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A Controlled, Multicentre Trial of Manual Therapy in Low-Back Pain

Initial Status, Sick-leave and Pain Score During Follow-up

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101 outpatients with acute or subacute low-back pain were randomly allocated to one of two treatment groups. One group was given standardized conventional but optimal activating treatment by primary health care teams. The other group received manual treatment such as manipulation, specific mobilization, muscle stretching, auto-traction, and cortisone injections. The two groups were similar in most of the pretrial variables, including age, sex, previous low-back pain problems, sick-leave, previous treatment, findings at the physical examination, quality-of-life score, disability rating, and pain score.

After one month in the study, the proportion of patients on sick-leave was six times larger in the conventionally treated group than in the group receiving the specific manual treatment. The difference diminished over time but was still significant after eight months. Two slightly different pain scores ("pain at the moment" and "pain during the last weeks"), initially similar in the two groups, diminished in both groups but were significantly lower in the manual treatment group during the study.

The group receiving specific manual treatment thus had a significantly better outcome than the group receiving conventional treatment as far as sick-leave and pain score are concerned.

Key words: low-back pain, manual therapy, controlled randomized trial, primary health care, sick-leave, pain score.

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Low-back pain is a major diagnostic and therapeutic problem, causing much suffering and large costs to the community (1). Followers of manual therapy argue that the discipline to some extent offers a solution to this problem, but this mode of therapy is still controversial and its possible efficacy is not yet considered satisfactorily documented, especially regarding the possibilities of reducing sick-leave. In spite of this, manual therapy is growing in popularity among physicians, physiotherapists, and patients.

Short-term effects achieved by manual therapy have been demonstrated in some well-designed and well-performed trials (2–6), but possible long-term effects are yet to be demonstrated. For this reason, a randomized clinical trial was performed in patients with low-back pain in which the effect of manual therapy was compared with that of conventional treatment. The hypothesis was that the therapeutic approach to low-back pain according to the Scandinavian school of manual therapy can reduce sick-leave and pain more effectively than optimized conventional treatment given by a primary health care team. In this first report, prerandomization data for the two treatment groups and the effect of treatment measured as sick-leave statistics and pain scores during follow-up are presented.

STUDY POPULATION AND METHODS

The study was performed as a multicentre trial in Kopparberg County, Sweden, during the period February 1988 to April 1989. Six primary health care

or occupational health care centres, representing a catchment area of 56000 residents, and the Skönvik Rehabilitation Clinic participated. All patients attending the primary health care or occupational health care centres who fulfilled the inclusion criteria for the study were entered. Only a few patients declined to participate, most frequently because of long distance from home to the Skönvik Rehabilitation Clinic.

The criteria for inclusion were:
- Age 20–60 years.
- Conditions with acute or subacute low-back pain with or without pain radiating to one or both legs not demanding surgical treatment or specific rheumatological care. Patients with proven or suspected herniated disc were included if surgery was not considered. Low-back pain was to dominate the clinical picture but other musculoskeletal symptoms were allowed.
- Symptom duration of 3 months or less, preceded by at least 2 months' relative freedom from symptoms. Milder chronic cases were thus included, as long as they did not experience a need for treatment between the earlier acute periods.
- Consent to treatment and follow-up for 4 months.
- Agreement not to consult other therapists in addition to the treatment offered in the study.
- Absence of other conditions or circumstances which might jeopardize completion of treatment and follow-up (e.g. alcoholism or severe psychiatric disorders).

At the first contact with the patient, a preliminary assessment of the criteria for inclusion was made by the reception nurse. The final decision was made by the general practitioner (GP) at the first consultation, after which the patient received standardized information concerning the study. The patients were told that rapid treatment was guaranteed in both study groups – there were normally waiting-lists for physiotherapy at the centres. After having accepted participation and after examination by the GP, the patients were randomly allocated to one of two groups, an experimental group or a conventional treatment group. One hundred and one patients, 48 women and 53 men, were recruited, of whom 48 were allocated to the experimental group and 53 to the conventional treatment group. The patients in the experimental group were treated at the Skönvik Rehabilitation Clinic and those in the conventionally treated group were treated at the health care centre where they were recruited.

Baseline data

Information was obtained by questionnaires about the patients' education, working conditions, physical activity during leisure time, smoking and alcohol intake habits, earlier low-back pain infirmity, treatment before the start of the study, and symptom duration at the beginning of the study.

Two different pain scores ("pain at the moment" and "pain during the last weeks") and fifteen different disability rating scores (DRS) (sports, running, heavy lifting, heavy physical work, making a bed, leaning over a washbasin, carrying a bag, sitting more than briefly, getting up from sitting, moderate physical work, walking up stairs, taking walks, riding a car, lying still, and dressing/undressing) were measured using visual analogue scales (VAS) presented to the study population in questionnaires. The scales were 100 mm long, the left end representing no pain or no disability (0 mm) and the right end maximum pain or maximum disability (100 mm). The distance in mm from the zero point to the patient's marking was used as the pain score or DRS respectively. In a similar way the participants were asked to rate their quality of life in various aspects, as listed in Table III, using visual analogue scales, 0 mm representing "very bad" and 100 mm "excellent, could not be better" (7). 27 different symptoms, mainly of a psychosomatic character, were surveyed by questions answered by "yes" or "no" concerning experience of symptoms during the preceding three months (7).

The standardized physical examination was discussed with all involved doctors three times and was virtually a traditional orthopaedic examination. The straight leg raising test (SLR) was considered positive if raising the leg provoked pain in the lifted leg or in the contralateral leg or in the lower back.

Experimental treatment

The basis of Swedish manual therapy is the classical osteopathic techniques as described by Stoddard (8) and the continental tradition as represented by Lewit (9). These techniques for mobilization, manipulation, and muscle stretching have been further developed by Evjent and Hamberg, as described in two therapeutic manuals (10, 11), and they form an important part of the experimental treatment.

All patients were treated with thrust techniques or more gentle specific mobilization. Almost all pa-

Table I. *Baseline data for the two treatment groups regarding age, sex, and some social data. NS = non-significant difference between the two treatment groups.*

	Conventional treatment	Experimental treatment	p =
Age, years	39	35	NS
Female/male, %	53/47	42/58	NS
Educational level			
elementary school, %	21	17	NS
comprehensive school, %	8	19	NS
G.C.E., vocational, folk, high school, %	36	25	NS
university, %	35	39	NS
Working half-time or more, %	93	98	NS
Type of occupation			
light, %	15	16	NS
moderately heavy, %	19	19	NS
heavy, %	58	48	NS
very heavy, %	8	17	NS
Physical activity during leisure			
inactive, %	14	16	NS
moderately active, %	65	65	NS
active, %	17	17	NS
regular vigorous activity, %	4	2	NS
Smokers, %	26	56	0.004
Drinking wine or spiritus once a week or more often, %	6	2	NS

tients were treated with muscle stretching, and they were taught muscle stretching exercises according to Evjent and Hamberg (12). An essential therapeutic manoeuvre was a modified technique for treatment of dysfunctions of the sacroiliac joint according to Kubis (13). 15% of the patients were treated with auto-traction (14).

Steroid injections (Lederspan®, triamcinolone), often in combination with "needling" (9) and local anaesthetics (Citanest® 0.1%, prilocaine hydrochloride), were given according to manual diagnostic findings. 26 patients (54%) were given steroid injections (1.7 injections per patient, range 1–4). The average for the whole group was 0.9 injections per patient. The injections were mostly given round the paracoccygeal structures and the insertion of the piriformis and the gluteus medius/minimus tendons on the greater trochanter.

Conventional treatment

The patients received active, optimal (e.g. immediate and frequent consultations, minimal time on the physiotherapy waiting-list, early x-ray investigations, etc), and standardized conventional treatment. All staff participating in the conventional treatment were trained in similar therapeutic techniques and diagnostic items. The therapeutic strategy was activation of the patients. In addition, they received drugs, low-back pain school training, active back exercises, corsets, taping, short-wave, ultrasonic waves, transcutaneous nerve stimulation (TNS), transcutaneous electric muscle stimulation (TEMS), heat, cold, postural exercises, and in some cases plunge-bath training and massage. The doctors were instructed to minimize sick-leave in various ways.

Treatment intensity during the first 4 months

Recurrences were treated in both groups and the therapists could give as many treatments as they found indicated.

The patients in the experimental group were seen by the doctor (SB) on average 3.5 times, 2.8 times for treatment and 0.7 times for short consultations (for those who showed complete recovery since the last visit). They were treated individually by a physiotherapist on average 2.0 times. 19% of the patients also had group treatment (medical training therapy (MTT), 0.8 times per patient).

The patients in the conventionally treated group were seen 3.8 times by a doctor and had physiotherapist treatment 8.6 times, 6.8 times individually and

Table II. *Previous low-back pain problems and treatments given.*

	Conventional treatment	Experimental treatment	p =
Earlier low-back pain infirmity			
ever had similar problems, %	83	67	NS
chronic symptoms, %	30	33	NS
chronic problems between acute periods, mm on 100 mm visual analogue scale (mean)	19	29	NS
number of acute periods (mean)	3	7	NS
years since the first acute period (mean)	10	7	NS
Symptom duration at the beginning of the study, days (mean)	20	35	0.013
Sick-leave during the last two years			
none, %	72	54	NS
1–5 days, %	4	8	NS
6–30 days, %	6	19	NS
31–90 days, %	9	15	NS
>90 days, %	9	4	NS
Treatment before start of the study			
any treatment, %	45	42	NS
by physician, %	13	10	NS
by physiotherapist, %	8	4	NS
by others (chiropractors, drs of naprapathy), %	28	28	NS

1.8 times in groups. 89% received individual physiotherapy, compared with 56% in the experimental group.

33% of the experimental patients and 8% of the control patients were not seen by a physiotherapist, mostly due to rapid recovery. The experimental patients were treated almost exclusively during the first 3 weeks, while the control patients received continuous treatment to a larger extent.

Measures of efficacy

Data on sickness benefit were obtained from the National Health Insurance Company, which runs the national health insurance scheme. The data included

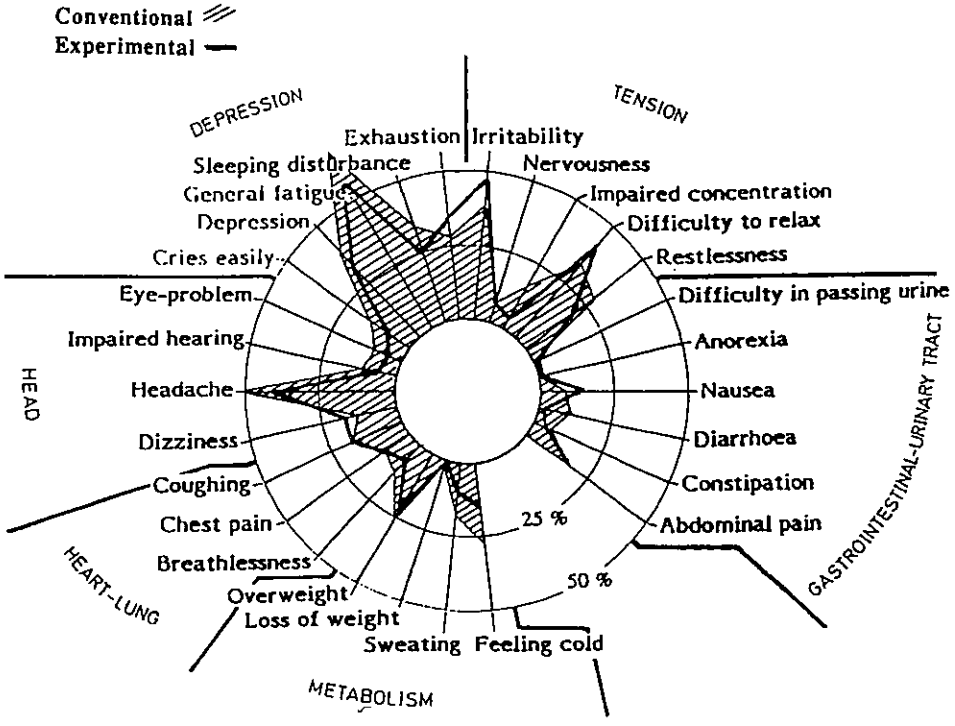

Fig. 1. Prevalence (%) of 27 symptoms in the two groups during the three months before the start of the study. The inner, middle, and outer circles represent 0%, 25%, and 50%, respectively. The symptoms are grouped into categories.

Table III. *Quality of life measures, means. These variables were measured on a visual analogue scale, 100 mm long, where 0 mm represents the worst possible situation and 100 mm the best possible.*

	Conventional treatment	Experimental treatment	p =
Home and family situation	87	85	NS
Housing situation	88	84	NS
Work situation	66	68	NS
Leisure situation	76	77	NS
Economy	70	74	NS
Health	65	63	NS
Hearing	84	86	NS
Eyesight	77	82	NS
Memory	73	75	NS
Fitness	53	53	NS
Appetite	87	83	NS
Mood	76	75	NS
Energy	71	73	NS
Patience	73	74	NS
Confidence	70	78	NS
Sleep	73	79	NS
Concentration	75	76	NS
Sexual life	73	76	NS
Friends	80	79	NS
Fatigue without reason	67	71	NS
Morning fatigue	65	58	NS
Headache	73	76	NS
Stomach problems	77	81	NS
Anxiety	77	79	NS

starting date, ending date, and diagnosis for all sick-leave periods. Pain scores were measured using the same type of visual analogue scale as was presented to the participants at baseline; it was mailed to the patients at one, two, and four months after the start of the study.

Statistical analysis

Summary statistics were computed using standard methods. Possible relationships were tested with Student's t-test and Pitman's non-parametric permutation test (15). The latter has the advantage that no assumptions have to be made about the distribution of the variables and the functional form of relationships. The results yielded are similar to those of Haenszel's chi-square test. Only two-tailed tests were used. P-values less than 5% were regarded as indicating statistical significance.

RESULTS

Baseline data

Table I shows baseline data regarding age, sex, education, type of occupation, leisure activities, smoking habits, and alcohol consumption habits. The only significant difference between the two treatment groups was that a larger proportion of the patients in the experimental group were smokers than in the conventional treatment group.

Data on earlier low-back pain infirmity, symptom duration before the start of the study, sick-leave during the last two years, and treatment given before the start of the study are presented in Table II. The symptom duration was significantly longer in the experimental group than in the conventionally treated group. No other significant differences were found.

Figure 1 shows a profile of the 27 symptoms. No significant differences between the two treatment groups were found.

Quality of life data measured at baseline are shown in Table III. There were only minor differences and none of these was statistically significant.

Table IV. *Initial subjective status (means) – pain, disability rating score (DRS) measured with a visual analogue scale ranging from 0 mm (no pain or no disability) to 100 mm (maximum pain or maximum disability).*

	Conventional treatment	Experimental treatment	p =
Pain score			
at the moment	49	53	NS
during the last weeks	64	59	NS
Disability rating score (DRS)			
all 15 DRS variables	55	57	NS
"light" 11 DRS variables	47	50	NS
"heavy" 4 DRS variables	76	74	NS

Table V. *Findings at initial physical examination.*

	Conventional treatment	Experimental treatment	p =
Height, cm (mean)	173	173	NS
Weight, kg (mean)	74	72	NS
Severe pain scoliosis, %	8	13	NS
Severe observed pain influence, %	4	13	NS
Observed stiff mobility pattern, %	2	13	NS
Observed difficulties sitting, walking, etc, %	15	31	0.02
Lumbar spine flattened, %	38	44	NS
Local pain caused by, %			
lumbar flexion	64	85	0.03
lumbar extension	45	60	NS
side-bending			
to the right	49	44	NS
to the left	38	50	NS
Lumbar spine tenderness, %			
interspinal	36	42	NS
paravertebral			
right	40	35	NS
left	45	38	NS
Tender sacroiliac joint, %			
right	34	35	NS
left	21	23	NS
Positive straight leg raising test (SLR), %			
right	19	40	0.04
left	15	25	NS
Straight leg raising test, degrees (mean)			
right leg	84	76	0.03
left leg	84	81	NS
Pseudoradicular pain, %			
right leg	9	21	NS
left leg	8	8	NS
True radicular pain, %			
right leg	8	13	NS
left leg	4	13	NS

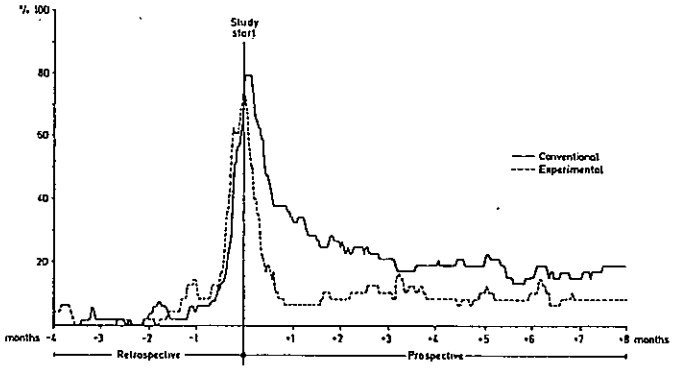

Fig. 2. Percentage of patients on sick-leave due to low-back problems in the experimental group and among those receiving conventional treatment from 4 months before to 8 months after the start of the study.

The same was true for the baseline pain and disability rating scores shown in Table IV.

Findings at the baseline physical examination are shown in Table V. Statistically significant differences were found for observed difficulties in sitting and walking, local pain on lumbar flexion and positive SLR test, indicating that the experimental group was more affected than the group receiving conventional treatment. Few neurological signs and abnormal findings concerning other parts of the locomotor system (thoracic spine, hips, knees, feet, etc.) were found.

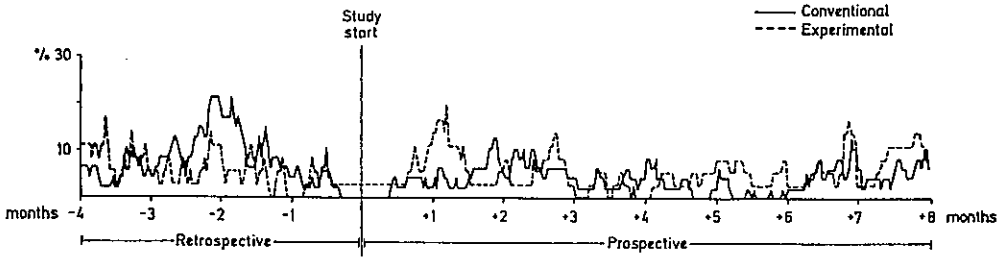

Fig. 3. Percentage of patients on sick-leave due to complaints other than low-back pain.

Sick-leave statistics

The proportion of patients on sick-leave due to low-back pain in the two groups is presented in Figure 2. During the four months preceding the start of the study the proportion of patients on sick-leave was similar in the two groups, but after the start of the study the proportion declined faster than in the conventional treatment group. At the end of the first month in the study, the proportion of patients on sick-leave was 6 times larger in the conventionally treated group than in the experimental group. This difference diminished over time, but after 8 months the proportion on sick-leave was still 2.3 times larger in the conventionally treated group. This difference is statistically significant ($p = 0.015$). 19% of the patients were still on sick-leave after 8 months, compared with 8% in the experimental group. The average number of days on sick-leave per patient due to low-back pain during the 8 months' follow-up was 58.5 in the conventionally treated group and 25.4 in the experimental group.

The corresponding data for sick-leave due to causes other than low-back pain are shown in Figure 3. There were only minor differences between the groups, indicating that there was no significant shift to other diagnosis.

Pain score

The score for "pain at the moment" in the two groups at the start of the study and at one, two, and four months of follow-up are shown in Figure 4, and the corresponding data for "pain during the last weeks" are shown in Figure 5. The scores were similar in the two groups at the start of the study, but during the first four months of follow-up the experimental group reported significantly lower scores and thus less pain.

DISCUSSION

According to a frequently used rule of thumb, a study population of more than 300 patients is needed to achieve similarity of baseline characteristics in most respects when patients are randomly allocated to two treatment groups. In our study, the patient group was smaller and some differences in baseline characteristics might therefore be expected. Overall, these differences favoured the conventional treatment group, indicating that had the two groups been more alike at baseline the differences in treatment effect might have been even larger.

All measurements were made in a standardized way. To avoid observer bias, different doctors, GPs, and physiotherapists were used for the two groups. With this design, the risk of the therapists performing the treatment with less enthusiasm in the control group was avoided. The problem of alternative or parallel treatment given by independent therapists was closely supervised. The present work seems to

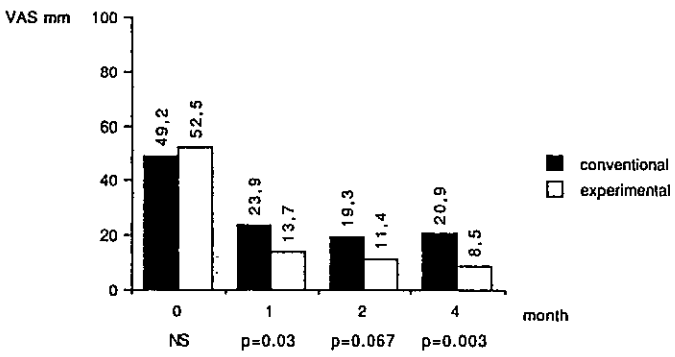

Fig. 4. Mean pain-score "at the moment" at the start of the study (0 months) and at 1, 2, and 4 months' follow-up. VAS = visual analogue scale.

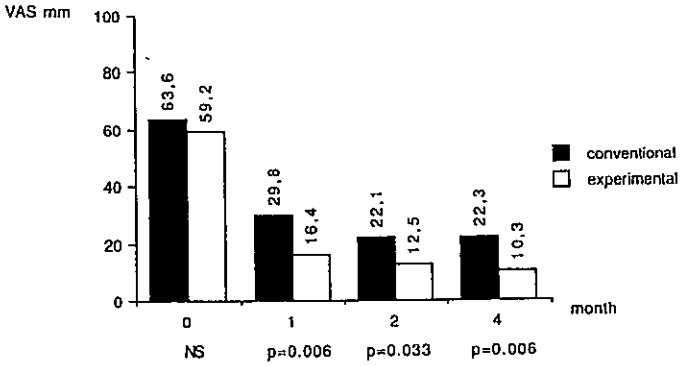

Fig. 5. Mean pain-score "during the last weeks" at the start of the study (0 months) and at 1, 2, and 4 months' follow-up. VAS = visual analogue scale.

be the first in this field in which this factor has been taken into consideration. 8% of the control patients and none in the experimental group received parallel therapy by chiropractors or doctors of naprapathy during the first 4 months of the follow-up period.

The drop-out rate was low (3 patients). During the analyses the intention-to-treat approach was used, which means that no patients were excluded after randomization even if they did not receive the intended treatment or if, after the start of the study, they turned out not to fulfil criteria for inclusion. In almost all earlier trials the alternative approach, the actually-treated approach, has been used, which means that only those who actually received the intended treatment to a reasonable extent were included in the analyses (5). If this latter approach is used, the randomization is broken and the results are more difficult to interpret. There is thus no obvious bias that could affect the conclusions of this study.

To the best of our knowledge, the present work is the first published work with convincing evidence of a reduction of sick-leave achieved by manual therapy. There was no important compensatory shift to sick-leave due to complaints other than low-back pain in the experimental group. No follow-up longer than six weeks, with an acceptable drop-out rate, is available (4), which makes our investigation, based on public sick-leave statistics with no drop-outs or missing data, the longest follow-up in the literature up to now.

There were also convincing differences between the two treatment groups in favour of manual therapy concerning the two different pain scores. These differences were, as far as significance is concerned, unexpectedly found to become stronger with time, and the pain score "at the moment" was 2.5 times larger at 4 months of follow-up in the conventionally treated group than in the experimental group.

An influence on pain score of manual therapy has previously been demonstrated by Rasmussen (3) and Brodin (5). In Rasmussen's investigation, the follow-up period was short, two weeks.

It could be argued that the reduction of sick-leave was achieved by SB's unwillingness to order rest and sick-leave, but the same attitude was taken in the conventionally treated group. Wisely performed manual medicine in a wider sense, being a good basis for a trustful patient-doctor relationship and for changing the sick-leave behaviour of the patients, might indeed contribute to a diminished sick-leave frequency, but since the sick-leave frequency fluctuated parallel to the pain score, which cannot be controlled by the therapist, sick-leave appears to be an acceptable measure of health if combined with some measure of pain.

In this study, two different approaches were compared, with a defined, complete therapeutic arsenal in each group, where the therapist is free to choose between different methods depending on diagnostic findings. In previous studies, two single methods or incomplete therapeutic arsenals were compared. The complete therapeutic arsenal in the experimental group might be the main reason for the good results of manual therapy in this investigation, since there are probably many different aetiological factors behind low-back pain. Another factor which was vital for our results is the steroid injections, which have not been used in combination with manual treatment in any previous investigation.

CONCLUSIONS

The results of this study show that manual therapy according to the Scandinavian school of manual medicine, in which the use of steroid injections is a part, is superior to conventional activating treatment in Swedish primary health care for reducing sick-leave costs and low-back pain. The manual treatment also seems to be less costly in spite of the better treatment results, since the treatment volume was smaller in the experimental group. The differences between the two groups decreased during follow-up, but nevertheless, in spite of the conventionally treated group's receiving continuous treatment during the follow-up to a larger extent than the manual treatment group, there was a persisting difference after 8 months. This implies a persisting treatment effect which could hardly be explained by an expectation effect only.

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