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A CONTROLLED STUDY ON THE OUTCOME OF INPATIENT AND OUTPATIENT TREATMENT OF LOW BACK PAIN

Part III. *Long-Term Follow-Up of Pain, Disability, and Compliance*

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ABSTRACT. The long-term outcome results of inpatient and outpatient treatment of low back pain (LBP) were studied in 476 subjects (aged 35–54, 63% men) randomly assigned to three study groups: inpatients ($n=157$), outpatients ($n=159$), and controls ($n=160$). The study included changes in the severity of low back pain, grade and disability, compliance with self-care, data on disability pensions, and days of sickness allowance during a 2.5-year follow-up period. These variables were used as outcome criteria. Pain and disability had decreased significantly in the two treated groups up to the 3-month follow-up. LBP was still a little slighter in the inpatients at the 1.5-year and 22-month follow-ups, but there were no significant differences between the groups in disability caused by LBP. The refresher programme carried out 1.5 years after the first one did not bring about as clear short-term improvement in pain and disability as the first treatment. During the whole 2.5-year follow-up compliance with self-care was better in the two treated groups, especially in the inpatients. Days of sickness allowance had increased somewhat more in the controls than in the inpatients during the follow-up. No differences between the groups were found in the number of disability pensions granted.

Key words: low back pain, outcome of treatment, compliance.

The magnitude and diversity of problems connected with chronic low back pain, its prevention, rehabilitation, and management has been widely recognized, and the need for preventive and early rehabilitation measures has been strongly emphasized (e.g. 1, 14, 15). There are, however, only a few studies in which the outcome of secondary prevention of low back trouble has been investigated in a controlled fashion (cf. 8, 9, 12, 13, 14, 16, 19, 22). Results from outcome studies have been controversial; to compare results from different studies is difficult because of the diversity of study designs, treatments applied, patient samples, evaluations of outcome, and follow-up periods. Promising results have been reported from, among others, the studies of Mayer et al. (19) and Linton et al. (14) where the problem of chronic low back pain has been attacked with new approaches.

The present study is a controlled prospective study on the outcome of interventions consisting of both preventive and rehabilitative components. The sample of the study comprised subjects with a risk of back pain disability assessed on the basis of their former back pain and work history. Two kinds of interventions were used, i.e. inpatient and outpatient treatment. The interventions consisted of educational components, e.g. on ergonomic factors, back and relaxation exercises, and other physical therapy modalities, emphasizing the role of self-care in the prevention and early rehabilitation of low back disability.

The present paper deals with outcome results based on the 2.5-year follow-up period of the two intervention modalities, using pain, disability, compliance with self-care, and days of sickness allowance as criteria. In addition, data on disability pensions are presented. In Parts I and II of the study (10, 20) the short-term effects, i.e. results of the 3-month follow-up, were described. Long-term effects on physical measurements are presented in another paper (21).

MATERIAL AND METHODS

Subjects. The subjects ($n=476$, aged 35–54, 63% male) were selected from among blue-collar workers employed by two State Institutes and various enterprises in the Helsinki Metropolitan Area, and farmers from Southern Finland. Selection was carried out by a mailed questionnaire, the final selection being made in an examination by a physiatrist. The main criteria for selection were (*a*) the subject had been enganged in physically strenuous or moderately strenuous work for at least ten years, (*b*) he/she had suffered from chronic or recurrent low back pain for at least two years, (*c*) it had affected his/her working and physical capacity, (*d*) it had caused sick-leaves during the past two years, and (*e*) low back pain was the major health problem of the subject; no other

severe long-term illnesses were present. The subjects were randomly assigned to three intervention groups: the *inpatient* group, the *outpatient* group, and the *control* (no treatment) group.

Procedure. The study comprised pre-treatment examinations, one treatment period plus a refresher programme after 1.5 years, and five follow-ups. The pre-treatment examinations consisted of, for instance, examinations by a physiatrist and a physiotherapist, and questionnaire surveys. The follow-ups were carried out 3, 8, and 18 months after the first treatment and 3 and 12 months after the refresher programme. Apart from the 8-month follow-up, which was a questionnaire survey, all other follow-ups also comprised physical measurements and/or a physiatrist's examination.

The physiatric and physical examinations have been described earlier (20). The questionnaires had items on, e.g. the frequency and intensity of back pain, disability caused by low back pain (e.g. 3, 10, 22), and previous back care. Data on psychological and behavioural factors connected with low back trouble were also gathered. Data on disability pensions and sickness allowances were obtained from the records of the Social Insurance Institution.

In all, 402 subjects attended the 2.5-year follow-up, i.e. altogether 85% of the original sample was reached at the final examinations. Data on sickness allowances and disability pensions were, however, obtained for all the subjects in the original sample. A careful analysis between those who had dropped out of the study and the remaining subjects showed that there was no systematic and statistically significant selection bias present affecting the outcome results.

Contents of treatment. The first inpatient programme consisted of a 3-week rehabilitation period at a rehabilitation centre. The outpatients took part in a 15-session back treatment programme (twice a week during a 2-month period) either at the work place or at the local health centre. The outpatients participated in the programme during their working hours, whereas the inpatients had a 3-week leave from work during their treatment. A more detailed description of the treatment programmes is given by Mellin et al. (20) and Härkäpää et al. (10).

Both treatment modes were carried out in groups of 6–8 patients. The programmes comprised a modified Swedish back school, back and muscle relaxation exercises, and heat or electrotherapy prior to the back exercise sessions. These sessions were led by a physiotherapist. The inpatients received massage and attended physical exercises and muscle strength exercises during their treatment programme. Both in- and outpatients attended two structured group discussions, led by a psychologist, on how to cope with chronic pain, plus one discussion on back care led by a physician. All in- and outpatients were taught a back exercise programme to be carried out after treatment.

The aim of the refresher programme (2 weeks for inpatients, 8 sessions for outpatients) 1.5 years later was to rehearse and revive the self-care skills learned earlier.

The control group received written and oral instructions on back exercises and ergonomics during the physiatrist's examination at the beginning of the study and at the 3-month, 1.5-year and 2.5-year follow-ups.

The accomplishment of back exercises was checked in all groups at the 3-month, 1.5-year, and 2.5-year follow-ups and corrected, if necessary, by the physiatrist.

Outcome variables. The following indexes and variables are used to describe outcome results (cf. 10):

1. *The Pain Index* (range 0–400, reliability = 0.89) is a sum of four items which describe the severity of low back pain (*a*) in general, (*b*) in the morning, (*c*) after the work day, and (*d*) in the evening.

2. *The LBP Disability Index* (range 0–45, reliability = 0.89) comprises 15 items describing disability caused by low back pain during the past month in different situations and activities.

3. *Long-term gains.* A variable describing long-term gains was formed on the basis of changes in the LBP Disability Index from pre-treatment to the 2.5-year follow-up. The reliable change index (RC) suggested by Jacobson et al. (11) for outcome research was used as a criterion for a "true" change. This means that the difference score (post–pre) is divided by the standard error of measurement (S_E): $RC = (X_2 - X_1)/S_E$, and $S_E = s_1\sqrt{1 - r_{xx}}$, where r_{xx} = the reliability of the measure. An RC larger than 1.96 would be unlikely to occur ($p < 0.05$) without actual change. Thus, with an $r_{xx} = 0.89$ a difference score of 5 points in the LBP Disability Index would indicate an actual change. In addition, if the pretreatment value of the Disability Index was ≤ 5 points, no gain was recorded. Three groups describing long-term gains were formed: (*a*) *clear gain*, i.e. a 5-point decrease at the 3-month follow-up plus at least three of the other follow-ups when compared with the pre-treatment score, and no increase in disability during the 2.5-year follow-up period, (*b*) *slight gain*, i.e. a 5-point decrease at the 3-month follow-up plus at least two of the other follow-ups, and (*c*) all other changes were recorded as *no gain*.

4. *Compliance and self-care. Accomplishment* of back exercises was rated by the physiatrist with a 4-point scale (0–3) indicating the number of faultless back exercises demonstrated by the patient at the examinations. Other data on compliance were based on the subject's answers to the questionnaires, i.e. on the *frequency of back exercises* (1 = none, ..., 4 = daily), the *frequency of relaxation exercises* (1 = none, ..., 4 = daily), and *compliance with ergonomic instructions* at work (1 = always, ..., 4 = never) during the previous month.

5. *Days of sickness allowance.* According to the National Sickness Insurance Scheme sickness allowance is payable to all employed and self-employed people between 16 and 65 who are incapable of doing their ordinary work or comparable work because of illness, for a maximum of 300 working days. The first seven working days of a period of interruption of employment, plus the day on which incapacity began, are not covered (25). Here, the data are presented as the average number of days of sickness allowance due to all diseases, musculoskeletal disorders and spinal disorders during a one-year period prior to the pre-treatment phase and the 1.5-year and 2.5-year follow-up phases, respectively.

6. *Disability pensions.* Data on disability pensions are presented here as the number of subjects who were granted a disability pension by June 1988; the average follow-up period per subject was 4.5 years.

Statistical analyses. Treatment effects, based on the Pain Index and the LBP Disability Index, were tested with one-way analyses of covariance (BMDP1V) using the change scores (each follow-up vs. pretreatment) of each index as dependent variables, study groups as grouping factors, and age as the covariate. Differences between each of the study

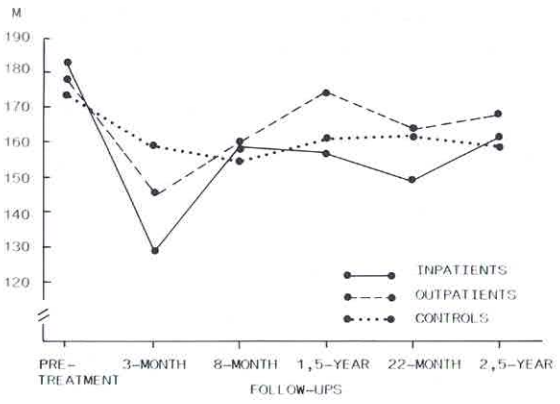

Fig. 1. Mean scores of the Pain Index by study group at the pre-treatment phase and the five follow-ups.

groups were also analyzed with *t*-tests for independent groups.

Differences between the study groups in the number of those with long-term gains, the accomplishment and frequency of back and relaxation exercises, compliance with ergonomic instructions, and granted disability pensions were tested with the χ^2-test.

Differences between the study groups in the number of days of sickness allowance were tested with one-way analysis of variance and *t*-tests for independent groups after a logarithmic transformation of the data (4).

RESULTS

There were no statistically significant differences between the study groups in the pre-treatment data (cf. 10).

Changes in the Pain Index

Mean scores of the Pain Index by study group at the initial phase and at each of the follow-ups are presented in Fig. 1. The short-term effect, i.e. 3-month follow-up results, was evident in both treated groups (cf. 10). At the 8-month follow-up the groups did not differ from each other in a statistically significant way. There was a tendency to differences between groups in the changes of the Pain Index from pre-treatment to the 1.5-year follow-up ($F(2/409) = 2.82$, $p<0.06$). The decrease in LBP was greatest in the inpatients who differed significantly from the outpatients ($t(409) = 2.36$, $p<0.02$), but not from the controls. A corresponding tendency can be seen at the 22-month follow-up ($F(2/393) = 2.45$, $p<0.09$) which was carried out three months after the refresher programme: the decrease in LBP was greatest in the inpatients who differed significantly from the controls ($t(393) = 2.05$, $p<0.04$), but not from the outpatients. At the final 2.5-year follow-up the study groups did not differ from each other.

Changes in the LBP Disability Index

The pre-treatment and follow-up mean scores of the LBP Disability Index are presented in Fig. 2. As according to the Pain Index, disability caused by low back pain had decreased in both treated groups, when compared with the controls, from the pre-treatment phase to the 3-month follow-up (cf. 10). Long-term changes in disability showed no statistically significant differences between the groups at any of the follow-ups.

Long-term gains

According to the criteria mentioned above 25% of the inpatients had a clear long-term gain from the treatment during the 2.5-year follow-up period (Table I). The respective proportions were 14% for the outpatients and 10% for the controls. The three-group Chi-square test showed a statistically significant difference between the study groups (χ^2 (4) = 14.21, $p<0.01$): the inpatients and controls differed from each other significantly (χ^2 (2) = 11.76, $p<0.01$), and there was a tendency to a difference between the inpatients and outpatients (χ^2 (2) = 5.65, $p<0.10$), but no difference between the outpatients and controls (χ^2 (2) = 2.12, NS).

Compliance with self-care

Accomplishment of back exercises was significantly better in the two treated groups than in the control group at both the 1.5-year and 2.5-year follow-ups. A significantly greater proportion of the inpatients

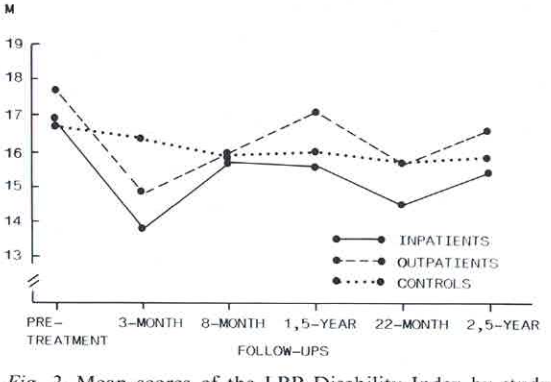

Fig. 2. Mean scores of the LBP Disability Index by study group at the pre-treatment phase and the five follow-ups.

Table I. *Frequencies (%) of those with clear, slight, or no gain according to the changes in the LBP Disability Index during the 2.5-year follow-up period, and statistical significances (p) of differences between the groups (χ^2)*
I = inpatients, O = outpatients, C = controls

	In-patients ($n=152$)	Out-patients ($n=137$)	Controls ($n=144$)	p
Clear gain	25	14	10	All: <0.01
Slight gain	12	13	19	I–O: <0.10
No gain	63	73	71	I–C: <0.01
				O–C: NS

could demonstrate three back exercises at the physiatrist's examination when compared with the outpatients and controls. Also the outpatients had learnt the exercises better than the controls (Table II).

The study groups also differed in the reported frequency of back exercises at both the 1.5-year and 2.5-year follow-ups. The inpatients reported having done their exercises more frequently than the outpatients ($p<0.01$) and the controls ($p<0.01$ and 0.05). The outpatients and controls did not differ significantly from each other (Table III).

Approximately 30% of the treated subjects reported having done relaxation exercises at least once a week during the month prior to the 1.5-year follow-up; the respective percentage was 51% at the 2.5-year follow-up. The groups did not differ in a statistically significant way from each other (Table III).

Most of the subjects, irrespective of study group, reported having followed ergonomic instructions at work. The inpatients differed significantly from the controls at both follow-ups ($p<0.02$ and 0.001), and from the outpatients at the 2.5-year follow-up ($p<0.01$). There was also a significant difference between the outpatients and controls at the 1.5-year follow-up ($p<0.05$) (Table III).

Days of sickness allowance

During the year prior to the pretreatment phase, there were no statistically significant differences between the study groups in the number of sickness allowance days due to either spinal disorders, all musculoskeletal disorders, or all diseases (Table IV). In all groups average days of sickness allowance increased during the follow-up period when compared with the year prior to the pre-treatment phase. The increase in sickness allowance days for all diseases from pretreatment to the 2.5-year follow-up was greatest in the control group, which differed significantly from the inpatients ($t(306) = -2.17$, $p<0.03$) but not from the outpatients. There was also a non-significant tenden-

Table II. *Accomplishment of back exercises (%) by study group at the 1.5- and 2.5-year follow-ups, and statistical significances (p) of differences between the groups (χ^2)*
I = inpatients, O = outpatients, C = controls

		No. of faultless exercises				
		0	1–2	3	p	
1.5-year	I	19	16	65	All groups	0.0002
follow-up	O	29	21	51	I–O:	0.02
	C	44	19	37	I–C:	0.001
					O–C:	0.01
2.5-year	I	8	8	84	All groups	0.0001
follow-up	O	17	8	75	I–O:	0.02
	C	26	21	53	I–C:	0.001
					O–C:	0.001

Table III. *Frequency of back and relaxation exercises and compliance with ergonomic instructions (%) by study group at the 1.5- and 2.5-year follow-ups, and statistical significances (p) of differences between the three groups (χ^2)*

	Years	In-patients	Out-patients	Controls	*p*
Back exercises at least once a week	1.5	73	53	55	0.01
	2.5	80	66	67	0.01
Relaxation exercises at least once a week[a]	1.5	29	37		NS
	2.5	51	51		NS
Compliance with ergonomic instructions	1.5	88	86	75	0.03
	2.5	88	74	66	0.001

[a] Data gathered only from the two treated groups.

cy towards a difference between the inpatients and outpatients ($t(305) = -1.72$, $p<0.09$) in the increase of sickness allowance days from pre-treatment to the 2.5-year follow-up.

The increase in days of sickness allowance due to all musculoskeletal disorders from the pre-treatment phase to the year prior to the 2.5-year follow-up was also greater in the control group than in the inpatient group ($t(306) = -1.94$, $p<0.05$), and a non-significant tendency to a corresponding difference between the inpatients and controls in days of sickness allowance due to spinal disorders was also evident ($t(306) = -1.88$, $p<0.06$).

Disability pensions

Altogether 45 subjects (10%) of the original sample had been granted a disability pension by June 1988. Ten per cent of the inpatients, 8% of the outpatients and 12% of the controls had received a disability pension during the average follow-up period of 4.5 years. The study groups did not differ on a statistically significant level from each other in the number of pensions granted.

DISCUSSION

The sample studied comprised chronic low back pain sufferers for whom the risk of long-term or permanent

Table IV. *Average days of sickness allowance due to all diseases, musculoskeletal disorders, and spinal disorders by study group at the pre-treatment examinations, and mean scores of the differences between pre-treatment and the 1.5-year and 2.5-year follow-ups*

Significance tests are based on the data after logarithmic transformations

	Inpatients	Outpatients	Controls	*p*
All diseases				
Pretreatment	8.8	9.2	8.8	NS
1.5-yrs vs. pretr.	+4.7	+4.3	+7.4	NS
2.5-yrs vs. pretr.	+3.8	+9.2	+12.0	NS[a]
Musculoskeletal disorders				
Pretreatment	7.0	7.0	6.2	NS
1.5-yrs vs. pretr.	+2.4	−0.2	+6.9	NS
2.5-yrs vs. pretr.	+3.4	+5.9	+8.2	NS[b]
Spinal disorders				
Pretreatment	5.2	6.0	3.7	NS
1.5-yrs vs. pretr.	+0.3	−0.2	+3.8	NS
2.5-yrs vs. pretr.	+1.6	+2.2	+4.8	NS[c]

[a] I vs. C: <0.03; I vs. O: <0.09.
[b] I vs. C: <0.05.
[c] I vs. C: <0.06.

disability due to LBP was higher than average. All subjects were at work at the time of the screening; although some subjects had been on extensive sick-leaves, the sample is not directly comparable to, for instance, pain clinic populations (17, 18, 23) or to patients attending multimodal rehabilitation programmes (5, 6, 19), or those referred for treatment because of acute back pain (2).

Long-term follow-up studies are rare, due to the fact that they are generally expensive, as well as trying and burdensome for both subjects and researchers. Subjects who drop out of the study form an additional problem. In our study the overall drop-out rate at the 2.5-year follow-up (15%) for self-assessments can be regarded as tolerable. In other controlled intervention studies drop-out rates have varied, for example, between 14% and 65% (7, 8, 19, 24, 26). The analysis of the subjects who dropped out of the present study revealed no such selection bias that would have a bearing on the between group differences in the outcome results. Furthermore, data on sickness allowances and disability pensions were obtained for all subjects in the original sample, which gives a solid basis for conclusions.

The results showed clear short-term (3-month) effects of both treatment modes after the first treatment programme, when compared with the control intervention (10). Subjective short-term effects of the refresher programme were not as clear: the effects of the refresher course could be seen only in the inpatients' lowered level of back pain, but no significant improvement was evident in disability caused by LBP. The second treatment was substantially shorter than the first one, and this may have affected the self-assessments of back trouble, although respective physical measurements indicated a significant improvement in physical functions (21) after the refresher programme. As the present design was in this respect a new one, further analyses are needed before these controversial results can be interpreted.

In the average long-term changes in self-assessments there was a slight tendency that pain and disability had decreased more in the inpatient group when compared with the other two groups. In addition, a significantly greater proportion of the inpatients as compared with the controls could be classified in the clear gain group. While the criteria for a clear long-term gain, reflecting a "true" change (cf. 11), were purposefully kept rather strict, these criteria were reached only by a quarter of all inpatients. The results are less favourable than, for instance, those obtained through more extensive and strenuous physical training programmes (e.g. 8, 19), where the subjects were, however, more severely disabled, and not directly comparable with our sample.

Furthermore, although days of sickness allowance had increased in all groups during the follow-up period, inpatient treatment seemed to have a slight buffering effect in this respect. Our results resemble those reported by Linton et al. (14), though in our study the follow-up period was remarkably longer. However, no between-group differences were evident in the number of disability pensions granted during the average 4.5-year follow-up period.

Finally, throughout the whole follow-up period of 2.5 years the study groups differed significantly from each other in compliance with self-care. The inpatients seemed to be more motivated to self-care and to have adopted a more or less regular way of coping with their back pain through back exercises. Also the outpatients seemed to have learnt these instructions better than the controls. The results confirm those reported earlier from the short-term outcome (10): mere instructing without guided practice is not sufficient for the learning of self-care skills and their maintenance. Still, it seems that in the present subject sample, with moderate symptoms and currently in physically strenuous work, a more or less frequent self-care after the treatment was not effective enough to maintain short-term treatment gains brought about by the first treatment programme.

To conclude, the overall results showed that occasional back treatment periods were not essentially more efficient in preventing or slowing down the subjective disability process than repeated physical check-ups and self-care instructions. The treatment seemed, however, to produce short-term improvement in the subjects' back trouble, offer short-term relief from pain, and, for the inpatients, rest and relief from daily work stress. The treatment gives also a better opportunity for learning basic pain-management skills. The results did not, however, yield information on what were the essential components in the treatment that brought about the short-term improvement, or what aspects in the subjects' self-care would have been crucial in producing favourable long-term effects. One of the main tasks, in the future, thus seems to lie in finding out and developing feasible methods for the maintenance and improvement of treatment gains. For those at risk for back pain disability an intensive treatment period may be useful as a part of a more comprehensive preventive plan, but

not as a sole means for solving the back problem. As low back trouble is regarded as a multifaceted problem, regular check-ups and group exercises and discussions are probably needed to enhance motivation for self-care and physical activity (14) and encourage pain self-management, together with improvements and advancements in work methods and working environment.

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