A Randomized, Placebo-Controlled Trial of Exercise Therapy in Patients with Acute Low Back Pain

A. Faas, MD*, A.W. Chavannes, MD,† J.Th.M. van Eijk, PhD,* and J.W. Gubbels‡

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To assess the efficacy of exercise therapy for acute low back pain, a randomized, placebo-controlled trial was performed in 40 Dutch general practices. Patients received either exercise instruction with advice for daily life by a physiotherapist; placebo ultrasound therapy by a physiotherapist; or usual care by the general practitioner. All patients received analgesic agents and information on low back pain before randomization. Four hundred seventy-three patients were included. No differences in number of recurrences, functional health status, or medical care usage could be found among the three groups. In the exercise group, duration of recurrences was shorter and patients were less tired during the first 3 months than in the usual care group, but no differences were found between the exercise and placebo groups. It was concluded that exercise therapy for patients with acute low back pain has no advantage over usual care from the general practitioner. [Key words: low back pain, therapy, exercise, recurrence]

Every week the Dutch general practitioner is consulted by two to three patients with a new low back pain episode.[30,32] In 80–90% of these cases it concerns nonspecific back pain.[2] Therapy prescribed for nonspecific back pain varies widely among physicians. At the first consultation 13%, and at the second one 30% of the patients are referred to a physiotherapist.[5] The efficacy of many therapies for nonspecific back pain is called into question.[8,12, 19,26] Nonetheless, a combination of exercises and advice for treatment of nonspecific back complaints has won a firm position in the arsenal of the Dutch general practitioner.[15] Exercises and advice, as applied in 'back schools' or by physiotherapists during exercise therapy, aims at patient self reliance in effectively dealing with back pain. Bergquist-Ullmann[3] claims a positive effect, but this could not be confirmed by others.[21,22] Lankhorst et al state that positive results can be expected if instructions for exercises and advice are given and applied in case nonspecific back pain is at an early stage, that is, in cases of acute low back pain. [21,23] Conversely, Gilbert advises the general practitioner to restrict treatment to information about back pain combined with analgesics because of the favorable course of acute nonspecific back pain.[14] Because of the frequent use of exercise therapy, the controversial points of view on this subject and the methodologic flaws of research in this field, we initiated a clinical trial on the effects of exercise therapy concerning recurrences, functional health status, and medical care usage in patients with nonspecific acute low back pain.

Methods

Patients. Patients who consulted their general practitioner for a new back pain episode were selected. Inclusion criteria included pain between T12 and the gluteal folds with or without radiation into the upper leg, pain for 3 weeks or less and age between 16 and 65 years. Criterial for exclusion were radiation of pain below the knee, signs of nerve root compression or neurologic deficit, back pain caused by trauma, previous back pain episode within 2 months before entry, previous back surgery, suspicion of malignancy, M. Bechterew, or other rheumatoid diseases, pelvic obliquity > 1.5 cm, a gibbus > 1 cm, or pregnancy. Patients were selected by 40 general practitioners from ten different towns and villages.

Design. After selection and informed consent all patients received standardized information on back pain by the general practitioner. Subsequently the doctor's assistant

From the *Department of General Practice and Nursing Home Medicine, Institute for Research in Extramural Medicine, Amsterdam, †Department of General Practice, University of Utrecht, Utrecht, and ‡Department of Methodology and Statistics, University of Nijmegen, Nijmegen, The Netherlands. This study was initiated by the Dutch College of General Practitioners and was supported by the Praeventie Fonds. We thank Prof L.M. Bouter and Prof M. de Haan for editorial comments.
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handed to the patient a sealed envelope containing the kind of therapy. The patient received either no further therapy (usual care group) or placebo ultrasound treatment by a physiotherapist (placebo group) or exercise therapy by a physiotherapist (exercise group). Random assignment was performed in blocks of six for each general practitioner. In this design the doctor was not informed of the kind of therapy, thereby making it a single-blind study. During the first month, all patients were provided with paracetamol tablets. Whenever the general practitioner found signs of nerve-root irritation, these patients were excluded from further participation in the trial. Follow-up took place 2 weeks, 4 weeks, and 12 months after visit to the doctor's practice, as well as once a month by a mailed questionnaire during the 11 intervening months. Twenty physiotherapists participated in the study.

Exercise therapy and usual care were compared. The placebo group was included in the design to control the attention of the physiotherapist by comparison of the exercise and placebo group.

According to data from the literature the probability of a recurrence was assumed to be 50%.[3] The required size of the entire study group was determined on 459 patients. A study with three research groups of 153 patients each, has a power (100-β) of 0.95 to distinguish a relevant difference of 20% of the patients with a recurrence, with $\alpha = 0.05$.

Usual Care. All patients included received information on back pain and were given analgesics on demand, hence usual care without further therapy means: getting information from the general practitioner as well as analgesics. We trained the general practitioners to discuss the origin and course of this class of back pain, the role of the general practitioner in the exclusion of other specific causes of back pain, the importance of warmth, physical activity, and the methodologic reasons to return on a number of occasions.

Placebo Therapy. Ultrasonography was performed for 20 minutes by a physiotherapist, twice a week for 5 weeks with the lowest possible dose next to zero (0.1 watt/cm^2, intermittent, no heat effect).

Exercise Therapy. Each patient was instructed individually by a physiotherapist for 20 minutes twice a week for 5 weeks. The total program consisted of eight exercises and seven pieces of advice for daily life. The set of exercises consisted of a semi-fowler resting position,[18,34] a resting position with knees on the chest,[18,29] a limbering exercise by alternating side movements with knees bent, a stretching exercise of the ilopsoas[18] (all exercises in supine position), pelvic flexion in supine position, in hand–knee and in upright position,[18,20] and isometric abdominal exercises.[18,20,29] Resting positions were instructed first for pain relief. The patient received information on the anatomy of the back and advice about standing, bending, lifting, and carrying, lying during pain, sitting and driving a car.[18,24,25,34] Problems with performing the exercises or applying the advice in daily life were discussed and together with the patient attempts were made to resolve them.[9] Every session was recorded by the physiotherapist. Patients were advised to exercise and to apply the advices daily; even if they had no back pain. A written compliance contract was made up with the patient. An audiotape and a book with complete instructions were provided to every patient.

Outcome Measurements. With (85-mm long) visual analog pain scales the patient indicated the amount of pain at that moment and the maximum pain during the previous month.[17] Functional health status was measured by using the Dutch version of the Nottingham Health Profile questionnaire, which was completed by the patient (at that moment and at its worst during the previous month).[10,16] The questionnaire measures the perceived health in six dimensions (pain, loss of mobility, tiredness, emotional problems, social isolation, and sleeping problems; score range for each dimension, 0–100) and the influence of perceived health on seven areas (paid job, jobs around the home, social life, family relationships, sex life, hobbies, holidays) of daily life (score, 0–7 areas). In-between general practitioner consultations for back pain (besides the 3 follow-up consultations) were registered and afterward controlled for registration bias by checking the patient's file kept by the doctor. On the basis of the same file, consultations for reasons other than back pain were assessed.

The main outcome parameters considered were: number and duration of pain episodes and recurrences, change in functional health status (Nottingham Health Profile questionnaire) in relation to the baseline in month 1, months 2–3, and months 4–12 after inclusion, mobility problems (Nottingham Health Profile questionnaire) and influence on daily life (Nottingham Health Profile questionnaire) during back pain and in between consultation of the general practitioner for back pain with therapy, if any.

To assess the pain episodes we assumed that the monthly pain measurements with the visual analog pain scales (past month and at this moment) included two successive periods of 15 days, so that for each patient 24 pain measurements for the whole year were available. The cut-off point for pain or no pain was drawn at 11 mm. In this way a pain episode lasted at least 15 days. All pain episodes occurring after the first pain episode from entry were defined as recurrences. Mobility problems and number of influenced areas of daily life during the pain episodes were determined (mean score and relative duration).

Exercise compliance and advice application were measured six times during the follow-up period by a questionnaire ('did you do one or more exercises or apply advice during past 2 months?'). Compliance was defined as that part of the follow-up period in which exercises were performed and advice was applied. On the basis of the median value patients were divided into patients with relatively good or poor exercise compliance or advice application.

Analysis. Analyses were performed with all patients ("intention to treat" analysis). We compared the exercise group with the usual care group and the exercise group

with the placebo group. After that, the analysis with the three groups was repeated with only those patients from the exercise and placebo group who received the full program ("on treatment" analysis). Criteria for "on treatment": ability to carry out all exercises and advice without any help (exercise group), having started therapy within 14 days, having visited the physiotherapist not less than 8 times, and no therapy outside the protocol during intervention (exercise and placebo group). Finally, the analysis with the three groups was performed using the patients from the on treatment analysis but with only those patients in the exercise group who had good exercise compliance or a good application of the advice ("best cases" analysis).

Control on unequal distribution of baseline characteristics in the three groups after randomization was conducted by discriminant analysis (only those characteristics not used in modification analysis).[1]

All patients who dropped out were used in the analyses until they dropped out.

For statistical analysis of the effects analysis of variance (F test, multivariate analysis of variance) was used for means and χ^2 test for proportions. We used the SPSS.PC 3.1 statistical package (SPSS, Chicago, IL) and Medstat (Astra Gruppen, Albertsund, Denmark) for the 95% confidence intervals of proportions.[27,33]

All figures presented are from the intention to treat analyses.

■ Results

Study Sample

Five hundred twenty-five patients met the inclusion criteria. Four hundred seventy-three patients gave informed consent and were included in the trial during the period October 1987 to December 1988 and subjected to randomization.

Table 1. Baseline Characteristics in the Three Therapy Groups at Entry (n = 473)

	A	B	C	Total
n	155	162	156	473
Age (mean)	36	38	36	36
16–24 years (%)	16	12	15	14
25–44 years (%)	61	64	67	63
45–65 years (%)	23	24	19	22
Gender (% female)	41	42	47	43
Education (%)				
low	47	57	57	54
intermediate	40	34	34	36
high	12	9	9	10
Insurance (% sick fund)	76	77	77	77
Employed (%)	79	74	78	77
Previous back pain (%)	72	74	72	73
Previous physiotherapy (%)	30	34	35	33
Previous specialist for back pain (%)	8	11	8	9
Duration of back pain (%)				
1–7 days	71	69	63	68
8–14 days	23	25	28	25
15–21 days	7	6	9	7
Radiation into upper leg (%)	26	22	21	23
Pain (VAS),* mean	36.6	36.8	36.1	36.5
NHP part 1,† mean				
Pain	38.0	36.6	38.1	37.1
Mobility problems	24.1	23.3	24.3	23.9
Tiredness	19.4	21.3	24.7	21.8
Emotional problems	8.2	7.7	8.5	8.1
Social isolation	3.7	4.5	4.6	4.3
Sleeping problems	14.7	13.4	11.7	13.2
NHP part 2,‡ mean				
No. of influenced areas of daily life	2.4	2.3	2.3	2.3

*Visual analog scale.
†NHP, part 1, 6 dimensions, score range 0–100 per dimension.
‡NHP, part 2, number of influenced areas of daily life, score range 0–7.
A = usual care group, B = placebo group, C = exercise group.

The 52 patients who declined to participate did not differ from the included group of patients with regard to age, sex, employment, previous therapy for back pain, or radiation of pain. However, they had a higher level of education, more often a private insurance and less pain than those patients who were included.

A total of 60 patients dropped out during the follow-up period: 23 in the usual care group, 17 in the placebo group, and 20 in the exercise group ($P = 0.5$). Of these 60 patients 22 were excluded by the general practitioner during the follow-up period because of possible nerve-root irritation, 10 patients dropped out because of relocation, serious illness, or other external reasons, and 28 patients stopped of their volition. In the first month 29 patients dropped out. The reason for dropping out ($P = 0.2$) as well as the time of dropping out (first month or after, $P = 0.3$) are equally distributed over the three therapy groups.

Missing data on the individual items of the 24 questionnaires were replaced in a rational way with the help of the available information and without reduction of variance. For 255 patients the data were complete over all 24 measurements. In the case of 121 patients less than 20% of the measurements were missing and 97 patients missed more than 20%, equally distributed over the three therapy groups.

In Table 1 baseline characteristics are presented. Neither the individual characteristics nor the most discriminating combination of characteristics were found to be significantly different among the three therapy groups, using discriminant analysis. Because differences of those variables not used in the modification analysis were very small among the 3 groups, we did not take into account any of the baseline characteristics as potentially confounding variables in the analysis. The same was true for the number of paracetamol tablets taken during the first month.

Compliance During Treatment

In the exercise group 118 of the 156 patients met the criteria for on treatment during the intervention period and in the placebo group 145 out of the 162 patients. Treatment outside the protocol did not occur during this period.

Compliance After Treatment

After 3 months, 82% of the patients said they had done exercises during the past 2 months, after 12 months this was still 54% of the patients. Half of the patients stated they had done exercise for 7 months or more and also half of the patients stated that they applied advice for 7 months or more.

Outcome

Number and Duration of Pain Episodes. Patients had a total of 1246 pain episodes including 775 recurrences (2 patients had no visual analog pain scale score over 11 mm at all). Three hundred twenty-two patients had one or more recurrences (range 1–7) during the follow-up period. The number of patients with either no recurrence, one recurrence or more did not differ among the 3 groups (Table 2). The mean number of recurrences per patient was 1.6 (SD 1.6). The mean duration of the pain episodes was 57 days in the usual care group, 54 days in the placebo group, and 58 days in the exercise group (exercise—usual care $P = 0.8$, exercise—placebo $P = 0.4$), whereas the duration of recurrences was 53 days in the usual care group, 41 days in the placebo group, and 45 days in the exercise group (exercise—usual care $P = 0.02$, exercise—placebo $P = 0.5$). The total duration of back pain (first episode after entry and all recurrences together) is not different among the groups ($P > 0.3$ in all cases). No effect modification could be found of duration of the back pain episode at entry or development of this episode (suddenly, gradually), pain ra-

Table 2. Patients with Back-Pain Recurrences, (%)

	Usual Care (n = 155)	Placebo (n = 162)	Exercise (n = 154)	95% Confidence Intervals of Difference: Exercise—Usual care	95% Confidence Intervals of Difference: Exercise—Placebo
Number of recurrences					
0	47 (30)	55 (34)	47 (30)	(-10.1–10.5)	(-13.7–6.9)
1	38 (25)	39 (24)	35 (23)	(-11.3–7.7)	(-10.7–8.0)
2	27 (17)	21 (13)	29 (19)	(-7.2–10.0)	(-2.2–13.9)
3	28 (18)	25 (15)	21 (14)	(-12.6–3.7)	(-9.6–5.9)
>3	15 (10)	22 (14)	22 (14)	(-2.6–11.8)	(-6.9–8.4)

Exercise versus usual care, $\chi^2 = 2.51$, df = 4, $P = 0.6$.
Exercise versus placebo, $\chi^2 = 2.27$, df = 4, $P = 0.7$.

diation at entry, or age. Nor were any significant differences found with on-treatment or best cases analysis.

Functional Health During the Follow-Up Period. Changes of functional health status during the follow-up period mainly occurred in the dimension pain, mobility problems, and tiredness, especially during the first month (Figure 1, mean change per successive measure point). We tested the mean change during month 1, months 2–3, and months 4–12 (Table 3). During the first 3 months there was a significant decrease in tiredness in the exercise group compared to the usual care group, but not in comparison with the placebo group. The same goes for the bigger decrease of emotional problems during the first month (Table 3). The decrease of influence on daily life mainly took place during the first month and was not significantly different among the three therapy groups during the three successive periods. The percentage of patients with bedrest for back complaints did not differ either (Table 3). Effect modification of age, sex, back pain history, previous treatment by a physiotherapist, pain, mobility problems, or radiation of pain at entry could not be found. With the on-treatment analysis and best cases analysis we also found a bigger decrease of tiredness in the exercise group than in the usual care group, but identical to that in the placebo group.

Functional Health During Back Pain. Mobility problems or influence on daily life did not differ significantly among the three groups during back pain (Table 4). No effect modification could be shown for back-pain history, radiation of pain, or mobility problems at entry. Nor with the on-treatment or best cases analysis were any differences found among the three groups.

Usage of Medical Care. A total of 106 patients went to the general practitioner for an in-between consultation because of back pain. There were no significant differences between the exercise and usual care groups, nor were there any between the exercise and placebo groups (Table 5, $P > 0.2$ in all cases). In the usual care group patients were more often (difference 3%) referred for extra physiotherapy than in the exercise group, but there was no difference between the placebo and exercise groups. On their own initiative 12 patients consulted an alternative practitioner for their back pain (5 in usual care, 2 in placebo, and 5 in the exercise group). Effect modification could not be shown for age, sex, back-pain history, or treatment by a physiotherapist, complaining behavior, number of consultations of the general practitioner in the past 3 years, and pain, mobility problems or radiation of pain at entry. Nor were there any differences between the groups in the on-treatment and best cases analysis ($P > 0.5$ in all cases).

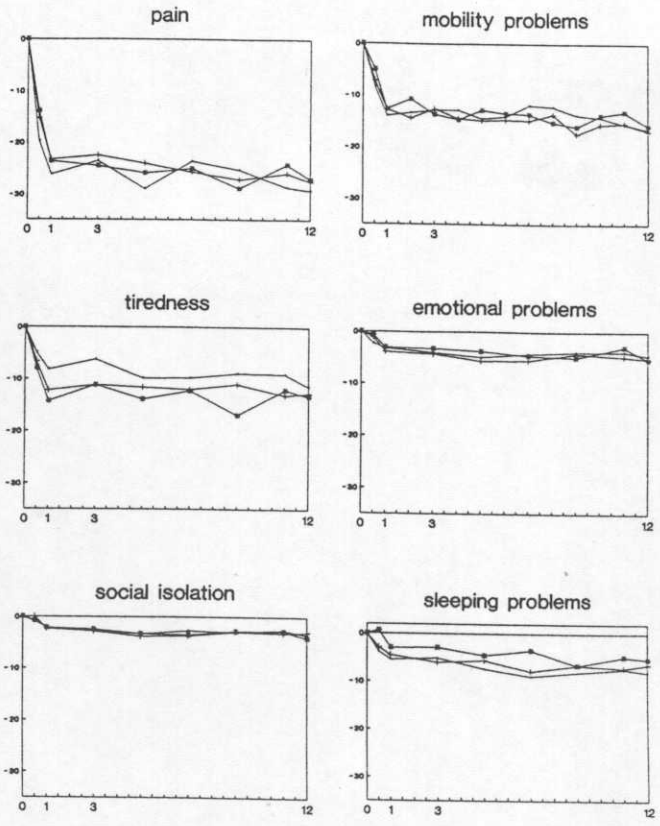

Figure 1. Mean changes during follow-up in the six separate Nottingham Health Profile dimensions. X axis, months after entry. Y axis, change = score during follow-up minus score at entry, a negative value indicates a decrease of problems.

During the follow-up period 89% of the patients consulted the general practitioner for other reasons than back pain and a mean of 2.4 (SD 1.6) consultations per patient took place. The 3 groups did not differ significantly in this respect, nor did they when the consultation frequency was examined separately for musculoskeletal and connective tissue problems, emotional problems, or other problems ($P > 0.1$ in all cases).

■ Discussion

In this randomized trial no positive effects of exercise therapy could be shown on the number of recurrences, functional health status, perceived problems in daily life, and on medical care usage. Indeed, recurrences in the exercise group took less time to recover than in the usual care group, but they took the same time as in the placebo group. Also, patients in the exercise group felt less tired during the first 3 months than patients in the usual care group, but there was no difference between exercise and placebo groups. Any positive effects are fully accounted for by the physiotherapist's attention for the patient.

The population in our study sample is a bit younger than the group of back-pain patients from the Dutch National Study.[1] Analysis with control for

Table 3. Changes of Functional Health Status (NHP) During Month 1, Months 2–3, and Months 4–12

	Month 1			Month 2–3			Month 4–12		
	A (n = 146)	B (n = 154)	C (n = 145)	A (n = 130)	B (n = 141)	C (n = 130)	A (n = 134)	B (n = 143)	C (n = 137)
Pain, mean (SD)	-22(22)	-19(23)	-19(21)	-24(30)	-22(28)	-24(24)	-27(26)	-26(26)	-26(23)
Mobility problems, Mean (SD)	-11(17)	-10(18)	-9(19)	-12(18)	-13(19)	-12(20)	-14(18)	-15(19)	-14(19)
Tiredness*									
% with decrease	23	29	36	19	28	33	34	34	39
% with increase	10	10	15	9	5	9	13	14	14
Sleeping problems									
% with decrease	28	28	23	23	28	23	33	33	28
% with increase	10	12	20	11	12	20	15	16	20
Emotional problems†									
% with decrease	32	32	38	35	31	33	39	36	37
% with increase	12	17	20	12	7	13	19	15	18
Social isolation									
% with decrease	10	12	14	12	13	11	13	14	15
% with increase	6	7	8	2	2	3	5	4	7
No. of influenced areas of daily life, mean (SD)	-1.5(1.8)	-1.1(2.0)	-1.1(2.0)	-1.7(1.9)	-1.5(2.2)	-1.4(2.2)	-1.8(1.9)	-1.7(2.1)	-1.5(2.0)
Bedrest (% > 0 day)	22	19	21	23	20	25	36	34	33

*Month 1: exercise versus usual care $P = 0.01$, exercise versus placebo $P = 0.12$.
Month 2–3: exercise versus usual care $P = 0.03$, exercise versus placebo $P = 0.21$.
†Month 1: exercise versus usual care $P = 0.049$, exercise versus placebo $P = 0.28$.
A = usual care, B = placebo, C = exercise group.
n: minimum number of patients per therapy group.

Table 4. Perceived Mobility Problems and Influence on Daily Life During Back Pain

				95% Confidence Intervals of Difference	
	Usual Care (n = 155)	Placebo (n = 161)	Exercise (n = 154)	Exercise—usual Care	Exercise—Placebo
Mobility problems (NHP)					
% Patients with any problems	94	95	95	(-3.7–6.2)	(-4.3–5.1)
Mobility problems (0–100), mean (SD)	20 (15)	19 (16)	20 (14)	(-3.5–3.3)	(-2.4–4.3)
Relative duration,* mean (SD)	74 (31)	73 (32)	75 (31)	(-5.8–8.1)	(-4.3–9.5)
Influence on daily life (NHP)					
% Patients with any influence	90	88	94	(-2.3–10.1)	(-1.1–11.5)
influenced areas (0–7), mean (SD)	1.5(1.4)	1.5(1.5)	1.6(1.4)	(-0.2–0.4)	(-0.2–0.4)
Relative duration,* mean (SD)	59(35)	55(36)	63 (34)	(-3.7–12.1)	(-0.1–15.5)

*Relative duration of mobility problems or of influence on daily life: (duration of problems or influence/duration of all pain episodes after entry) × 100; range 0–100.

Table 5. Medical Care (GP) Usage for Low-Back Pain During Follow-up Year, No. Patients (%)

	Usual Care (n = 155)	Placebo (n = 162)	Exercise (n = 156)	95% Confidence Intervals of Difference	
				Excercise—Usual Care	Exercise—Placebo
With in-between consultation	39 (25.2)	34 (21.0)	33 (21.2)	(-13.4–5.4)	(-8.8–9.1)
Therapy at in-between consultation					
No therapy	13 (8.4)	13 (8.0)	17 (10.9)	(-4.0–9.1)	(-3.6–9.3)
Analgesics	16 (11.0)	17 (10.8)	13 (8.5)	(-8.5–4.5)	(-8.6–4.3)
Physiotherapy	10 (6.5)	4 (2.5)	3 (1.9)	(-9.0–-0.1)	(-3.8–2.7)
First consultation during					
Month 1–3	20 (12.9)	15 (9.3)	10 (6.4)	(-13.0–0.1)	(-8.7–3.0)
Month 4–12	19 (12.3)	19 (11.7)	23 (14.7)	(-5.1–10.8)	(-4.4–10.5)

age did not produce a different outcome, however. So it is not to be expected that in a sample with a more representative age distribution effects of exercise therapy can be shown.

Also Farrel,[11] Davies,[6] Lindequist,[22] Gilbert,[13] Waterworth,[31] and Berwick[4] did not find any favorable effect of exercise and advice in patients with comparable back pain. Extension and back strengthening exercises were not included in our set of exercises so comparison with flexion programs would be possible. It is questionable whether extension exercises should have a place in the treatment of acute back pain. Only Stankovic found positive results with extension exercises, but his study has a number of methodologic drawbacks: no placebo group and difference of treatment duration between the two compared groups.[19,28] Therefore, a placebo effect cannot be excluded.

During the instruction by the physiotherapist, a strong emphasis has been placed on discussing the problems in exercising and applying the advice with the objective to maximize compliance. After 3 months in our study 82% of the patients still did exercises (Deyo: 46%).[7] Nevertheless, we could not prove a favorable effect of exercise and advice in either the total exercise group or the subgroup with good compliance.

Our findings are relevant to the general practitioner because patients who are referred to a physiotherapist for exercise therapy or to a back school in this way receive a lot of needless, expensive attention for complaints that in most cases would have disappeared spontaneously anyway. By learning to do exercises, practicing at home and applying the advice in daily life, back complaints occupy too important a place for a long time in spite of the favorable prognosis. Also from the point of view of prevention of somatization this attention is undesirable.

We conclude that in case of nonspecific acute back pain, exercise therapy should not be recommended. The general practitioner should confine himself to providing the patient with relevant information on back pain combined with analgesics if desired.

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Address reprint requests to

A. Faas, MD
Department of General Practice and
Nursing Home Medicine
Institute for Research in Extramural Medicine
Vrije University of Amsterdam
vd Boechorststraat 7
1081 BT Amsterdam
The Netherlands