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Recent History

Efficiency and Costs of M..



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
[Clinical Studies: Treatment]

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Abstract

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.

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 al ¹⁸ 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 Netherlands ⁵³ costs resulting from low 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 al ²⁴ 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 normally 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.

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).

	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)	174.9 (8.7)	175.8 (8.9)	174.6 (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 (8.5)	36.8 (10.5)	37.2 (10.5)
Years spent at this work	11.8 (10.7)	12.6 (10.4)	9.9 (8.5)
Days off 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	7.8 (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 of sick-leave due to LBP	2.2 (2.4)	2.0 (1.4)	2.2 (2.4)
Months on sick-leave	4.8 (3.6)	5.2 (2.9)	4.7 (2.1)
Pain intensity lower back and buttocks (VAS)	53.7 (21.3)	50.9 (19.2)	55.0 (23.0)
Pain intensity lower extremity (VAS)	24.9 (21.3)	24.2 (22.9)	28.7 (28.6)
Function (OLBPOQ)	51.2 (10.7)	49.9 (10.5)	50.0 (11.9)

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

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

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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).

	MET (n = 70)	CP (n = 70)	SE (n = 70)
Baseline	76.0 (2.0)	76.0 (2.0)	76.0 (2.0)
After treatment	57.0 (2.0)	57.0 (2.0)	76.0 (2.0)
1-year follow-up	68.0 (2.0)	68.0 (2.0)	76.0 (2.0)

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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 = 70)	CP (n = 70)	SE (n = 70)
Baseline	68.0 (2.0)	68.0 (2.0)	68.0 (2.0)
After treatment	58.0 (2.0)	58.0 (2.0)	68.0 (2.0)
1-year follow-up	68.0 (2.0)	68.0 (2.0)	68.0 (2.0)

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

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 CT groups *versus* the SE group, and no statistical difference between the two physiotherapy groups (Table 4).

	MET (n = 72)	CP (n = 63)	SE (n = 73)
Mean (SD)	21.88 (8.12)	21.81 (8.12)	22.88 (8.12)

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

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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).

	MET (n = 72)	CP (n = 63)	SE (n = 73)
Mean (SD)	48.12 (12.34)	48.12 (12.34)	48.12 (12.34)

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

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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).

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

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

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.

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

	MET (n = 71)	CP (n = 67)	SE (n = 70)
No. of working days on sick leave the year up to inclusion (12 mos)	8321	7654	8431
No. of working days on sick leave from inclusion and 1-year follow-up (15 mos)	11,797	9967	13,547

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

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)

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	MET (n = 68)*	CP (n = 63)	SE (n = 70)
Costs in (11,797 WD = NOK 600) (9967 WD = NOK 600) (13,547 WD = NOK 600) NOK	= NOK 7,054,200	= NOK 5,980,200	= NOK 8,152,200

* Two missing values, government employees workers are not registered at the local Social Security office.
MET = medical exercise therapy; CP = conventional physiotherapy; SE = self-exercise; WD = working days; FOCK = Norwegian kroner; NOK = 600, the average cost per working day on sickness certificate I.
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.

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

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	MET (n = 68)	CP (n = 67)	SE (n = 70)
Costs in NDK	NDK 77 × 36 treatments × 68 patients = NDK 191,268	NDK 120 × 36 treatments × 67 patients = NDK 289,440	NDK = 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 = NDK 77, the costs for one CP treatment = NDK 120.

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

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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).

	MET (n = 71)	CP (n = 67)	SE (n = 70)	Total (n = 208)
Work	41	42	40	123
Disability 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.

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

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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 al [33](#) 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 al [26](#) 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 stimulation [9](#) are no better or even worse than those of the control or placebo group. Clinical guidelines from the United States [4](#) and the United Kingdom [44](#) 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 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 nocebo 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 al ²⁴ is advocating the same approach for patients in a late subacute stage or early subchronic stage. Indahl et al ²⁴ included patients on sick leave only up to 12 weeks. Their only outcome variable was return to work, and they obtained surprisingly 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 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.

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 Carmen ³⁹ 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 Harth ⁴⁹ cited the study of Mitchell et al ³⁹ 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 al ³⁷ 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 Harth ⁴⁹ 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 ICDH. 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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