A Randomized Trial of Exercise Therapy in Patients With Acute Low Back Pain

Efficacy on Sickness Absence

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Study Design. A randomized, placebo-controlled trial in which patients received either usual care by a general practitioner (information and analgesics), or placebo physiotherapy given by a physiotherapist, or exercise therapy given by a physiotherapist.

Objective. To assess the efficacy of exercise therapy on sickness absence from work in patients with acute low back pain.

Summary of Background Data. Exercise therapy during the nonchronic phase of back pain is considered to reduce sickness absence, but this opinion is controversial.

Methods. Patients with acute nonspecific low back pain and a paid job were included for analysis. Sickness absence (number of days) was checked monthly during the 1-year follow-up period and compliance was also assessed.

Results. From 40 general practices 363 patients who were gainfully employed were included. In the exercise therapy group the percentage of patients with sickness absence was higher and the duration of absence was longer than in the placebo and usual care groups, but these differences were not significant. Indications of more absence in the exercise therapy group appeared to be based largely on a greater number of patients with absences during the first 3 months. Patients in the exercise group who had not reported sick at entry had more sickness absences during the follow-up year than patients in the usual care and placebo group. Good compliance did not affect the results.

Conclusions. Exercise therapy for patients with acute low back pain does not reduce sickness absence. [Key words: exercise therapy, low back pain, randomized trial, sickness absence] **Spine 1995;20:941–947**

Complaints of the locomotor apparatus are one of the most important causes of sickness absence in the Netherlands. Back pain is the most frequent diagnosis.[26] Exercise therapy in combination with ergonomic counseling—applicable to the work situation and to daily life in general—is considered a promising approach to reduce sickness absence due to back pain. This optimism is mainly based on the results of one trial in which a short-lasting positive effect on duration of absence was demonstrated in patients with subacute back pain.[3] Instruction of the patient in the early phase of back pain—when it has not yet become chronic—was considered important from the point of view of prevention.[12] The Dutch general practitioner sees two or three new patients with back pain per week; most patients have acute nonspecific back pain. Fifteen to thirty percent of the patients consulting the general practitioner because of acute back pain are referred to a physiotherapist.[6,25] Conversely, Gilbert advises the general practitioner to restrict treatment in case of acute back pain to information about back pain combined with analgesics, considering what is known about the efficacy of physiotherapy for acute back pain.[11] Because of the opposing points of view on this subject, a study on the efficacy of exercise therapy in patients with acute low back pain was carried out. Our hypothesis was that exercise therapy, which could also be applied in daily life, would not only diminish back pain recurrences but also would diminish sickness absence as well. Results concerning recurrences, functional health, and medical care usage have already been published.[9] This article deals with the question: does exercise therapy given by a physiotherapist reduce sickness absence more effectively than would the usual care by the general practitioner?

Methods

Patients. Patients who consulted their general practitioner for back pain were selected. Inclusion criteria were pain between T12 and the gluteal fold with or without radiation to the upper leg, pain for 3 weeks or less, and age between 16 and 65 years. Exclusion criteria were back pain in the preceding 2 months, radiation of pain into the lower leg, signs of nerve root compression or neurologic deficit (positive straight leg raising test, muscle weakness, paresthesia, or abnormal reflexes), back pain due to trauma, previous back operation, suspicion of ankylosing spondylitis (erythrocyte sedimentation rate >25mm), morning stiffness >1 hour) or malignancy, pelvic obliquity >1.5 cm in standing position, gibbus >1 cm in anterior flexion position, or pregnancy. Patients were selected

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by 40 general practitioners in 10 different towns and villages in the Netherlands.

Design. A randomized, single-blind clinical trial with three therapy groups was chosen. After selection and informed consent patients were given standardized information about back pain by the general practitioner. Thereafter patients saw the doctor's assistant who handed them a sealed envelope containing a note stating the therapy group. Patients were randomized by general practitioner in blocks of six. Patients each received either no further therapy (usual care group), placebo therapy by a physiotherapist (placebo group), or exercise therapy by a physiotherapist (exercise therapy group). The placebo group was included to cover the possibility of a placebo effect due to attention from the physiotherapist. The general practitioner was not informed about the kind of therapy. During the first month paracetamol tablets were supplied as analgesic to be used according to need. Follow-up occurred every 2 weeks during the first month and once monthly thereafter. The total follow-up was 12 months. Patients in whom the general practitioner found radiation into the lower leg or other possible neurologic signs of nerve root compression were excluded from follow-up study.

Sample size was determined by the major question in this study: what is the effect of exercise therapy on the number of recurrences during the follow-up year? The required size of the total study population was set at 459 patients with back pain (power of 0.95 to distinguish a relevant difference of 20% of the patients with a recurrence, with $\alpha = 0.05$).

Usual Care. As all patients received information about back pain and analgesics before therapy group assignment, "no further therapy" signifies information from the general practitioner about back pain and analgesics without further treatment. The general practitioners gave information according to a fixed protocol. General practitioners were trained to discuss these aspects: cause and course of this kind of back pain, the role of the general practitioner in excluding other specific causes of back pain, the importance of heat, movement and short-lasting bed rest to deal with back pain, and the requirement of return visits by the patient to the general practitioner for follow-up.

Placebo Therapy. Ultrasound of 20 minutes' duration, at the lowest possible dose (0.1 watt/cm^2, intermittent), was administered by a physiotherapist twice weekly for 5 weeks. Because of the intermittent character and the minimal level of the dose without heat effect, this treatment was considered a placebo treatment. A record of each treatment was kept by a physiotherapist.

Exercise Therapy. Each patient received 20 minutes' individual instruction from a physiotherapist, twice weekly, for 5 weeks. The total program consisted of eight exercises and seven pieces of advice applying to daily life, including work. The set of exercises consisted of a semi-fowler resting position,[15,27] a resting position with knees on the chest,[15,24] a limbering exercise by alternating side movements with knees bent, a stretching exercise of the m. ileopsoas,[15] (all exercises in supine position), pelvic flexion in supine position, in hand–knee and upright position,[15,17] and isometric abdominal exercises.[15,17,24] Resting positions were taught first to reduce pain. If necessary the physiotherapist could change the order of instruction. The patient was taught about the anatomy of the back and instructions on how to stand, bend, lift, and carry objects, how to sit and drive, and how to lie during back pain.[15,20,21,27] Problems with performing the exercises or applying the advice to work or everyday life in general were discussed and attempts were made, together with the patient, to find solutions in order to maximize compliance.[8] Patients were advised to exercise daily and to apply the advice daily, even if they were free of pain.[10] A written compliance contract was drawn up with the patient. The patient received an audiotape as well as a book with complete instructions. Every session was recorded by the physiotherapist. Placebo and exercise therapy were administered by 24 physiotherapists. The therapists were trained to ensure uniformity as far as possible.

Outcome Measurements. Follow-up by the general practitioner took place after 2 and 4 weeks and after 12 months. During the intervening 11 months patients filled in a mailed questionnaire monthly. If the patient did not appear at the follow-up consultation or the mailed questionnaire was not returned, the patient was asked by the doctor's assistant to attend the consultation or to return the mailed questionnaire.

Patients filled in a monthly questionnaire stating whether they had reported sick and how many days of work had been lost because of illness during the previous month. The reason for the sickness absence was not asked for, so that other reasons as well as back pain may have been involved.

To determine the individual pain episodes, pain was recorded each month according to visual analog pain scales (double recording: pain at the moment and worst pain during the past month).[14] During the first consultation age, sex, level of education, history of back pain, pain, mobility problems,[13] emotional problems, and sick reporting were measured.

After 2 and 4 weeks the doctor's assistant counted the number of paracetamol tablets the patient had taken.

Compliance was measured six times during the follow-up period by asking patients to reply to a questionnaire as to whether and how often each week they had exercised during the past 2 months. They were also asked whether advice had been followed at work, during household work, in social life, family life, and sex life, pursuing of hobbies, or during holidays. Compliance was expressed as a percentage of the time during which the patient exercised or applied advice during the follow-up period. On the basis of the median value patients were divided into patients with relatively good or poor exercise compliance or advice application.

As effect parameters we used the percentage of patients with sickness absence during the 12 months of follow-up, during the first month, months 2 and 3, months 4–12, and the number of days lost during the 12 follow-up months per patient. Concerning the total back pain period (all episodes after entering the trial) effect parameters were: the percentage of patients with sickness absence, the number of days lost and the relative duration of the absence per patient (duration of absence during back pain/duration of back pain period × 100).

The monthly pain measurements made with the visual analog pain scales (past month and present time) were taken as two subsequent 15-day periods. Thus 24 pain measurements per patient were obtained, covering the entire year. The pain

threshold was set at 11 mm. Two patients had no pain episodes. A pain episode had a minimal duration of 15 days. The number of days absent measured during a particular episode was coupled to each episode of pain. This allowed the sickness absence during back pain to be determined. Finally, episodes were subdivided into short, medium, and long. For each subgroup of episodes the percentage of episodes with sickness absence, the number of days lost per episode and the relative duration of sickness absence were determined.

Analysis. All analyses were carried out with patients who were gainfully employed when they entered the trial. In the 'intention to treat' analysis the results of exercise therapy were compared to those of the usual care group and the results of exercise therapy were also compared to those of placebo treatment. Thereafter the analyses were repeated with patients from the usual care group and with patients from the exercise therapy group and placebo group who met criteria ("on treatment" analysis). The criteria for "on treatment" were as follows: able to perform independently all exercises and heed advice (exercise therapy group), started therapy within 14 days, visited the physiotherapist at least 8 times, and had no therapy outside the protocol during the period of intervention (exercise therapy and placebo group). Finally a "best cases" analysis was carried out with all patients from the "on treatment" analysis, but for the exercise therapy group this included only patients with good exercise compliance or advice application. For the analysis of absences during short, medium, and long episodes the pain episode was used as unit for analysis. All dropouts were included in the analysis until the moment of dropping out.

Statistical analysis included the chi square test for proportions, analysis of variance (F-test, multivariate analysis of variance) for averages and the Mann-Whitney test for medians. A check for uneven distribution after randomization of the patient characteristics at entry in the three therapy groups was performed by discriminant analysis (using only those variables that were not used in the analysis of effect modification).[2] We used the SPSS PC statistical software package.[22] All values presented in the tables refer to results of the intention to treat analysis.

■ Results

Study Sample

Of 525 patients meeting inclusion criteria 52 refused to participate; 473 patients entered the study after giving informed consent. At the moment they entered the study 363 patients had a paid job. Analyses in this article are based on these 363 patients with a paid job. The 52 patients refusing participation had a higher level of education, more had private medical insurance and, in general, the group complained of less pain than the 473 patients included in the study. Of the 363 patients receiving a salary 41 dropped out during the follow-up period. Of these, 15 were in the usual care group, 12 in the placebo group, and 14 in the exercise therapy group. Of the 41 patients, 16 were withdrawn because of signs of possible nerve root irritation (established by the general practitioner during follow-up and distributed as follows: usual care 4, placebo 5, and exercise therapy 7), 9 patients dropped out because of relocation, serious illnesses, or other circumstances beyond their control, and 16 patients decided to stop of their own accord (5 in the exercise group, 6 in the placebo group, and 5 in the usual care group). Twenty patients dropped out during the first month. Both the reasons and the time of dropping out were equally distributed among the three therapy groups.

Table 1. Baseline Characteristics of the Three Groups Patients With Paid Work (n = 363)

	Usual care	Placebo therapy	Exercise therapy	Total
Number of patients	122	119	122	363
Age (mean)	34	37	35	36
Sex (% men)	66	71	62	66
Education (%)				
Low	48	54	55	52
Intermediate	38	34	35	36
High	14	12	10	12
Previous back pain (%)	75	76	71	74
Previous physiotherapy for back pain (%)	30	37	30	35
Prevsious consultation of specialist for back pain (%)	10	12	10	11
Duration of back pain (%)				
1–7 days	69	66	64	66
8–14 days	23	27	29	26
15–21 days	8	7	7	7
Radiation into the upper 1 = g (%)	25	20	23	23
Pain (VAS) (mean)	36.8	37.0	35.0	36.2
Mobility (NHP) (mean)	23.1	23.0	24.4	23.5
Emotional problems (NHP) (mean)	7.4	7.2	7.7	7.4
Reported sick (%)	62	65	62	64

VAS = visual analog scale. NHP = Nottingham Health Profile.

Table 1 shows the baseline characteristics of the three therapy groups. Sixty-six percent were males and fifty-three percent had a low level of education. More than half only had back pain lasting 1–7 days and 35% had been treated earlier for back pain by a physiotherapist. At the moment of entering the study 64% of patients had reported sick at work.

According to discriminant analysis it appeared that there were no significant differences among the three therapy groups with respect to either individual baseline characteristics or the most discriminating combinations of these characteristics. Moreover, as differences were small, the baseline characteristics were not considered as potential confounders in the analysis. The number of paracetamol tablets used during the first month was unevenly distributed over the three therapy groups (average number in usual care group, 13; placebo group, 9; and exercise group, 9; $P = 0.027$). There was no correlation with the number of sickness absence days (Pearson correlation 0.04, ns). Moreover, the average number of paracetamol tablets per therapy group differed little. Therefore, the number of paracetamol tablets was not considered as a possible confounder when the effects were evaluated.

Table 2. Sickness Absence During Total Follow-up Period and During Month 1, Months 2 and 3, and Months 4–12 After Inclusion (n = 363)

	Usual care	Placebo	Exercise therapy
Number of patients	94	100	96
Month 1–12 % ≥ 1 day			
% ≥ 1 day	72.3	70.0	82.3
Duration of sickness absence (days), mean (SD)	29, (61)	25, (47)	28, (43)
percentiles (25/50/75)	0/11/28	0/12/21	6/20/31
Number of patients	116	114	114
Month 1			
% ≥ 1 day	59.5	61.4	71.4
Number of patients	108	108	104
Month 2–3			
% ≥ 1 day	22.2	26.9	29.8
Number of patients	97	108	100
Month 4–12			
% ≥ 1 day	36.0	30.7	33.3

Number of patients = number of patients in each group minus drop-outs and minus patients with missing values.
% ≥ 1 day: percentage of patients in each group with at least 1 day of sickness absence.
SD = standard deviation.

Table 3. Sickness Absence During Back Pain (n = 361)

	Usual Care	Placebo	Exercise therapy
Number of patients	119	116	118
% ≥ 1 day	75	77	84
Duration of sickness absence (days), mean (SD)	23, (55)	20, (34)	22, (41)
percentiles (25/50/75)	0/7/18	1/9/29	2/11/29
Relative duration of sickness absence, mean (SD)	34, (31)	37, (33)	41, (34)

% ≥ 1 day = percentage of patients with at least 1 day of sickness absence.
Relative duration of sickness absence = (sum of days of sickness absence during all pain episodes/sum of duration of all pain episodes) × 100.
SD = standard deviation.

Compliance

In the exercise group, 92 of the 122 patients met criteria for "on treatment" and 40 patients had a good compliance (more than 7 months doing exercise or applying advice). At least 90% of the patients in the exercise group never had problems as a result of pain with the exercises or advice during the the instruction period. In the placebo group 108 of the 119 patients met criteria for "on treatment."

Outcome

Sickness Absence During the Follow-Up Period. The percentage of patients with sickness absence during the follow-up period (12 months) was 82.3 in the exercise therapy group, 72.3 in the usual care group, and 70.0 in the placebo group (Table 2). The higher amount of absence in the exercise therapy group was mainly attributable to a higher percentage of patients with absences during the period of instruction by the physiotherapist. The differences found were not statistically significant. The total number of days lost (median) during the follow-up was highest in the exercise therapy group. These differences were not statistically significant either.

Absence During Back Pain. During back pain (all pain episodes after entering the trial) more days were lost by patients in the exercise therapy group than in the usual care or placebo groups, although the differences were not statistically significant (Table 3). The groups did not differ with respect to average number of days lost nor with respect to relative duration of the sickness absence. The number of days lost showed a skewed distribution. When the median was tested, the difference between exercise therapy and usual care was significant ($P = 0.02$), but the difference between exercise therapy and placebo ($P = 0.5$) was not. The slight difference could have been a slight placebo effect as a result of the care by the physiotherapist.

No modification of the effect could be demonstrated due to age, sex, level of education, duration of pain at entry, previous back pain, previous physiotherapy for back pain, or degree of pain or loss of mobility at the time of entrance into the trial.

Analysis of the sickness absence of the group that had not reported sick at entry showed that more patients in the exercise therapy group than in the usual care group and in the placebo group had reported sick during the follow-up year (Table 4). The subgroup that had reported sick at entry showed no significant difference among the three therapy groups. The analyses were then repeated with patients from the "on treatment" group and with patients with good compliance. The results were similar to those obtained for the "intention to treat" analysis: a nonsignificant higher percentage of sickness absence in the exercise therapy group owing to a higher percentage of time lost during the first 3 months. The median loss of time during periods of back pain in the exercise therapy group differed significantly

Table 4. Percentage of Patients With Sickness Absence During Follow-up in the Group That Did Not Report Sick at Entry

	Usual care	Placebo	Exercise therapy
Number of patients	33	34	38
Month 1–12*			
% ≥ 1 day	39.4	38.2	65.8
Month 1–3†			
% ≥ 1 day	20.5	25.6	53.8
Month 4–12‡			
% ≥ 1 day	38.2	23.5	41.5

* Exercise therapy versus usual care $P = 0.047$. Exercise therapy versus placebo $P = 0.035$.
† Exercise therapy versus usual care $P = 0.01$. Exercise therapy versus placebo $P = 0.05$.
‡ Exercise therapy versus usual care $P > 0.05$. Exercise therapy versus placebo $P > 0.05$.
% ≥ 1 day = percentage of patients with at least 1 day of sickness absence.

Table 5. Sickness Absence During (Short, Intermediate, and Long) Pain Episodes (n = 965)

	Usual care	Placebo	Exercise therapy
Short episodes (15 days) number of episodes	127	111	125
% episodes with sickness absence	22	17	22
Duration of sickness absence (days), mean (SD)	1, (3)	2, (3)	2, (4)
Percentiles 25/50/75	0/0/0	0/0/0	0/0/0
Relative duration of absence	22 (42)	17 (38)	22 (42)
Intermediate episodes (16–60 days) number of episodes	108	108	116
% episodes with sickness absence	47	47	50
Duration of sickness absence (days), mean (SD)	3, (6)	6, (10)	6, (9)
Percentiles 25/50/75	0/0/7	0/0/10	0/0/11
Relative duration of absence	39 (44)	42 (47)	43 (46)
Long episodes (> 60 days) number of episodes	90	95	89
% episodes with sickness absence	61	50	57
Duration of sickness absence (days), mean (SD)	26, (51)	18, (30)	22, (49)
Percentiles 25/50/75	0/5/22	0/3/22	0/3/26
Relative duration of absence	27 (37)	25 (39)	29 (34)

Relative duration of sickness absence during pain episode = (duration of absence/duration of episode) × 100.
SD = standard deviation.

from that in the usual care group but not from that of the placebo group. Neither good exercise performance ("on treatment") nor good compliance modified the differences between groups.

Sickness Absence During Short, Intermediate, and Long Episodes. Patients from the usual care group experienced a total of 321 pain episodes, those from the placebo group 314 and those from the exercise therapy group 330. The pain episodes were subdivided into short (15 days or shorter), intermediate (>15 days and ≤60 days), and long (>60 days; Table 5). The duration of episodes was equally distributed over the three therapy groups ($P > 0.8$). There were no differences between exercise therapy and usual care groups, or between placebo and exercise therapy groups with respect to percentage of episodes with sickness absence, number of days of absence per episode and relative duration of absence ($P > 0.1$ in all cases).

■ Discussion

We were unable to find a favorable effect of exercise therapy on sickness absence with respect to the number of patients with sickness absence or duration of this absence. We found instead that the various analyses indicated more and longer absences in the exercise therapy group, particularly during the period of instruction by the physiotherapist. Additional absences occurred in the group that had not reported sick when entering the trial.

If a person with a paid job in the Netherlands reports sick, a medical check takes place within 1–10 days by a medical inspector of the industrial insurance administration office. The general practitioner does not play any role in checking up on sickness absence. All patients were fully compensated by refunds, which was the usual procedure with all salaried persons in the Netherlands during the trial. So, the amount of compensation could not have biased sickness absence. Insofar as the medical inspectors influenced the duration of the sickness absence, this will have occurred totally independent of the intervention.

Our trial was centered in the general practice setting. The information on sickness absence of the included patients could only be gathered directly from the patient. Information from the the medical inspector, which we preferred, was not available. Periods of absence that are ascribed to a disease need not always be caused by that disease.[1] Therefore we decided only to assess the duration of sickness absence by self report and not the reason. We assessed sickness absence during back pain in an indirect way by analyzing nonspecific sickness absence during back pain. In our opinion the unfavorable results in the exercise group cannot be attributed to the use of this indirect way of assessing sickness absence during back pain.

Sickness absence was measured retrospectively. It is possible that the number of days reported for the previous month was not completely accurate. We think that small inaccuracies are of less importance regarding the effect variable "percentage of patients with sickness absence."

Job satisfaction and spinal loads for each job were not assessed. We suppose that also these unknown baseline characteristics were most likely equally distributed over the three therapy groups by randomization and therefore did not bias the results.

Because the general practitioner gave the information on back pain to all the patients in the three groups in the same way and because thereafter that therapy assignment took place by the doctor's assistant, the general practitioner's information could not have biased the results.

We used ultrasound in the lowest possible doses. A detuned apparatus was not used because the physiotherapists were not willing to use a detuned apparatus for 20 minutes, two times a week during 5 weeks. Our ultrasound dose was lower than 0.001 W/cm^2. All trials dealing with efficacy of ultrasound in patients with low back pain used higher doses than 0.5 W/cm^2, only one trial used a dose of 0.08 W/cm^2.[12] A minimal effect cannot be excluded, but is very unlikely.

Visiting a physiotherapist takes time and can influence a patient's sickness absence. By comparing exercise therapy and placebo therapy (both during 5 weeks) the net effect of exercise therapy could be assessed and bias by time-consuming visits be excluded.

Exercise therapy in this trial consisted only of flexion exercises. This was the usual type in the Netherlands

when we started the trial. Moreover, by using flexion exercises we could compare our results with other trials in patients with acute low back pain. Our main goal was that patients could apply the set of exercises and advice not only during the instruction period but also after the instruction period in daily life. A high intensity exercise therapy would have been more difficult to apply in daily life. That only 5 patients from the 16 who decided to stop came from the exercise group and the big majority of the exercise therapy group never had problems with the exercises or advice indicate that exercise therapy in this trial was not boring and was accepted by the patients.

An explanation for the likely unfavorable effect of exercise therapy could be that the instruction in the exercise therapy group required much attention; these patients were therefore more involved with their back pain and thus decided to report or remain ill. Duration of the exercise therapy was probably not a factor. In the Netherlands, being referred to a physiotherapist usually involves an average of 20 treatments.[3] A treatment duration of 10 sessions therefore can be considered as relatively short. Stimulating the patient to return to work as quickly as possible was not mentioned explicitly in the protocol for the physiotherapist. The net effect of exercise therapy on sickness absence could thus be assessed, but this omission certainly could also have amplified the negative consequences of the attention given by the physiotherapist.

Compliance was assessed by self reporting. Patients could have overstated the compliance. We were unable to solve this problem and believe that there is a need for better instruments to assess patient compliance in trials. By the "best cases" analysis we tried to determine results in the group in which exercise therapy theoretically had the best chance.

Patients with back pain in the last 2 months were excluded to be sure that no contamination by a recent physiotherapy treatment took place and to be sure that patients entered with a new pain episode. Sixty-six percent of the included patients had back pain for only 1–7 days. Because we found no effect modification by pain duration at entry and because the selected group was also representative for other baseline characteristics, conclusions from this trial can be used for patients with acute low back pain in general practice.

Lindquist and Berwick did not find, for comparable patients with acute back pain, any difference with respect to sickness absence between the group receiving exercises with instructions and the control group either.[5,19] However, Bergquist-Ullmann and Stankovic found a favorable effect on sickness absence in the group with exercises and instructions during the first pain episode (at entry) but no effect on sickness absences thereafter.[4,23] However, because of their design it cannot be excluded that the short-lasting effect on sickness absence was a placebo effect in these trials. Also the efficacy of extension exercises alone or in combination with flexion exercises still has to be proven.[16]

We conclude that concerning sickness absence, exercise therapy in patients with acute low back pain has no advantages over usual care of the general practitioner. The best way a general practitioner can play a role in reducing sickness absence by encouraging an early return to work.[7]

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