

T. Seferlis
G. Németh
A. M. Carlsson
P. Gillström

Conservative treatment in patients sick-listed for acute low-back pain: a prospective randomised study with 12 months' follow-up

Received: 6 October 1997
Revised: 10 March 1998
Accepted: 27 April 1998

Abstract We evaluated three different conservative treatment methods for acute low-back pain patients in groups following a manual therapy programme, an intensive training programme, or a general practitioner programme, the latter serving as the control group. Patients aged 19–64 years on sick leave for low-back pain with or without sciatica were included in a prospective randomised study evaluating outcomes such as impairment, pain, functional disability, socio-economic disability and satisfaction with the treatment or explanations. Evaluation by unbiased observers was performed at 1, 3 and 12 months. The three treatment groups were comparable at baseline. With regard to satisfaction, the patients in the manual therapy programme and those in the intensive training programme were more satisfied with the treatment than those in the general practitioner programme at all follow-ups. With regard to the explanations of current low-back pain episodes, the patients in the manual therapy programme were more satisfied than those in the general practitioner programme at all follow-ups. The manual therapy programme group were also more satisfied with the explanations than those in the intensive training programme

at the 1-month follow-up. However, no differences were revealed between the groups with respect to outcomes on measures of impairment, pain, functional disability or socio-economic disability. All three study groups showed rapid improvement. After 1 month a significant improvement was noted in all outcome values compared with the values on entry to the study. Within the limitations discussed in our study, it is concluded that (1) patients sick listed with acute low-back pain, with or without sciatica, will be significantly improved after 1 month regardless of conservative treatment programme; (2) they will be more satisfied with the treatment if they are referred to a manual treatment programme or a training treatment programme; (3) they will be more satisfied with the explanations of the acute low-back problem if they are referred to one of the above groups, especially the manual treatment group; (4) they will not show any other differences with respect to subjective and objective variables, either at short-term or at long-term follow-ups.

Key words Prospective · Randomised · Manual therapy · Intensive training · GP care · Follow-ups

T. Seferlis (✉) · G. Németh
Department of Orthopaedic Surgery,
Karolinska Hospital
S-171 76 Stockholm, Sweden
Fax: +46-8-517 764 46

A. M. Carlsson
Department of Psychiatry,
St. Göran's Hospital, Stockholm, Sweden

P. Gillström
Division of Surgery and Rehabilitation,
Karolinska Hospital, Stockholm, Sweden

Introduction

Although acute low-back pain is very common in the West and incurs large social costs, there is still little agreement on what treatment is the best [1, 6, 9, 20]. Several studies of different treatment methods have shown contradictory results. One explanation of the controversial results may be the study design and lack of long-term follow-ups with unbiased observers. There are two main types of conservative treatment: individual manual treatment programmes and programmes stressing training as the important factor.

A meta-analysis by Shekelle et al. [23], comprising 23 controlled trials, showed that spinal manipulation is of short-term benefit in some patients, particularly those with uncomplicated, acute low-back pain. In a systematic review of 36 randomised clinical trials, Koes et al. [15] found that the efficacy of spinal manipulation for patients with acute or chronic low-back pain was not demonstrated.

Blomberg et al. [3] concluded in a prospective randomised study that manual therapy combined with injections and training was superior to standard treatment. Studying patients with acute low-back pain, Carey et al. [5] found similar outcomes of care from primary care practitioners, chiropractors and orthopaedic surgeons. Patients seen by chiropractors reported greater satisfaction with the examination and explanation of the problem. In another study, continuing ordinary activities within the limits of pain led to more rapid recovery than either bed rest or back-mobilising exercises [17]. Another comparison showed that chiropractic treatment was more effective than hospital outpatient treatment, mainly in chronic or severe back pain [18]. In one study by Faas et al. [12], exercise therapy for patients with acute low-back pain gave no advantage over general practitioner care. In another study by the same author, therapy did not reduce sickness absence [11].

Since there is no consensus about the treatment of acute low-back pain patients, it is of great interest to evaluate different treatment programmes and find which is the most effective.

The aim of the present study was to compare a manual treatment programme, an intensive training programme and a general practitioner programme in patients sick listed for acute low-back pain with or without sciatica regarding impairment, pain, functional disability, socio-economic disability and patient's satisfaction with treatments and explanations of their low back pain.

Patients and methods

Patients

The study population comprised 180 patients, 95 men and 85 women, mean age 39 years (range 19–64). Of these, 114 (63%) were manual workers and 66 (37%) were office workers. Fifty percent were smokers. The patients were referred to us from general practitioners, occupational doctors (i.e. physician specialised in occupational related diseases) or from our emergency ward. They gave their informed consent to participate and also agreed not to undergo any other treatment during the study year. The study was approved by the Karolinska Hospital Ethical Committee. Inclusion and exclusion criteria are listed in Table 1.

Study design (Fig. 1)

Consecutive patients referred to our department sick listed for acute low-back pain for up to 2 weeks were examined by an orthopaedic spine surgeon and a pain psychologist. Patients fulfilling our inclusion criteria were randomised into one of the three treatment programmes, which thereby contained 60 patients each. Follow-ups were done at 1, 3 and 12 months by unbiased observers.

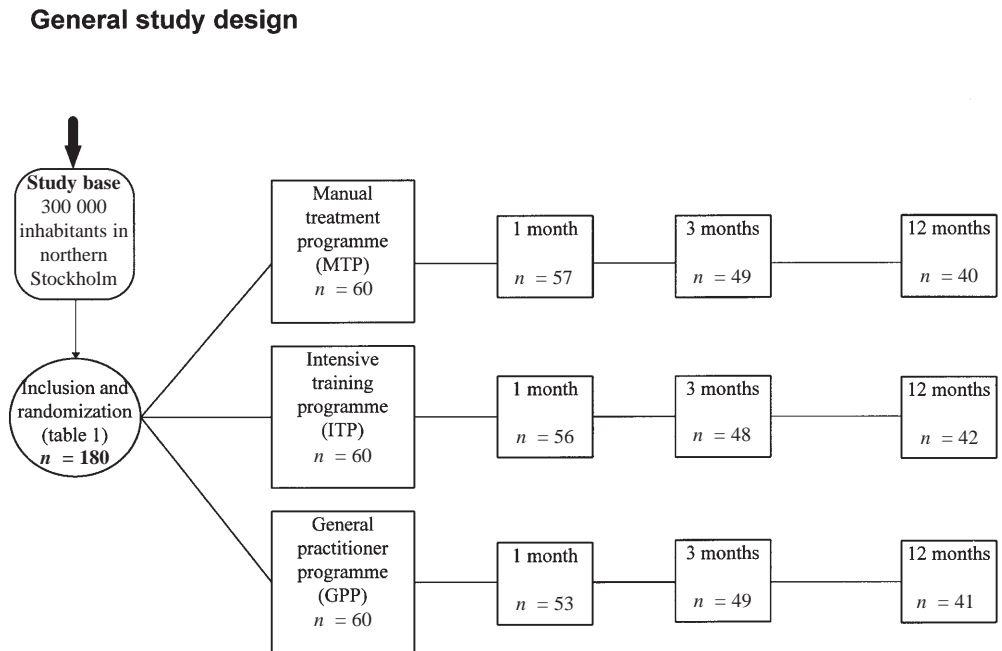
All dropouts were followed and divided into "controlled dropouts" and "non-controlled dropouts". The first group consisted of patients that required surgery during the study year, and thus were unable to follow the prescribed treatment programme. The second group contained patients leaving the study by their own choice for other reasons.

Records were obtained from the Social Insurance Office concerning duration of sick leave(s) for low-back pain during the

Table 1 Inclusion and exclusion criteria (*LBP* low-back pain)

Inclusion criteria	Exclusion criteria
Low-back pain with or without sciatica requiring sick leave	Sick listed and/or treated for low-back pain within 1 month before study entry
A sick leave period for LBP less than 2 weeks before entering the study	Previous spine trauma or surgery
18–64 years of age	Inflammatory disease
Employed	Tumours of the spine
	Symptoms from cervical spine, thoracic spine or upper extremities
	Clinical symptoms or severe low-back disease demanding surgery
	Severe/major medical disease
	Pregnancy
	Drug and alcohol addiction
	Psychiatric disease/disorder
	Unsatisfactory knowledge of the Swedish language

Fig. 1 Study design and number of patients included in each study group. Inclusion criteria are listed in Table 1



study year, for the dropouts. In addition, we obtained data on the number of treatment sessions. These patients were also interviewed to establish whether they had the same job at the end of the study year and if they had had any other treatments.

The “intention to treat” principle was mainly followed. Thus, the dropouts remained in the treatment group as far as they still participated in the study. At the end of the study, information for all dropouts was collected regarding sick leave, number of treatments, change of job, recurrences and other treatments.

Study treatments

Manual therapy programme (MTP)

The programme and the number of treatment sessions were decided by the physiotherapist.

The MTP treatment was tailored to each and included:

1. Information
2. Autotraction
3. Manipulation of the lumbar facet joint and manipulation of the sacroiliac joint, intended to separate the joint surfaces
4. General mobilisation of the lumbar spine by passive three-dimensional coupled movements
5. Segmental and level-specific passive mobilisation with supposed facet locking
6. Auto-mobilisation
7. Muscle Energy Technique (MET). The therapist resists the patients' static muscular contraction. The contraction causes a small active movement with a short lever in the target joint
8. Different types of stretching
9. Controlled training of co-ordination and stability in the spine and extremity joints

Intensive training programme (ITP)

Patients in the intensive training group received training for about 8 weeks (three times/week), with the number of sessions determined by the physiotherapist. The programme included informa-

tion, muscle training and general condition training. Muscle training included exercises to decrease muscle fatigue and increase muscle strength and co-ordination in e.g. abdominal, gluteal, paraspinal, shoulder and lower-extremity muscles. The training was planned with respect to pain and clinical findings on entry to the study as follows: (1) mobility exercises without load and (2) increasing load on muscle groups to increase motor unit activation. First, exercises at 20–35% of maximum muscle strength were prescribed to decrease fatiguability. Second, exercises at 70–95% of maximum muscle strength were prescribed to increase muscle strength and co-ordination. Most treatments were conducted with patients in small groups.

General practitioner programme (GPP) – the control group

This is the most common treatment modality for low-back pain patients. The patients in this group were referred to their general practitioner (GP) from whom they received standard treatment, i.e. rest, sick leave, drug prescription (e.g. analgesics, anti-inflammatory drugs), advice about posture and information about the self-curing nature of the disease. For patients failing to recover, low-back school and physiotherapy were often prescribed later.

Patients in the MTP and ITP groups started treatment very early, 1–3 days after randomisation, while patients in the GPP group started later. Treatment was free for the MTP and ITP groups, but not for the GPP patients. This was because we wanted the latter group to receive the normal treatment currently offered by GPs.

The duration of treatment was decided by the therapist and the patients were encouraged to continue with exercises at home after finishing the treatment programme. If a patient had a recurrence during the study year, he or she was referred to the treatment group again for further treatment.

Questionnaires

Pain

A Pain Questionnaire developed by Carlsson [6] was used to describe patients' pain experience. It contained questions regarding

Table 2 Outcome variables. Measurements at entry and follow-ups at 1, 3 and 12 months. Variables 7, 8 and 9 were assessed after finishing the study

<i>Impairment</i>	
1. Findings at physical examination	
2. Mobility of the spine	
<i>Pain</i>	
3. Pain intensity	
4. Pain frequency	
5. Consumption of analgesics	
<i>Functional disability</i>	
6. Oswestry Disability Rating Index	
<i>Socio-economic disability</i>	
7. Sick leave(s) duration during the study year	
8. Recurrences during the study year	
9. Change of job because of low-back pain	
<i>Satisfaction</i>	
10. Satisfaction with treatment	
11. Satisfaction with explanations of current episode of low-back pain	

pain intensity, frequency, location and quality, and consumption of analgesics. Both the pain intensity and pain frequency were registered three times close to the follow-ups, and the means were calculated and considered as the variable values for the follow-ups.

Intensity. The intensity of pain was recorded on a modified Borg ten-point numerical scale [4], where 1 corresponded to “no pain” and 11 to “maximal pain”. The patient was asked: “How severe is the pain right now?”

Frequency. Pain frequency was a variable with eight possible alternative answers to the question: “How often do you have pain?” “1 corresponded to “no pain” and 8 corresponded to “always, never pain-free”.

Location and quality of pain. Standard pain drawings were used.

Functional score

The validated and widely used Oswestry Low Back Disability Questionnaire [13] was employed to estimate the patient’s disability at the first visit and the follow-ups.

Working conditions

Patients’ working conditions were assessed with a questionnaire which included variables shown to be of importance [1], i.e. work environment, work postures, lifting and forceful movements, repetitive work, vibrations, patients’ estimation of load at work, physical activities in leisure time and workplace environment.

Medical history and sick leave

Demographic variables in this questionnaire included information about previous sick history, treatment during the past year and characteristics of the current episode of low-back pain. In addition, we obtained from the Social Insurance Office records on sick leave for low-back pain or other reasons during the previous 2 years and during the study year for each patient.

Physical examination

A thorough examination of the spine and the lower extremities was undertaken on entry to the study and during the follow-ups. The Lasegue sign, the reflexes of the lower extremities and motor and sensory function were tested. Spinal mobility was examined using a Debrunner kyphometer [8]. We tested deviation of the spine in forward bending, difficulties in walking, pain scoliosis and tenderness of the spinal area. Non-organic signs according to Wadell et al. [26] were also included in the clinical examination.

Outcome variables and analysis

Outcome variables are listed in Table 2. All variables for all patients were assessed on entry and at follow-ups at 1, 3 and 12 months. Comparisons were made between the three treatment programmes at each follow-up. In addition, the differences between the 1 month follow-up values and the baseline values were calculated for individual patients. Subsequently, the three study programmes were compared with respect to improvement over time.

Table 3 Outcome: impairment, pain and functional disability

	Entry (n = 180)	1 month (n = 166)	3 months (n = 146)	12 months (n = 123)
<hr/>				
<i>Findings at physical examination</i>				
Lumbar pain scoliosis, yes: n (%)	21 (11)	11 (7)	3 (2)	None
Pain on movement, yes: n (%)	95 (53)	27 (16)	15 (10)	7 (6)
Pain on palpation of lumbar spine, yes: n (%)	94 (52)	33 (20)	19 (13)	8 (7)
Lasegue sign positive, yes: n (%)	38 (21)	17 (10)	6 (4)	4 (3)
Sagittal mobility of the lumbar spine: mean (SD)	40 (17)	50 (20)	56 (19)	64 (17)
<i>Pain</i>				
Intensity: mean (SD)	5.1 (1.4)	4.6 (1.7)	3.5 (2.6)	2.5 (1.7)
Frequency: mean (SD)	6.3 (1.5)	5.2 (1.9)	3.8 (2.1)	3.1 (1.9)
Consumption of analgesics, yes: n (%)	122 (67)	71 (43)	36 (25)	26 (21)
<i>Disability</i>				
Oswestry score: mean (SD)	30 (1.8)	20 (18)	11.7 (12)	9.8 (11)

Table 4 Outcome: socio-economic disability at 1-year follow-up (*MTP*, manual treatment programme, *ITP*, intensive training programme, *GPP* general practitioner programme, control group)

Sick leaves and recurrences	MTP (<i>n</i> = 40)	ITP (<i>n</i> = 42)	GPP (<i>n</i> = 41)
Days off work for low-back pain			
Mean (SD)	57 (78)	49 (76)	52 (63)
Median (range)	28 (4–365)	23 (5–365)	30 (4–365)
4–14 days (<i>n</i>)	6	6	4
15–28 days (<i>n</i>)	14	19	14
29–50 days (<i>n</i>)	8	8	10
51–90 days (<i>n</i>)	5	5	8
91–365 days (<i>n</i>)	7 ^b	4 ^b	5 ^b
Days off work for other reasons			
Mean (SD)	16 (45)	9 (11)	20 (50)
Median (range)	4 (0–275)	3 (0–46)	6 (0–275)
Disease-specific sick leave rate ^a			
Mean (SD)	17.6 (25)	13.6 (20.8)	16.7 (21.3)
Median (range)	18 (2–100)	14 (1.4–100)	17 (1.1–100)
Recurrences during the study year			
None: <i>n</i> (%)	26 (65)	29 (69)	24 (60)
1 recurrence: <i>n</i> (%)	10 (25)	7 (17)	12 (30)
2 recurrences: <i>n</i> (%)	2 (5)	3 (7)	4 (10)
3 or more recurrences: <i>n</i> (%)	2 (5)	2 (5)	None

^aDisease-specific percent rate: $\frac{100 \times \text{days off work for low-back pain}}{365 - \text{days off work other reasons}}$

^bOne patient off work during the whole study year

Subgroup analysis

We wished to check whether comparable results would be obtained with groups that were homogeneous with respect to symptoms and severity. In a second step, therefore, from each of the three treatment groups three subgroups were created as listed below, and the analyses were repeated:

1. Patients with only low-back pain (without sciatica, or positive Lasegue) on entry to the study
2. All patients not improved at 1-month follow-up
3. Patients with only low-back pain (without sciatica, or positive Lasegue), not improved at 1-month follow-up

For the second and third subgroups, “no improvement” was defined as being sick listed for low-back pain or pain intensity ≥ 5.1 or Oswestry ≥ 30 .

Statistics

The MEDLOG statistical database [19] was used for input, storage and analyses of data using standard statistical methods.

The “intention to treat” principle was mainly used in the statistical analysis. Thus, all patients remained in the group they were assigned to by randomisation, even the dropouts, as far as they participated in the measurements. The exceptions were for measures of sick leave and recurrences during the study year.

Continuous variables are expressed as means and category variables as frequencies. For ordinal scaled variables, medians were used. For interval scaled variables, comparisons between groups were performed with Student’s *t*-test or one-way analysis of variance (ANOVA) when two or three means were tested, respectively. For analysing ordinal scaled variables we used the chi-square test for comparing frequencies and the Wilcoxon or the Kruskal-Wallis test for comparing two or three medians, respectively. $P < 0.05$ was considered statistically significant.

Results

Analyses of baseline characteristics between the three treatment groups on entry to the study revealed no differences regarding ergonomics, impairment, pain, sick leave, functional disability or findings on clinical examination.

During the study year, 48 patients (27%) underwent CT or MRI examinations because of persisting severe symptoms or deterioration. Disc herniation was found in 33 patients (18%). There were no differences between the study groups with respect to these parameters.

Outcome

Patients in all three groups had improved significantly according to outcome variables at the 1-month follow-up.

Impairment, pain and functional disability (Table 3)

Regarding pain, on entry to the study the patients scored 5.1 on the modified Borg scale, indicating moderate pain. Pain intensity decreased significantly to 4.6 at 1 month, 3.5 at 3 months and 2.5 at the 1-year follow up. Pain frequency halved from 6 to 3. Consumption of analgesics had decreased at the 1-year follow-up, with 21% consuming analgesics regularly compared to 67% on entry.

Table 5 Outcome: satisfaction with treatment and with explanations of the problem, by group. Mean (SD) on a 1–5 scale (5 = very satisfied, 4 = somewhat satisfied, 3 = doubtful, 2 = rather disappointed, 1 = very disappointed)

Satisfied with	MTP	ITP	GPP	<i>P</i> < 0.05
Treatment of low-back pain at:				
1 month	4.4 (0.8)	4.3 (0.8)	3.4 (1.2)	MTP & ITP > GPP
3 months	4.5 (0.6)	4.4 (0.6)	3.5 (1.1)	MTP & ITP > GPP
12 months	4.3 (0.9)	4.1 (1.1)	3.6 (1.2)	MTP & ITP > GPP
Explanations of the low back pain problem at:				
1 month	4.2 (1.0)	3.8 (0.9)	3.4 (1.3)	MTP > ITP & GPP
3 months	4.4 (0.7)	4.0 (0.9)	3.5 (1.1)	MTP & ITP > GPP
12 months	4.2 (1.0)	3.8 (1.1)	3.5 (1.3)	MTP > GPP

Socio-economic disability (Table 4)

There were no differences between the study groups regarding socio-economic disability. Mean sick leave was 53 days (SD 72) and the median was 27 days. Twenty-five percent of the patients had one episode or recurrent low back pain during the study year and 7% had two or three recurrences.

At the 1-year follow up, 85% of the patients in all three groups had remained in the same job, 5% had moved to lighter work. Only one or two patients in each study group had changed jobs because of low-back pain.

Satisfaction (Table 5)

At all follow-ups, the MTP and ITP groups were more satisfied with the treatment than was the GPP control group. With regard to the explanations of current low-back pain episodes, the patients in the MTP group were more satisfied than the GPP (control) group at all follow-ups. The MTP group was also more satisfied than the ITP group at the 1-month follow-up. The subgroups were further analysed as described below.

Number of treatment sessions

The mean number of treatment sessions in the MTP group, with individual treatment, was ten. In the ITP group, with training in small groups, the number of treatments was 18. In contrast to these figures, the mean number of treatments in the GPP group was four, while 19 patients (46%) received no treatment (i.e. physiotherapy, low-back school) beyond one or more visits to the GP. Comparisons between these 19 patients and the 22 who were referred to physiotherapy did not reveal any differences regarding outcome variables, including the satisfaction variables.

Analysis of subgroups

In general, in all three subgroups (defined in the Methods section), as in the main groups studied, the patients in the MTP and the ITP treatment group were more satisfied with treatment and explanations of current episode of low-back pain than the controls at the 1- and 3-month follow-ups, although there were slight differences between the subgroups at the 1-year follow-up. No differences were found with regard to other outcome variables. The subgroup results therefore confirm the findings from the main groups.

Dropouts (Table 6)

Comparison between the group who completed the study and the dropouts as a group revealed differences in "age" (dropouts younger) and occupation (over-representation of blue-collar workers among dropouts). In addition, there was no difference in Wadell's sign between dropouts and non-drop-outs. Reasons for withdrawal, time of withdrawal and distribution between the groups are shown in Table 6.

The dropouts included some patients who were operated on for disc herniation during the study period. We divided the dropouts into:

1. "Controlled dropouts", i.e. those excluded because of operation during the study, and
2. "Non-controlled dropouts", i.e. those who left for other reasons

Controlled dropouts (n = 17 at 1-year follow-up). Fifteen patients (8%) had disc herniation surgery during the study. Of these, seven had positive Lasegue sign at the first visit (of 38 patients with positive Lasegue in the whole group). However, some patients with negative Lasegue sign at the first visit deteriorated during the study year, developing positive Lasegue sign and severe clinical symptoms, and eight patients required surgery for disc herniation.

Comparing baseline characteristics among the three groups (controlled dropouts, non-controlled dropouts and patients not leaving the study) revealed significant differ-

Table 6 Dropouts: reasons and time of leaving the study

Reason and time of leaving	MTP (n = 20)	ITP (n = 18)	GPP (n = 19)	Total (n = 57)
Due to rapid improvement				
1-month follow-up	1	1	2	4
Due to operation				
1-month follow-up	2 ^a	–	–	2
3-month follow-up	3	3	–	6
1-year follow-up	3 ^b	4	2	9
Not satisfied with the project				
1-month follow-up	1	–	3	4
3-month follow-up	2	1	3	6
1-year follow-up	2	1	5	8
Other reasons/diseases				
1-month follow-up	–	2	2 ^a	4
3-month follow-up	1	3 ^d	–	4
1-year follow-up	2 ^c	1	–	3
Reason unknown				
1-month follow-up	–	–	1	1
3-month follow-up	1	2	–	3
1-year follow-up	2	–	1	3

^aOne patient operated on for cauda equina syndrome, one patient operated on for gastric ulcer

^bOne patient operated on for neurinoma

^cOne patient had intestinal cancer

^dOne patient had multiple sclerosis

^eOne patient had Mb Bechterew

ences. The controlled dropouts compared to non-controlled dropouts and patients not leaving the study exhibited the following characteristics: (1) higher mean age, (2) sitting more at work, (3) more satisfaction at the workplace, (4) previous sciatica common, (5) no special reason for current low-back pain episode, (6) pain on coughing, (7) highest values for pain, (8) movement pain and positive Lasegue sign, (9) higher mean Oswestry score, (10) less lumbar spine mobility.

Non-controlled dropouts (n = 40 at 1-year follow-up). The non-controlled dropouts were characterised as follows: (1) younger, (2) blue-collar workers over-represented, (3) had stated a reason for current low-back pain episode, (4) current symptoms started at work, (5) lower Oswestry score, (6) almost all had negative Lasegue sign, (7) greater lumbar spine mobility.

Records were obtained from the Social Insurance Office concerning duration of sick leave(s) for low-back pain during the study year³, for the dropouts. These patients were also interviewed regarding whether they had the same job at the end of the study year. Mean sick leave duration was 62 days (SD 79), the median value being 36 days, and this was statistically significant compared to the treated patients who completed the study. Twenty-three patients of 40 (58%) had no recurrence of low-back pain

during the study year, 85% were doing the same work after 1 year. Regarding the “controlled dropouts”, the mean sick-leave was 128 days (SD 81), the median value being 116 days. Twelve patients of 17 (70%) had the same or lighter work, one patient had changed job because of low-back pain and three patients were sick listed at the end of the year.

Discussion

The study design represents a pragmatic approach to patients with low-back pain. Our main inclusion criterion was sick leave for low-back pain with or without sciatica. This may have created a heterogeneous material. However, the mixture of patients with or without sciatica mirrors the real situation for a clinician and thus this is the situation that should be evaluated. Notably some patients presenting with only low-back pain developed a positive Lasegue sign during the study year. Among the 15 who underwent lumbar disc surgery only 7 had shown positive Lasegue sign on entry. Of the 142 patients with low-back pain only, about 12% deteriorated, requiring further examination and 8 (6%) were later operated on for disc herniation. This reflects one of the difficulties in having a pure low-back pain patient group.

About one-third of patients experiencing low-back pain stay home from work [2]. The life-time prevalence of sickness absence due to low-back pain has been estimated to be 15–18% [24]. Patients with disabling symptoms and thus on sick leave may well not recover as soon as those with mild, non-disabling symptoms. Thus we selected on “sick leave” as one of our inclusion criteria.

Our study, like most other prospective studies, has the drawback of dropouts. This was managed with an “intention to treat” analysis. Thus, the dropouts were also followed and evaluated and further divided into “controlled” and “non-controlled” drop outs. There was no systematic influence from the dropouts on any of the treatment groups.

The controlled dropouts consisted of patients who underwent surgery during the study year and therefore could not participate in the treatment programmes. Fifteen patients underwent surgery for disc herniation and two for other reasons. Median duration of sick leave for this group was 128 days.

Regarding the non-controlled dropouts, ten patients (6%) had left by the first follow-up. At the second follow-up, the numbers leaving had risen to 25 (14%) and at 12 months the total was 40 (22%). Thus the non-controlled group is very well characterised with respect to time and reasons for leaving the study (Table 6). Analysis showed differences between the non-controlled dropout group and the study group with respect to age and severity of disabling symptoms, the dropouts being younger and less disabled. Van den Hoogen et al. [14] also reported that pa-

tients with less severe low-back pain participated less often or did not complete the follow-up study.

Non-controlled dropouts also had a longer duration of sick leave, with a median of 36 days compared with 27 days in the whole study group. In general the non-controlled dropouts were younger, were more likely to be blue-collar workers, had stated a reason for their current low-back pain episode, their current symptoms started at work, had lower Oswestry score, and had less symptoms. They also reported less satisfaction at work compared to the controlled dropouts. Several questions arise from these findings, which prompt further investigations. Are this group not motivated with regard to their jobs? Does the fact that the symptoms start at work indicate workers are seeking compensation claims? Are younger persons more prone to stay on sick leave?

Our inclusion criteria with a mixture of patients with or without sciatica mirrors the real clinical situation. Broad inclusion criteria increase the risk of heterogeneous groups with no specific diagnosis, making it more difficult to detect a special effect of a certain treatment. However, the study population was rather large and the dropouts were few during the early phase. Future studies should focus on more homogeneous groups, requiring a more specific diagnosis of the low-back pain symptoms.

To further analyse our three groups with respect to homogeneity, we analysed three subgroups. These subgroups exhibited the same outcomes as seen in the main treated groups. Thus we conclude that although our main groups were slightly heterogeneous with regard to sciatica or not, rapid improvement or not, this did not influence the main outcome results.

In clinical studies of low-back pain there are difficulties in having a control group with *no* treatment (patients in pain expect treatment when they visit a doctor). Notably, 19 patients in the GPP group never started physiotherapy. On the other hand, the controls were offered what was, and still is, the “golden standard” for acute low-back pain, i.e. outpatient treatment by GPs according to current low-back programmes. It was of interest to compare existing standard treatment with other treatment methods believed to be of greater efficacy.

All groups, including the control group, showed significant, rapid improvement at 1 month. This is interpreted as the natural course of low-back pain. The improvement continued at 3- and 12-months follow-ups, and regarding “sagittal lumbar mobility” all groups had reached normal values by then (Fig. 2) [25]. On the other hand, the non-controlled dropouts had a significantly longer duration of sick leave at the 1-year follow up.

As for satisfaction, our study revealed significant differences between the study groups in satisfaction with treatment and explanations of current symptoms, mainly in favour of the MTP group. The great importance of explanations of symptoms among patients with low-back pain has been stressed previously [10].

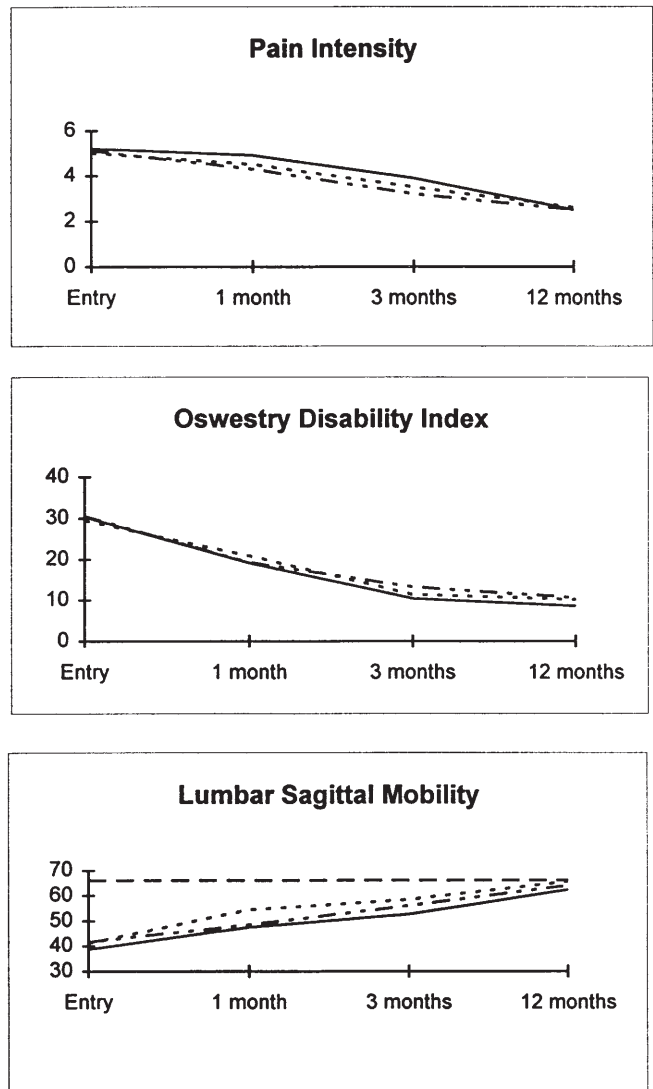
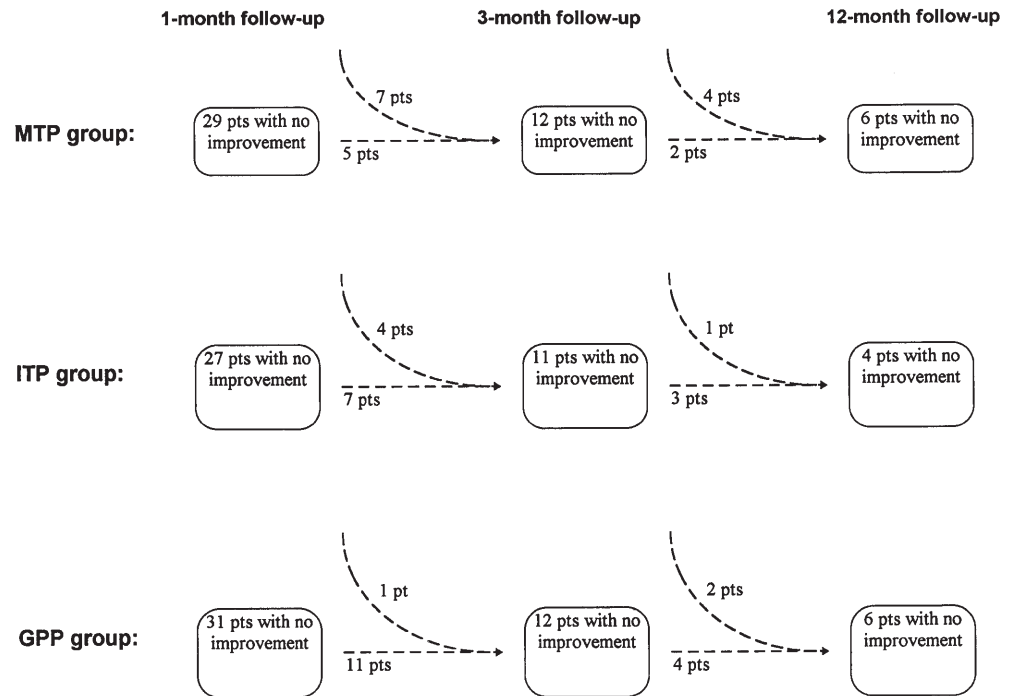


Fig. 2 Pain intensity, Oswestry and lumbar sagittal mobility at entry and at follow-ups for the three treatment groups (..... Manual treatment programme; - · - · - Intensive training programme; — General practitioner programme; - - - Reference mobility figures from normal individuals [25])

Carey [5] compared treatment by chiropractors, orthopaedic surgeons and general practitioners. His chiropractor group were more satisfied than the others. This is in agreement with our study; both the manual treatment group and the intensive training group were more satisfied with the treatment than the GPP group. One explanation of the difference between the GPP group versus the MTP/ITP groups may be that the controls had few (if any) treatment sessions and they started treatment later than the others. The explanation may be even simpler: the placebo effect of personal contact with, and involvement of, care staff. Regarding the difference in “satisfaction with explanations” between groups, one additional explanation may

Fig. 3 Patients scoring “not improved” in the different treatment groups at the different follow-ups. *Arrows joining horizontal arrows indicate patients with recurrence re-entering the study*



be that the treatment in the manual group was individual, that in the training group in small groups.

There were no differences in impairment, disability or socio-economic outcome such as sick leave. An important factor to consider when results are “non-significant” is statistical power ($100-\beta$). Differences in pain intensity of 2 on a scale of 10; pain frequency of 2 on a scale of 8; Oswestry disability score of 10 and sagittal lumbar mobility of 15 should be considered as clinically relevant. Calculating these differences in this material revealed that, with a risk level of 5% (α), a power of 80% ($100-\beta$) and a one-sided hypothesis, it would be possible to detect a difference between the MTP, ITP and GPP groups of 1.2 units in pain intensity, 1.3 units in pain frequency, 9 units in Oswestry and 12 units in sagittal lumbar mobility. These factors thus met the above-mentioned clinical criteria with good margins. Sick leave was the only factor that did not meet these criteria, with the given assumptions, 52 days of difference would be necessary for detection. This is probably because some patients in all groups were sick listed for long periods during the study, resulting in very high standard deviations for sick leave. Future evaluations of sick leave duration should use large samples, because standard deviations with respect to sick leave with low-back pain diagnosis are very large.

We were not able to confirm the finding in Shekelle’s [23] meta-analysis that manual treatment was of short-term benefit. On the other hand our conclusions agree with Koes et al. [15], where in a systematic review of 36 randomised clinical trials the efficacy of spinal manipulation for patients with acute or chronic low-back pain was

not demonstrated. Our results also agree with those of Faas et al. [11, 12], indicating no advantage of exercise therapy over usual care from GPs. They do not agree with those of Blomberg et al. [3], in whose study several treatment methods were used by the same therapist, who was also the evaluator.

The recurrence rate was high (35%) during the study year, as in other studies [2]. Thus, at each follow-up there were patients scoring “not improved”. Were these the same at all follow-ups, or different patients? Further analysis (Fig. 3) showed that some patients improved while others had a recurrence, thus scoring high disability at the different follow-ups. In the current study we report 18% herniated discs, 2.5 pain scale and 21% analgesics consumption at 1 year. These figures may seem high. However, our data mirrors reality. There may be several reasons.

1. Many other studies focus on patients *reporting* low-back pain. Our study focuses on patients *sick leave* due to *acute* low-back pain. Thus this is a selected group of patients.
2. Our follow-ups were done meticulously, with interviews, questionnaires and examinations carried out separately by an orthopaedic spine specialist and a pain psychologist.
3. Our study is a long-term follow-up study with 12 months as its end point.

Figures approximately corresponding to ours have been reported. Long et al. [16] state that 33% low-back pain patients had disc herniation and 20% underwent surgery. In another study, by van den Hoogen et al. [14], the authors

report 35% persistent low-back pain after 12 weeks and 10% at the 12-month follow-up.

There were large differences between the study groups with respect to number of treatment sessions. This was probably because the number was decided by the therapist. The training group was planned to train regularly for several weeks. The socio-economic consequences of this are the subject of a later paper [22].

In summary the current study shows that patients sick listed with acute low-back pain, with or without sciatica will be:

1. Significantly improved after 1 month regardless of conservative treatment programme
2. More satisfied with the treatment if they are referred to a manual or a training treatment programme
3. More satisfied with the explanations of the acute low-back problem if they are referred to the above groups, especially the manual treatment group

Patients will not show any other differences regarding subjective and objective variables at either short-term or long-term follow-ups.

Conclusion

Within the limitations of our study we conclude that manual treatment or intensive training do not give better treatment results than conventional GP care in patients sick listed for acute low-back pain, although the patients are less satisfied with GP care.

Acknowledgements This work was supported by grants from AMF-Sjukförsäkring, Stockholm, Sweden. The authors thank Kristina Isacson for collection of data and for discussions.

References

1. Andersson BG (1981) Epidemiologic aspects on low-back pain in industry. *Spine* 6:53–60
2. Biering-Sorensen F (1983) A prospective study of low back pain in a general population. III. Medical service-work consequence. *Scand J Rehabil Med* 15: 89–96
3. Blomberg S, Svärdsudd K, Mildnerberger FA (1994) A randomised study of manual therapy with steroid injections in low-back pain. Telephone interview follow-up of pain, disability, recovery and drug consumption. *Eur Spine J* 3:246–254
4. Borg G (1990) Psychophysical scaling with applications in physical work and the perception of exertion. *Scand J Work Environ Health* 16 [Suppl 1]: 55–58
5. Carey TS, Carret J, Jaskman A (1995) The outcomes and costs of care for acute low back pain patients seen by primary care practitioners, chiropractors, and orthopaedic surgeons. *N Engl J Med* 5:913–917
6. Carlsson AM (1986) Personality characteristics of patients with chronic pain in comparison with normal controls and depressed patients. *Pain* 3:373–382
7. Cherkin D, Deyo AR, Wheeler K, Ciol AM (1995) Physician views about treating low back pain. *Spine* 20:1–10
8. Debrunner HU (1972) Das Kyphometer. *Z Orthop Ihre Grenzgeb* 110:389–392
9. Deyo RA (1983) Conservative therapy for low-back pain. *JAMA* 250:1057–1066
10. Deyo RA (1984) Patient satisfaction with medical care for low-back pain. *Spine* 11:28–30
11. Faas A, Chavannes AW, van Eijk JThM, Gubbels JW (1993) A randomised, placebo-controlled trial of exercise therapy in patients with acute low back pain. *Spine* 18:1388–1395
12. Faas A, van Eijk J Th, Chavannes AW, Gubbels JW (1995) A randomised trial of exercise therapy in patients with acute low back pain. *Spine* 20:941–947
13. Fairbank J, Davies J, Couper J, O'Brien J (1980) The Oswestry Low Back Disability Questionnaire. *Physiotherapy* 8:271–273
14. Hoogen H van den, Koes B, Devillé W, Eijk J van den, Bouter L (1997) The prognosis of low back pain in general practice. *Spine* 22:1515–1521
15. Koes BW, Assendelft WJJ, van der Heijden GJMG, Bouter L (1996) Spinal manipulation for low back pain. An updated systematic review of randomised clinical trials. *Spine* 21:2860–2873
16. Long D, BenDebba M, Torgersson W, et al (1996) Persistent back pain and sciatica in the United States: patient characteristics. *J Spinal Disord* 9:40–58
17. Malmivaara A, Häkkinen U, Aro T, Heinrichs ML, Koskeniemi L, Kosma E, Lappi S, Palhoeimo R, Servo C, Vaaranen V, Hernberg S (1995) The treatment of acute low back pain – bedrest, exercises, or ordinary activity. *N Engl J Med* 6:351–355
18. Meade TW, Dyer S, Browne W, Townsend J, Frank AO (1990) Low back pain of mechanical origin: randomised comparison of chiropractic and outpatient treatment. *BMJ* 300:1431–1437
19. MEDLOG – Clinical Data Management System Rel. 94.11. MEDLOG Systems, Incline Village, Nevada
20. Scheer JS, Radack LK, O'Brien RD (1995) Randomised controlled trials in industrial low back pain relating to return to work. 1. Acute interventions. *Arch Phys Med Rehabil* 76:966–973
21. Seferlis T, Németh G, Carlsson AM, Gillström P (1998) Acute low back pain patients exhibit a five fold increase in sick leave because of other disorders. A case-control study. (Submitted for publication)
22. Seferlis T, Lindström L, Németh G (1998) Cost-minimisation analysis of three conservative treatment programmes in 180 patients sick listed for acute low-back pain. (Submitted for publication)
23. Shekelle PG, Adams AH, Chassin MR, Hurwitz, Brook RH (1992) Spinal manipulation for low-back pain. *Ann Intern Med* 117:590–598
24. Skovron ML (1992) Epidemiology of low back pain. *Baillière's Clin Rheumatol* 6:559–573
25. Stockholmsundersökningen (1993) Stockholm's study on 358 "back-healthy" men and women (in Swedish). MUSIC Books, Stockholm
26. Waddell G, McCulloch J, Kummel E, Vennor R (1983) Nonorganic physical signs in low-back pain. *Spine* 2:117–125