

Methodological considerations of clinical studies on low back pain.

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Hovedfagsoppgave i fysioterapi

Thesis for the Degree of Cand. San. in Physiotherapy



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CONTENTS

	Page
I. ABBREVIATIONS	3
II. SUMMARY IN ENGLISH AND NORWEGIAN	4
III. GENERAL INTRODUCTION	7
IV. AIMS OF STUDY	10
V. SPINE PUBLICATION, TORSTENSEN ET AL. 1998	12
VI. MATERIAL AND METHODS	22
VII. BRIEF SUMMERY OF THE RESULTS	27
VIII. GENERAL DISCUSSION	29
<i>METHODOLOGICAL EVALUATION I</i>	30
<i>-Letter to the editor from Eriksen and Ursin</i>	30
<i>-Methodological shortcomings of the Indahl study</i>	32
<i>-Validity of return to work as an outcome measure</i>	34
<i>- Comparison of systems</i>	36
<i>-Medical doctors sicklisting practise</i>	37
<i>-Other studies using return to work (RTW) as outcome measure</i>	38
<i>- Indahl et al. 5 year follow up</i>	39
<i>-Molde Hagen`s replication of the Indahl study</i>	40
<i>- RTW rates in 4 Norwegian and 1 Swedish study</i>	42
<i>METHODOLOGICAL EVALUATION II</i>	43
<i>-The Cochrane Back Review Group</i>	43
<i>Hansen et al. study (1993)</i>	46
<i>Hemmilä et al study (1997)</i>	47
<i>Torstensen et al. study (1998)</i>	48
<i>Why do different interventions come out indifferent</i>	50
IX. CONCLUSIONS	54
X. REFERENCES	56

I. ABBREVIATIONS

CP = conventional physiotherapy
GP = general practitioner
MET = medical exercise therapy
RTW = return to work
RCT = randomised controlled trial
SE = self exercise

II. SUMMARY IN ENGLISH AND NORWEGIAN

SUMMARY

Methodological considerations of clinical studies on low back pain.

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On the basis of the publication by Torstensen et al. *Spine* 1998;23:2616-24, three aspects are discussed in this thesis; 1) that methodological shortcomings of studies may explain the high return to work (RTW) rate in the Indahl study and not the intervention by reducing fear about back pain and maintaining a normal activity level (Indahl et al. *Spine* 1995;20 (4):473-477); 2) that RTW is not a valid outcome measure; 3) that conventional physiotherapy (CP) is documented effective for chronic low back pain and that different interventions tend to come out indifferent.

Return to work (RTW) is the ultimate outcome measure of the effectiveness of an intervention. However, it is not a reliable, sensitive or valid outcome measure. It may be influenced more by other variables than those traditionally recognised by health workers. In the Torstensen et al. *Spine* publication RTW was one of the outcome variables evaluated comparing the effectiveness of the progressively graded medical exercise therapy (MET), conventional physiotherapy (CP), and self-exercise by walking (SE) (a modified Indahl approach) in patients with chronic low back pain. The study design of the Torstensen et al. *Spine* publication was a multicenter, single blinded, randomised controlled trial (RCT) with a one-year follow up. Of the 208 patients included in this study, 71 were randomly assigned to medical exercise therapy (MET), 67 to conventional physiotherapy (CP), and 70 to self-exercise (SE) by walking applying a modified Indahl approach. Thirty-three (15.8%) patients dropped out during the treatment period. No difference was observed between MET and CP groups, but both were significantly better than the SE group i.e. modified Indahl intervention regarding less pain and improved function. However, RTW was approximately 60% in all three groups, i.e. no significant difference was observed.

In the *Spine* publication by Torstensen et al. we were not able to reproduce the very high RTW rate published by Indahl et al. Norwegian researchers suggest that this is due to a placebo effect giving the self exercise group i.e. the modified Indahl intervention a peculiar and unusual treatment. In another Norwegian randomised controlled trial The Indahl intervention was reproduced. However, at the two year follow up they found no difference between the two intervention groups regarding RTW. These findings may be explained by methodological differences between the studies.

The Torstensen et al. publication has also been evaluated by the Cochrane Back Review Group, obtaining 7 out of 9 possible points for methodological quality. On the background of two other studies of high methodological quality and the Torstensen et al. publication, the reviewers concluded that there was strong evidence that exercise therapy is more effective than usual care by General Practitioners (GP's) and that exercise therapy and CP are equally effective. Concluding that different interventions come out indifferent indicates that these interventions evaluated through RCTs are of equal value.

Key words: RCT, back pain, medical exercise therapy, conventional physiotherapy, self exercise, outcome measures, return to work, patient satisfaction, sick listing practice, validity.

SAMMENDRAG

Metodiske vurderinger av kliniske studier på ryggsmarter.

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Med bakgrunn i publikasjonen av Torstensen et al. Spine 1998;23:2616-24, er tre aspekter diskutert i denne hovedfagsoppgaven; 1) at metodiske svakheter av studier kan forklare den høye tilbakegangen til arbeid i Indahl et al. sin studie (Indahl et al. Spine 1995;20 (4):473-477) hvor man fokuserte på å minske redselen og stimulerte til et fortsatt normalt aktivitetsnivå; 2) at tilbakegang til arbeid ikke er et valid effektmål i kliniske studier; 3) at tradisjonell fysioterapi er effektivt for pasienter med kroniske ryggsmarter, og at vidt forskjellige intervensjoner kommer likt ut i slike studier.

Tilbakegang til arbeid er samfunnets ultimate mål om en behandlingsmetode er effektiv. Men, tilbakegang til arbeid er ikke et reliabelt, sensitivt eller valid effekt mål. Tilbakegang til arbeid påvirkes antageligvis mer av faktorer som ligger utenfor det område helsevesenet tradisjonelt arbeider. I Torstensen et al's studie var tilbakegang til arbeid en av effekt parameterne hvor man sammenlignet medisinsk treningsterapi, tradisjonell fysioterapi og egentrening som turgåing (en modifisert Indahl intervensjon). Designet var en multisenter, enkelt blindet, randomisert, kontrollert studie med et års oppfølging. Av 208 inkluderte pasienter, så ble 71 randomisert til medisinsk treningsterapi (MTT), 67 til tradisjonell fysioterapi (TF), og 70 til egentrening (ET) som turgåing (modifisert Indahl intervensjon). Trettitre (15.8%) pasienter falt fra under behandlingsperioden. Ingen forskjell ble observert mellom MTT og TF, men begge var signifikant bedre en ET gruppen med mindre smerter og bedre funksjon. Tilbakegang til arbeid var ca 60% i alle tre grupper, i.e. ingen signifikant forskjell mellom gruppene ble observert.

I Torstensen et al.'s studie klarte vi ikke å reprodusere de høye tallene vedrørende tilbakegang til arbeid publisert av Indahl et al. Norske forskere foreslår at dette skyldes en placebo effekt ved at man gav egentreningsgruppen i.e. modifisert Indahl intervensjon, en merkelig og uvanlig behandling. Indahls intervensjon har også blitt reprodusert i en annen norsk klinisk kontrollert studie. Ved toårs oppfølging fant man ingen forskjell mellom primærlegens behandling og Indahl intervensjonen. Disse forskjellene kan forklares grunnet metodiske forskjeller mellom studiene.

Studien har også blitt evaluert av Cochrane Back Review Group hvor Torstensen et al. studie får 7 ut av 9 mulige poeng for metodisk kvalitet. Med bagrunn i denne og to andre studier av høy metodisk kvalitet konkluderer man at det er sterk dokumentasjon for at øvelses behandling er mer effektivt en primærlegens behandling og at øvelsesterapi og vanlig tradisjonell fysioterapi er like effektivt for pasienter med kroniske ryggsmarter. Konklusjonen at forskjellige behandlingsformer kommer likt ut indikerer at disse intervensjonene, når evaluert gjennom randomiserte studier, er likverdige.

Nøkkelord: Klinisk kontrollert studie, ryggsmarter, fysioterapi, medisinsk treningsterapi, egentrening, tilbakegang til arbeid, pasienttilfredshet, sykemeldingspraksis, validitet.

III. GENERAL INTRODUCTION

In 1992 the Ministry of Health and Social affairs in Norway started a program to see what could be done to decrease sick leave and improve life satisfaction for people with musculo-skeletal pain and dysfunction. The program's running head was; " Program for trygd og rehabilitering". Twentyseven different projects were funded, and the program ran from 1992 to 1997 and was externally evaluated in 1997 by Dag Bruusgaard and Willy Eriksen (1). One of these 27 projects was "The Oslo Physiotherapy Low Back Pain Project", of which I was project leader. (*The Oslo Physiotherapy Low Back Pain Project, Ministry of Health and Social Affairs, the Norwegian national budget, chapter no. 0720.63/97, program trygd og rehabilitering (May 1993-june 1997)*) (2). The design of the study was presented internationally in 1995 (3), and the main outcome results were presented at the International Society for the Study of Lumbar spine (ISSLS) spine conference in Belgium June 1998 (4). The main findings was published in Spine December 1998 (5). This publication together with the communications that followed (14 , 16, 37, 76), and the methodological evaluation by the Cochrane Back Review Group (20), is the basis for this thesis.

The Spine publication (5), which is a part of the Oslo Physiotherapy Low Back Pain Project (2), comparing the outcome between three different interventions; 1) medical exercise therapy (MET), 2) conventional physiotherapy (CP), and 3) a modified Indahl intervention (6), where the patients were given information about back pain and motivated to stay active exercising on their own walking (self exercise (SE)). We found that MET and CP came out equal on all outcome measures and significantly better than SE. These results were opposite to what Indahl et al. (6) documented in 1995. The different conclusions made from the current study compared to Indahl et al. (6) might be due to methodological differences.

Another surprising finding from our study (5) was the positive results from the conventional physiotherapy CP. This finding is supported by several other studies on patients with neck and back pain that got similar results to ours(7, 8, 9, 10, 11, 12, 13). Both from a clinical and scientific point of view it is interesting that completely different types of interventions came out indifferent. When a randomised controlled trial (RCT) had included a group receiving conventional physiotherapy as one of the active therapies, this group came out just as effective as the other active interventions. On a positive note, when the different interventions were compared with no treatment or a minimal intervention with little or no support/attention from a physiotherapist/medical doctor, the active treatments did better. One exception is one recent study of high methodological quality comparing McKenzie therapy, chiropractic

treatment and a minimal intervention consisting of a booklet (13), where the one year follow-up showed no difference between groups.

The Spine publication (5) showing that a combination of mostly so called passive physiotherapy methods was just as effective as MET and even better than the Indahl approach, has been controversial (1, 14, 15, 16). In the published evaluation of the program “trygd and rehabilitering” (1), The Oslo Physiotherapy Low Back Pain Project was given a blank page where the evaluators wrote two lines; “only received preliminary information”. This was amazing because the external evaluator received annual reports about the progress as well as preliminary results. These documents were a part of the information given to the Ministry of Health and Social Affairs. In 1997 Bruusgaard and Eriksen had enough information to report the study in a proper way. Recently Bruusgaard has described The Indahl study (6) in a publication in the Norwegian Medical Journal (15) as the most important study ever published in Norwegian low back pain research. Eriksen and Ursin (14) criticise the Spine publication in a letter to the Spine editor, stating the following; “*quite to the contrary we believe that their control group was given a peculiar and unusual treatment even for Norwegian medical practice.....the reason given for offering their peculiar treatment is an apparent misunderstanding of the therapeutic principles offered by Indahl et al.*”. The heading of their letter to the editor was; “*The Pain of Sognsvann walks*”. Eriksen and professor Ursin are leading the Norwegian Network for Controlled Clinical Trials for Low Back Patients and Ursin is also one of the co-authors of Indahl’s 5 year follow up of the original study (17). In one of a series of articles on the topic of low back pain published in the Norwegian Medical Journal, Brox et al (17) declined to include the Spine publication (5) in their review, but included the Indahl 5 year follow up which was published in the same issue of Spine. Brox et al’s conclusions were in favour of the “Indahl intervention”.

The positive effects of conventional physiotherapy (5) is supported by other randomised studies (9,18). A view which has recently been supported scientifically through the most recent updated systematic review by The Cochrane Back Review Group on the effect of exercises in patients with chronic low back pain (19,20). They conclude; “*There is strong evidence that exercise therapy is more effective than usual care by General Practitioners (GPs) and that **exercise therapy and conventional physiotherapy** (consisting of hot packs, massage, traction, mobilisation, short-wave diathermy, ultrasound, stretching, flexibility and co-ordination exercises, electrotherapy) **are equally effective.***” (19,20).

IV. AIMS OF STUDY

The basis for this thesis is the Spine publication (5) where the effectiveness of an active graded exercise approach of MET, CP, and a modified Indahl approach by combining information about back pain and SE by walking were compared in patients with long-lasting low back pain.

The aim of this thesis was to evaluate the results and the methodological quality of the Spine publication (5), compared with the Indahl et al. study (6, 17) and the Molde Hagen et al. study (93, 94). Further, if methodological differences could explain the different outcomes regarding RTW.

Finally, why different interventions come out indifferent in patients with neck and/or back pain.

V. The Spine publication (5):

Torstensen TA, Ljunggren AE, Meen HD, Odland E, Mowinckel P, Geijerstam S. Efficiency and costs of medical exercise therapy, conventional physiotherapy, and self exercises in patients with chronic low back pain: a pragmatic, randomized, single-blinded, controlled trial with 1-year follow-up. Spine 1998;23:2616-24.

■ Efficiency and Costs of Medical Exercise Therapy, Conventional Physiotherapy, and Self-Exercise in Patients With Chronic Low Back Pain

A Pragmatic, Randomized, Single-Blinded, Controlled Trial With 1-Year Follow-Up

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Study Design. A multicenter, randomized, single-blinded controlled trial with 1-year follow-up.

Objectives. To evaluate the efficiency of progressively graded medical exercise therapy, conventional physiotherapy, and self-exercise by walking in patients with chronic low back pain.

Summary and Background Data. Varieties of medical exercise therapy and conventional physiotherapy are considered to reduce symptoms, improve function, and decrease sickness absence, but this opinion is controversial.

Methods. Patients with chronic low back pain or radicular pain sick-listed for more than 8 weeks and less than 52 weeks (Sickness Certificate II) were included. The treatment lasted 3 months (36 treatments). Pain intensity, functional ability, patient satisfaction, return to work, number of days on sick leave, and costs were recorded.

Results. Of the 208 patients included in this study, 71 were randomly assigned to medical exercise therapy, 67 to conventional physiotherapy, and 70 to self-exercise. Thirty-three (15.8%) patients dropped out during the treatment period. No difference was observed between the medical exercise therapy and conventional physiotherapy groups, but both were significantly better than self-exercise group. Patient satisfaction was highest for medical exercise therapy. Return to work rates were equal for all 3 intervention groups at assessment 15 months after therapy was started, with 123 patients were back to work. In terms of costs for days on sick leave, the medical exercise therapy group saved

906,732 Norwegian Kroner (NOK) (\$122,531.00), and the conventional physiotherapy group saved NOK 1,882,560 (\$254,200.00), compared with the self-exercise group.

Conclusions. The efficiency of medical exercise therapy and conventional physiotherapy is shown. Leaving patients with chronic low back pain untampered poses a risk of worsening the disability, resulting in longer periods of sick leave. [Key words: chronic low back pain, costs, function, medical exercise therapy, pain, physiotherapy, randomized trial, sickness absence] *Spine* 1998; 23:2616-2624

Disorders of the musculoskeletal system are the most common causes of absence from work, and low back pain (LBP) represents the dominating subgroup.⁴² The same statistics from 1985 show that the average duration of every such work-related back pain episode in Sweden was 35 days in 1985. In a recent large population survey from Norway, Hagen et al¹⁸ found that as many as 21.6% of the respondents had experienced noninflammatory rheumatic low back pain during the past month. Epidemiologic studies indicate that 60% to 80% of the population in the Western industrialized world will experience acute LBP at some stage in their lives.^{14,15,47,56} However, because of a very favorable natural history, 80% to 90% of the patients will recover and be back to work within 6 to 8 weeks;^{14,44} 60% will be symptom-free within the first 4 weeks; and a small proportion (8-10%) of those with acute pain will end up with chronic LBP.⁴⁴

Even though the incidence of diseases causing low back pain has not increased, at least over the past 20 to 30 years, costs related to back pain have been increasing steadily.^{14,17} Especially during the past 10 to 15 years, costs have exploded and reached epidemic proportions.^{44,57} In the Netherlands⁵³ costs resulting from low

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Device status category: 1.

back pain account for as much as 1.5% of the Gross National Product, and of this 1.5%, only 3% is used for treatment purposes. Thus, as much as 97% of the costs result from long-term sick leave, reemployment, and early retirement. A small group, therefore, comprising approximately 10% of those with chronic LBP, accounts for 80% to 90% of the total costs for LBP.

The efficacy and efficiency of different treatment modalities have been questioned for the last 10 to 15 years, with quite a few systematic review articles and meta-analyses.²⁷ Even though the guidelines for doing controlled trials are articulated, the majority of the older studies are flawed by their use of poorly evaluated outcome measures, making it impossible to formulate any clear conclusions and recommendations regarding effective treatment methods for low back pain.^{27,28} Studies with improved research methodology have been published over the past 5 years, indicating a battery of treatment methods that might be used successfully.⁵⁴

In the acute stage of LBP (1 to 7 days),^{14,47} the best treatment seems to be no treatment, not interfering with the very favorable natural course. Bed rest and various exercise methods make the patient worse, and the best treatment is to maintain a normal activity level combined with a graded return to work.^{12,35} According to consensus reports from the United Kingdom,⁴⁴ Sweden,⁴⁰ and the United States,⁴ different physiotherapy modalities^{32,50} are given little credit and regarded as methods with no positive effects.^{4,40,44} Examples are electrotherapy, massage, and lumbar traction, which so far are shown to have no real effect in patients with acute LBP.^{9,36,52}

In the subacute stage of LBP (1 to 7 weeks),⁴⁷ there is some evidence for the effectiveness of physical exercises. A pragmatic approach could be recommended that combines methods such as conventional physiotherapy (putting together heat, massage, mobilization techniques, electrotherapy, traction, and some exercises) and manual therapy, including soft tissue mobilization, stretching techniques, and manipulation. It is believed that the optimal period for a thorough assessment and treatment program for LBP is within the 4- to 6-week period after the acute insult, which is the time when the natural history curve starts to flatten out.^{14,15}

In the chronic stage of LBP (12 weeks and longer), there is an increasing acceptance as well as scientific evidence that various exercise regimens designed by physiotherapists are effective.^{11,54} However, there is no evidence to indicate what kind of exercises are superior to others.¹¹ A much appraised study by Indahl et al²⁴ showed that there is a very good prognosis, even in patients with early chronic low back pain, with the use of self-exercise by walking rather than conventional treatment methods known from primary health care. This group found a significantly higher rate of return to work among the self-exercising patients, whom they thoroughly examined and compared with those being treated by the primary care physician.

The aim of this study was to compare the efficiency regarding outcome measures and costs at three functional levels^{7,59} for three different chronic low back pain interventions: 1) medical exercise therapy (MET), 2) conventional physiotherapy (CP), and 3) self-exercise (SE) by walking and maintaining an ordinary activity level.

■ Methods

Patients. Patients from 22 social security offices in Oslo who had been sick-listed 8 to 52 weeks (Sickness Certificate II) with ICPC codes L02, L03, L84, and L86 were sent written information about the project. (The national Insurance Act in Norway covers all employed and unemployed persons seeking work. Persons with more than 8 weeks of sick leave must be issued a special Sickness Certificate II to be eligible for more sickness benefits.) Patients giving their consent to participate in the study were assessed by a physician according to more specific selection criteria.

Inclusion criteria included pain in the lower back with or without leg pain, age of 20 to 65 years, birth in Norway, employment, completion of other treatment types, and no preference regarding the three treatment alternatives. Criteria for exclusion were prolapse with neurologic signs and symptoms requiring surgery, spondylolisthesis, hip arthrosis, previous back surgery, suspicion of malignancy, known rheumatic joint disease, pain in areas other than the lower back, and other somatic or psychological dysfunction making it difficult to follow the treatment program. Psychological dysfunction was classified by additional ICPC codes for depression and other psychiatric diagnoses.

The required size for the total sample was determined on 210 patients. Power analyses indicated that a study with three research groups of 70 would need a power of 95% to detect a clinical relevant difference of 20%. The level of significance was set at 0.05.

The study, approved by the Regional Ethics Committee, was performed according to the Helsinki Declaration. All subjects were thoroughly informed by personal instruction. Written informed consent was obtained at inclusion. The project was approved by the Data Inspectorate.

Design. This was a controlled, randomized, single-blinded, multicenter study with a 1-year follow-up period. To ensure balance with regard to gender, a stratified randomization was carried out using SAS 6.08 (SAS Institute Inc., NC) with Windows 3.4 (Microsoft Corp., Seattle, WA). The randomization lists were administered by a nurse, with no other personnel having access to the lists. After selection and informed consent, all patients went through a standardized assessment by a physician. Patients fulfilling the inclusion criteria were assigned to one of the three intervention groups. They received either MET or CP, or were instructed to maintain an ordinary activity level, walking on their own (SE). Single blinding was assured by having the same physician perform the assessments at inclusion, posttreatment, and 1 year later.

Thirty-three physiotherapists from 20 different private physiotherapy clinics in Oslo participated in the study, making it a multicenter trial. Ten physiotherapists from four different clinics treated patients assigned to the MET group, and 23 physiotherapists from 16 other clinics treated patients assigned to the CP group. The physiotherapy should reflect what nor-

mally is offered in a primary health care setting, making it a pragmatic trial.

All patients received 36 treatments, each lasting for 1 hour (three treatments every week for 12 weeks). This dosage conforms to suggestions from Manniche et al,³⁶ who recommend a dose-response relation in applying exercises. The patients in the SE group walked for 1 hour three times a week for 12 weeks. To make sure that the patients in the SE group followed their treatment plan, the project leader phoned them every second week during the intervention period (six contacts). Follow-up assessments for all patients took place at termination of intervention and 1 year later (3 and 15 months after inclusion). To ensure that the patients were not lost to the 1-year follow-up, all had a short telephone interview (15–20 minutes) 6 months after the end of the intervention.

Medical Exercise Therapy. The progressively graded exercise MET system was developed by the Norwegian physiotherapist Oddvar Holten during the early 1960s.^{31,50} The aim of the exercises is to normalize function by using specific exercises for mobilizing hypomobile areas of the spine and by designing stabilizing exercises for other parts. In 1967, MET was sanctioned by the Norwegian Health Authorities as a treatment method with its own defined criteria. Under continuous supervision by the physiotherapist, MET is given for 1 hour to groups with a maximum 5 patients. Each patient in the group has an individually designed exercise program related to symptoms, clinical diagnosis, needs, and expectations. To obtain information regarding these aspects, the initial assessment includes history-taking and a clinical examination, which is the basis for choosing the appropriate exercises and their grading.

Progressions for the exercises are made possible by the use of specially designed exercise equipment such as the wall pulley, lateral pulley, angle bench, multipurpose bench, incline board, wall bar, deloading frame, dumbbells, and bar bells (Steens Physical, Ski, Norway). In using the MET equipment, the grading is a function of the starting position, resistance applied, range of motion, number and speed of repetitions, number of sets, and number of treatments during the week.

Patients are given seven to nine different exercises. They perform two to three sets of 20 to 30 repetitions each, with 30 seconds of rest between each set. Before the treatment, patients perform a maximum test of each exercise, doing preferably 40 repetitions with a defined weight resistance, from a defined starting position, within a defined range of motion, and with a defined speed. This testing is done on empirical grounds, with a maximum test consisting of approximately 40 repetitions. Subtracting 20% of these 40 repetitions, the patient, for treatment purposes, does 32 repetitions in three sets with a 30-second break between each set, using the principle of interval training.

By performing seven to nine different exercises, most patients during each treatment do nearly 1000 repetitions, possibly influencing mechanisms such as endurance, circulation, and coordination. The grading of the exercises makes it possible to exercise with no (or virtually no) pain. At least the pain should not increase during training. The exercises are graded in such a way that the patients work in trunk flexion, extension, and rotations, exercising the abdominal and back muscles as well as the upper and lower extremities.

In the introductory phase, exercise positions are selected to give the intervertebral disc a minimal pressure (*i.e.*, standing and lying as compared with sitting). The patient has a 10- to

15-minute warm-up before the exercise program and should break into a sweat during the treatment. To make sure that the program is optimal, all exercises are regraded when necessary, and new exercises are added as required.

Conventional Physiotherapy. The patients assigned to the CP group received a combination of methods such as heat or cold, massage, stretching, different forms of electrotherapy, traction, and a few exercises on the treatment table. The physiotherapists applied these methods in relation to the patient's symptoms and what they anticipated to be effective. They could combine any of their methods available, except for an extensive exercise program. To a large extent, the clinics based their practice on CP with no specialization. Each physiotherapist registered the number of treatments and the combination used for each patient.

Maintaining an Ordinary Activity Level: Self-Exercise by Walking. All patients included in this group received information about self-exercise by walking and the importance of this activity for the back. The patients were to walk for 1 hour three times each week. The walking was not organized and could be performed individually whenever the participant had time. Preferably there was to be 1 day of rest between each hour walking.

Outcome Measures. The primary aim of this study was to evaluate the efficiency of the three different interventions, using measures of pain, functional activities of daily living and return to work, and cost-benefit analysis. Therefore, it was logical to record outcome measures at three different functional levels according to the World Health Organization's International Classification of Impairments, Disabilities, and Handicaps (ICIDH).^{7,25,59}

Pain intensity was recorded by means of two 100-mm visual analogue scales (VAS) for back and leg pain separately. At termination of treatment and 1 year later, the patients were asked how their pain today compared with that at the start of the treatment. Their responses were rated on a VAS 200-mm-long, with a 0 at the center that indicated no change. Values to the right represented a deterioration and increase in pain, with an end point at the 100 mm denoting the worst pain ever. Values to the left indicated improvement and decrease in pain, with end point at 100 mm that meant no pain. Functional capacities on disability level were measured using The Oswestry Low Back Pain Disability Questionnaire.^{3,13}

At termination of the intervention, patients were also asked to assess how satisfied they were with the treatment by answering questions graded on a four-point scale as follows: 1 (completely satisfied), 2 (partly satisfied), 3 (not satisfied), and 4 (dissatisfied).

Return to work and total costs were registered for each patient during the study (*i.e.*, 15 months after inclusion). Data regarding return to work and costs were collected for each patient from the 22 social security offices.

Statistical Analyses. Intention-to-treat analyses were performed with all participants in the study. Patients dropping out for reasons other than the treatment to which they had been randomized (dropout Type A) were given the baseline registration for the missing data points during the follow-up period. At the follow-up assessment, patients dropping out because of the treatment to which they were randomized (dropout Type B) were given the worst score registered for any patient in their treatment group.

Table 1. Baseline Characteristics in the Three Therapy Groups at Entry (n = 208): Mean (SD)

	MET (n = 71)	CP (n = 67)	SE (n = 70)
Age (yr)	42.1 (11.2)	43.0 (12.0)	39.9 (11.4)
Height (cm)	174.0 (8.7)	175.0 (8.9)	174.0 (11.4)
Weight (kg)	76.6 (14.9)	77.7 (18.5)	78.7 (17.0)
Body mass index (BMI)	24.7 (4.9)	25.6 (4.9)	25.4 (4.1)
No. of years in school	11.4 (2.8)	10.9 (2.3)	11.5 (3.1)
Hours on work	35.2 (9.5)	36.8 (10.5)	37.2 (10.5)
Years spent at this work	11.6 (10.7)	12.6 (10.4)	9.9 (8.5)
Changed work last year (n)	1.4 (1.9)	1.8 (2.5)	2.8 (7.4)
Since first time back pain (years ago)	6.3 (8.0)	6.5 (7.4)	6.1 (7.0)
No. of back pain	7.0 (7.4)	10.5 (21.6)	8.6 (12.1)
Years since first time on sick-leave	7.8 (8.9)	9.7 (14.5)	6.2 (7.0)
Times on sick-leave due to LBP	2.2 (2.4)	2.0 (1.4)	2.2 (2.4)
Months on sick-leave	4.9 (3.8)	5.2 (2.9)	4.7 (2.1)
Pain intensity lower back and buttocks (VAS)	53.1 (21.3)	50.9 (19.2)	55.0 (21.0)
Pain intensity lower extremity (VAS)	24.9 (21.3)	24.2 (22.9)	28.7 (28.8)
function (OLBPDQ)	51.2 (10.7)	49.9 (10.5)	50.0 (11.9)

MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise; OLBPDQ = Oswestry Low back Pain Disability Questionnaire; LBP = low back pain.

The mean was used as an index of localization, and standard deviation as index of dispersion. One-way analyses of variance were used for differences between the three different intervention groups at any given time. Repeated measures (analyses of variance) were applied for variables with registrations over time. The assumptions for the statistical methods were checked using Jackknife residuals, Cook's *d*, and Mallows *C_p*. Time-to-event data were analyzed with a log-rank test. The level of significance was set at 0.05, and all tests were two-sided.

■ Results

Study Sample

Of 210 patients, 208 met the inclusion criteria, were included in the trial (May 1993 to May 1996), and were divided into groups randomly. Of these 208 patients, 71 (34 men and 37 women) were randomly assigned to MET, 67 (35 men and 32 women) to CP, and 70 (34 men and 36 women) to SE. During the 12-week intervention period, a total of 33 patients (15.8%) dropped out, whereas there were no dropouts during the following 1-year follow-up period. Of the 33 dropouts, there were

12 in the MET group (7 Type A, 5 Type B), 8 in the CP group (3 Type A, 5 Type B), and 13 in the SE group (1 Type A, 12 Type B). Baseline characteristics were not found to be significantly different across the three therapy groups (Table 1).

Outcomes

Pain. After treatment, pain intensity was significantly reduced in the lower back and buttock ($P = 0.01$), as well as in the lower extremities ($P = 0.003$), both in favor of the MET and CP groups *versus* the SE group (Table 2). There was no significant difference between the MET and CP groups. At the 1-year follow-up, pain intensity in the lower back and buttock showed no significant difference among any of the three groups. However, pain intensity in the lower extremity was significantly lower ($P = 0.005$) in MET and CP groups than in the SE group. Again, there was no statistical difference between the two physiotherapy groups (Tables 2 and 3).

Compared with pretreatment, pain after treatment termination showed a highly significant difference ($P = 0.00006$) in favor of the MET and CP groups *versus* the SE group. Again, no statistical difference was found between the two physiotherapy groups. The results were similar at the end of the 1-year follow-up period, with a highly significant difference ($P = 0.0002$) in favor of the MET and CP groups *versus* the SE group, and no statistical difference between the two physiotherapy groups (Table 4).

Function. After treatment, there was a difference in function ($P = 0.01$) that was in favor of the MET and CP groups compared with the SE group, but no statistically significant difference between the MET and CP groups. Also at the end of the 1-year follow-up period, analyses of function showed significant differences ($P = 0.005$) in favor of the MET and CP groups *versus* the SE group, but no statistically significant difference between the two physiotherapy groups (Table 5).

Patient Satisfaction. Of the 208 participants in this study, 189 were asked how satisfied they were with the treatment. Twenty-six patients (34.2%) in the MET group, 19 patients (32.2%) in the CP group, and 6 patients (9.5%) in the SE group were completely satisfied with their treatment (Table 6).

Cost Benefit Analyses and Return to Work. Adding the costs of the treatment to the costs of being on sick leave, the

Table 2. Pain Intensity (VAS) in the Lower Back and Buttock at Baseline, After Treatment, and at the 1-Year Follow-up (n = 208): Mean (SD)

	MET (n = 71)	CP (n = 67)	SE (n = 70)
Baseline	53.1 (21.3)	50.9 (19.2)	55.0 (21.0)
After treatment	37.2 (25.3)	39.0 (28.0)	50.4 (27.2)
1-year follow-up	40.5 (24.4)	42.9 (29.5)	50.0 (28.0)

MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise.

Table 3. Pain Intensity (VAS) in the Lower Extremities at Baseline, After Treatment, and at 1-Year Follow-up (n = 208): Mean (SD)

	MET (n = 71)	CP (n = 67)	SE (n = 70)
Baseline	24.9 (21.3)	24.2 (22.9)	28.7 (28.8)
After treatment	18.8 (24.9)	24.5 (27.4)	35.2 (33.9)
1-year follow-up	21.2 (21.7)	25.7 (24.5)	35.7 (33.8)

MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise.

MET group had costs that were \$122,531.00 (NOK 906,732) less and the CP group had costs that were \$254,200.00 (NOK 1,882,560) less than those of the SE group (Tables 7–9).

Of the 208 participants in this study, 123 (59.1%) were back to work by the end of the 1-year follow-up period: 41 patients (57.7%) in the MET group, 42 patients (62.7%) in the CP group, and 40 patients (57.1%) in the SE group (Table 10). Twenty-three patients were receiving disability benefits, 34 patients were receiving occupational rehabilitation, and 21 patients were receiving unemployment and rehabilitation benefits (Table 10).

■ Discussion

In this randomized trial, positive effects of MET and CP could be shown as compared with SE in a number of outcome measures including pain, activities of daily living, patient satisfaction, number of days on sick leave, and total costs. However, it was not possible to show a statistically significant difference between the two physiotherapy groups at any time for any outcome variable.

The literature^{10,11,16,21,34,36,43,48} contains evidence that active dynamic exercises are effective in patients with chronic low back pain, and the results from the current study support this view. As shown, MET is a cost-effective treatment. A maximum of five patients treated in a group setting makes the costs of each treatment relatively low and the efficiency high. The higher patient satisfaction in the MET group compared with that in the other intervention groups adds to the value of the MET variety.

In another Norwegian study, Ljunggren et al³³ looked at return to work rates, comparing the efficacy of two exercise programs. At the 1-year follow-up assessment, high return rates were found, but there was no difference

between groups. It is difficult to say, however, whether the outcome was any better than that which would have occurred during the natural course of the disorder with no exercise. The patients included in the Ljunggren et al study were not directly comparable with the participants in the current study, who had pain of longer duration.

In a Danish study, Johansen et al²⁶ did not use return to work as an outcome variable; rather they used pain and function. They compared an aerobics program with intensive back extension exercises. Both groups improved significantly, but there was no difference between groups.

Despite agreement that exercises are effective for patients with chronic low back pain, there is no evidence showing what type of exercise or exercise program is most effective. Results showing no difference between groups underline the importance of having a true control group in comparing the potent effective method with the natural history.

The negligible outcome difference between the active approach of MET and the more passive approach of CP suggests that a number of complex human elements influence outcome variables differently and independently of intervention type. The satisfactory results for the CP group are surprising, especially considering that results of randomized controlled trials (RCTs) on different forms of passive physiotherapy such as heat,³⁶ massage,³⁶ traction,⁵² and transcutaneous electrical nerve stimulation⁹ are no better or even worse than those of the control or placebo group. Clinical guidelines from the United States⁴ and the United Kingdom⁴⁴ refer to these modalities as methods with no documented effect.

In the current pragmatic trial, the physiotherapists could choose the appropriate modality in relation to the patient's symptoms, needs, and expectations. Probably a better effect can be expected from such an approach than

Table 4. Change in Pain Intensity After Treatment and at 1-Year Follow-up Using a 200-mm-Long VAS (n = 208): Mean (SD)

	MET (n = 71)	CP (n = 67)	SE (n = 70)
After treatment	27.8 (39.6)	28.8 (40.5)	2.2 (38.8)
1-year follow-up	32.7 (36.6)	29.2 (44.1)	2.9 (54.5)

MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise.

Note: In the 200-mm-long VAS 0 indicated no change, the negative values to the right a deterioration and increase in pain with an end point at the 100 mm of worst pain ever, the positive values to the left indicating improvement and decrease in pain with end point pain free at 100 mm. An increasing/high positive value is a measure of recovery with less pain.

Table 5. Function as Activities of Daily Living Using the Oswestry Low Back Pain Disability Questionnaire (n = 208): Mean (SD)

	MET (n = 71)	CP (n = 67)	SE (n = 70)
Baseline	51.7 (10.7)	49.4 (10.5)	50.0 (11.9)
After treatment	46.2 (13.1)	46.9 (13.1)	52.7 (16.6)
1-year follow-up	44.1 (13.79)	43.0 (12.9)	50.6 (16.6)

MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise.

from testing single varieties from a battery of interventions. When patients are given a treatment that does not comply with their expectations and beliefs, they may experience the negative placebo effect. This is a constant threat to both the internal and external validity of any RCTs. The authors assume that this possible confounder was not present in the current study, wherein the physiotherapists treated the patients as they normally would.

The results of this study are also supported by several pragmatic RCTs, where there was no difference between the groups when CP was compared with chiropractic treatment,⁴⁶ with manual therapy,²⁹ with an intensive dynamic back extension program,²¹ and finally with medical exercise and the McKenzie approach.⁵⁵ However, when placebo and the usual care given by the general practitioner also are included in these trials,^{21,29} the CP variety shows better results. The results from the current study are similar in that the CP group did just as well as the MET group and better than the SE group.

To the authors' knowledge, this is the first controlled trial using self-exercise by walking to maintain a normal activity level for patients with chronic low back pain. There is good evidence now for applying such an approach to patients with acute low back pain.^{12,35} Both these studies showed that maintaining a normal activity level was superior to using different physiotherapy approaches and the treatment provided by the physician.

Only one study by Indahl et al²⁴ is advocating the same approach for patients in a late subacute stage or early subchronic stage. Indahl et al²⁴ included patients on sick leave only up to 12 weeks. Their only outcome variable was return to work, and they obtained surpris-

ingly good results with a much higher return rate for the experimental group. At the end of a 200-day follow-up period, 70% in the experimental group and only 40% in the control group had returned to work.

It is questionable, however, whether this study qualifies as a true randomized trial because in a true RCT, all patients are included when randomization occurs.^{6,23,45,51} This is done to give all the included patients the same amount of attention in terms of being assessed and knowing that they participated in a research project. In the study by Indahl et al,²⁴ the patients in the control group never knew they participated in a study, and neither did their physician responsible for terminating their sick leave. Therefore, the most efficient intervention for the experimental group might have been participation in the study including the thorough examination, extensive information and care taking, and written information about the patient's condition to the physician and social security office responsible for terminating sick leave.

When the patient's physician and social security office are not blinded regarding the outcome of the assessment and intervention at the back treatment clinic, there is a potential threat to the internal validity of the study. In using return to work as the only outcome variable, it is urgent that the patient's physician and insurance office be left untampered. Thus, it is problematic to draw conclusions from the study by Indahl et al^{23,24,51} regarding the use of self-exercise and light activity for patients with late subacute or subchronic low back pain.

However, in the current study, patients with low back pain of longer duration were included (mean time on sick

Table 6. Patient Satisfaction With Treatment (n = 189)

	MET (n = 67)	CP (n = 59)	SE (n = 63)	Total (189)
Completely satisfied	26	19	6	51
Satisfied	28	21	24	73
Partly satisfied	9	14	25	48
Dissatisfied	4	5	8	17
Missing data	4	8	7	19

MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise.

Note: During the treatment, 33 of the 208 included patients dropped out. However, it was possible to ask some of the patients who dropped out how satisfied they were with the treatment they started on; thus, the number of patients asked is 189.

Table 7. Number of Working Days on Sick-Learn the Year up to Inclusion, During the Treatment Period (3 Months), and at the 1-Year Follow-up After Termination of Treatment (15 Months) (n = 208)

	MET (n = 71)	CP (n = 67)	SE (n = 70)
No. of working days on sick-learn the year up to inclusion (12 mos)	8321	7654	8431
No. of working days on sick-learn from inclusion and 1-year follow-up (15 mos)	11,757	9967	13,567

MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise.

Table 8. Direct Costs Due to Working Days on Sick-Leave During the Treatment and Follow-up Period: A Total of 15 Months Weeks (n = 206)

	MET (n = 69)*	CP (n = 67)	SE (n = 70)
Costs in NOK	(11,757 WD × NOK 600)	(9,967 WD × NOK 600)	(13,587 WD × NOK 600)
	= NOK 7,054,200	= NOK 5,980,200	= NOK 8,152,200

* Two missing values; government employed workers are not registered at the local Social Security office.

MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise; WD = working days; NOK = Norwegian kroner; NOK = 600, the average cost per working day on sickness certificate II.

Note: The average costs for one working day due to sick-leave for patients on sickness certificate II is estimated by the local insurance offices to be approximately NOK 600.

leave, 5 months), following the approach advocated by Indahl et al,²⁴ leaving the patients untampered and using self-exercises and light activity only, and a risk of worsening the disability with longer periods on sick leave was found.

The duration of sick-listing might be one of the most important predictors for return to work. An indication of this is given by Lindstöm et al,³⁰ who included patients just as they passed the sick-listing period of 8 weeks only. The intervention focused on the place of work, combining workplace visits with a progressive exercise program and an operant-conditioning behavioral approach. Satisfactory results were reported for the experimental group, in which 80% were back to work after 12 weeks versus 58% in the control group.

In the current study, the outcome measure most relevant to society, return to work, showed no difference between any of the three groups. However, both physiotherapy groups had fewer days on sick leave than the SE group during the treatment and follow-up period (see Table 7). When costs per working day are calculated, both physiotherapy groups saved a substantial amount of money compared with the SE group, and surprisingly, the CP group saved the most (see Table 8). The economic savings were quite substantial and indicate that it is possible to save large amounts of money by using physiotherapy as MET and CP compared with leaving the patient on his own walking.

Table 9. Direct Costs of Each of the Three Interventions (n = 206)

	MET (n = 69)	CP (n = 67)	SE (n = 70)
Costs in NOK	NOK 77 × 36 treatments × 69 patients = NOK 191,268	NOK 120 × 36 treatments × 67 patients = NOK 289,440	NOK = 0

* Two missing values; government employed workers are not registered at the local Social Security office.

MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise.

Note: The costs for one MET treatment = NOK 77; the costs for one CP treatment = NOK 120.

Table 10. Work Status at 1-Year Follow-up (n = 206)

	MET (n = 71)	CP (n = 67)	SE (n = 70)	Total (n = 208)
Work	41	42	40	123
Disablement benefit	9	9	5	23
Occupational rehabilitation	13	8	13	34
Unemployment benefit	2	1	0	3
Rehabilitation benefit	2	4	12	18
Dead	0	2	0	2
Single parent benefit	2	0	0	2
Retirement pension	0	1	0	1
Missing data	2	0	0	2
Total	71	67	70	208

* Two missing values; government employed workers are not registered at the local Social Security office.

MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise.

When group differences are considered in terms of costs, the results of the current study are similar to those in a much appraised study by Mitchell and Carmen.³⁹ This group looked at return to work and costs, comparing functional restoration (FR) with that of a control group referred to their primary clinician for a variety of treatments typically provided in the community. Looking at return to work at the end of a 1-year follow-up period, Mitchell and Carmen³⁹ found no difference between the groups: 79% in the experimental group and 78% in the control group had returned to work. Regarding costs, this 1% difference over a 30-month period resulted in a saving of 1.3 million Canadian dollars in favor of the FR group.

Teasell and Harth⁴⁹ cited the study of Mitchell et al³⁹ as the only prospective properly randomized trial with an adequate control group conducted on FR. The findings are in strong contrast to the results of Mayer et al³⁷ and Hazard et al,²² who published impressive results with high return to work rates for FR groups compared with control groups. In their review Teasell and Harth⁴⁹ expressed serious reservations regarding the validity of the two latter studies, both having flawed research methodology and neither characterized as true RCTs.⁴⁹

A recent RCT in Bergen, Norway, compared the effect of an FR program of 4 weeks' duration on patients with chronic low back pain with mean time sick leave of 5 months.¹⁹ The control subjects were referred back to their primary clinician. At the end of a 12-month follow-up period, return to work showed no statistical difference between the two groups: 52% in the FR group and 53% in the control group had returned to work. The return to work rates in the current study are similar to these figures, as is mean time on sick leave.

Return to work is considered a crucial outcome measure because it is tied so closely to potential costs to third-party payers and society. However, it is also an outcome measure that seems to live its own life, being influenced by factors outside the domain of any medical or therapeutic intervention.^{2,8,20} The aforementioned

studies support this view, as do the results from three other well-designed studies^{1,38,41} from Finland and Norway, where the return to work rate was disappointingly low and no better than in any comparison or control groups. However, the FR approach including different forms of exercise resulted in improved physical function on the impairment level. A factor that complicates the picture even more is the fact that comparing health care data across borders is problematic, because the Nordic countries have a social structure completely different from that in the United States.⁵

Different outcome measurements probably measure different entities, and there is little or no correlation between pain, activities of daily living, patient satisfaction, and return to work.⁵⁸ Thus, to get a fuller picture of the intervention a combination of relevant outcome measures should be used.^{7,8,25} The current study took this problem into account by using outcome measures on different functional levels according to the ICIDH. Measurements on impairment and disability levels showed highly significant differences in favor of the two physiotherapy interventions (MET and CP) *versus* SE for pain and activities of daily living, but not for return to work.

The results from this study show that both MET and CP are equally effective and are superior to leaving patients on their own to maintain a normal activity level including walking. For the first time it has been shown that different forms of physiotherapy can save a substantial amount of money. It is time to reconsider the negative attitude toward CP. There is evidence that a pragmatic approach combining different modalities in relation to the needs of the patient is an effective way to manage chronic low back pain.

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References

1. Alaranta H, Rytökoski U, Rissanen A, et al. Intensive physical and psychosocial training program for patients with chronic low back pain. *Spine* 1994;19:1339-49.
2. Baldwin MJ, Johnson WG, Butler RJ. The error of using returns-to-work to measure the outcomes of health care. *Am J Ind Med* 1996;29:632-41.
3. Beattie P, Maher C. The role of functional status questionnaires for low back pain. *Aust Physiother* 1997;43:29-38.
4. Bigos SJ. Acute low back pain in adults. In: Bigos SJ, ed. *Clinical Practise Guidelines, Number 14: Acute Low Back Problems in Adults*. Rockville, MD: U.S. Department of Health and Human Service. Agency for Health Care Policy and Research. ACHPR Publication No. 95-0642, 1994.
5. Brody BA, Lie RK. Methodological and conceptual issues in health care system comparisons: Canada, Norway, and The United States. *J Med Philos* 1993;18:437-63.
6. Chalmers TC, Celano P, Sacks HS, Smith H. Bias in treatment assignment in controlled clinical trials. *N Engl J Med* 1983;309:1358-61.
7. Delitto A. Are measures of function and disability important in low back care? *Phys Ther* 1994;74:452-62.
8. Deyo RA. Measuring the functional status of patients with low back pain. *Arch Phys Med Rehabil* 1988;69:1044-53.
9. Deyo RA, Walsh NE, Martin DC, Schoenfeld LS, Ramamurthy S. A controlled trial of transcutaneous electrical nerve stimulation (TENS) and exercise for chronic low back pain. *N Engl J Med* 1990;322:1627-34.
10. Elnagger IM, Nordin M, Sheikhzadeh A, Parnianpour M, Kahanovitz N. Effects of spinal flexion and extension exercises on low back pain and spinal mobility in chronic mechanical low back pain patients. *Spine* 1991;16:967-72.
11. Faas A. Exercises: Which ones are worth trying, for which patients, and when? *Spine* 1996;21:2874-9.
12. Faas A, Chavannes AW, van Eijk JThM, Gubbels JW. A randomized, placebo-controlled trial of exercise therapy in patients with acute low back pain. *Spine* 1993;18:1388-95.
13. Fairbank JCT, Couper J, Davies JB, O'Brian JP. The Oswestry Low Back Pain Disability Questionnaire. *Physiotherapy* 1980;66:271-3.
14. Frank JW, Brooker AS, DeMaio SE, et al. Disability resulting from occupational low back pain: Part II. What do we know about secondary prevention? A review of the scientific evidence on prevention after disability begins. *Spine* 1996;21:2918-27.
15. Frank JW, Kerr MS, Brooker AS, et al. Disability resulting from occupational low back pain: Part I. What do we really know about primary prevention? A review of the scientific evidence on prevention before disability begins. *Spine* 1996;21:2008-17.
16. Frost H, Klaber Moffet JA, Moser JS, Fairbank JCT. Randomised controlled trial for evaluation of fitness programme for patients with chronic low back pain. *BMJ* 1995;310:151-4.
17. Frymoyer JW, Durett CL. The economics of spinal disorders. In: Frymoyer JW, ed. *The Adult Spine: Principles and Practice*. 2nd ed. Philadelphia: Lippincott-Raven, 1997:143-50.
18. Hagen KB, Kvien TK, Bjørndal A. Musculoskeletal pain and quality of life in patients with non-inflammatory joint pain compared to rheumatoid arthritis: A population survey. *J Rheumatol* 1997;24:1703-9.
19. Haldorsen EMH, Kronholm K, Skouen JS, Ursin H. Multimodal cognitive behavioural treatment of patients sicklisted for musculoskeletal pain: A randomized controlled study. *Scand J Rheumatol* 1998;27:116-25.
20. Hall H, McIntosh G, Melles T, Holowachuk B, Wai E. Effect of discharge recommendations on outcome. *Spine* 1994;19:2033-7.
21. Hansen FR, Bendix T, Skov P, et al. Intensive, dynamic back-muscle exercises, conventional physiotherapy, or placebo-control treatment of low back pain. *Spine* 1993;18:98-107.
22. Hazard RG, Fenvick JW, Kalisch SM, et al. Functional restoration with behavioural support: A one-year prospective study of patients with chronic low back pain. *Spine* 1989;14:157-61.
23. Indahl Å. Letter to the editor. *Spine* 1996;21:657.
24. Indahl Å, Velund L, Reikeraas O. Good prognosis for low back pain when left untampered: A randomized clinical trial. *Spine* 1995;20:473-7.
25. Jette A. Physical disablement concepts for physical therapy research and practice. *Phys Ther* 1994;74:380-6.

26. Johansen F, Remvig L, Kryger P, et al. Exercises for low back pain. *J Orthop Sports Phys Ther* 1995;22:52-9.
27. Koes BW, Bouter LM, Beckman H, van der Heijden GJMG, Knipschild PG. Physiotherapy exercises and back pain: A blinded review. *BMJ* 1991;302:1572-6.
28. Koes BW, Bouter LM, Heijden GJMG van der. Methodological quality of randomized clinical trials on treatment efficacy in low back pain. *Spine* 1995;20:228-35.
29. Koes BW, Bouter LM, van Mameren H van, et al. Randomised clinical trial of manual therapy and physiotherapy for persistent back and neck complaints: Results of one-year follow-up. *BMJ* 1992;304:601-5.
30. Lindström I, Öhlund C, Eek C, et al. The effect of graded activity on patients with subacute low back pain: A randomized prospective clinical study with an operant-conditioning behavioral approach. *Phys Ther* 1992;72:279-93.
31. Ljunggren AE. Low-back pain: Strength tests and resistive exercises. In: Harms-Ringdahl K, ed. *Muscle Strength: International Perspectives in Physical Therapy*. Edinburgh: Churchill Livingstone, 1993:227-57.
32. Ljunggren AE. Natural history and clinical role of the herniated disc. In: Wiesel SW, Weinstein JN, Herkowitz HN, Dvorak J, Bell GR, eds. *The Lumbar Spine*. 2nd ed. Philadelphia: WB Saunders, 1996:473-91.
33. Ljunggren AE, Weber H, Kogstad O, Thom E, Kirkesola G. Effect of exercise on sick-leave due to low-back pain: A randomized, comparative, long-term study. *Spine* 1997;22:1610-17.
34. Mälkiä E, Ljunggren AE. Exercise programmes for subjects with low back disorders. *Scand J Med Sci Sports* 1996;6:73-81.
35. Malmivaara A, Häkkinen U, Aro T, et al. The treatment of acute low back pain: Bedrest, exercises, or ordinary activity? *N Engl J Med* 1995;332:351-5.
36. Manniche C, Lundberg E, Christensen I, Bentzen L, Christensen I, Lundberg E. Clinical trial of intensive muscle training for chronic low back pain. *Lancet* 1988;2:1473-6.
37. Mayer TG, Gatchel RJ, Kishino N, et al. Objective assessment of spine function following industrial injury: A prospective study with comparison group and one-year follow up. *Spine* 1985;10:482-93.
38. Mellin G, Härkäpää K, Vanharanta H, Hupli M, Heino R, Järvikoski A. Outcome of a multimodal treatment including intensive physical training of patients with chronic low back pain. *Spine* 1993;18:825-9.
39. Mitchell RI, Carmen GM. The functional restoration approach to the treatment of chronic pain in patients with soft tissue and back injuries. *Spine* 1994;19:633-42.
40. Nachemson A. *Ont I Ryggen: Orsaker, diagnostikk och behandling*. Stockholm, Sweden: Statens Beredning för Utvärdering av medicinsk metodik (S.B.U.), 1991.
41. Oland G, Tveiten G. A trial of modern rehabilitation for chronic low back pain and disability: Vocational outcome and effect of pain modulation. *Spine* 1991;16:457-9.
42. Riksförsäkringsverkets statistikinformation Is-R5, 1987 (In Swedish).
43. Risch SV, Norvell NK, Pollock ML, et al. Lumbar strengthening in chronic low back pain. *Spine* 1993;18:232-8.
44. Rosen M. *Back Pain: Reports of a Clinical Standards Advisory Group (C.S.A.G) Committee on Back Pain*. London: H.M.S.O., 1994.
45. Schultz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias: Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 1995;273:408-12.
46. Skargren EI, Öberg B, Carlsson PG, Gade M. Cost and effectiveness analysis of chiropractic and physiotherapy treatment for low back and neck pain: Six-month follow-up. *Spine* 1997;22:2167-77.
47. Spitzer WO, LeBlanc FE, Dupuis M, et al. Scientific approach to the assessment and management of activity-related spinal disorders: A monograph for clinicians. Report of the Quebec Task Force on spinal disorders. *Spine* 1987;12(Suppl):4-55.
48. Spratt KF, Weinstein JN, Lehman TR, Woody J, Sayre H. Efficacy of flexion and extension treatments incorporating braces for low back pain patients with retrodisplacement. *Spine* 1993;18:1839-49.
49. Teasell RW, Harth A. Functional restoration: Returning patients with chronic low back pain to work. Revolution or fad? *Spine* 1996;21:844-7.
50. Torstensen TA. The physical therapy approach. In: Frymoyer JW, Ducker TB, Hadler NM, Kostuik JP, Weinstein JN, Whitecloud III TS, eds. *The Adult Spine: Principles and Practice*. 2nd ed. Philadelphia: Lippincott-Raven, 1997:1797-1805.
51. Torstensen TA, Koes B, Glomsrød E, Seifert L, Glomsrød B, Hagen O. Letter to the editor. *Spine* 1996;21:656-7.
52. Van der Heijden GJMG, Beurskens AJHM, Dirx MJM, Bouter LM, Lindeman E. Efficacy of lumbar traction: A randomized clinical trial. *Physiotherapy* 1995;81:29-35.
53. Van Tulder MW, Koes BW, Bouter LM. A cost-of-illness of back pain in the Netherlands. *Pain* 1995;62:233-40.
54. Van Tulder MW, Koes B, Bouter LM. Conservative treatment of acute and chronic non specific low back pain: A systematic review of randomized controlled trials of the most common interventions. *Spine* 1997;22:2128-56.
55. Videman T, Leino-Arjas P. A comparison of medical exercise, the McKenzie approach, and traditional physical therapy in the treatment of occupational LBP patients. In: McKenzie R, Donelson R, eds. *Fifth McKenzie Institute International Conference*, Philadelphia, Pennsylvania, September 12-14, 1997.
56. Volinn E. The epidemiology of low back pain in the rest of the world: A review of surveys in low- and middle-income countries. *Spine* 1997;22:1747-54.
57. Waddell G. A new model for the treatment of low back pain. *Spine* 1987;12:632-44.
58. Waddell G. Clinical assessment of lumbar impairment. *Clin Orthop* 1987;221:110-20.
59. Wood PHN. The language of disablement: A glossary relating to disease and its consequences. *Int Rehabil Med* 1980;2:86-92.

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VI. MATERIAL AND METHODS

Additional information to the Spine publication (5)

The Spine study (5) (Figure 1, page 26) was designed as a prospective randomised pragmatic trial with block randomisation regarding sex, comparing three different interventions, MET, CP and SE as walking (a modified Indahl intervention). Patients with either local lumbar back pain or with radicular pain sicklisted for more than 8 weeks and less than 52 weeks (Sickness Certificate II) were evaluated for inclusion.

When the patient's local insurance office received a sickness certificate II, the certificate was reviewed by staff at the insurance office regarding what ICPC codes were used. If one of the following codes were used by the medical doctor; L02, L03, L84, or L86, written information was sent to the patient about the project describing the project and the different interventions. The patient could withdraw from the project at any time. Patients that returned their written consent to participate back to the local insurance office, where contacted either by the nurse, or a physiotherapist who on the phone went through the written information about the project as well as the inclusion/exclusion criteria. Those that did not fulfil the inclusion criteria were excluded on the phone. Patients that for some reason had misunderstood the written information sent from the insurance office, could if they wanted, withdraw from participating in the study. The patients who still gave their consent and fulfilled the inclusion criteria, were invited for a 4 hours assessment by a nurse, a medical doctor, and a physiotherapist at the University of Sports and Physical Education.

When the patient arrived at the medical office, they were informed by the nurse how to fill out the extensive questionnaire. The questionnaire contained questions regarding common background variables, the history of their back pain, social-, and life style variables. The patients' pain level and quality of pain and function was also registered. (See Spine publication (5), page 15 for further information). After answering these questions, which took from 30-45 minutes, the patient went through a standardised assessment by a medical doctor and a nurse. Again the patient was evaluated in relation to the inclusion/exclusion criteria, making it clear that there would be a randomisation process regarding the three interventions. Thus, the patient should at randomisation have no preference regarding the three different interventions.

The treatment for all patients in all three groups lasted for 3 months (36 treatments). There were three treatments a week, each treatment lasting approximately one hour.

Medical Exercise Therapy (MET).

The MET treatment were given by physiotherapists working at physiotherapy clinics that had specialised in this approach and who followed the criteria for medical exercise therapy (21, 22, 23, 24, 25, 26). The treatment consisted of exercises only, ranging from 7 to 9 different exercises doing from 2 sets of 20 to 30 repetitions to 3 sets of 20 to 30 repetitions. The treatment lasted at least one hour not including warm up. The exercises were designed according to the patient's symptoms, choosing comfortable starting position, working through the comfortable, preferred range and direction of motion. The speed was one repetition every two seconds having 30 to 60 seconds brake between each set. Performing one exercise before moving on to the next, the three sets were performed after each other using the principle of interval training. Starting positions in standing deloaded, lying, standing loaded, sitting and others were used to improve function (27).

The MET treatment initially focused on improving dynamic stability of the lower lumbar spine using functional standing starting positions working the upper extremity with the lower extremity stabilising the back. Focusing on patient awareness performing pelvic rotation, and stabilising the pelvis by tightening the abdominal muscles, the gluteal muscles and the pelvic floor. Both global and more local exercises where used for this purpose.

If the conclusion from the assessment was that the dysfunction could be related to a stiff lumbar spine, an increase in mobility was aimed for. Mobilising-, co-ordination-, and stabilising exercises to improve muscular balance and motor control were used to reach this goal. If the conclusion from the assessment was that the dysfunction was caused by a mobile/hypermobility lumbar spine, an increase in stability was aimed for applying both stabilisation-, and co-ordination exercises, improving muscular balance and motor control. For many patients mobilising exercises were also given if the patient had a stiff thoracic spine where thoracic segments were either mobilised globally or locally (segmentally), taking off some of the stress on the lumbar spine.

In accordance with the initial finding from the physiotherapy assessment of the patient's preferred range and direction of movement, exercises were performed in flexion, extension, rotation, and side flexion. Specially designed exercise equipment was used to optimally grade the loading of the exercises, applying the principles of gravity assisting, gravity resisting,

unloading/deloading the trunk. Weights from the lat.pulley, ordinary pulleys, dumbbells, barbells, and weight cuffs were also used to increase the resistance when exercising..

Conventional physiotherapy treatment (CP)

The patients receiving the CP treatment was treated at physiotherapy clinics in Oslo that combined methods in a pragmatic fashion. The physiotherapists were given written information about the study and that their treatment should not differ from what they normally did. The physiotherapists treating patients in the CP group combined heat/cold, different forms of electrotherapy (ultrasound, TENS, laser, interferential therapy and short wave diathermy), traction, stretching, mobilisation (no manipulation), some exercises on the treatment table and information. However, it was made clear that these patients should not have a large exercise program like the MET approach. Each therapist filled in a formulary regarding what methods he/she used/combined for each patient at each treatment. Each treatment lasted for approximately one hour.

Self exercise (SE) as walking – a modified Indahl intervention.

The patients walked approximately for 1 hour 3 times a week in their neighbourhood. At randomisation the positive effects about physical activity as walking was explained, increasing the blood flow to the muscles of the back. Further, that walking is the most basic and important movement for the back, normalising the mobility and function of the back. A physiotherapist phoned each patient every 14 days to make sure that the patient complied with the intervention that they had been randomised to. The conversation on the phone was focusing on the advice/information about the importance of maintaining a normal function as walking. Patients that expressed dissatisfaction with the intervention were motivated to keep at it with the prospect that it would take some time before any improvements could be expected.

Outcome measures.

Pain intensity was measured using a visual analogue scale (VAS), function was measured using a functional questionnaire, The Oswestry Low Back Pain Questionnaire (5). Patient satisfaction was evaluated, and return to work was registered both in % at 12 months follow up, and in numbers of days on sick leave from inclusion to 15 months later (3 months intervention period + 12 months follow up). Costs for treatment as well as for being on sick leave was calculated.

Statistical procedures.

Intention-to-treat analyses were performed with all participants in the study. Patients dropping out for reasons other than the treatment to which they had been randomised (dropout Type A) were given the baseline registration for the missing data points during the follow-up period. At the follow-up assessment, patients dropping out because of the treatment to which they were randomised (dropout Type B) were given the worst score registered for any patient in their treatment group. The mean value was used as an index of localisation, and standard deviation as index of dispersion. One-way analyses of variance were used for differences between the three intervention groups at any given time. Repeated measures (analyses of variance) were applied for variables with registrations over time. The assumptions for the statistical methods were checked using Jackknife residuals, Cook's *d*, and Mallows *C_p*. Time to event were analysed with a log-rank test. The level of significance was set at 0.05, and all tests were two-sided.

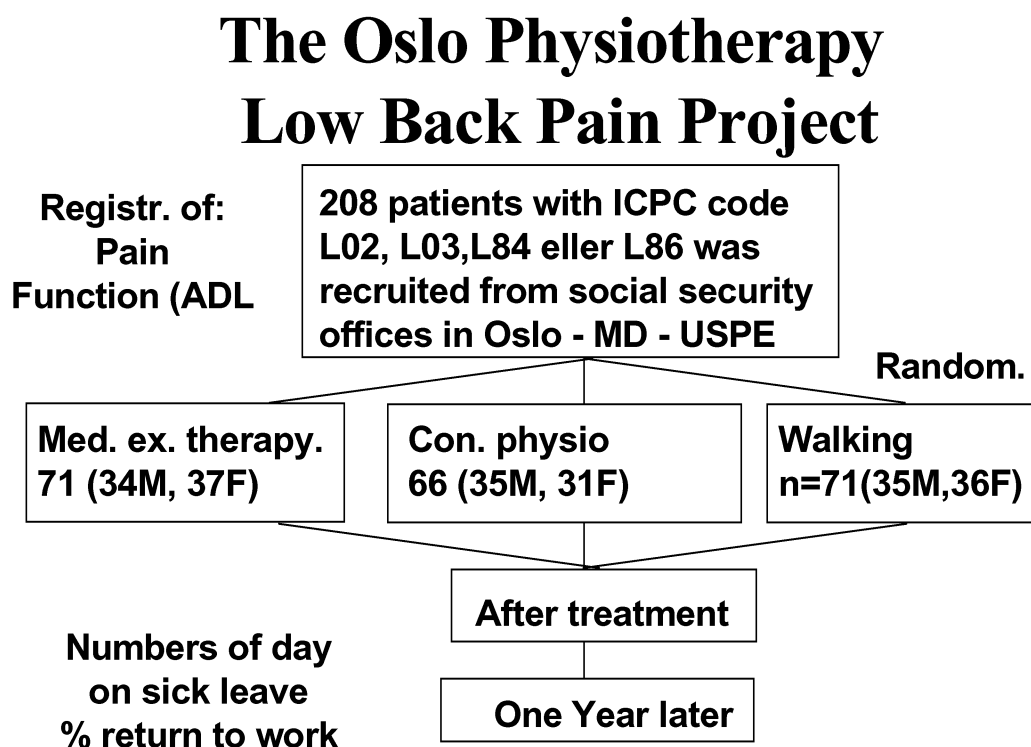


Figure 1: The design of the “The Oslo Physiotherapy Low Back Pain Project”. MD is the medical doctor at the University for Sports and Physical Education (USPE). M=male, F=women.

VII. BRIEF SUMMERY OF THE RESULTS
Additional information to the Spine publication (5)

Thirty-three (15,8 %) patients dropped out during the treatment period. There were no dropouts at the one year follow up. After treatment and at one year follow up, no difference in function, pain or return to work was observed between the medical exercise therapy and conventional physiotherapy groups, but both were significantly better than the self-exercise group. Patient satisfaction was highest for medical exercise therapy. RTW rates were equal for all 3 intervention groups at assessment 15 months after therapy was started, with a total of 123 out of the 208 included patients back to work. Forty-one patients (57.7%) in the MET group, fortytwo patients (62.7%) in the CP group, and forty patients (57.1%) in the SE group had returned to work at one year follow up. However, when looking at number of working days off on sick leave for each group during the intervention and follow up period (15 months), the MET group had 11757 days, the CP group 9967, and the SE group 13567. There were no statistical differences between the groups. Keeping in mind that there were no statistical significant differences between the groups one can still calculate the costs for days on sick leave. Using an average number of 600 NOK as costs per working day, the medical exercise therapy group saved 906.732 Norwegian Kroner (NOK) (\$122.531.00) and the conventional physiotherapy group saved NOK 1.882.560 (\$254.200.00), compared with the self-exercise group.

After the Spine publication (5) in 1998 we have recognised the fact that 600 NOK is far too low, and that a more correct cost per working in day in 1994 was 1.500 NOK.

Patient satisfaction was highest for male patients in the MET group and lowest for male patients in the SE group.

VIII. GENERAL DISCUSSION

METHODOLOGICAL EVALUATION I

- Letter to the editor from Eriksen and Ursin*
- Methodological shortcomings of the Indahl study*
- Validity of return to work as an outcome measure*
- Comparison of systems*
- Medical doctors sicklisting practise*
- Using return to work (RTW) as outcome measure*
- Indahl et al. 5 year follow up*
- Molde Hagen`s replication of the Indahl study*
- RTW rates in 4 Norwegian and 1 Swedish study*

METHODOLOGICAL EVALUATION II

- The Cochrane Back Review Group*
- Hansen et al. study (1993)*
- Hemmilä et al study (1997)*
- Torstensen et al. study (1998)*
- Why do different interventions come out indifferent?*

The efficiency of MET and CP is shown. Leaving patients with long lasting low back pain untampered poses a risk of worsening the disability, resulting in longer periods of sick leave.

The results from the study are conclusive, giving a better understanding that a pragmatic approach combining different methods as the physiotherapists normally would do clinically, is an effective approach for treating chronic back pain. The methods used in such a pragmatic approach have in systematic reviews (16, 28) and clinical guidelines from Sweden (29, 30), Denmark (31), Norway (32), Canada (33), United Kingdom (34) United States (35), New Zealand (36), of having no positive effect either for acute or chronic low back pain. However, after the well performed systematic reviews by van Tulder et al. (19,20), conventional physiotherapy performed in a pragmatic fashion, may in the future be accepted as an effective treatment approach. An approach where physiotherapists combine methods related to the patient's signs and symptoms needs and wishes.

Methodological evaluation I

Letter to the editor from Eriksen H, and Ursin H

The current study (5) has been evaluated by Eriksen and Ursin in a letter to the Spine editor (14), and The Cochrane Back Review Group (19,20).

In the second paragraph in their letter to the editor Eriksen and Ursin (14) state; *"This seems quite impressive (the results from the current study (5)), but we believe the conclusion to be wrong. Quite to the contrary, we believe that their "control" group (The modified Indahl intervention) was given a peculiar and unusual treatment, even for Norwegian medical practice. The patients were allowed to walk on their own around Sognsvann, a lake north of the University of Sports in Oslo, three times a week. The patients did not seem to like the "treatment", a large number refused to participate, and less than half were satisfied (41%). In no way does this treatment represent a "control" group or is representative of what anyone in Norway would offer their patients. Our conclusions is that it was this peculiar treatment that was rather expensive for society and for the patients"*, and Eriksen and Ursin continue in paragraph 4; *"the reason for offering their peculiar treatment is an apparent misunderstanding of the therapeutic principles offered by Indahl et al. (6). A prescription of three walks around Sognsvann per week does not leave patients "untampered". Judging from*

the patients reports and behaviour, it sounds more like a “nocebo” treatment – the opposite of placebo. It certainly differs from Indahl’s aggressive fear reduction and encouragement of “normal” activity. The results obtained by these authors in their two “treatment” groups have a sickness compensation level corresponding to other twice the level reported if the patients had been offered the real Indahl treatment.

When designing the Oslo Physiotherapy Low Back Pain study, we carefully chose not to have any control group or placebo group but three comparison groups. Both ethical and methodological problems arising when including a placebo control group is well articulated in the literature, thus we wanted to comply with the latest recommendations not putting patients through unnecessary strain participating in the study. The patients did not walk around Sognsvann but were told that they could walk wherever preferred. Further, the included patients came from all parts of Oslo, making it impossible and impractical to make them all walk around Sognsvann. Some walked in the forests around Oslo, and others on the pavement in the area they lived. These patients were followed up on the phone every 14 days, a total of 6 contacts each lasting from approximately 5 to minutes to 15 minutes duration, making sure that they did the self-exercise as walking. During these conversations the message at randomisation was reinforced; that their back pain was not dangerous, they should stay active resulting in increased blood flow to muscles and other structures in the back etc.

During the early 1990s Aage Indahl presented his approach at several meetings in Norway. I attended several of them and what Indahl was focusing on was the importance of being active, normalize the gait, as well as trying to be as flexible as possible, or to quote from his Spine publication in 1995 (6), page 474, 5th paragraph; *“regardless of the cause of LBP, our view that the back problems are mainly caused by enhanced stabilization by the lumbar paraspinal muscles was stressed. All patients, regardless of findings, were told to mobilize the lumbar spine by light activity. No fixed exercise goals were set by the therapist, but rather the patients were given the guidelines and encouragement to set own goals as this has been shown to give better effect. Great emphasis was put on the effort to remove fear about LBP and focus on sickness behavior. Major misunderstandings about the causes of LBP were dealt with”*. In the Spine publication (5) the modified Indahl intervention was described the following way; *“Maintaining an ordinary activity level: Self exercise by walking. All patients included in this group received information about self-exercise by walking and the importance of this activity for the back . The patients were to walk for one hour three times*

each week. The walking was not organized and could be performed individually whenever the participant had time. Preferably there was to be 1 day rest between each hour walking.

When the patient was randomised to the self-exercise group, the nurse explained why walking and maintaining a normal activity level was important. That the walking would increase the blood supply to the back muscles, that it would loosen up the muscles of the back and normalise function. The reason why we decided to make the patient self exercises as walking three times a week each of one hour, was to make sure that all patients in all three intervention groups were given the same amount of intervention, a total of 36 treatments each of approximately 1 hour. This should in principle be correct according to the original Indahl intervention (6), opposing Eriksen and Ursin implications. However, we designed our study to make sure that we kept records as to what happened to the patients allocated to the self exercise group, which was not the case for the Indahl study (6). We did probably not give the patients as much information as Indahl (6) in relation to removing fear about back pain, sickness behaviour, and general information about back pain. Nobody would today disagree with Indahls approach. It is a common sense approach dealing with back pain at an early stage.

Methodological shortcomings of the Indahl study

In a letter to the Spine Editor (37) we discussed different methodological weaknesses related to the Indahl study. The problem of validity and sensitivity related to using return to work as an outcome variable, how letters to the patient's primary physician and the patient's local insurance office may have influenced the termination of sick leave. Another weakness is that the investigators did not control for compliance in the experimental group and the fact that the randomisation method used (alternation) probably does not prevent bias sufficiently. The different aspects are discussed below in more detail:

- 1) The methodological issues concerning Indahl's study are a weakness in relation to the internal validity of the study. The patients in the control group never knew that they participated in a study, nor did their primary physicians responsible for terminating sick leave know that their patients were taking part in a study. Thus, an important part of the intervention in the Indahl study was knowledge about participating in the study, being called to the Back Clinic, answering a whole range of questionnaires, taken care of, being assessed, taken x-rays or CT/MRI scans, the intervention with fear reduction and waking, the three months and one year follow ups at the Back clinic.

- 2) It is questionable if Indahl's study should be called a randomised clinical trial (RCT) because in a true RCT all patients are physically included when randomisation occurs. This is done to give all included patients the same amount of attention from being assessed and from knowing that they are participating in a research project. In this case the experimental group are getting all the positive effects of both the placebo and the Hawthorne effects, while the control group do not even know that they are participating in the study. This methodological shortcoming makes it difficult to determine if the results are due to the Indahl intervention (6) or the confounders described above.
- 3) The investigators did not control for compliance in the experimental group. During the follow-up period, patients in the experimental group may have received physiotherapy or other kinds of therapy. No information is presented about possible co-interventions, so the effect of the initial described intervention may thus be contaminated.
- 4) Another methodological shortcoming is that the randomisation method used (alternation) probably does not prevent sufficient bias. It is also unclear from the study whether the outcome assessment (i.e., return to work) was assessed in a strictly blinded manner.
- 5) After being assessed at the Low Back Pain Clinic at Østfold Central Hospital, a letter was sent to the patient's primary physician with a copy to the patient's local insurance office. The letters basically state that there is no serious pathology and nothing really wrong with the patient's back. Such a letter might have been a very important instrument for the primary physician to terminate sick leave, because the patient had been assessed properly by a low back pain specialists, x-rays and even CT or MRI scans were taken, and no serious pathology was discovered. Also knowing that a copy of the letter was sent to the local insurance office might have pushed the primary physician even more to terminate sick leave.
- 6) Another shortcoming of the study was to use return to work as the only outcome measure. Even though RTW may be regarded the ultimate success of an intervention, the validity and sensitivity of RTW as an outcome measure remains questionable (38, 39, 40, 41), and recommends that other more valid and sensitive effect variables be used to evaluate interventions for back pain. Return to work does not necessarily correlate with a patient's symptoms or any other variable related to the low back pain dysfunction. Many return to work despite the fact that they still have back pain and sciatica, while others are on long term sick leave with what could be characterised as minor, non significant symptoms. The reason for the discrepancy between symptoms and return to work are all the different factors influencing a person's ability to RTW, such as individual-, psychological-, and

social factors. There is today evidence that there is little or no correlation between pain, impairments and disability (42, 43). To confuse matter even more there is little or no correlation regarding RTW rates and health professions recommendations and beliefs regarding RTW. This was compared in a study (44) where the group of patients who were given no recommendations regarding return to work had a higher RTW rate at one year follow up compared to the comparison group where health professionals intervened giving advice regarding full or partial RTW. Return to work is obviously a complicated issue probably influenced more by other factors than those that health workers traditionally believe in.

Validity of return to work as an outcome measure

Through research at least twelve different variables have been identified that significantly will influence RTW. Many factors that are not related to low back pain specifically (45), but to individual-, social-, and psychological variables.

1. The length of the period being on sick leave with back pain: This factor is normally measured from the time one experienced the back pain or from the last day at work. The longer one has experienced the back pain or the longer one has been off sick leave, the poorer is the end result with increased disability and early retirement (46, 47, 48, 49). One study found that the chance of returning to work after 6 months on sick leave was only 50% and after two years off work due to back pain the RTW rate was close to zero (46).

2. The seriousness of a trauma resulting in a back injury: The size and complexity of a back injury and the prognosis of such an injury correlate significantly with the ability to ever to return to work (47, 50, 51). Back injuries generally and injuries in the lumbar area specifically indicators for a poor prognosis in relation to return to work (52).

3. Age: Several researchers have reported that age is a significant factor in relation to return to work (53, 54, 55, 56, 57,). Increasing age coincide with an increasing chance of not returning to work.

4. Education: Higher education is synonymous with an increased chance of returning to work (58, 59). There might be several reasons for this, one being that a person with higher education probably has greater possibilities to make work changes to accommodate for his/her painful back. Another factor is that the type of jobs people with higher education have, usually do not involve a lot of heavy repetitive lifting with rotations. Lower education is more often associated with a more physical heavy type of work, which may make it more difficult to return to work when one already has back pain. Heavy, repetitive manual work is not

necessarily a risk factor for getting back pain, but when a person has back pain this type of work may be a poor prognostic factor for returning to work. However, Hagen et al. (57) found that education and socio-economic status are strong independent predictors for an increased incidence of disability retirement from back pain.

5. Socio-economic status: In a large population based study from Norway (57) including all employed men and women in Norway between the ages of 20 and 53 years in 1980 (n = 1,333,556), there was a consistent upward trend in the association between the disability retirement from non-inflammatory back pain and lower socio-economic position.

6. Sex: Men compared with women has a greater chance of returning to work (55). Hagen et al. (57) demonstrated that disability retirement from back pain was somewhat higher in women than in men.

7. Civil status: People who are married have a greater chance of returning to work (55).

8. Level of pain: Poor results in relation to return to work is associated with a high level of pain experience (50, 59), and sciatica with a positive lasegues test (60).

9. Site/distribution of pain: Hagen et al.(61) has shown that patients with sciatica return to work at a slower rate compared to patients with pain in the lumbar area only.

10. Psychosocial factors: Self experienced low level of function (62), high numbers of "pain descriptors" (63), depression (64), hysteria (65, 66, 67), hypochondriasis (68), and patients with an "introversive style" (69) are associated with low return to work. Low satisfaction with type of work, the work place generally, and with the closest superior boss (59, 60, 68, 70), increased stress, and misuse of alcohol is also documented to have a negative effect on return to work (59, 68).

11. Occupation: A high perceived work pressure/load is negatively associated with return to work (48, 56, 71). Tate (55) found that a higher work position was associated with an increased chance for returning to work. A good relationship with the employer was the strongest predictor for returning back to work in a rehabilitation period (72).

12. Environmental/societal factors: Compensation claims for an injury is associated negatively with return to work. The patient has to be sick (stay in a sickness/illness role) to be able to get the compensation, hence there is little motivation for improvement in relation to symptoms or RTW (73, 74,), juridical supports (46, 75), and relative good economy are all negatively correlated to RTW.

Deyo et al. (40) is sceptical to the use of RTW as the only outcome measure, page 2033S, second column, second paragraph, quote; "*Some observers advocate measuring only return to*

work as a treatment outcome for back problems, arguing that it is socially relevant and can be objectively measured. However, return to work is not simply a function of medical care but of the job environment, job autonomy, the availability of other sources of income, closeness to retirement age, and local economic conditions. It would be hazardous to judge the effectiveness of medical therapy on this basis alone, and the problem illustrates the value of multidimensional outcome assessment.”

One cannot conclude as to how much the above variables have influenced the return to work rates in Indahl's study, but in a research study they must not be ignored but discussed as possible confounding factors explaining the results. However, it is a fact that the Indahl study is suffering from a range of methodological shortcomings making it difficult to conclude that the impressive results regarding RTW, is due to the intervention described by Indahl (6) page 474. In light of the potential confounders presented above, Indahl's conclusions (6) need to be interpreted with caution.

Comparison of systems

In fact what Indahl did compare in his study was two systems. System one was the effect of being assessed at an early stage (8 weeks of sick leave) at a specialist back pain clinic including the described intervention. The second system was the effect of being treated by a primary medical doctor in a primary health care setting. Thus, Indahl did not leave his patients untampered, rather the opposite, performing an extensive intervention. It might have been more correct if Indahl had focused on this aspect in his original publication (6). In his answer (76) to our letter to the Editor (37), he writes that the trial was designed to test the effect of his intervention (at the specialist Back Pain Clinic) compared to the conventional system in Norway. If this is the case the original article published in 1995 should have had a different focus, discussing the difference systems, and how the systems themselves contributed to the major difference regarding RTW. He should have discussed the weaknesses and problems for the primary medical doctor being responsible for the sick listing. The primary physicians in Østfold county are according to Indahl's results doing a poor job getting patients back to work. It is therefore of interest to look at Indahl's results in relation to medical doctors sick-listing practise.

Medical doctors sick listing practise

In a Norwegian study (77) it was shown that the attitude of the physician when it comes to sick-listing could be described as two-phased. In the beginning of the sick listing period the general practitioners (GP) do what they can to get the patient back to work, but when not successful in this task, they tend to motivate the sick-role medically. In another Norwegian study (78), out of all consultations where sick-listing was considered, 91% were sick-listed. If patients took the initiative for certification, 95% received a certificate, while only 84% were certified sick leave when the initiative was taken by the doctor. It was concluded that the patient is a stronger controlling element than the GP. Haldorsen et al. (79), reported that there is an apparent random level of decision making for sickness certification for non specific musculoskeletal pain by medical doctors. They looked at the concept of disease, illness (being ill), and criteria for issuing sickness certificate for musculoskeletal pain using a postal survey based on case histories.

In Sweden Englund et al (80, 81) have found that sick listing is influenced by the medical doctor's speciality and sex as well as the patient's attitude to be sick listed. The patient's attitude to be sick listed was found to be the most important factor affecting sick listing where patients wishing sick-listing were sick-listed to a greater extent than those who were reluctant. In addition, GP sick-listed more than orthopaedic surgeons and less than psychiatrists. Female doctors sick-listed more than male doctors, irrespective of speciality and patient attitude. Haldorsen et al. (79) found that older GPs suggested sick listing more than younger ones, and that it was a tendency of female medical doctors to express more uncertainty in their decisions for acute low back pain and generalised muscle pain regarding sick listing. Englund et al. (80, 81) have also reproduced the findings from Norway (78), and found that 9% of all consultations included a consideration about sick-listing, and in only 6% of these instances was a certificate not issued. Thus 94% were sick listed. Musculoskeletal problems were by far the most common diagnosis. Female patients were more common partially sick-listed than males. Female GPs sick-listed a larger proportion of their patients than male doctors. Risk factors for long certification periods were in fact associated with long certification periods. Even in cases where the GP would not recommend sick-listing a certificate was issued in 87%. The opinion of the professional party therefore seems of limited importance in the decision to sick listing.

The letter from a Back Pain Specialist at the Back Pain Clinic at Østfold Central Hospital (6) may have played an important role for the GP's decision making regarding terminating sick leave. The general message from these letters stating that there is basically nothing wrong with the patients back, the fact that the letter comes from a specialist in back pain care, and the fact that a copy of the letter was sent to the patients local insurance office, are all confounding factors probably influencing the high RTW rate.

Setting aside all methodological shortcomings of the Indahl study as a research project, rather looking at it as a cohort study with two comparable groups, each representing two different systems to handle patients, there is no doubt that one "system" came out significantly better than the other. Thus the conclusion from the Indahl's study should have been that each county in Norway should establish a specialist Back Pain Clinic. Unfortunately did Indahl not focus on these important aspects in his original article (6).

Due to the methodological shortcomings of the Indahl study it is unclear what caused the positive effect. If it was, quoting Eriksen and Ursin (14); "*Indahl's aggressive fear reduction and encouragement of "normal activity"*", or other factors described above, or a combination of them all.

Other studies using RTW as outcome measure

There is evidence from several methodological high quality studies that such an approach is effective in patients with acute low back pain (82, 83). Also other treatment approaches have documented a high RTW rate for patients with acute and subacute LBP. Blomberg et al. (84, 85) was able to show a statistical significant difference regarding RTW comparing manual, therapy with steroid injections versus a pragmatic physiotherapy approach. At one month follow up Blomberg et al. showed that sick leave was 6 times higher in the group receiving conventionally physiotherapy. Even though the difference between groups did decrease over time, the proportion on sick leave at 8 months follow up was still statistical significant being 2.3 higher in the conventional physiotherapy group. At 8 months follow up 92% in the manual therapy combined with steroid injections had RTW while in the comparison group 81% had RTW.

For sub-acute low back pain, only one methodologically well performed study have been able to show positive effects regarding reducing sick leave returning patients to work. Lindström et

al. (86, 87, 88, 89) evaluated the effect of a fairly extensive intervention consisting of work place visit and on the basis of the visit designing an individual, sub-maximal, gradually increased exercise program with an operant-conditioning behavioural approach. Lindström et al's study is in many ways similar to Indahl et al's study, where Lindström et al. included patients that had been off work for at least 6 weeks and Indahl included patients that had been off work for 8-12 weeks. Lindström et al's control group was also given the treatment by the general practitioner, thus as Indahl et al. comparing two different systems. However, the big difference between the Indahl et al's study and the Lindström et al's study is that Lindström et al's study is of a high methodological quality getting the highest score (10 points) of the 20 studies included in the latest quality assessment of randomized controlled trials on the effectiveness of behavioural treatments for chronic low back pain (90). Indahl et al's study is not included in this review, and has since the original publication in 1995 never appeared in any of the systematic reviews within the framework of the Cochrane Back Review Group.

Indahl et al. 5 year follow up

In 1998 Indahl et al. published a five year follow up (17) still showing a highly significant difference between the two groups with regards to RTW. Eighty-one % from the active intervention group had returned to work, while 65% from the control group. Indahl et al. now explain very detailed, and probably more accurately, the intervention which took place some 5 years ago. In this publication (17) and another publication by Haldorsen et al. (91) the experimenters are assessing a whole range of psychometric variables. It is of course interesting to look at which variables are predicting return to work etc, but now a so-called randomised trial is "changed" to a cohort study where all the information about psychosocial issues have only been collected from the active intervention group that attended the back clinic. When doing a randomised trial all patients in all intervention groups must answer the same questions (questionnaires). Indahl et al. compares the difference between two groups looking at RTW rate as the only outcome variable. The next step would then be to look at predictors for outcome in both groups, and in this case how psychosocial variables could explain the difference in RTW found between the two groups. How the different interventions affected these variables and if they predicted outcome. However, in the Indahl et al. study (6,17) we have no information about these variables for the so-called control group. Thus the analyses by Haldorsen et al. (91) on Indahl et al's material is insignificant and uninteresting because we only get information about the group that came to the Back Clinic. What we want to know are the effect on these psychometric measures from the Indahl intervention, or to

quote Eriksen and Ursin; “*Indahl’s aggressive fear reduction and encouragement of “normal” activity*”, but then we need a group to compare data with. So in fact we have no knowledge if the Indahl intervention was a result of fear reduction and increased normal activity, which is really what Eriksen and Ursin bases their critique on (14). Today this is a hypothesis and to test the hypothesis a proper randomised trial has to be performed, a research design which is the golden standard in clinical research for evaluating effect of an intervention (92).

Molde Hagen`s replication of the Indahl study

Molde Hagen et al. (93, 94) have performed a similar study to Indahl et al’s. (6,17), with very much the same type of intervention, but the design much improved with the control group and the patients medical doctor knowing that they participated in the study. All included patients in both intervention groups filled out the same questionnaires at their local insurance office. Then they were randomised either to Molde Hagen’s Indahl intervention or back to the patient’s medical doctor’s treatment. In addition to informing about the positive effects of staying active, written reports from the spine clinic examination were sent to the patients GP and to the local insurance office, along with diagnosis and recommendations concerning the need for further diagnostic tests, treatment, job, and further sick leave. Molde Hagen should be commended for describing the “whole” intervention in detail. However, Molde Hagen was not able to reproduce such conclusive results regarding RTW as Indahl reported.

The results from Molde Hagen’s intervention with fear reduction, informing that back pain is not dangerous, stimulating normal activity, resulted initially in a higher RTW rate compared with the GP’s treatment. The difference in RTW showed a significant difference at 3 months follow up with 51.9% versus 35.9% RTW, at 6 months follow up 61.2% versus 45% RTW and at 12 months follow up 68.8% versus 56.4% RTW, all in favour of the Indahl et al. approach. Molde Hagen et al. (94) has also performed a two-year follow up which was presented at the Norwegian Society for Low Back Pain Research annual meeting in April 1999. The data presented showed that the significant difference between the two groups regarding RTW at one year follow up had disappeared and even turned, showing a higher RTW for the control group, the GPs treatment giving a RTW of 65.6% compared to 62% RTW for the intervention group (94).

One confounder explain the patients medical do very active intervention back pain as well as the obvious confounder the patients (24.4%=58 pat Indahl intervention. physiotherapist. One c because they were not s fear reduction, and ligh that additional treatment question is what type research point of view handled as drop outs ty probably dropped out b true RCT, Molde Hage predict a positive or a What are the characteri Molde Hagen might ad Hagen et al.'s study i regarding RTW disapp were initially cost-effi behalf of the patient. S is a need for specialist l setting returning patient

Eriksen and Ursin in intervention is a noceb prior to doing the stud type B the same score including patients. All t Affairs (2). In fact usir discover any difference such major differences

effect in the modified Indahl intervention used in our study (5). If this is so, it is an extremely important finding showing that patients with longstanding chronic low back pain get worse with a modified Indahl treatment and drop out of the treatment because they are dissatisfied. Our conclusions are based on valid data, because we in a controlled manner followed-up all patients regarding co-interventions during both the 3 months-, and one year follow up. In our publication the need for additional treatments is reflected through the drop outs type B and the poorer outcome generally. In Molde Hagen et al's study (83, 84), the drop out type B is mirrored through the high percentage of co-interventions in the Indahl group (25%). It would have been of great value knowing the drop out rate and number of co-interventions in the original Indahl study (6). However, this was not reported (6, 17).

RTW rates in 4 Norwegian and 1 Swedish study

RTW is the outcome measure judged by society as the optimal measure for success of an intervention. However, RTW is a rough outcome measure, neither sensitive, reliable or valid. The RTW rates may differ due to methodological differences, the time the patients have been on sick leave or the actual intervention. This is shown in table 1 from four Norwegian studies (5,6,17,93,94,95) and one Swedish study (86, 87).

Table 1: Return to work rates (RTW) in four different Norwegian studies and one Swedish study. The rates vary considerably which may be due to the actual intervention or methodological issues. At one year follow up the rates vary from 52% to 70%. In the Spine publication the one year follow up rates are around 60%.

Lindström et al. (86,87)	Indahl et al. (6,17)	Molde Hagen et al. (93,94)	Torstensen et al. (5)	Haldorsen et al. (95)
Included patients had been up to 6 weeks on sick leave. <u>3 months follow up</u> 80% versus 58% RTW	Included patients had been on (8-12) w. on sick leave <u>12 months follow up (6):</u> 70% versus 40% RTW <u>5 years follow up (17):</u> 81% versus 65% RTW	Included patients had been (8-12) w. on sick leave <u>3 months follow up (83)</u> 51.9% versus 35.9% <u>6 months follow up (83):</u> 61.2% versus 45% <u>12 months follow up (83):</u> 68.8% versus 56.4% <u>2 years follow up (84)</u> No difference betw. gr. 62.0% versus 65.5%	Included patients had on average been on sick leave for 5 months. (mean value=5 mon) <u>12 months follow up</u> MET = 57.7% CP = 62.7% SE = 57.1%	Included patients had on average been on sick leave for 5 months. (mean value=5 mon). <u>12 months follow up</u> Functional restoration group 52% versus the primary care physician; 53%

What is interesting is that the RTW rate for the active interventions vary from 52% to 80%, while the RTW rate for the comparison groups vary from 35.9% to 65.5%. It also seems like the earlier the interventions are started, the RTW rate at one year follow up is higher (5, 6, 17, 93, 94, 95). It was unexpected that the RTW rate at the two-year follow up in the Molde Hagen study (93, 94) was higher for treatment given by the GP (65.5%) compared with the Indahl intervention (62%). In another Norwegian study (95) the treatment by the GP gave a slightly higher RTW (53%) at one-year follow compared with a functional restoration program with (52%) RTW. Keeping in mind that the included patients in our study (5) had on average been on sick leave for 5 months, the RTW rate for all three intervention groups at one year follow up was acceptable compared to the other studies in table 1.

METHODOLOGICAL EVALUATION II

The Cochrane Back Review Group

The Spine publication has been evaluated in a recent systematic review within the framework of the Cochrane Back Review Group (19, 20). A total of 39 RCTs on acute or chronic back pain were evaluated. Studies published until April 1999 was included in the review. Each study was evaluated according to the below 9 different criteria regarding their internal validity

Table 2: *The methodological quality criteria according to the Cochrane Back Review Group (20,96)*

<i>Methodological quality criteria:</i>			
1) Concealment of treatment allocation	Yes	No	Do not know
2) Withdrawal/dropout rate	Yes	No	Do not know
3) Co-intervention avoided or equal	Yes	No	Do not know
4) Blinding of patients	Yes	No	Do not know
5) Blinding of observer	Yes	No	Do not know
6) Intention to treat analysis	Yes	No	Do not know
7) Compliance	Yes	No	Do not know
8) Similarity of baseline characteristics	Yes	No	Do not know
9) Blinding of care provider	Yes	No	Do not know

Of all the 39RCTs only one study got 8 points (82), a study where Malmivaara et al compared McKenzie therapy, versus an active exercise program versus information about staying active and the positive effects of returning to work as quickly as possible. The latter group came out significantly better than the Mckenzie group and the active exercise therapy group. Four studies got 7 points (5, 97, 98, 30). In addition to our Spine publication (5), the other studies are Bronfort et al. (97) who included 174 patients with chronic low back pain into three different intervention groups comparing trunk exercise combined with manipulation

(chiropractic treatment), stretching exercises plus spinal manipulation, and exercises only plus NSAID (500 mg naproxen twice a day). He found no difference between the groups. Deyo et al. (98) included 145 patients with chronic low back pain and randomised them into 4 different intervention groups, relaxation and stretching exercises with active tens, relaxation and stretching exercises with sham tens, tens only, sham tens only. He found no difference between the groups. Lindström et al. (86, 87) included 103 blue collar workers that had been on sick leave for 6 weeks only, randomised them into two intervention groups. One group was getting an extensive intervention consisting of a graded activity program, measurement of functional capacity, workplace visit, back school education, and individual, submaximal, gradually increased exercise program with an operant-conditioning behavioural approach. The patients in the other intervention group were given the usual care by the company health care physician.

Table 3: The methodological quality evaluation according to the Cochrane Back Review Group (20,86), of The Spine publication (5).

<i>Methodological quality criteria:</i>		
1) Concealment of treatment allocation	Yes	1 point
2) Withdrawal/dropout rate	Yes	1 point
3) Co-intervention avoided or equal	Yes	1 point
4) Blinding of patients	No	0 point
5) Blinding of observer	Yes	1 point
6)...Intention to treat analysis	Yes	1 point
7) Compliance	Yes	1 point
8) Similarity of baseline characteristics	Yes	1 point
9) Blinding of care provider	No	0 point
Number of methodological points;7 points out of 9 possible points		

In van Tulder et al. systematic review (20) The Spine publication (5) get 7 out of a maximum 9 points for methodological quality. The weak points of our study were according to van Tulder et al (20) point 4, blinding of patients and point 9, blinding of care provider. Both these points are impossible to fulfil in a pragmatic randomised controlled trial. In the information to the therapists participating in the study, the design including the treatment methods were explained in detail. Similar information was also given to patients that were asked to participate in the study where design and intervention methods was explained in detail. This is in accordance to the Helsinki Declaration involving humans in clinical research. One may argue that it is only possible to blind patients and care provider in a RCT when using electrotherapy, for example ultrasound. In such a study both patient and therapist can be

blinded in relation to active versus placebo ultrasound. Thus, it is impossible to blind patients and therapists giving the treatment, when the interventions are active exercises therapies, massage, traction, heat and cold or self-exercise as walking.

Van Tulder et al. (20) conclude in the review ” *There is strong evidence that exercise therapy is more effective than usual care by General Practitioners (GPs) and that **exercise therapy and conventional physiotherapy** (consisting of hot packs, massage, traction, mobilisation, shortwave diathermy, ultrasound, stretching, flexibility and co-ordination exercises, electrotherapy) are equally effective.*

This conclusion is based on three studies (5,9,18) of high methodological quality. When reaching the above conclusion, Van Tulder et al. (20) used four different levels of evidence. For the evidence to be strong, the evidence should be provided by generally consistent findings in multiple high-quality RCTs. For a study to be methodologically rated in group one, the study must have 5 or higher methodological quality criteria points, see table 2 and 3.

Table 4: *The rating system is divided into 4 levels of scientific evidence, where only studies that get 5 or higher methodological quality criteria points qualify as high quality RCTs. For the evidence to be strong, the evidence should be provided by generally consistent findings in multiple high-quality RCTs.:*

Level of evidence rating:

- 1) Strong evidence: provided by generally consistent findings in multiple high-quality RCT's
- 2) Moderate evidence: provided generally consistent findings in one high-quality RCT and one or more low-quality RCT's, or by generally consistent findings in multiple low-quality RCT's.
- 3) Limited or conflicting evidence: provided by only one RCT (either high or low quality) or inconsistent findings in multiple RCT's.
- 4) No evidence : no RCT's.

The three studies (5, 9, 18) are the basis for the above conclusion by van Tulder et al. (20). .
The studies are described in detail below, table 5.

Table 5 below: Characteristics of the three high quality studies concluding that a pragmatic approach combining different modalities are an effective approach for patients with chronic low back pain. (cited from van Tulder et al. (20)).

Hansen et al. 1993 (9):

Study	Methods	Participation	Interventions	Outcomes	Notes	Quality
Hansen (1993)	RCT; minimisation procedure was used for randomisation	180 patients with (sub)chronic low back pain with or without radiation, self-referred through internal company newspaper, 123 men and 57 women, aged 21-64 years.	<p><u>Intervention 1:</u> Intensive dynamic back-muscle training: trunk lifting, leglifting, pull to the neck, 5 sets of 10 repetitions each, a total of 300 contractions, 1 hour sessions twice weekly for 4 weeks (n=60)</p> <p><u>Intervention 2:</u> Physical therapy: manual traction, hot packs, massage and flexibility, coordination and slowly progressive back and abdominal muscle exercises, 1 hour sessions twice weekly for 4 weeks (n=59)</p> <p><u>Intervention 3:</u> placebo control: semihot packs and light traction (10% of body weight), 1 hour sessions twice weekly for 4 weeks (n=61).</p>	No significant differences in pain level (10-point scale) between groups post-treatment and after 1, 6 and 12 months. Overall treatment effect (10-point scale) of intervention 1 and intervention 2 significant higher than intervention 3.	Methodological quality score: concealment of treatment allocation (+), co-interventions avoided or equal (+), blinding of patients (-), blinding of observer (+), intention to treat analysis (-), compliance (-), similarity of baseline characteristics (+), blinding of care provider (-); total score 5.	B

Hemmilä et al. (1997) (18)

Study	Methods	Participation	Interventions	Outcomes	Notes	Quality
Hemmilä (1997)	RCT; randomised by drawing lots	114 patients with non-specific chronic low back pain with or without radiation, referred to a health center, aged 17 to 64 years	<p><u>Intervention 1:</u> exercise program: bending and rotation exercises, 10 times every 15 minutes, sit-up, archup and trunk rotation exercises, 10 times each, twice a day, autostretching, max 10 one-hour sessions to ensure performance, 6 weeks (n=35).</p> <p><u>Intervention 2:</u> bone setting: gentle mobilisation in sitting position, max. 10 one-hour sessions, 6 weeks (n=45).</p> <p>Intervention 3; physiotherapy: manual, thermal and electrotherapy (massage, manual traction, mobilisation, hot/cold packs, short wave diathermy, ultrasound, TENS), max.10 one hour sessions, 6 weeks (n=34).</p>	<p>Mean pain score (100 m.m) at baseline and 6 weeks, 3 and 6 months:</p> <p><u>Intervention 1:</u> Baseline: 40 m.m, 6 weeks: 30 m.m 3 months: 31 m.m 6 months: 29 m.m</p> <p><u>Intervention 2:</u> Baseline: 46 m.m, 6 weeks: 30 m.m 3 months: 29 m.m 6 months: 25 m.m</p> <p><u>Intervention 3:</u> Baseline: 43 m.m, 6 weeks: 25 m.m 3 months: 26 m.m 6 months: 25 m.m</p> <p>After 6 months intervention 1 more improved than intervention 2, no other significant differences between groups in pain provocation score and pressure pain threshold</p>	<p>Results only presented for 113 chronic (>7 weeks) patients.</p> <p>Methodologic quality score:</p> <p>Concealment of treatment allocation (+), withdrawal/drop-out rate (+), co-interventions avoided or equal (+), blinding of patients (-), blinding of observer (+), intention-to-treat analysis (+), compliance (-), similarity of baseline characteristics (+), blinding of care provider (-);</p> <p>total score 6.</p>	A

Torstensen et al. (1998) (5)

Study	Methods	Participation	Interventions	Outcomes	Notes	Quality
Torstensen (1998)	RCT; single-blinded; stratified randomisation by gender using SAS; randomisation lists were administered by a nurse, with no other personnel having access to the lists.	208 patients with chronic non-specific low back pain with or without radiation, from social security offices, sick listed for 8 to 52 weeks, 103 men and 195 women aged 20-65 years	<p><u>Intervention 1:</u> Medical exercise therapy: Progressively graded exercise therapy, groups with a maximum of 5 patients, mobilising hypomobile areas of the spine and stabilising exercises for other parts, use of specially designed exercise equipment (pulleys, benches, barbells, dumbbells), 7 to 9 different exercises, total of 1000 repetitions reps per session, 15 minutes warm-up period, sessions of 1 hour, 3 times per week, 12 weeks (n= 70).</p> <p><u>Intervention 2:</u> conventional physiotherapy, combination of heat or cold, massage, stretching, electrotherapy, traction, few exercises on the treatment table, treatment applied to what physiotherapist anticipated to be effective, sessions of 1 hour, 3 times per week, 12 weeks (n=67).</p> <p><u>Intervention 3:</u> self exercise by walking, walking was unorganised and could be performed</p>	<p>Mean (SD) pain intensity (VAS) in low back at baseline, post-treatment and after 1 year: <u>Treatment 1:</u> base l: 53.1 (21,3) post tr: 37,2 (25,3) 1 year: 40,5 (24,4) <u>Treatment 2:</u> base l: 50,9 (19,2) post tr: 39,0 (28,0) 1 year: 42,9 (29,5) <u>Treatment 3:</u> base l: 55,0 (21,0) post tr:50,4 (27,2) 1 year: 50,0 (28,0) Treatment 1 and 2 significant better than treatment 3 post treatment and after 1 year.</p> <p>Mean (SD) pain intensity (VAS) in leg at baseline, post-treatment and after 1 year: <u>Treatment 1:</u> base l: 24.9 (21.3) post tr: 18.8 (24.9) 1 year: 21.2 (21.7) <u>Treatment 2:</u> base l: 24.2 (22.9) post tr: 24.5 (27.4) 1 year: 25.7 (24,5) <u>Treatment 3:</u> base l: 28.7 (28.8) post tr: 35.2 (33.9) 1 year: 35.7 (33.8) Treatment 1 and 2 significant better than treatment 3 post treatment. No difference after 1 year.</p> <p>Mean (SD) functional status</p>	<p>Methodological quality score: Concealment of treatment allocation (+), withdrawal/drop-out rate (+), co-interventions avoided or equal (+), blinding of patients (-), blinding of observer (+), intention-to-treat analysis (+), compliance (+), similarity of baseline characteristics (+), blinding of care provider (-); total score 7</p>	A

			<p>whenever the participant had time, 1 hour walking, 3 times per week, 12 weeks (n=70)</p>	<p>(ADL) at baseline, post treatment and 1 year: <u>Treatment 1:</u> Base I: 51.7 (10.7) post tr: 46.2 (13.1) 1 year: 44.1 (13.79) <u>Treatment 2:</u> Base I: 49.4 (10.5) post tr: 46.9 (13.1) 1 year: 43.0 (12.9) <u>Treatment 3:</u> Base I: 50.0 (11.9) post tr: 52.7 (16.6) 1 year: 50.6 (16.6) Treatment 1 and 2 significant better than treatment 3 post treatment and after 1 year. <u>No.(%) of patients completely satisfied with their treatment:</u> Treatment 1: 26 (34%), treatment 2: 19 (32%), and treatment 3: 6 (10%). <u>No. (%) of patients returned to work after 1 year:</u> Treatment 1: 41 (58%), treatment 2: 42 (63%), treatment 3: 40 (57%); no significant differences between groups. <u>Indirect costs,</u> treatment 1: 7.05, treatment 2: 5..98 and treatment 3: 8.15 million Norwegian Kroner</p>	
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Why do different interventions come out indifferent?

In addition to the three studies included in the systematic review (5, 9, 18) there are other studies supporting the conclusion that conventional physiotherapy is effective for patients with neck-, or low back pain. In Finland Videman et al. (10) found that conventional physiotherapy was equal medical exercise and McKenzie physiotherapy in-patients with chronic low back pain. For patients with neck pain conventional physiotherapy is proven effective, where in Denmark Jordan et al. (11) reported no difference between conventional physiotherapy, chiropractic and the use of a neck exercise machine in patients with chronic neck pain. Jordan et al. study (11) is methodologically outstanding compared to other RCTs on the effect of conservative therapies in-patients with chronic neck pain.

In a Norwegian RCT published back in 1978 in the Norwegian Medical Journal (12), no difference was found between conventional physiotherapy and manual therapy in-patients with cervicobrachialgia. Out of 350 patients admitted to Telemark Central Hospital with a diagnosis of cervicobrachialgia, 50 patients were included after defined inclusion/exclusion criteria and randomised into three different intervention groups. Group 1, included 13 patients who received manual therapy as heat, soft tissue treatment (massage and stretching), and specific manipulation of hypomobile segments in the cervical column. Each treatment lasted for 40 minutes, two treatments a week for four weeks, a total of eight treatments. Group 2, included 21 patients receiving conventional physiotherapy consisting of heat, soft tissue treatment (massage and stretching) and traction in a "tru-track" traction bench. They were also instructed in home exercises. The treatment lasted for 60 minutes, three treatments a week for four weeks, a total of twelve treatments. Group 3 consisted of 16 patients receiving one placebo pill three times daily in four weeks. They were also informed about the dysfunction given simple advice on how to handle the dysfunction and asked to contact the hospital if they became worse. At five weeks follow up there was a statistical significant difference ($p < 0,025$) between the actively treated physiotherapy groups and the placebo group, but no difference between the manual therapy group and the conventional physiotherapy group. It can however be argued that the manual therapy group did better because the same effect was achieved with shorter treatment time and 30% fewer number of treatments.

In Sweden Skargren et al. (7) found no difference between conventional physiotherapy and chiropractic treatment in-patients with neck and/or back pain. Patients included in the study had acute, subacute and chronic neck and/or back pain. In a Dutch study by Koes et al. (8) on

patients with subacute nonspecific back and/or neck pain lasting for at least 6 weeks with median duration of present episode of approximately 52 weeks (chronic). The included patients were randomised to four different interventions; 1) manual therapy, 2) conventional physiotherapy, 3) placebo treatment consisting of 10 minutes examination, 10 minutes detuned ultrasound and 10 minutes detuned shortwave diathermy, and 4) continued treatment by the GP. They found no difference between the manual therapy and the conventional physiotherapy but both were highly statistically significant better than the GP's treatment. In this study neither the manual therapy nor the conventional physiotherapy were at any time statistically significantly better than the placebo ultrasound/ short wave diathermy group. However, there appears to be a trend in favour of manual therapy and conventional physiotherapy. Again number of treatments differed greatly between groups, where mean number of treatments in the manual therapy group was 5.4, in the conventional physiotherapy group 14.7, in the placebo therapy group 11.1 and in the GP group 1 treatment.

The conclusion is that several outcome studies of different conservative therapies with good research methodology end up with no difference between groups. This is a fact even though the interventions differ dramatically in theory and practical use, ranging from different forms of active exercise therapies, to different manual therapies, to a more pragmatic approaches such as conventional physiotherapy.

One major cause for this is the fact that we still do not know exactly what we are treating. Thus, patients with neck and/or back pain included in clinical trials are a heterogeneous group of patients. In most patients we cannot pinpoint the tissue structure at fault causing the back-, or neck pain. In Dallas in 1986 (99) Vert Mooney addressed the International Society for the Study of the Lumbar Spine asking the question: Where is the pain coming from? Mooney believed in 1986 that the pain was coming from the disc, and in selected patients that is probably true. There is also some hard evidence for this through the centralisation phenomenon where there is a relationship between symptoms, position of the trunk/back, and findings on discography (100, 101, 102, 103). However, when this analogy is tested in well performed randomised clinical trials in patients with acute and subacute low back pain, the effect is really no better than other treatments. So far, when performing well RCT it has not been able to show the same positive effects observed in the clinical setting treating individual patients (10, 13, 20, 82,). One argument for this discrepancy/inconsistency is that the "wrong"

patients have been included in RCT. However, there is documentation that findings on an organic level does not necessarily correlate with pain or function on an individual or societal level (42, 43).

For selected patients one can make an accurate tissue at fault diagnosis, believed to vary from 10% to 20% in patients with low back pain. For the rest 80% to 90%, it may at best be a qualified guess regarding where the pain is coming from. Compared with other diseases like diabetes or different heart diseases, we have not been able to make a clear understanding of the pathophysiology involved in back pain.

What we basically is treating is at best a symptom and a movement dysfunction, but as time passes on the sensory dimensions of the pain may become less important and the cognitive and emotional dimensions of pain become more involved. The argument is that the more chronic a problem, the more complex and diverse the pain mechanisms, the more futile the effort to direct treatment at a specific target tissue. Thus, the behavioural sciences have become more involved in the treatment of low back pain and disability dealing with elements like fear-avoidance beliefs using cognitive behavioural approaches treating back pain (104, 105, 106, 107, 108).

It is also still unclear what factors are causing back pain. Researchers have looked for different risk factors ranging from biomechanical-, to psychosocial factors. Kim Burton has stated (109); *" My reading of the evidence is that certain types of spine stressors can be related to back pain in various ways. This is really common sense anyway. The additional risk of these exposures compared to the risk of just being alive is really quite modest... removing physical stressors at work would not have a dramatic impact on the prevalence of this problem, since back pain is a common complaint among people of working age in all walks of life"*.

Another fact is that back pain as a disease has not increased over the last 30 to 50 years but disability due to back has increased dramatically (110). Gordon Waddell has clearly pointed this out:

- 1) There is no evidence of any change in low back pathology.
- 2) The prevalence of low back pain has not changed.

- 3) There is an exponential increase in chronic disability, medical certification and sickness benefits associated with non-specific back pain.
- 4) Recent changes to sickness benefit systems may be altering these trends.

There are discussions today that low back pain disability is a societal problem and not a medical problem (104, 110) and that our traditional medical treatment approaches have failed regarding treating low back disability returning patients to work.

With the knowledge that for most patients we cannot exactly locate the organic substrate causing the pain/dysfunction, and the fact that back pain is normal in all aspects of life. Further, that most of us (60% to 90%) will experience back pain one or several times during life (110), it may not be that strange that completely different treatment approaches come out indifferent. Multifactorial causes of a dysfunction in the musculoskeletal system probably requires a multitude of treatment approaches, needing clinicians with good clinical reasoning skills (111). However, to be able to return patients to work the treatment/rehabilitation should probably have some kind of work attachment and be designed specifically in relation to the patients work situation (86, 87). This is not the case today with the traditional medical system treating back pain.

VIII. CONCLUSIONS

There is today significant evidence that information about back pain, maintaining a normal activity level and reducing fear about back pain, is an effective approach for patients in the acute stage.

For patients with subchronic pain, due to methodological shortcomings of the Indahl et al. study, it is still unclear if such an approach is effective and more research is needed.

In the chronic stage, there is evidence that such an approach compared with medical exercise therapy and conventional physiotherapy is increasing the disability making the patient worse.

Because return to work is not a sensitive, reliable or valid outcome measure, it should not be used as the only outcome variable. Rather, one should apply a multitude of relevant outcome measures.

There is good evidence that a pragmatic approach combining different “passive” physiotherapy modalities is effective for patients with neck and low back pain.

X. REFERENCES

1. Bruusgaard D, Eriksen W. Plagsomt for pasienten, vanskelig for hjelpeapparatet og dyrt for samfunnet. Rapport nr.5/1997 Seksjon for trygdemedisin. Oslo: Institutt for allmenn- og samfunnsmedisin, 1997.
2. Torstensen TA. Oslo Fysioterapi Ryggprosjektet. Prosjektrapport til programmet trygd og rehabilitering (arbeid og aktivitet, trygd og rehabilitering), sosial- og helse departementet, kapittel no. 0720.63/97. Kompetansesenter i fysioterapi, Oslo, 1997.
3. Torstensen TA. The Oslo Physiotherapy Low Back Pain Project. Abstract presented at the World Congress for Physiotherapists, Washington, USA, pp 348, 1995
4. Torstensen TA, Ljunggren AE, Mowinckel P. Effectiveness and costs of medical exercise therapy, traditional physiotherapy and walking in patients with chronic low back pain. A pragmatic single blinded controlled trial with one year follow-up. Abstract presented at the International Society for the Study of the Lumbar Spine (ISSLS), Brussels, Belgium, june 9-13, pp 91, 1998.
5. Torstensen TA, Ljunggren AE, Meen HD, Odland E, Mowinckel P, Geijerstam S. Efficiency and costs of medical exercise therapy, conventional physiotherapy, and self exercises in patients with chronic low back pain: a pragmatic, randomized, single-blinded, controlled trial with 1-year follow-up. Spine 1998;23:2616-24.
6. Indahl A, Velund L, Reikeraas O. Good prognosis for back pain when left untampered. Spine 1995;20 (4):473-477.
7. Skargren EI, Öberg B, Carlsson PG, Gade M. Cost and effectiveness analysis of chiropractors and physiotherapy treatment for low back and neck pain: Six-month follow-up. Spine 1997;22:2167-77.
8. Koes B, Bouter L, van Mameren H, Essers AHM, Verstegen GHJR, Hofhuizen DM, Houben JP, Knipschild PG. The effectiveness of manual therapy, physiotherapy, and treatment by the general practitioner for non specific back and neck complaints. Spine 1992;17(1):28-35.

9. Hansen FR, Bendix T, Skov P, Jensen CV, Kristensen JH, Krohn L, Schioeler H. Intensive, dynamic back-muscle exercises, conventional physiotherapy, or placebo control treatment of low back pain. *Spine* 1993;18:98-107.
10. Videman T, Leino-Arjas P. A comparison of medical exercise, the McKenzie approach, and traditional physical therapy in the treatment of occupational LBP patients. In: McKenzie R, Donelson R, eds. Fifth McKenzie Institute International Conference, Philadelphia, Pennsylvania, September 12-14, 1997.
11. Jordan A, Bendix T, Nielsen H, Hansen FR, Host D, Winkel A. Intensive training, physiotherapy or manipulation for patients with chronic neck pain. A prospective, single blinded, randomized clinical trial. *Spine* 1998;23:311-318.
12. Kogstad DA, Karterud S, Gudmundsen J. Cervicobrachialgia. *Tidsskrift Norske Læger* 1978;98:845-848.
13. Cherkin DC, Deyo RA, Battie MPH, Street J, Barlow W. A comparison of physical therapy, chiropractic manipulation, and provision of an educational booklet for the treatment of patients with low back pain. *N Engl J Med* 1998;339:1021-1029.
14. Eriksen HR, Ursin H. The pain of Sognsvann walks. Letter to the editor. *Spine* 2000;25 (1):137-138.
15. Bruusgaard D. Kiropraktikk, kunnskap og politikk. *Tidsskr Nor Lægeforen* 2000;120(28):3454-3456.
16. Brox JI, Hagen KB, Juel NG, Storheim K. Har Treningsterapi og manipulasjon effekt ved korsryggsmerter? *Tidsskr Nor Lægeforen* 1999;119:2042-50.
17. Indahl A, Haldorsen EH, Holm S, Reikerås O, Ursin H. Five-year follow up study of a controlled clinical trial using light mobilization and an informative approach to low back pain. *Spine* 1998;23(23):2625-2630.

18. Hemmilä HM, Keinanen-Kiukaanniemi, Levoska S, Puska P. Does folk medicine work? A randomized clinical trial on patients with prolonged back pain. *Arch Phys Med Rehabil* 1997;78:571-7
19. van Tulder MW, Malmivarra A, Esmail R, Koes BW. Exercise therapy for low back pain. In: *The effectiveness of conservative treatment of acute and chronic low back pain*, editors: Tulder MW van, Koes BW, Assendelft WJJ, Bouter LM. EMGO Institute, Amsterdam, 1999.
20. van Tulder MW, Malmivarra A, Esmail R, Koes BW. Exercise therapy for low back pain. A systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine* 2000;25(21):2784-2796.
21. Holten O. Medisinsk treningsterapi. *Fysioterapeuten* 1976;43:9-14. (in Norwegian)
22. Torstensen TA. Medisinsk treningsterapi og manuell terapi. *Fysioterapeuten* 1990;57(16):16-19. (in Norwegian)
23. Holten O, Torstensen TA. Medical exercise therapy. The basic principles. *Fysioterapeuten* 1991;58(9):27-32. (in Norwegian)
24. Jacobsen F, Holten O, Faugli HP, Leirvik R. Medical exercise therapy. *Fysioterapeuten* 1992; 59(7):19-22. (in Norwegian)
25. Holten O, Faugli HP (editors). *Medisinsk treningsterapi*. Oslo. Universitetsforlaget, 1993. (in Norwegian)
26. Torstensen TA, Meen HDM, Stiris M. The effect of medical exercise therapy on a patient with chronic supraspinatus tendinitis. Diagnostic ultrasound-tissue regeneration: A case study. *Journal of Orthopaedics and Sports Physical Therapy (JOSPT)* 1994;20(6):319-327.
27. Torstensen TA. Medisinsk treningsterapi etter ryggoperasjon. *Fysioterapeuten* 1993;60(6):319-327. (in Norwegian)

28. Nordin M and Campello M. Physical therapy exercises and the modalities: when, what and why? *Neurologic Clinics of North America* 1999;17:75-89.
29. Jonsson E, Nachemson A. Ont i ryggen , ont i nacken. En evidensbaserat kunnskapssam-manställning, Stockholm: The Swedish Council on Technology assessment in Health Care (SBU), 2000. (in Swedish)
30. Harms-Ringdahl K, Holmström E, Jonsson T, Lindström I. Evidensbaserad sjukgymnastisk behandling. Patienter med ländryggsbesvär. Stockholm: The Swedish Council on Technology assessment in Health Care (SBU) and the Swedish Physiotherapy Association, no 102, 1999. (in Swedish),
31. Ondt i ryggen. Behandling og forebyggelse. Medicinsk teknologivurdering. København: Statens Institut for Medicinsk Teknologivurdering, 1998. (in Danish)
32. Vondt i ryggen. IK-2508. Statens helsetilsyns veiledningsserie 1995 Oslo: Statens helsetilsyn, 1995. (in Norwegian).
33. Spitzer WO, LeBlanc FE, Dupuis M, et al. Scientific approach to the assessment and management of activity-related spinal disorders: A monograph for clinicians. Report of the Quebec Task Force on spinal disorders. *Spine* 1987; 12(suppl 7):S1-S59.
34. Rosen M. Back pain: Reports of a Clinical Standards Advisory Group (C.S.A.G) Committee on a Back Pain. London: Her Majesty's Stationary Office (H.M.S.O)., 1994.
35. Bigos SJ, Bowyer O, Braen G et al. Acute low back pain in adults. Clinical Practise Guidelines, Number 14, ACHPR Publication No.95-0642. Washington DC, U.S.: Department of Health and Human Service. Agency for Health Care Policy and Research, 1994.

36. Kendall NAS, Linton SJ, Main CJ. Guide to assessing psychosocial yellow flags in acute low back pain: risk factors for long-term disability and work loss. Wellington, New Zealand: Accident Rehabilitation and Compensation Insurance Corporation of New Zealand and the National Health Committee, 1997.
37. Torstensen TA, Koes B, Glomsrød E, Seifert L, Glomsrød B, Hagen O. Letter to the editor. *Spine* 1996;21:656.
38. Deyo RA. Measuring functional status of patients with low back pain. *Arch Phys Rehabil* 1988;69:1044-53.
39. Baldwin MJ, Johnson WG, Butler RJ. The error of using return-to-work to measure the outcomes of health care. *Am J Ind Med* 1996;29:632-41.
40. Deyo RA, Andersson G, Bombardier C, Cherkin D, Keller RB, Lee CK, Liang MH, Lipscomb B, Shekelle P, Spratt KF, Weinstein JN. Outcome measures for studying patients with low back pain. *Spain* 1994;19:2032S-2036S.
41. Yelin E, Meenan R, Nevitt M, Epstein W. Work disability in rheumatoid arthritis: Effects of disease, social, and work factors. *Ann Intern Med* 1980;93:551-556.
42. Waddell G, Clinical assessment of lumbar impairment. *Clinical Orthopaedics and Related Reserach* 1987; (number 221):110-120.
43. Waddell G and Main CJ. Morris EW, Venner RM, Rae PS, Sharmy SH, Galloway H. Normality and reliability in the clinical assessment of backache. *Br Med J* 1982;284:1519.
44. Hall H, McIntosh G, Melles T, Holowachuk B, Wai E. Effect of discharge recommendations on outcome. *Spine* 1994;19:2033-7.
45. King PM. Predicting outcomes in return -to - work programs. *J Rehabil Outcomes Meas* 1998;2(4):55-62.

46. Peters P. Successful return to work for clients in a work-hardening center. *Work* 1994;4(1):9-21.
47. Burgel B, Gliniecki C. Disability behaviour: Delayed recovery in employees with work compensable injuries. *AAOHN* 1986;34:26-30.
48. Nachemson A. Work for all. *Clinical Orthopaedics* 1983;179:77-83.
49. Kasdan A, McElwain N. Return to work programs following occupational hand injuries. *Occupational Medicine* 1989;4:539-45.
50. Murphy K, Cornish R. Prediction of chronicity in acute low back pain. *Archives of Physical Medicine and Rehabilitation* 1989;65:334-37.
51. Bear-Lehman J. Factors affecting return to work after hand injury. *American Journal of Occupational Therapy* 1983;37:189-94.
52. Graly J et al. Factors influencing return to work for clients in a work-hardening center. *Work* 1994;4(1):9-21.
53. Frederickson B, Trief P, VanBeveren P. Rehabilitation of the patient with chronic back pain: A search for outcome predictors. *Spine* 1989;13:351-53.
54. Scheer S. *Multidisciplinary perspectives in vocational assessment of impaired workers*. Rockville, MD: Aspen, 1990.
55. Tate D. Workers disability and return to work. *American Journal of Physical Medicine and Rehabilitation* 1992;71:92-96.
56. Milhous R et al. Determinants of vocational disability in patients with low back pain. *Archives of Physical Medicine and Rehabilitation* 1989;70:589-96.

57. Hagen KB, Holte HH, Tambs K, Bjerkedal T. Socioeconomic factors and disability retirement from back pain. A 1983-1993 population-based prospective study in Norway. *Spine* 2000;25(19):2480-2487.
58. Guck T et al. Prediction of long-term outcome of multidisciplinary pain treatment. *Archives of Physical Medicine and Rehabilitation* 1989;67:693-96.
59. Edwards B et al. A physical approach to the rehabilitation of patients disabled by chronic low back pain. *Medical Journal of Australia* 1992;156:693-96.
60. Battié MC, Bigos SJ. Industrial back pain complaints. A broader perspective. In Brown MD, Rydevik B, editors. *Causes and cure of low back pain and sciatica. The Orthopaedic Clinics of North America* vol 22, nr 2. London: W,B. Saunders Company, 1991, pp 273-282.
61. Hagen KB, Thune O. Work incapacity from low back pain in the general population. *Spine* 1998;38:2091-2095.
62. Lancort J, Kettlehut M. Predicting return to work for lower back pain patients receiving worker's compensation. *Spine* 1992;17:629-40.
63. Leavitt F, Garron D. Psychological disturbance and pain report differences in both organic and nonorganic low back pain patients. *Pain* 1979;7:187-95.
64. Greenough C, Fraser R. The effects of compensation of recovery from low back injury. *Spine* 1984;14:947-55.
65. Bergquist-Ullman L. Acute low back pain in industry: A controlled prospective study with special reference to therapy and confounding factors. *Acta Orthopaedica Scandinavia* 1977;170 (Suppl):1-117.
66. Bigos S et al. A prospective study of work perceptions and psychosocial factors affecting the report of back injury. *Spine* 1991;16:1-6.

67. Frymoyer J et al. Psychologic factors and low back pain disability. *Clinical Orthopedica* 1985; (195):178-84.
68. Frymoyer J, Cats-Baril W. Predictors of low back pain disability. *Clinical Orthopedics* 1987; (221):89-98.
69. Gatchell R et al. Millon Behavioral Health Inventory: Its utility in predicting physical function in patients with low back pain. *Archives of Physical Medicine and Rehabilitation* 1986;67:878-82.
70. Bigos SJ, Battié MC, Fisher LD, et al. A prospective study of work perceptions and psychosocial factors affecting the report of back injury. *Spine* 1990;16 (1): 978-985.
71. Matheson L et al. Work hardening: Occupational therapy in industrial rehabilitation. *American Journal of Occupational Therapy* 1985;39:314-21.
72. Voaklander D, Beaulne A, Lessard R. Factors related to outcome following a work hardening program. *Journal of Occupational Rehabilitation* 1995;5(2):71-85.
73. Beals R. Compensation and recovery from injury. *Western Journal of Medicine* 1984; (180):233-37.
74. Greenough C, Fraser R. Comparison of eight psychometric instruments in unselected patients with back pain. *Spine* 1991;16:1068-74.
75. Taylor M. Return to work following back surgery: A review. *American Journal of Industrial Medicine* 1989;16:79-88.
76. Indahl Å. Letter to the editor. In response. *Spine* 1996;21:657.
77. Westin S. *Becoming disabled: a sociomedical analysis of individual adaptations to life after long-term unemployment*. Trondheim: Det Kongelige Norske Videnskabers Selskabs Skrifter, Vol. 2, 1990.

78. Larsen BA, Förde OH, Tellnes G. Legens kontrollfunktion ved sykemelding (Physician's role in certification for sick leave). *Tidsskr Nor Laegeforen* 1994;114:1442-4. (in Norwegian)
79. Haldorsen EMH, Brage S, Johannesen TS, Tellness G, Ursin H. Musculoskeletal pain: concepts of disease, illness, and sickness certification in health professionals in Norway. *Scand J Rheumatol* 1996;25:224-232.
80. Englund L, Tibblin G, Svärdsudd K. Variations in sick-listing practice among male and female physicians of different specialities based on case vignettes. *Scand J Prim Health Care* 2000;18:48-52.
81. Englund L, Svärdsudd K. Sick-listing habits among general practitioners in a Swedish county. *Scand J Prim Health Care* 2000;18:81-86.
82. Malmivarra A, Hakkinen U, Aro T, et al. The treatment of acute low back pain: Bed rest, exercises, or ordinary activity? *N Engl J Med* 1995;332:351-355.
83. Faas A, Chavannes AW, van Eijk JThM, Gubbels JW. A randomized, placebo-controlled trial of exercise therapy in patients with acute low back pain. *Spine* 1993;18:1388-95.
84. Blomberg S. A pragmatic approach to low back pain including manual therapy and steroid injections; a multicentre study in primary health care. Comprehensive summaries of Uppsala dissertations from the Faculty of Medicine. (Acta Universitatis Upsaliensis, No 394) Almqvist & Wiksell, Stockholm, 1992.
85. Blomberg S, Svärdsudd K, Mildemberger F. A controlled, multicentre trial of manual therapy in low back pain; initial status, sick-leave and pain score during follow-up. *Scand J Primary Health Care* 1992;10:170-178.
86. Lindström I. A successful intervention program for patients with subacute low back pain. Thesis. Göteborg, Sweden: Göteborg University 1994.

87. Lindström I, Öhlund C, Eek C, et al. The effect of graded activity on patients with subacute low back pain: a randomized prospective clinical study with an operant-conditioning behavioural therapy approach. *Phys Ther* 1992;72:279-293.
88. Lindström I, Öhlund C, Eek C, et al. Mobility, strength, and fitness after a graded activity program for patients with subacute low back pain: a randomized prospective clinical study with a behavioural therapy approach 1992;17:641-652.
89. Lindström I, Öhlund C, Nachemson A. Physical performance, pain, pain behaviour and subjective disability in patients with subacute low back pain. *Scand J Rehabil* 1995;27:153-160.
90. Van Tulder MW, Ostelo R, Vlaeyen JWS, Linton SJ, Morley SJ, Assendelft WJJ. Behavioural treatment for chronic low back pain. A systematic review within the framework of the Cochrane Back Review Group. *Spine* 2000;25:2688-2699.
91. Haldorsen EM, Indahl Å, Ursin EM. Patients with low back pain not returning to work. A 12-month follow-up study. *Spine* 1998;23:1202-1208.
92. Bloch R. Methodology in clinical back pain trials. *Spine* 1987;12:430-432.
93. Molde Hagen E, Eriksen HR, Ursin H. Does early intervention with a light mobilization program reduce long-term sick leave for low back pain? *Spine* 2000;24:1973-1976.
94. Molde Hagen E, Eriksen H, Ursin H. Prosjekt Hedemarksrygg – 2 års oppfølging. En randomisert kontrollert klinisk studie. I abstrakt boken til Norsk Forening for Ryggforskning, Soria Moria, Oslo, 16-17 April, 1999, side 12.
95. Haldorsen EMH, Kronholm K, Skoen JS, Ursin H. Multimodal cognitive behavioural treatment of patients sicklisted for musculoskeletal pain: a randomized controlled study. *Scand J Rheumatol* 1998;27:116-125.

96. van Tulder MW, Assendelft WJ, Koes BW, et al. Method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group for Spinal Disorders. *Spine* 1997;22:2323-2330.
97. Bronfort G, Goldsmith CH, Nelson C et al. Trunk exercise combined with spinal manipulation or NSAID therapy for chronic low back pain: a randomized, observer blinded clinical trial . *J Manipulative Physiol Ther* 1996;19:570-582.
98. Deyo RA, Walsh NE, Martin DC, et al. A controlled trial of transcutaneous electrical nerve stimulation (tens) and exercise for chronic low back pain. *N Engl J Med* 1990;73:322:1627-1634.
99. Mooney V. Where is the pain coming from. *Spine* 1987;12:754-759.
100. Beattière PF, Brooks WM, Rothstein JM, Sibbitt WL, Robergs RA, MacLean T, Hart BL. Effect of lordosis on the position of the nucleus pulposus in supine subjects: A study using magnetic resonance imaging. *Spine* 1994;19:2096-2103.
101. Donelson R, Grant W, Kamps C, Medcalf R. Pain response to sagittal end range spinal motion. A prospective, randomised, multicentered trial. *Spine* 1991;16S:S206-S212.
102. Donelson R, Silva G, Murphy K. Centralisation phenomenon. Its usefulness in evaluating and treating referred pain. *Spine* 1990;15:211-213.
103. April C, Medcalf R, Grant W. Discographic outcomes predicted by the centralisation of pain and directional preference. Proceedings from the 4. McKenzie Institute International Conference, Cambridge, England, 1995.
104. Gannik DE. Situationel sygdom. Fragmenter til en social sygdomsteori basert på en undersøgelse af ryglidelser. Fredriksberg c, Danmark; 1999. (in Danish)
105. Burton K. New british occupational back pain guidelines: Blueprint for an early return to work. *The Back Letter* 2000;15(5):49,55-58.

106. Vlaeyen JWS, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 2000;85:317-332.
107. Enright SJ. Cognitive behavioural therapy-clinical applications. *BMJ* 1997;314:1811-1816.
108. Al-Obaidi SM, Nelson RM, Al-Awadhi S, Al-Shuwaie N. The role of anticipation and fear of pain in the persistence of avoidance behaviour in patients with chronic low back pain. *Spine* 2000;25(9):1126-1131.
109. Burton AK, Waddell G, Tillotson KM, Summerton N. Information and advice to patients with back pain can have a positive effect. *Spine* 1999;24:2484-2491.
110. Waddell G. The epidemiology of back pain. In: *The back pain revolution*: Edinburgh: Churchill Livingstone; 1998:69-84.
111. Jones M. Clinical reasoning: the foundation of clinical practice. Part 1. *The Australian Journal of Physiotherapy* 1997;43(3):167-170.