41	46	41

FIGURE 3 Exercise program of the intensive training group (1. = Total time of one exercise session (min), 2. = Total number of repetitions during one exercise session, 3. = Total number of sets during one exercise session

Home exercises:
The home program also consisted of three different exercise programs using the same principles used with the gym-like program. The subjective perceived exertion of the home gymnastics was controlled according to Borg´s ratings of perceived exertion (RPE) from 6 to 20 scale (Borg 1982, 1998). The goal was that all subjects would exercise once a day. The home program was checked by a physiotherapist once a month. (figure 4)



1.	49.4	47.1	44.4
2.	14	14	13
3.	13.9	13.8	13.3

FIGURE 4 Exercise program of the home exercise group (1. = Total time of one exercise session (min), 2. = The average number of exercise sessions during one month, 3. = Subjective perceived exertion (RPE)

Control group:
The control (C) group was required to undergo the same measurements as the intensive and home training groups, but no information or guidance of ergonomics or training was provided. The control subjects were free to follow any treatment protocol they wished.

There was no difference between the three study groups in the usage of physiotherapy services during the follow-up period. Among all the subjects only a few subjects attended ordinary physiotherapy, and they scattered among the different groups. The exercise frequency of all these three study groups is presented in table 8. The adherence rate was controlled, and the subjects in the intensive training group participated in the exercise sessions during the three month period 24 times (range 15-31), on the average.

TABLE 8 Exercise frequency and regimen during the intervention period of the study

Group	Exercise frequency Times/week mean	 range	 Total mean/week	Exercise regimen in intensive training and home exercise
Intensive training group				
guided exercises	2	1-3	5	Strength exercises in 3-4 sets of 7-10 repetitions at 60-80% of 10RM
home exercises	3.1	1-7		Endurance exercises in 3-4 sets of 15-20 repetitions at 30-40% of 10RM
Home exercise group				
home exercises	3.5	1-8	3.5	
Control group	0	0	0	

10RM = Ten repetitions maximum
(Reproduced with permission of Clinical Rehabilitation)

6.4 Statistical analysis

Traditional statistical methods were used to describe the data. Similarities within and between continuous background and outcome variables were studied using the Pearson correlation coefficient and by Spearman correlation coefficient in non-parametric situations (Hicks 1995). Differences in the non-parametric variables between the three study groups were evaluated with χ^2-tests. The 95% confidence intervals defined the range within which the true values existed (Campbell & Machin 1995).

One way analysis of variance (ANOVA), was used in the evaluation of the differences between the three study groups at each measurement sessions. In conjunction with ANOVA the LSD (Least Significant Difference) Post Hoc Test was used for further analysis of the results.

The changes in the parametric outcome variables during the study period were evaluated by using paired t-tests and ANOVA for repeated measures followed by Bonferroni post hoc procedures. Kappa, McNemar and Fisher´s exact tests were used for the analyses of changes at the level of participation (Campbell & Machin 1995, Hicks 1995). Multivariate analysis (MANOVA) was used to analyse the interactions of the three study groups by measurement session (II, IV).

The power of this study was checked according to Altman´s nomogram for calculation of sample size (Altman 1991). The effect size of the outcome variables was determined with the calculations (Baseline mean - follow-up mean/baseline standard deviation) presented by Mannion et al. (1999). The significance level was set at .05. All the statistical analyses were performed using the Statistical Package for Social Sciences (SPSS+).

7 RESULTS

7.1 Changes in impairments

7.1.1 Low Back Pain (I-IV)

The overall low back pain intensity was light or moderate among all the subjects and it decreased significantly (p<0.015-0.001) in both the intensive training and home exercise groups during the whole study period. In the control group the low back pain intensity decreased significantly (p<.05) during the first three months (figure 5).

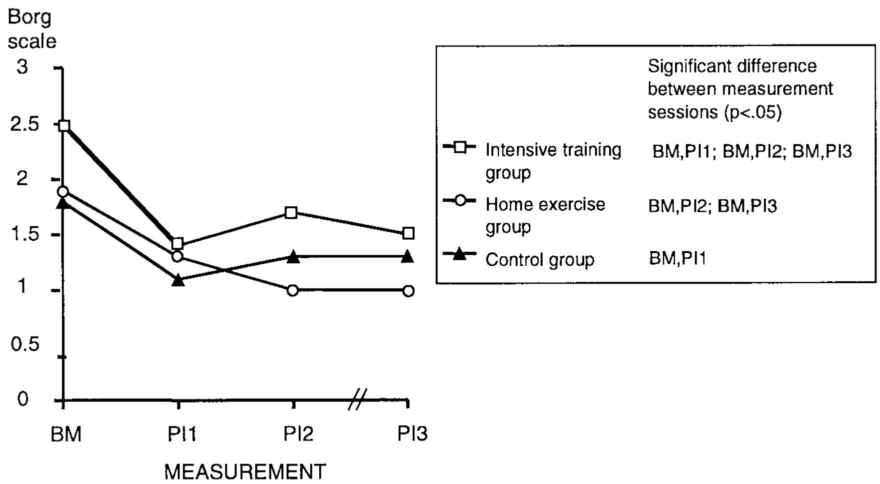


FIGURE 5 The changes between measurement sessions in back pain intensity among the three study groups (BM = Baseline measurement session, PI1 = The first post-intervention measurement session, PI2 = The second post-intervention measurement session, PI3 = The third post-intervention measurement session)

7.1.2 Muscle strength and endurance (I)

An improvement of statistically significant muscle performance was achieved with the three months intensive and home exercise programs. The positive changes were more pronounced in the dynamic muscle strength tests and in the isometric endurance of trunk extensors than in the maximal isometric tests. (figures 6,7). No remarkable gains in muscle performance occurred in the control group.

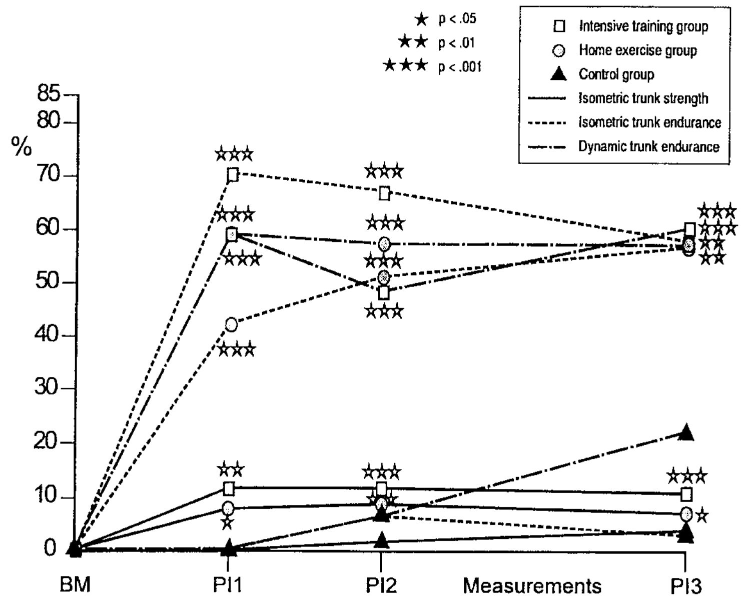


FIGURE 6 The changes (%) between measurement sessions (BM-PI3) in the sum indexes of lower limb isometric strength and dynamic knee bend. Follow-up values have been analyzed by comparison with the baseline measurements (Reproduced with permission from Munksgaard International Publishers Ltd., Copenhagen, Denmark)

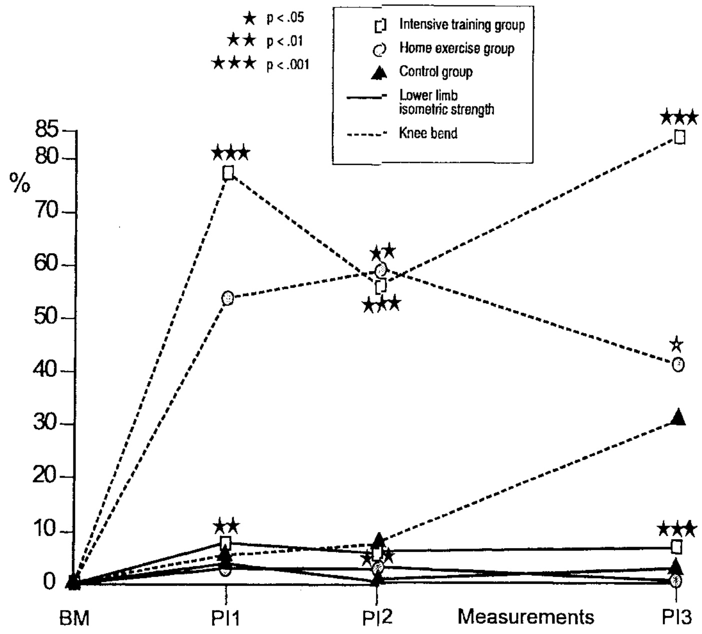


FIGURE 7 The changes (%) between measurement sessions (BM-PI3) in the sum index of lower limb isometric strength and dynamic knee bend. Follow-up values have been analyzed by comparison with the baseline measurements (Reproduced with permission from Munksgaard International Publishers Ltd, Copenhagen, Denmark)

The subjects in the intensive training and home exercise groups whose baseline values were below the mean obtained gains in Oswestry and low back pain intensity.

Pain during the test situation affected the test performance. In the tests of the isometric and dynamic endurance of the trunk extensors and in the sit-up test, the subjects who had a test pain intensity >5 achieved statistically significantly ($p<0.05$) lower results.

7.1.3 Spinal and muscle flexibility (II)

Lumbar flexion and extension did not change during the study (figure 8). Spinal rotation increased statistically significantly ($p<.002$) in the intensive training group during the intervention period (figure 9). However, spinal rotation decreased statistically significantly among all subjects when the baseline and last follow-up values were compared. A similar non-significant pattern was also detected in lumbar flexion and extension.

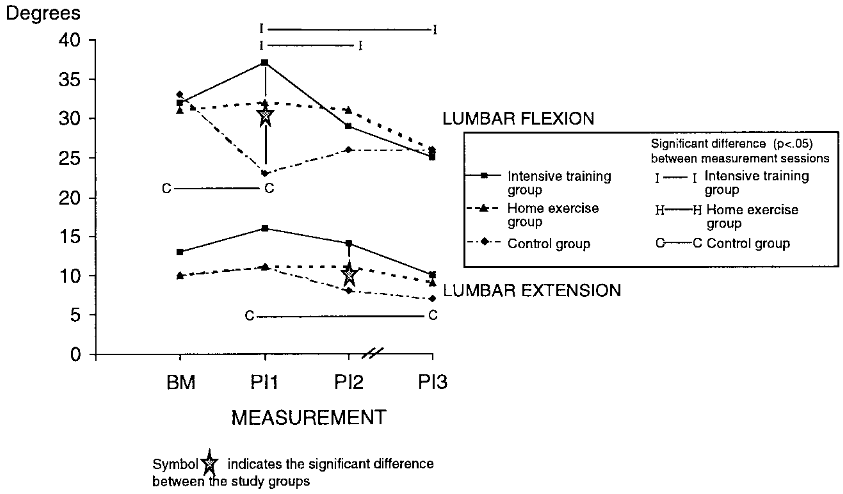


FIGURE 8 The changes between measurement sessions (BM-PI3) in lumbar flexion and extension among the three study groups (Reproduced with permission from Whurr Publishers Limited, London, United Kingdom)

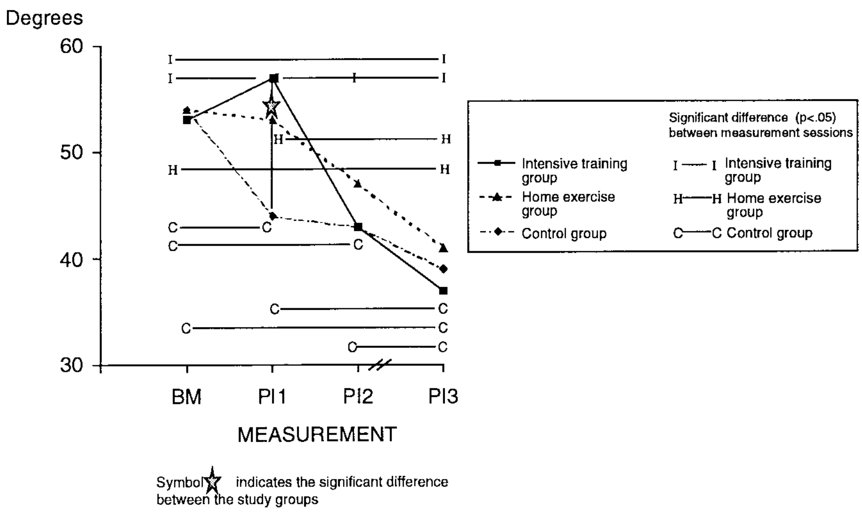


FIGURE 9 The changes between measurement sessions (BM-PI3) in spinal rotation among the three study groups (Reproduced with permission from Whurr Publishers Limited, London, United Kingdom)

The changes in spinal lateral flexion and iliopsoas flexibility were non-significant and minimal among all subjects. Erector spinae flexibility improved significantly ($p<.05$) in the intensive training, and this gain was still present at the third post-intervention measurement session (figure 10). In both exercise groups hamstring flexibility increased significantly ($p<.05$), but this gain was lost during the follow-up period. (figure 11)

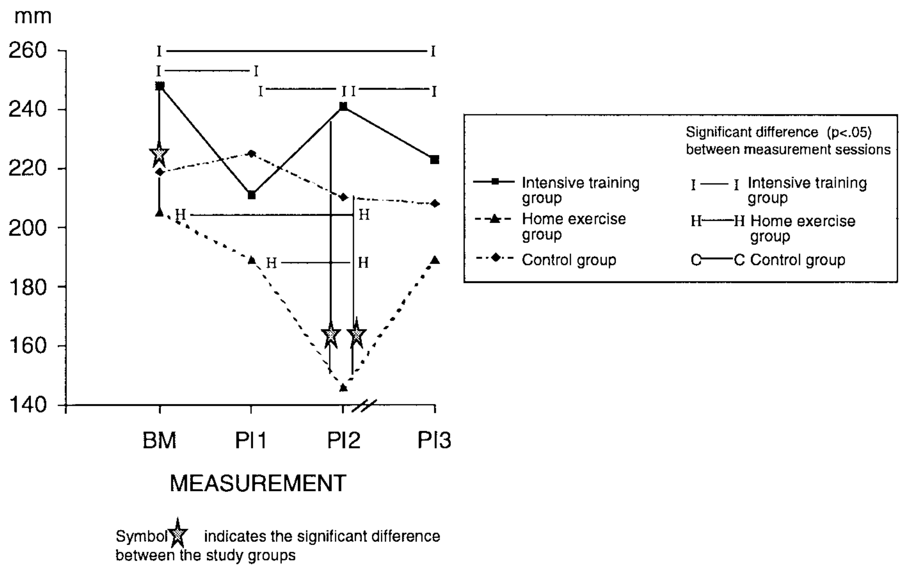


FIGURE 10 The changes between measurement sessions (BM-PI3) in erector spinae flexibility among the three study groups (Reproduced with permission from Whurr Publishers Limited, London, United Kingdom)

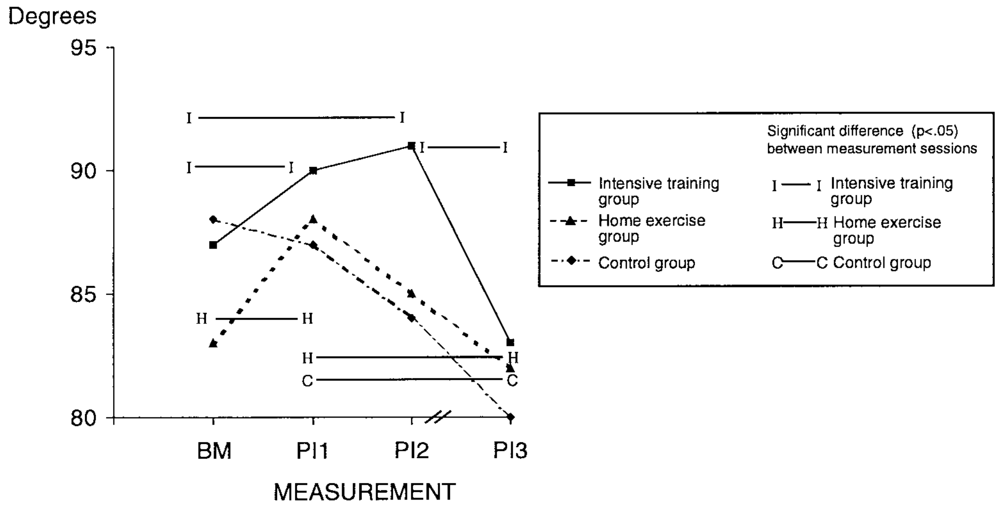


FIGURE 11 The changes between measurement sessions (BM-PI3) in hamstring flexibility among the three study groups (Reproduced with permission from Whurr Publishers Limited, London, United Kingdom)

In the test of lumbar extension the asymptomatic subjects in the test situation had significantly higher (p=.004) values than the symptomatic subjects.

7.1.4 Psychomotor performance (III, V)

The reliability of the equipment for psychomotor speed tests was studied beforehand with healthy subjects. The test-retest Pearson correlation coefficient varied from .57 to .82, and the coefficient of variation from 12 to 24%.

The choice reaction time of lower limbs did not change during the study period. Movement time decreased significantly (p<.001-.04) and flight time increased (p<.001-.04) for all the subjects during the study (figure 12). There were no differences between the three study groups, and there were no statistically significant changes within each study group.

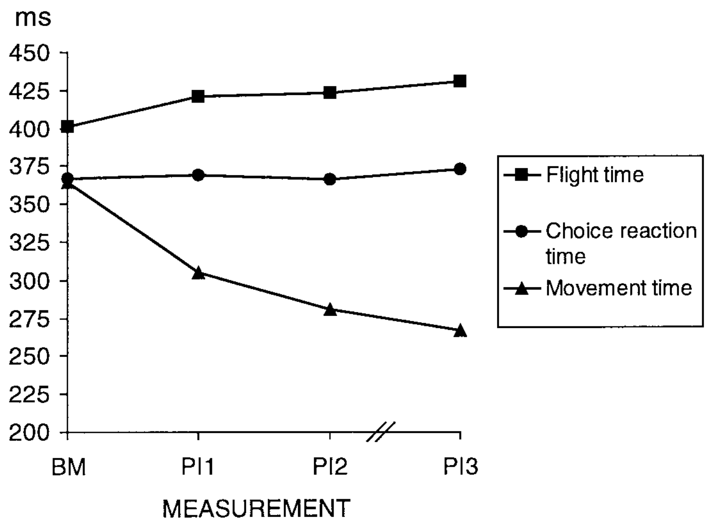


FIGURE 12 Choice reaction, movement and flight times among all subjects during different measurement sessions

The psychomotor speed was significantly (total reaction time p<.005, choice reaction time p<.004, movement time p<.029) faster in the asymptomatic group compared with the symptomatic group, but there were no differences in flight time between the asymptomatic and symptomatic group.

7.1.5 Postural sway (IV)

The amplitude of sway did not change during the study. During the intervention period, the velocity of sway for the tests with eyes open and closed increased in the home exercise group, and it remained above the baseline values at every post-intervention measurement session (figure 13).

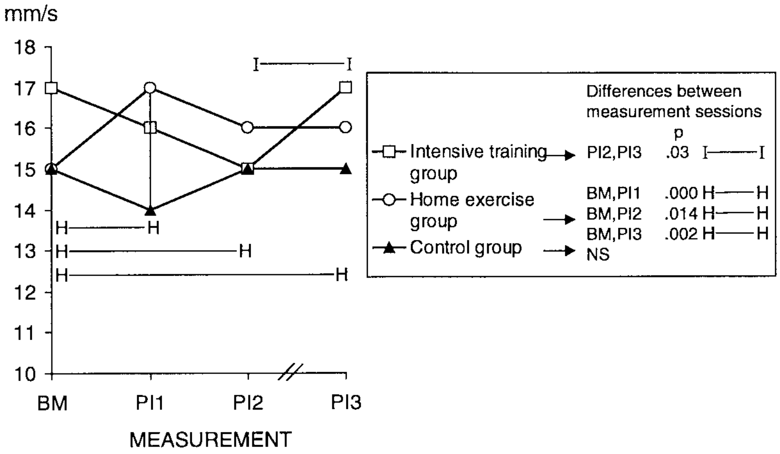


FIGURE 13 Velocity of sway in anterior-posterior direction with eyes open test

The subjects in the intensive training and home exercise groups who had their postural sway values below the mean value at the baseline measurement, gained in the more demanding test situations (eyes closed and tandem standing) in low back pain and the Oswestry Index.

7.2 Changes in activity (I)

The Oswestry Index was low (below 20 percent) for all the subjects, and it decreased significantly for both exercise groups ($p<.025$ - $<.001$) during the entire study period. In control group the significant ($p<.05$) decrease in the Oswestry Index occurred between the baseline and the first follow-up measurement. (figure 14)

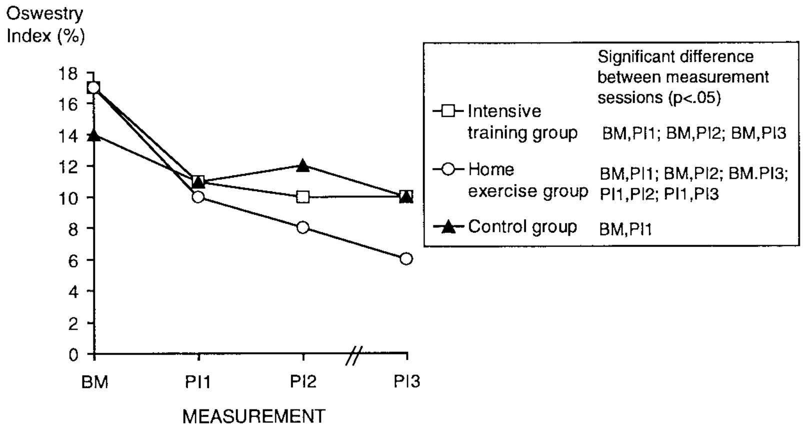


FIGURE 14 The changes between measurement sessions (BM-PI3) in Oswestry Index among the three study groups

7.3 Changes in participation

Almost all the subjects (>90%) had restrictions at work during the initial phase of the study (figure 15). There were no differences between the three study groups in relation to restrictions at work during any measurement session. Restrictions at work decreased in the home exercise and control groups between the baseline and the third post-intervention measurement. In the intensive training group the decrease occurred between the baseline and the second post-intervention measurement (appendix 3).

Over half (58%) of the subjects had been on sick leave during the previous year (figure 16). There were no differences between the three study groups in sick leaves during any measurement session. A decrease in the number of sick leaves seemed to occur in all the three study groups between the baseline and the follow-up measurements (appendix 3).

Most of the subjects (79%) reported restrictions in recreational hobbies due to low back pain (figure 17). At the first post-intervention measurement, more subjects in the home training group (χ^2= 6.52, df=2, p=.038) reported restrictions in recreational hobbies when compared to the intensive training or control group. No changes occurred in restrictions in recreational hobbies (appendix 3).

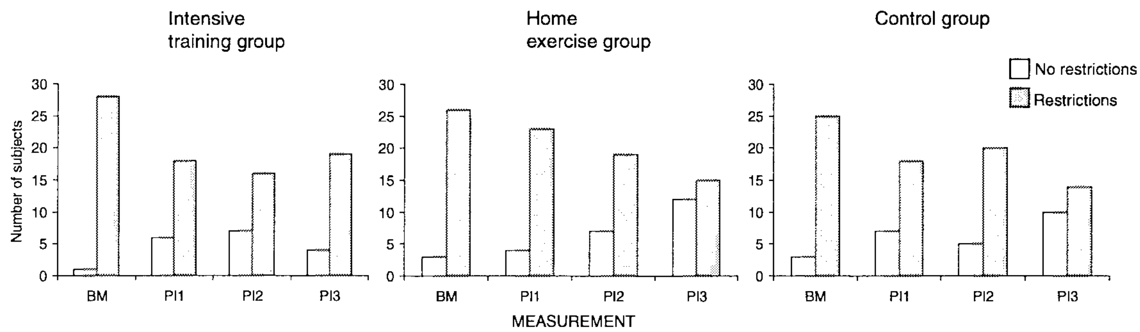


FIGURE 15 The changes in restrictions at work between measurement sessions among the three study groups

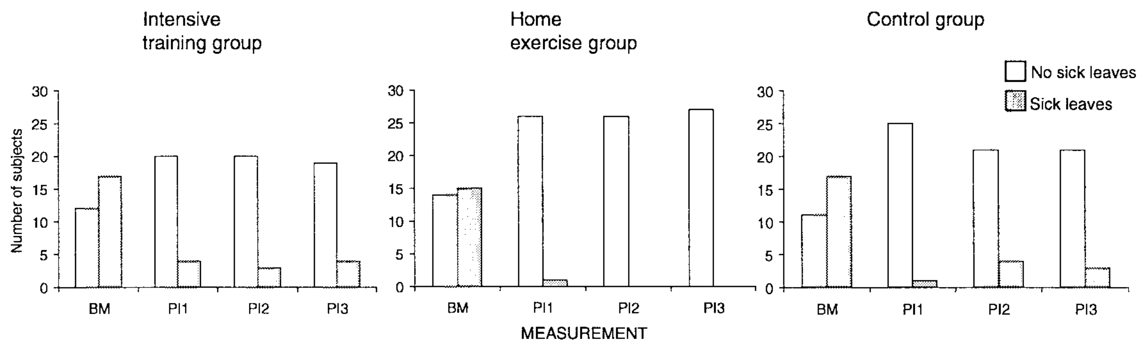


FIGURE 16 The changes in sick leaves between measurement sessions among the three study groups

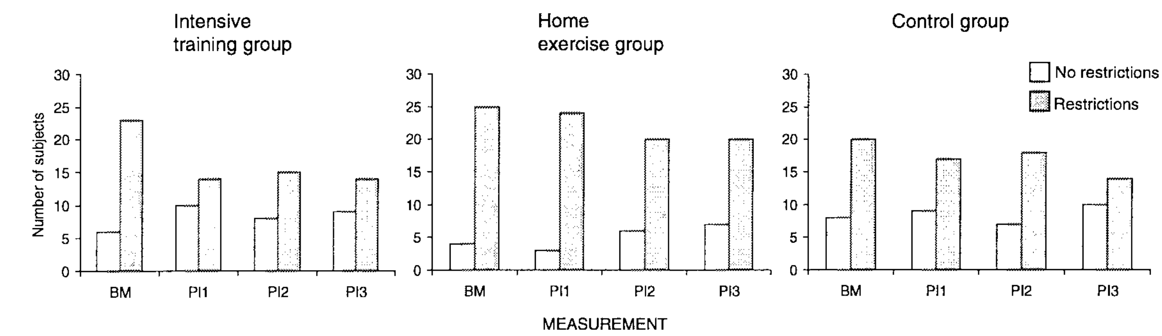


FIGURE 17 The changes in restrictions in recreational hobbies between measurement sessions among the three study groups

7.4 Associations between impairments, activity and participation (I-IV)

No significant correlation was found between low back pain and the Oswestry Index (study I). Muscle performance, and spinal or muscle flexibility did not correlate low back pain or the Oswestry Index (I, II). There were no associations between psychomotor performance and the Oswestry Index (III) and low back pain. Postural sway was not significantly associated with the Oswestry Index (IV) or with low back pain. Restrictions at work, sick leaves or restrictions in recreational hobbies had no remarkable correlations with the other outcome variables at the different levels of ICIDH- classification (appendix 4).

7.5 Summary of main findings

The confidence intervals of continuous outcome variables and the ranges with the modes of the discrete variables, are presented in table 15.

TABLE 15 Confidential intervals (95% CI) at baseline

Variable	CI
Low back pain	1.7-2.4
Muscle strength and endurance	
- Isometric trunk extension	668-783 N
- Isometric trunk flexion	437-514 N
- Isometric knee extension	472-541 N
- Isometric ankle extension	439-517 N
- Isometric ankle flexion	201-228 N
- Isometric endurance of trunk extensors	127-157 s
- Dynamic endurance of trunk flexors	25-33 repetitions

(continues)

Table 15 (continues)

Variable	CI
- Knee bend	33-54 repetitions
- Dynamic endurance of trunk extensors	31-42 repetitions
Spinal flexibility	
- lumbar flexion	29-36 degrees
- lumbar extension	9-13 degrees
- spinal rotation	51-57 degrees
- lateral flexion	187-207 mm
Muscle flexibility	
- erector spinae	204-233 mm
- hamstring	84-91 degrees
- iliopsoas	21-26 degrees
Psychomotor performance	
- choice reaction time	348-387 ms
- movement time	326-381 ms
- total time	680-755 ms
- flight time	388-423 ms
Postural sway	
-velocity of sway	
ant-post, eyes open	15-17 mm/s
ant-post, eyes closed	18-21 mm/s
ant-post, tandem standing	29-38 mm/s
med-lat, eyes open	11-13 mm/s
med-lat, eyes closed	13-15 mm/s
med-lat, tandem standing	26-36 mm/s
-amplitude of sway	
eyes open	16-20 mm
eyes closed	18-24 mm
tandem standing	24-32 mm
Oswestry Index	15-19
Participation (dichotomous variables)	
-restrictions at work	range 1-7, mode 2
-sick leaves	range 1-6, mode 1
-restrictions at recreational hobbies	range 1-5, mode 3

ant-post = anterior-posterior direction, med-lat = medio-lateral direction

Short and long term positive changes occurred primarily in the intensive training and home exercise groups in low back pain, muscular performance, spinal rotation, erector spinae flexibility, postural sway and Oswestry Index. A summary of the main findings is presented in table 16.

TABLE 16 Summary of main findings

Variable	Effects Intensive training group 1.	2.	Home exercise group 1.	2.	Control group 1.	2.	Paper
Low back pain	+	+	0	+	+	0	I,II
Muscle strength and endurance							I
- Isometric trunk extension	0	+	+	+	0	0	
- Isometric trunk flexion	+	+	0	0	0	0	
- Isometric knee extension	+	+	0	0	0	0	
- Isometric ankle extension	0	0	0	0	0	-	
- Isometric ankle flexion	+	+	0	+	0	+	
- Isometric endurance of trunk extensors	+	+	+	+	0	0	
- Dynamic endurance of trunk flexors	+	+	+	+	0	0	
- Knee bend	+	+	0	+	0	0	
- Dynamic endurance of trunk extensors	+	+	+	+	0	0	
Spinal flexibility							II
- flexion	0	0	0	0	-	0	
- extension	0	0	0	0	0	0	
- spinal rotation	+	-	0	-	-	-	
- lateral flexion	0	0	0	0	0	0	
Muscle flexibility							II
- iliopsoas	0	0	0	0	0	0	
- erector spinae	+	+	0	0	0	0	
- hamstring	+	0	+	0	0	0	
Psychomotor performance							III
- choice reaction time	0	0	0	0	0	0	
- movement time	0	0	0	0	0	0	
- total time	0	0	0	0	0	0	
- flight time	0	0	0	0	0	0	
Postural sway					IV		
-velocity of sway							
ant-post, eyes open	0	0	+	+	0	0	
ant-post, eyes closed	0	0	0	0	0	0	
ant-post, tandem standing	0	0	0	0	0	0	
med-lat, eyes open	0	0	+	0	0	0	
med-lat, eyes closed	0	0	+	0	0	0	
med-lat, tandem standing	0	0	0	0	0	0	
-amplitude of sway							
eyes open	0	0	0	0	0	0	
eyes closed	0	0	0	0	0	0	
tandem standing	0	0	0	0	0	0	
Oswestry Index	+	+	+	+	+	0	I,II
Participation							
-restrictions at work	0	0	0	+	0	+	
-sick leaves	+	+	+	+	+	+	
-restrictions in recreational hobbies	0	0	0	0	0	0	

+ = positive change, - = negative change, 0 = no change
1.= Changes during the intervention period of the study (BM-PI1)
2.= Changes between the baseline and the last follow-up measurements (BM-PI3)
ant-post = anterior-posterior direction, med-lat = medio-lateral direction

8 DISCUSSION

8.1 Analysis of the quality of the study

The methodological quality of the first paper (I) has been analyzed earlier by Harms-Ringdahl et al. (1999) according to the system of Koes et al. (1991, 1995). In that analysis, the total points were 41 but, this previous analyse was only based on the first (I) publication. The current analysis showed that the level of quality was moderate with 57 total points (appendix 5). In addition, the first paper (I) has been considered to be worthy of inclusion in to the Paris task force report (Abenhaim et al. 2000).

Study population
The ninety subjects in this study were convergent in age and gender and comparable to persons who commonly suffer from low back pain in Finland (Heliövaara et al. 1989) and are assigned to physiotherapy. In this respect, the findings are generalizable to the Finnish population. The good initial status of the subjects in the outcome measurements limits the application of the results to a group of low back pain subjects with mild or moderate symptoms.

As has been stated in many earlier studies (Cherkin 1998, Foster 1998), the exact classification of low back pain was also difficult in this study. The subjects were examined by two medical doctors, firstly, during attendance at their local occupational health care services, and then at the Central Finland Hospital so that a correct medical diagnosis could be guaranteed. There were a few of subjects who were diagnosed with a prolapsed disc and spinal stenosis, and these exceeded the inclusion criteria. This may have been due to an inadequate quality of the diagnostic procedures, or the fluctuation or worsening of symptoms. The subjects in this study were classified as having both chronic (paper II) and subacute (paper III) low back pain, and this reflects the difficulties in the use of different overlapping classification systems (Spitzer et al. 1987, Waddell 1998, von Korff 1994). In the future, more attention needs to be given to a more precise and standard method of categorisation and definition of a subject´s initial situation.

At baseline, the homogenuity of the subjects, in regard their basic background factors and outcome parameters was achieved with a clear description of inclusion criteria and with the randomisation and matching procedure. There was a slight non-significant difference at the baseline between the study groups, with the intensive training group being favoured in relation to the duration of low back pain. This may have had an influence on the positive results of this group, that is, the findings may have been due to a time factor and spontaneuous recovery. A longer baseline period, and repetition of the baseline measurements, may have stabilised the baseline situation and reduced the effects of researcher attention, but then the process of waiting for therapy would also have been increased.

A randomised, controlled study design, which is the most valuable (Koes et al. 1995, van Tulder et al. 1997b), but also more expensive and difficult to perform (Andersson et al. 1994), was partly achieved in this study. The mixture of randomisation, matching and recruitment of the intensive training group with an almost convinience sample may be considered to be a methodological weakness of this study. After pre-stratification of the most important background factors for the home and control groups, the randomisation procedure was only used for these two groups. This partial randomisation procedure did not adversely affect the positive findings of the home exercise group. The intensive training group was not exposed to randomisation because of the slow rate of subject recruitment. More rapid subject recruitment may be achieved with multicenter research. On the other hand, randomisation with a small number of subjects may cause heterogeneity between study groups, but this can be avoided by matching (Koes et al. 1991). The cross-over design will produce stronger evidence of the effects of therapeutic exercise, and then also a smaller number of subjects will be approved. In these kinds of extensive and so far expensive trials, the multicenter studies may be the most purposeful and practical for physiotherapists in clinical practice.

One disadvantage in longitudinal follow-up studies is the increased number of drop outs. In this study the total drop out rate was 19% and an adequate description of the drop-outs was provided. During the follow-ups, drop-outs from the intensive training group occurred due to, for example, very heavy gardening activities, and overall, the reasons were not associated with the exercise programs. Koes et al. (1991) suggested an intention to treat analysis, when the drop out rate reached 20%.

Koes et al. (1995) suggested a figure of over 50 subjects for each subject group, but according to the sample size calculations (Altman 1991), the number of subjects was sufficient. A power analysis (Altman 1991) was made after the study. This analysis (appendix 6) demonstrated that the sample size was sufficiently large with a power significance of 0.7-0.8 at the level 0.5 in the same outcome variables where statistically significant changes occurred. The lack of the values for clinically relevant changes in the most commonly used outcome measurements made the power assessments only directive, and fairly large variation and differences between genders (for example, in the isometric muscle tests and in psychomotor performance) may require more detailed analysis.

In many clinical trials the small number of subjects is due to the lack of extensive research resources. Koes et al. (1995) stated that type II errors increase with small sample sizes and the differences which are clinically relevant may disappear. In this study, combining the similar trends in the results of intensive training and home exercise groups may enhance the findings of the positive effects of exercise.

Interventions

In this research work the main aim of the therapeutic exercises was to change physiological functions. The intensive training and home exercises were planned according to the principles of exercise physiology and an attempt was made to describe them thoroughly (reference IV and figures 3,4 and table 8). The therapeutic exercise programs were combinations of strength, endurance, psychomotor performance and balance exercises. Also, ergonomic counselling was provided to the intensive training and home exercise groups.

The therapeutic exercise programs in this study were not standardised (in terms of resistance, number of repetitions etc.), because they were tailored according to the level of each individual. The interventions also have to be matched with the subject´s problem (DeRosa & Portefield 1992). Progression was achieved by increasing load, the number of repetitions or by making the movements more challenging by altering postural demands, or with unstable and smaller bases of support. In the intensive training group, a few subjects reported side effects, such as muscle soreness, in the beginning of the first program, but these disappeared and did not prevent the subjects from participating in the exercises.

It seems that some kind of individual guidance, for example, on proper posture during activities of daily living and in working situations is necessary (Hall & Brody 1999). Jette & Delitto (1997) has stated that exercise programs are always combinations of, for example, guidance, motivation and feedback. Therefore the interpretation of pure effects of exercise is difficult. Mannion et al. (1999) suggested that the main effects of exercise can be observed as a central effect, and not as physiological adaptations. On the other hand, the main effects of these exercise programs may be peripheral, for example, in the increase of circulation. It still remains unclear as what the most beneficial component of these exercise programs was.

A real control group was used in this study. A placebo group was not used, as it is still unclear what kind of physiotherapy is effective, and what is not (Torstensen et al. 1998). In many previous studies the other kinds of physiotherapy modalities have served as the control treatment, but what constitutes an adequate placebo treatment, when the effects of the therapies are not known? The inclusion of a pure control group makes it possible to draw indicative conclusions about the efficacy of therapeutic exercise although there are still many unanswered questions. The non-treatment control group served as a reference for spontaneous recovery, non-specific effects and fluctuations in low back pain, since von Korff (1994) has presented that dysfunction and the severity of pain may vary within the same subject over time. The control of co-interventions, for example, extra physiotherapy sessions, occurred throughout the study, and the most important confounding variables were controlled with the questionnaires.

In this study, participation in the exercise sessions was controlled with diaries and this was of a good level. Frequent follow-ups, for example, once a month with the home exercise group, may increase the level of compliance (Ljunggren et al. 1997). Also, written and illustrated instructions have been shown to lead to higher compliance than verbal instructions alone (Schneiders et al. 1998). Home exercises were as effective as the intensive training program, and they are obviously more economical. This type of home exercises can be recommended to low back pain subjects whose situation is not very severe and these home exercise programs can also be implemented in private clinics or health care centers. In relation to cost-effectiveness, group therapies may be preferred (Harms-Ringdahl et al. 1999, Mannion et al. 1999), but individual guiding is required at the beginning of the exercise programs and also continuously so that the programs can be modified according to the needs of each subject. Individual guidance to physical recreational activities after therapeutic exercise programs is essential to quarantee the maintenance and continuity of physical activity (Taimela et al. 2000).

Overall, the level of physical activity did not change during the study, because, for example, the intensive training group replaced their ordinary activities with this program (Mälkiä et al. 1995). It is obvious, that the increase in physical activity during leisure time may only occur within certain individual time limits.

Measurements

An attempt was made to blind the measurements; the measurers attempted to remain unaware of the group allocations and they did not have access to the results of the previous measurements. Blinding was not totally successful, as the same educated staff made the measurements during every measurement session, and naturally they had entered into discussions with the subjects. The subjects surely knew to which of the three groups they had been allocated. However, equivalent attention was paid and homogenous instructions were provided to the subjects during the measurement sessions.

Deyo et al. (1994) suggested that there should be multiple dimensions in the outcome measurements. In this study the measurements were comprised of the different levels of ICIDH-2 classification (WHO 1999), and thus they were multidimensional. After all this study concentrated mainly on the physiological level and there was a shortage of measurements of the psychological and social components, which are always associated with the effects of exercise and the experience of low back pain (Mannion et al. 1999).

To achieve sufficient validity and reliability for the measurements, the present study used a battery of conventionally, clinically used and documented tests. The subjective and objective measurement methods were used and they have been stated to be equally reproducible (Deyo et al. 1994). The measurements, suggested by Deyo et al. (1994), for example quality of life, were missing. In the future, the inclusion of qualitative method to this same population, will provide a deeper understanding of the low back problems.

The measurements were performed as laboratory tests, not in a real environment, but all these tests are used, or are applicable, in physiotherapy practice, except the quite expensive force platform measurements. The measurements lasted approximately four hours and, therefore, possible fatigue may have had an influence on the findings. However, the measurements were always made at the same time of day, and in the same order by the same measurer. Thus, the results can be considered to be comparative.

Impairment

The measurements in this study were predominantly at the level of body structure and function, and therefore related to physiological impairments. The assessments of anatomical and psychological impairments (Hall & Brody 1999) may provide a better basis for the proper planning of physiotherapy. Pain intensity, which was measured using the Borg scale (Borg 1998), was low, and that may have allowed the good initial values in the other outcome parameters, for example, in muscular performance. Measurements of postural sway with force platform at least in more demanding test situations (Luoto 1999) or with more severe subjects, may be suitable for detecting the impairments and monitoring the effects of exercise.

Activity

In this study, the changes and limitations in activity were only measured with the Oswestry Index, which is suggested to be a relevant, sensitive and descriptive of the disease-specific functional status of a subject (Deyo et al. 1994, Deyo et al. 1998). In future studies, the increase in measurements at the level of activity, for example with scales presented by Salen et al. (1994) or Kopec & Esdaile 1995, Kopec et al. 1995) are preferable. There is a lack of objective assessment methods of activity and the overall situation of the subject always has effects on the results. The Oswestry Index is based on subjective ratings, therefore, for example, motivation and pain may have an influence on it. It would also be interesting to have reference values and changes in the Oswestry Index among healthy subjects. There were some blank responses in the Oswestry Index, mainly in the section of sexual behaviour. In these cases, the entire Oswestry Index was not included in the analysis. This then resulted in a decrease in the number of subjects in statistical oneway analysis of variance.

Participation

Participation was analysed with modified questions from earlier Finnish studies (Lukinmaa 1990, Mälkiä et al. 1988) and the analyses of reliability were missing. Several researchers (for example van Tulder et al. 1997a) have recommend return to work as one of the most relevant outcome measures, but in this study it was not relevant, as the subjects had minimal restrictions in working capacity due to low back pain. It appears that more sensitive measurements and longer follow-up periods are needed to see the changes in participation. With these kinds of well-conditioned subjects, participation may not be the main focus of therapeutic exercise program.

Overall, some of the measurements used in this study are not sufficiently sensitive to change, or they measure parameters that could not reasonably be expected to change with non-specific exercises. The effect size was calculated (appendix 7) for continuos variables as presented by Mannion et al. (1999), and the effect size values confirmed the findings of gains, for example, in low back pain, muscle performance, spinal rotation and in the Oswestry Index.

Koes et al. (1995) proposed that adequate follow-up periods be longer than 6 months, and this was achieved in this study. At the same time, it has been considered that the status of subjects may change due to the episodic nature of low back pain (Waddell 1998). Also, it is well known that, the effects of physical exercise, for example, on muscle strength, are not retained for long periods of time.

Data analysis and presentation

In this study, appropriate statistical analysis were performed. Intention-to-treat analysis suggested by Koes et al. (1991,1996) was not made. Separate worst case analyses were not included in the analyses, because the overall results of the outcome variables were near normal, and they exceeded reference values, for example, in muscle performance (Alaranta et al. 1990, 1994c). However, it would have been practical to evaluate the subjects with very good or bad outcomes separately. In some analysis the subjects were divided into two groups according to their values in the outcome variables above and below the average, and it can be supposed that all the outcome measures of the persons in those groups remained on the same sides of the average. However, this analysis was missing in this study.

The change in outcome variables was analysed with repeated t-test, which will increase the rate of type I errors. This can be corrected by adjusting alpha levels more stringent or by using Bonferroni post hoc procedures, as was done in this study. There is still a need for some calculations of errors. Standard deviation within the subject (SW) reveals the quantity of measurement error in each measurement (Bland & Altman 1996).

Analyses of changes between the categories at the level of participation based on Kappa agreements and McNemar´s and Fisher´s exact tests. In these cross-tabulation calculations the number of subjects in some cells was less than the expected frequency and due to this, there is no possibility to interpret these results very convincingly. In the future, this can be avoided by increasing the number of subjects or by using different kinds of procedures for the categorisation of these variables.

8.2 Results

Low back pain is rarely cured completely and the results of follow-up studies longer than 3 months may be less favourable as recurrences in low back pain are common (von Korff et al.1993). Outcome depends also on the initial status of the subjects (Bendix et al. 1998, Cooper et al. 1996, Mannion et al. 1999, Meade et al. 1990). Low initial scores (= close to normal values) in the outcome measures (for example low back pain and Oswestry Index) may have a tendency to show smaller changes (DiFabio & Boissonnault 1998) and vice versa (Mannion et al. 1999). Koes et al. (1992b) have stated that the effects of physiotherapy may be mostly explained with non-specific factors, for example, with extra attention. Even the beliefs of patients can have important effects on the outcomes of the physiotherapy they receive (Cherkin 1998).

The decrease in low back pain was similar to several earlier studies (Kankaanpää 1999, Mannion et al. 1999, Torstensen 1998). The effect size varied from 0.60 to 1.0 (appendix 7) and the result was permanent in both exercise groups. When analysing low back pain and its outcome variables, multidimensional nature, subjective experience and natural course of pain need to be taken into account (Deyo et al. 1994).

The muscular performance of these subjects was very good compared with healthy subjects (Alaranta et al. 1990, 1994c), even at the baseline measurements. Muscle strength and endurance increased with intensive training and home exercises. These improvements were comparative, for example, with knee bend (20-50% increase) and back endurance (20-40% increase), and similarly, with the earlier study by Alaranta et al. (1994b). The positive findings were more pronounced in the dynamic muscle strength tests, as well as in the isometric endurance of trunk extensors. The dynamic nature of the exercise programs may explain this kind of trend.

The most pronounced changes in spinal and muscle flexibility occurred in spinal rotation, which is consistent with Mannion´s (1999) findings. He found that spinal movements in the sagittal plane, such as lumbar flexion and extension, may only improve few degrees. In Alaranta´s et al. (1994b) study, spinal rotation, lateral flexion and hamstring flexibility increased approximately 12% with active rehabilitation and more remarkable changes occurred during the first three months, and the gains were still present at the 12 months follow-up. The more valuable and permanent gains in flexibility may presuppose more specified exercises that have to be executed continuously.

The effect of learning was seen in psychomotor performance, where all subjects improved their movement time and vertical jump. In psychomotor performance, no remarkable improvements occurred with therapeutic exercise, even if Kauranen (1999) and Luoto (1999) have found that rehabilitation may change psychomotor performance. It is evident that there is also a need for more specific exercises and a large amount of practice before any effects can be expected (Schmidt 1988). The findings of deficits in motor performance (Hodges & Richardson 1996, Taimela et al.1993) and in postural control (Alexander et al. 1998, Byl & Sinnot 1991, Luoto et al. 1998) indicate the importance of the exercising of motor control, skills, and coordination in the physiotherapy of low back pain subjects.

The amplitude of postural sway did not change with exercises, but the velocity of sway increased in home exercise group. The velocity-based parameters may be more sensitive for the detection of change, also reported by

Luoto (1999), than the amplitude-based variables among moderate low back pain populations. In more severe situations, or in more demanding test situations, changes may also be seen with in the amplitude of sway.

Generally, the changes in low back pain, muscular performance and in the Oswestry Index exceeded the limits of 95% confidence limits, and hence, it can be considered that real changes occurred in these variables. The changes in spinal flexibility, psychomotor performance and postural sway occurred within the confidence limits, which may indicate the natural variation within a subject in these variables. The changes should exceed the limits in order for the results to be considered to be related to the therapeutic exercise program rather than individual variation.

Activity

A reduction of activity limitations is an important goal for physiotherapy, because low back problem definitely causes restrictions in activity. The overall Oswestry Index score was low in all the subjects and the scores were remarkably lower than in Hupli´s study (1998). However, he had subjects with more severe complaints and some of them were inpatients. The Oswestry Index in this study decreased, and this supports earlier findings (Delitto et al. 1993, Kankaanpää 1999, Lindström 1994, Mannion et al. 1999, Torstensen et al.1998). The decrease was approximately 10%, which is in accordance with Delitto´s et al. (1993) and Beursken´s et al. (1996) results in interventional studies. The effect size of the Oswestry Index ranged from 0.74 to 1.03 (appendix 7) in the exercise groups, and it is higher than in Mannion´s study (1999). The higher effect size in the current study can be explained by the difference in study methodology, for example, in measurements and exercise modalities. The decrease in activity limitations also occurred in the control group between the baseline and the first post-intervention measurement, which may present the Hawthorne effect or normal fluctuation of low back pain symptoms.

Two forms of activities (public and private component) exist in the Oswestry Index according to Fisher & Johnston (1997). The public component of Oswestry index may have some associations with the level of participation of the ICIDH-2 classification, and this may have caused the mild correlations between Oswestry Index and the variables at the level participation (appendix 4). The obvious development of functional disability in the course of low back pain, which was documented by Oswestry index in this study, may serve as a point of control for more effective rehabilitation procedures.

Participation

Only some notable changes in participation occurred, and this is consistent with the results reported by Alaranta et al. (1994b). The reason for this might have been the good initial status of the subjects and in addition, the inclusion criteria presumed working status. The design of the questions was not equal at each measurement session, because, for example, at the initial stage, the questions described the situation a year before, and in the follow-ups the analyses were only concerned with the previous time periods of three or six months. This may explain the smaller number of sick leaves and restrictions at the follow-ups.

Therefore, a longer follow-up is needed for the analysis of the importance of exercise effects in regards to the measurements at the participation level (Bendix et al. 1996, Patrick et al. 1995). The changes in participation may also need more multidimensional interventions, such as functional restoration program (Bendix et al. 1996, 1998) with psychosocial counselling, which may enable the stronger use of social participation. In addition, the positive findings in relation to participation throughout the study may be explained by the period of economic recession in Finland at that time. People did not dare to have their restrictions in working capacity recognized, due to the fear of unemployment.

Contrary to several earlier studies (for example Alaranta et al. 1994d, Era 1987), no remarkable associations between the variables at the same level of ICIDH-2 classification existed. However, studies which are consistent with the current study also exist, for example, Leveille et al. (1999) did not find any associations between low back pain and balance in older women and Biering-Sörensen (1984) only found low correlations between muscle performance and flexibility. The variables at the different levels of ICIDH-2 classification did not associate with each other. In current study there were no associations between low back pain and activity, even if in Cooper´s et al. (1996) study low back pain and Oswestry Index were positively correlated, and also postural sway and functional ability in the elderly have been found to be associated (Era et al. 1997). Perhaps these variables do not describe the same thing (Waddell 1998) or their relationship can not be observed so directly (Cooper (1996). The further evaluation of the relationships between the different levels of the classification will require the use of loglinear statistical models. Even if it was not clearly established in this study, functional limitations may be associated with, and may restrict, a person´s social interactions, activities and roles (Hall & Brody 1999).

In this study it was possible to set out some criteria values (above and below the mean) of the variables, such as muscle performance, to indicate gains in the other variables, such as low back pain and activity. The definition of such limits also in spinal and muscle flexibility, psychomotor performance, and balance may also assist the physiotherapists in the assessment of the subjects who are going to gain benefit from the therapeutic exercises. The results of this study were analysed within the groups, but naturally, the individual assessment of the subjects may be more relevant for physiotherapy practice and more appropriate for the subjects. In research this may be achieved with quasi-experimental single case study design.

8.3 Fitting the ICIDH-2 model to therapeutic exercise interventions of subjects with low back pain

The planning for this study was started over ten years ago when the "atmosphere" of active rehabilitation was gradually growing. From the very beginning, this research work has based on the old disablement model (WHO 1980) and previously on the ICIDH-2 model (WHO 1999). In this study, the model has been feasible and it can be recommended for inclusion in physiotherapy research and clinical practice (Hendricks et al.1997). Firstly, it can be used in the assessment of a subject´s status, by the selection of proper assessment methods and measurement variables, and for the formulation of the goals for physiotherapy. Secondly, it can be used for focusing physiotherapy treatment or the study interventions on a relevant level or levels. Finally, it can be used for the execution of suitable outcome measures and for the detection the changes at the different levels. With this model it is also possible to expand the focus of attention from pure biomedical context to broader biopsychosocial context.

The purpose of this research work was to measure change, not effectiveness. Changes at any level of the ICIDH-2 classification may depend on many factors that obscure the pure effects of therapeutic exercise program (WHO 1999). With low back pain subjects also the contextual factors (WHO 1999), such as personal factors (for example, marital status, number of children, smoking) and environmental factors (mechanical demands of work, exposure to vibration) also have effects on the changes in a subject´s performance and on the recurrence of low back pain.

Many ideas for further studies will rise from this study. How can the diminishing resources be used in the most beneficial and effective ways for subjects with low back pain, and therefore, for example, the economical advantage of home exercises is worth studying. More research is also needed for the development of reliable and valid measurements of the levels of activity and participation. It would be of great importance to evaluate the contents of the interventions in more detail, before decisions about clear cause-effect relationships of the therapeutic exercises are made. Even the analyse of one single testing or exercise movement would provide valuable information. For example, Kankaanpää (1999) observed that the gluteus maximus and biceps femoris muscles clearly became fatigued during the Biering- Sorensen test and thus, there may be a need to exercise these muscles more effectively. Further studies should also concentrate on studying the longevity of the positive changes achieved with therapeutic exercise, which is of great value for the subject and for the provider of physiotherapy.

Physiotherapy research is always concerned with two aspects: appropriateness "doing the right things" in measurements, as well as interventions and effectiveness "doing the right things well" (Kane 1994). If we are fulfilling the above-mentioned demands in physiotherapy research, then we may always ask: Are our results statistically significant?, and Are they clinically significant as related to physiotherapy practice? In physiotherapy practice the following questions will arise: What is the importance of muscle performance, spinal and muscle flexibility, psychomotor performance and balance for the life of a person with low back pain? and Do the changes in body functions really reflect changes in the activity or participation?.

9 CONCLUSIONS

1) Low back pain reduced with therapeutic exercise programs performed in either intensive training groups or with individual home exercises.
2) The muscle strength and endurance of low back pain subjects increased with therapeutic exercise programs. Muscle strength and endurance did not correlate with low back pain or with Oswestry Index.
3) Spinal rotation and hamstring muscle flexibility improved with therapeutic exercise programs, but the gain reduced during the follow-up period. Flexibility of erector spinae muscle increased slightly with intensive training program. Both spinal and muscle flexibility did not correlate with low back pain or with Oswestry Index.
4) Psychomotor performance did not change with these therapeutic exercise programs.
5) The changes in the velocity of postural sway associated with home exercise program.
6) The reduction in activity limitations associated with the therapeutic exercise programs.
7) Changes at the level of participation; restrictions at work or recreational hobbies or in sick leaves were not clearly associated with these therapeutic exercise programs.
8) Associations between the outcomes at the different levels of the ICIDH-2 classification are not straightforward.

Clinical considerations

For individuals with good initial status at the levels of activity and participation, the therapeutic exercise programs can be performed effectively individually in the home environment. In any case, the exercises have to be progressive, supervised, customised and controlled by a professional with the knowledge of biomechanics, exercise physiology and pathology. In order to enhance psychomotor performance and postural sway, more specific and tailored therapeutic exercise programs may be required.

The assessment of outcome should include sensitive measurements at the different levels of the ICIDH- classification, and the changes at the level of participation will require longer periods of time to occur or different kinds of interventions.

10 TIIVISTELMÄ

Tutkimuksen tarkoituksena oli selvittää WHO:n ICIDH-2-luokitukseen pohjautuen, kolmen kuukauden terapeuttisen harjoittelun aiheuttamia muutoksia selkäpotilaiden kehon toiminnoissa ja koetussa toimintakyvyssä sekä työssä ja vapaa-ajan harrastuksissa.

Työterveyspalveluihin hakeutuneista 90 selkäpotilaasta 86 jaettiin kolmeen ryhmään: ensimmäiset 29 ohjattiin suoraan kolmen kuukauden intensiiviseen harjoitteluun ja seuraavat 57 koehenkilöä satunnaistettiin joko kotivoimisteluryhmään tai kontrolliryhmään. Alkumittausten jälkeen suoritettiin seurantamittaukset heti interventioiden loputtua ja lisäksi kolmen ja kuuden kuukauden kuluttua interventioiden päättymisestä. Mittaukset sisälsivät selkäkivun voimakkuuden arvioinnin, vartalon ja alaraajojen lihasvoiman ja kestävyyden, liikkuvuuden, alaraajojen valintareaktioajan, liikeajan sekä maksimaalisen hyppytestin ja pystyasennossa tapahtuvan huojunnan mittauksen voimalevyllä. Selkävaivan aiheuttamaa haittaa työssä ja vapaa-aikana sekä sairauspoissaoloja tiedusteltiin kyselylomakkeella.

Selkäkivun voimakkuus ja selkävaivan aiheuttama toimintakyvyn haitta vähenivät intensiivisessä harjoittelu-, ja kotivoimisteluryhmässä. Lisäksi lihasvoima ja kestävyys lisääntyivät ja säilyivät seurantajakson ajan harjoitteluryhmillä. Lihasvoima ja kestävyys eivät olleet yhteydessä selkäkipuun. Selkärangan rotaatio, selkälihasten ja reiden takaosan lihasten joustavuus lisääntyivät terapeuttisella harjoittelulla. Liikkuvuus ei ollut yhteydessä selkäkipuun. Alaraajojen psykomotoriikassa, kehon huojunnassa tai selkävaivan aiheuttamassa haitassa vapaa-ajanharrastuksissa ei tapahtunut merkittäviä muutoksia. Selkävaivan aiheuttamat haitat työssä ja sairauspoissaolot vähenivät jonkin verran tutkimuksen aikana kaikilla ryhmillä.

Tutkimustulokset osoittivat, että kolmen kuukauden progressiivisella, ohjatulla ja kontrolloidulla terapeuttisella harjoittelulla voidaan saavuttaa positiivisia muutoksia selkäkivussa, lihasten toiminnassa, liikkuvuudessa ja toimintakyvyssä. Muutokset voidaan saada aikaan joko ryhmämuotoisella harjoittelulla tai kotona suoritetun harjoitusohjelman avulla. Psykomotorisen toiminnan ja tasapainon muutokset vaativat kuitenkin spesifimmän harjoittelun. Muutokset sairauslomissa, selkävaivan aiheuttamassa haitassa työssä tai vapaa-aikana edellyttävät ilmeisesti myös monitahoisempia interventioita, pidempiaikaista seurantaa sekä muiden osallistumisen tasolle vaikuttavien tekijöiden huomiointia.

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Appendix 1

Inclusion criteria

1) Place of residence in Jyväskylä region
2) Age 20-55 years
3) Emploeyd and no more than three months sick leave during past year
4) Low back pain
   - the subject´s major problem
   - reduced working and/or physical capacity
   - symptoms for more than three years
   - pain at rest or with stress
   - localisation to lumbar area and buttocks
   - pain may radiate to lower limbs, but without neurological symptoms
5) No other chronic diseases

Appendix 2 Variables of participation

RESTRICTIONS AT WORK DUE TO LOW BACK PAIN

Question

To What degree does your back cause problems in your profession and work duties?

1) No problems at all
2) I can perform my work duties, but they cause low back pain
3) I am forced often to easy my work pace or to change the way I work
4) I am forced to be on sick leave quite often
5) It has caused me to be unemployed and I have had difficulties in finding work
6) I am totally incapacitated from doing work
7) It affects my working habits, how?

For further analysis class 1 = no problems, from 2 to 7 = problems

SICK LEAVES

Question

In total how long have you been on sick leave during the last three months because of your back problems?

1) Not at all
2) Under 2 weeks
3) From 2 weeks up to 1 month
4) Over 1 month, but under 2 months
5) From 2 to 3 months
6) Over 3 months

For further analysis class 1 = no sick leaves, from 2 to 6 = sick leaves

RESTRICTIONS IN RECREATIONAL HOBBIES

Question

Does your low back pain problem limit your ability, at his time, to perform your usual recreational activities?

1) Very much
2) Much
3) To some degree
4) A little
5) Not at all

For further analysis classes from 1 to 4 = restrictions, 5 = no restrictions

Appendix 3
Restrictions at work due to low back pain

	INTENSIVE TRAINING GROUP				HOME EXERCISE GROUP				CONTROL GROUP			
	χ^{2*}	1	2	Sig	χ^{2*}	1	2	Sig	χ^{2*}	1	2	Sig
BM-PI1	3.1	ns	.23	ns	19.4	ns	.84	.001	8.8	ns	.52	.015
BM-PI2	2.4	.03	.19	ns	9.2	ns	.52	.010	0.4	ns	.12	ns
BM-PI3	4.9	ns	.36	ns	4.2	.004	.27	ns	3.1	.008	.23	ns
PI1-PI2	10.1	ns	.67	.004	18.2	ns	,86	.000	2.9	ns	.34	ns
PI1-PI3	5.6	ns	.49	.046	7.1	.031	.44	.017	5.2	ns	.44	ns
PI2-PI3	11.6	ns	.65	.004	11.2	ns	.60	.001	8.8	ns	.54	.006

BM-PI1 = Changes during the intervention period of the study
BM-PI2 = Changes between the baseline and the second post-intervention measurements
BM-PI3 = Changes between the baseline and the third post-intervention measurements
PI1-PI2 = Changes between the first and second post-intervention measurements
PI1-PI3 = Changes between the first and third post-intervention measurements
PI2-PI3 = Changes between the second and third post-intervention measurements
χ^2 = Chi square value
* = Some cells had expected count less than 5
1 = McNemar test
2 = Kappa value
Sig = Significance by Fisher´s exact test
ns = non significant

Appendix 3
Changes in sick leaves in the three study groups

	INTENSIVE TRAINING GROUP				HOME EXERCISE GROUP				CONTROL GROUP			
	χ^{2*}	1	2	Sig	χ^{2*}	1	2	Sig	χ^{2*}	1	2	Sig
BM-PI1	4.1	.004	.29	ns	1.1	.000	.08	ns	0.76	.000	.06	ns
BM-PI2	3.1	.004	.24	ns	≈	≈	≈	≈	0.69	.006	.11	ns
BM-PI3	4.4	.008	.32	ns	≈	≈	≈	≈	0.98	.003	.08	ns
PI1-PI2	1.1	ns	.23	ns	≈	≈	≈	≈	0.15	ns	-.07	ns
PI1-PI3	5.8	ns	.49	ns	≈	≈	≈	≈	6.1	ns	.50	ns
PI2-PI3	8.8	ns	.54	.006	19.4	ns	.84	.001	14.3	ns	.74	.000

BM-PI1 = Changes during the intervention period of the study
BM-PI2 = Changes between the baseline and the second post-intervention measurements
BM-PI3 = Changes between the baseline and the third post-intervention measurements
PI1-PI2 = Changes between the first and second post-intervention measurements
PI1-PI3 = Changes between the first and third post-intervention measurements
PI2-PI3 = Changes between the second and third post-intervention measurements
χ^2 = Chi square value
* = Some cells had expected count less than 5
1 = McNemar test
2 = Kappa value
Sig = Significance by Fisher´s exact test
ns = non significant
≈ = No statistics are computed because sick leaves are constant

Appendix 3
Changes in restrictions of recreational hobbies in the three study groups

	INTENSIVE TRAINING GROUP				HOME EXERCISE GROUP				CONTROL GROUP			
	χ^{2*}	1	2	Sig	χ^{2*}	1	2	Sig	χ^{2*}	1	2	Sig
BM-PI1	8.8	ns	.54	.006	19.4	ns	.84	.001	14.3	ns	.74	.000
BM-PI2	5.8	ns	.48	.033	7.2	ns	.51	.028	9.1	ns	.60	.007
BM-PI3	4.5	ns	.41	ns	1.4	ns	.22	ns	13.8	ns	.73	.000
PI1-PI2	8.9	ns	.63	.006	13.0	ns	.70	.005	2.8	ns	.34	ns
PI1-PI3	2.8	ns	.35	ns	4.6	ns	.41	ns	13.8	ns	.73	.000
PI2-PI3	6.6	ns	.54	.023	19.4	ns	.84	.028	13.8	ns	.73	.000

BM-PI1 = Changes during the intervention period of the study
BM-PI2 = Changes between the baseline and the second post-intervention measurements
BM-PI3 = Changes between the baseline and the third post-intervention measurements
PI1-PI2 = Changes between the first and second post-intervention measurements
PI1-PI3 = Changes between the first and third post-intervention measurements
PI2-PI3 = Changes between the second and third post-intervention measurements
χ^2 = Chi square value
* = Some cells had expected count less than 5
1 = McNemar test
2 = Kappa value
Sig = Significance by Fisher´s exact test
ns = non significant

Appendix 4
Correlations of outcome variables

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1	1																
2	-.15	1															
3	-.18	.77**	1														
4	-.25*	.72*	.66**	1													
5	-.09	.54**	.50**	.54**	1												
6	-.25**	.49**	.46**	.56**	.27*	1											
7	-.30**	.17	.10	.18	.13	-.06	1										
8	-.41**	.21	.28**	.37**	.20	.13	.52**	1									
9	-.26*	.12	.07	.22*	.01	.08	.36**	.43**	1								
10	-.18	-.08	-.13	-.05	-.11	-.13	.54**	.23*	.57**	1							
11	-.09	-.12	-.15	-.02	.10	-.13	-.02	.06	.09	.06	1						
12	.09	-.12	-.19	-.17	-.07	-.12	-.08	-.12	-.04	.06	.33**	1					
13	-.15	.19	.24*	.30**	.22*	.15	.23*	.33*	.11	.23*	.11	.17	1				
14	.02	.26*	.20	.21	.17	.08	.22*	.28*	.03	.02	.12	-.16	.30*	1			
15	-.00	-.24*	-.12	-.29**	-.25*	-.21	-.10	.03	.01	-.17	.01	-.03	.12	-.07	1		
16	.09	.03	.05	.03	.03	.18	-.12	-.22*	.02	-.07	-.15	-.20	-.21*	-.33**	.12	1	
17	.07	.03	-.19	.01	-.10	-.17	.15	.01	.00	.17	.29**	.14	.02	.19*	.02	.36**	1
31	.31**	-.00	.02	-.01	.02	-.03	-.16	-.21	-.05	-.10	.02	-.50	-.08	-.03	-.15	.12	-.05
32	.20	-.06	-.00	.16	.01	-.00	-.08	-.01	-.02	-.11	.00	-.08	.12	.24*	-.07	-.05	-.03
33	.09	.23*	.22*	.21	.09	.08	-.12	-.08	-.09	-.19	.21	-.06	-.00	.01	.03	.13	.02
34	-.18	-.12	-.06	-.19	-.18	-.26*	.21	.20	.08	.25*	.09	.01	-.15	-.07	.16	-.05	.15

* = Statistical significance $p < .05$
* *= Statistical significance $p < .01$

Appendix 4
Correlations of outcome variables

	1	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
1	1																	
18	.24*	1																
19	.24*	.65*	1															
20	.25*	.96*	.82*	1														
21	-37*	-.17	-.40*	-.35*	1													
22	.11	-.07	.09	.06	.00	1												
23	.00	-.02	.15	.12	.08	.75**	1											
24	-.06	.00	-.03	-.01	.14	.56**	.70**	1										
25	.41**	.10	.08	.13	-.13	.73**	.60**	.52**	1									
26	.19	.13	.22	.23*	-.00	.63**	.75**	.56**	.75**	1								
27	-.09	.06	-.01	.03	.12	.51**	.66**	.97**	.49**	.53**	1							
28	.03	-.02	.21	.18	-.05	.34**	.27*	.27*	.25*	.20	.33**	1						
29	-.02	-.01	.28*	.23*	-.09	.20	.39**	.15	.14	.27*	.21	.53**	1					
30	-.05	.01	-.05	-.02	.14	.42**	.53**	.88**	.35**	.36**	.89**	.35**	.21	1				
31	.31**	.08	.06	.13	-.13	.13	.22	.12	.04	.20	.10	.03	.12	.15	1			
32	.20	.00	-.12	-.06	.04	.12	.00	.10	.14	.13	.10	.17	-.12	.10	.34**	1		
33	.09	-.09	.04	.03	.07	.08	.13	-.07	.01	.16	-.13	.11	.13	-.19	.22*	.34**	1	
34	-.18	.12	-.17	-.12	-.02	.05	-.20	-.02	.13	.02	.04	.03	-.08	-.02	-.39**	-.12	-.07	1

* = Statistical significance $p < .05$
**= Statistical significance $p < .01$

Appendix 4 Correlations of outcome variables

	18	19	20	21	22	23	24	25	26	27	28	29
1	.24*	.24*	.25*	-.37**	.11	.00	-.06	.41**	.19	-.09	.03	-.02
2	-.15	-.34**	-.33**	.61**	.06	.07	-.06	-.02	.05	-.07	-.07	-.05
3	-.25*	-.34*	-.36*	.47**	.05	.09	.02	-.04	.00	.02	-.05	-.06
4	-.25*	-.35**	-.38**	.72**	-.07	.01	-.01	-.16	-.02	-.02	-.08	-.14
5	-.11	-.35**	-.31**	.32**	.08	-.01	-.04	.11	-.01	-.06	.05	-.08
6	-.06	-.09	-.08	.43**	-.07	.07	-.04	-.06	.05	.01	.12	.12
7	-.20	-.29**	-.29**	.33**	.11	.05	.00	.12	.03	-.05	-.25*	-.05
8	-.36**	-.39**	-.44**	.53**	.14	.04	.15	.04	-.05	.08	-.10	-.13
9	-.11	-.19*	-.17*	.37**	.00	-.00	.02	-.03	.00	-.01	-.03	-.12
10	-.02	-.15	-.09	.16	.18	.01	.08	.10	-.01	.04	-.13	-.11
11	.00	.01	.03	.06	.11	.02	.11	.15	.04	.08	.06	-.04
12	-.03	-.00	.01	-.14	-.00	.02	.03	.10	.02	-.01	.11	-.10
13	-.21	-.32**	-.31**	.44**	.21	.14	.22	.13	.03	.17	.18	.02
14	-.03	-.22*	-.19	.23*	.17	.13	.11	.24*	.19	.08	-.05	-.01
15	.06	.08	.08	-.18	-.03	-.00	-.16	-.05	-.05	-.17	.12	-.06
16	.12	.29**	.26*	-.13	.06	.03	-.15	.03	.09	-.10	.06	.11
17	.08	-.09	-.02	.08	.03	-.11	-.08	.09	.02	-.09	-.08	-.06

* = Statistical significance $p < .05$
** = Statistical significance $p < .01$

Explanations for the appendix 4
1 = Low back pain
2 = Isometric trunk extension
3 = Isometric trunk flexion
4 = Isometric knee extension
5 = Isometric ankle extension
6 = Isometric ankle flexion
7 = Isometric endurance of trunk extensors
8 = Dynamic endurance of trunk flexors
9 = Knee bend
10 = Dynamic endurance of trunk extensors
11 = Lumbar lexion
12 = Lumbar extension
13 = Spinal rotation
14 = Lateral flexion
15 = Iliopsoas
16 = Erector spinae
17 = Hamstring
18 = Choice reaction time
19 = Movement time
20 = Total time
21 = Vof sway, ant-post, eyes open
23 = Velocity of sway,ant-post, eyes closed
24 = Velocity of sway,ant-post, tandem standing
25 = Velocity of sway,med-lat, eyes open
26 = Velocity of sway,med-lat, eyes closed
27 = Velocity of sway, med-lat, tandem standing
28 = Amplitude of sway, eyes open
29 = Amplitude of sway, eyes closed
30 = Amplitude of sway, tandem standing
31 = Oswestry Index
32 = Restrictions at work
33 = Sick leaves
34 = Restrictions at recreational hobbies

Appendix 5 Methodological quality of the study

	Points
Study population	
A Inclusion and exclusion criteria are described	1
B Relevant baseline characteristics are comparable:	
-duration of complaints	1
-values of outcome measures	1
-age	1
-recurrences	1
-radiating complaints	1
C Randomisation procedure is described	2
D Drop-outs and reasons are described	3
E Loss to follow-up <20%	2
F Amount of subjects <50 in each group	-
Interventions	
G Intervention protocols are established	5
H Comparisons between different interventions	5
I Co-interventions avoided	5
J Comparison with real control group	5
Measurement of effect	
K Attempt at blinding measurers	1
L Measured and reported	
-pain	2
-functional status	2
-spinal flexibility	2
-medical consumption	1
M Blinded measurement	
-pain	2
-functional status	2
-medical consumption	2
N Measurements	
-after intervention	3
-3 and 9 months after intervention	2
Data-presentation and analysis	
O No intention to threat analysis	-
P Frequencies of the most important outcome variables are presented	5
total	57

(Koes et al. 1991)

Appendix 6 Power

VARIABLE	Estimation of Clinically relevant Change δ	sd	δ/sd	Needed N for 0.7-0.8 Power
Low back pain	2.0	1.5	1.33	22
Muscle strength and endurance				
- Isometric trunk extension (N)	100	265	0.38	220
- Isometric trunk flexion (N)	75	176	0.43	160
- Isometric knee extension (N)	75	162	0.46	150
- Isometric ankle extension (N)	75	182	0.41	180
- Isometric ankle flexion (N)	50	63	0.79	50
- Isometric endurance of trunk extensors (s)	120	70	1.71	18
- Dynamic endurance of trunk flexors (repetitions)	10	20	0.50	100
- Knee bend (repetitions)	10	48	0.21	500
- Dynamic endurance of trunk extensors (repetitions)	10	26	0.38	170
Spinal flexibility				
Lumbar flexion (degrees)	10	14.5	0.69	65
Lumbar extension (degrees)	10	8.6	1.16	22
Spinal lateral flexion (mm)	100	44.7	2.23	17
Spinal rotation (degrees)	20	14.3	1.39	18
Muscle flexibility				
Erector spinae flexibility (mm)	100	64.3	1.56	22
Hamstring flexibility (degrees)	20	14.3	1.39	17
Iliopsoas flexibility (degrees)	10	11.8	1.18	18
Psychomotor performance				
- choice reaction time (ms)	50	83	0.60	65
- movement time (ms)	50	142	0.35	180
- total time (ms)	100	190	0.52	110
- flight time (ms)	100	76	1.32	18
Postural sway				
-velocity of sway				
ant-post, eyes open (mm/s)	3	4.8	0.63	70
ant-post, eyes closed (mm/s)	4	6.6	0.61	70
ant-post, tandem standing (mm/s)	5	19.5	0.25	350
med-lat, eyes open (mm/s)	2	3.4	0.59	75
med-lat, eyes closed (mm/s)	3	4.4	0.68	55
med-lat, tandem standing (mm/s)	5	21.7	0.23	400
-amplitude of sway				
eyes open (mm)	5	7.3	0.68	55
eyes closed (mm)	7	12.3	0.57	75
tandem standing (mm)	7	19.4	0.36	180
Oswestry Index	20	8.4	2.38	22
Participation				
-restrictions at work				
-sick leaves				
-restrictions at recreational hobbies				

(by Altman 1991)
sd= Standard deviation at the baseline measurement

Appendix 7 Summary of effect sizes

Variable	Effects Intensive training group 1.	2.	Home exercise group 1.	2.	Control group 1.	2.	Paper
Low back pain	0.85	1.0	0.40	0.60	0.41	0.29	I
Muscle strength and endurance							I
- Isometric trunk extension	0.40	0.61	0.25	0.38	0.04	0.12	
- Isometric trunk flexion	0.52	0.28	0.18	0.21	0.11	0.07	
- Isometric knee extension	0.33	0.39	0.19	0.19	0.12	0.06↓	
- Isometric ankle extension	0.11	0.00	0.05	0.23↓	0.24↓	0.38↓	
- Isometric ankle flexion	0.67	0.67	0.14	0.43	0.29	0.43	
Isometric endurance of trunkextensors	1.55	1.75	1.54	1.62	0.07	0.34	
Dynamic endurance of trunk flexors	1.09	0.72	0.88	0.81	0.20	0.08↓	
- Knee bend	1.26	1.36	1.16	0.94	0.04↓	0.36	
Dynamic endurance of trunk extensors	1.60	1.75	1.43	1.50	0.07	0.32	
Spinal flexibility							II
- lumbar flexion	0.35	0.35↓	0.00	0.55↓	0.66↓	0.42↓	
- lumbar extension	0.09	0.36↓	0.05	0.33↓	0.16	0.33↓	
- spinal rotation	0.85	1.00↓	0.13↓	0.81↓	0.60↓	1.20↓	
- lateral flexion	0.50	0.61	0.11	0.07	0.13↓	0.24↓	
Muscle flexibility							II
- iliopsoas	0.45	0.27↓	0.18	0.27	0.27	0.00	
- erector spinae	0.77	0.49	0.21	0.14	0.04	0.27	
- hamstring	0.24	0.29↓	0.42	0.08↓	0.00	0.43↓	
Psychomotor performance							III
- choice reaction time	0.01	0.16	0.09	0.14↓	0.02↓	0.12	
- movement time	0.38	0.79	0.57	0.88	0.50	0.63	
- total time	0.28	0.62	0.50	0.70	0.34	0.45	
- flight time	0.74	1.14	0.27	0.40	0.06	0.22	
Postural sway							IV
-velocity of sway							
ant-post, eyes open	0.13	0.06	0.47↓	0.36↓	0.33	0.00	
ant-post, eyes closed	0.34	0.03	0.11	0.07	0.09↓	0.45↓	
ant-post, tandem standing	0.35	0.15	0.21	0.21	0.28	0.04↓	
med-lat, eyes open	0.26↓	0.00	0.49↓	0.11↓	0.22	0.07	
med-lat, eyes closed	0.07↓	0.12	0.30↓	0.20	0.05↓	0.22↓	
med-lat, tandem standing	0.14	0.28	0.23	0.24	0.32	0.10↓	
-amplitude of sway							
eyes open	0.27	0.16	0.12	0.30	0.43	0.33	
eyes closed	0.04↓	0.04	0.30↓	0.02	0.28↓	0.51↓	
tandem standing	0.23	0.59↓	0.16	0.26	0.13	0.16	
Oswestry Index	1.03	1.21	0.74	1.16	0.34	0.46	I

(continues)

Appendix 7 (continues)

Participation -restrictions at work -sick leaves -restrictions at recreational hobbies

(Mannion 1999)

1.= Effect size during the intervention period of the study (BM-PI1)
2.= Effect size between the baseline and the last follow-up measurements (BM-PI3)
↓= negative effect

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