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The Effectiveness of Manual Therapy, Physiotherapy, and Treatment by the General Practitioner for Nonspecific Back and Neck Complaints

A Randomized Clinical Trial

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In a randomized trial, the effectiveness of manual therapy, physiotherapy, continued treatment by the general practitioner, and placebo therapy (detuned ultrasound and detuned short-wave diathermy) were compared for patients (n = 256) with nonspecific back and neck complaints lasting for at least 6 weeks. The principle outcome measures were severity of the main complaint, global perceived effect, pain, and functional status. These are presented for 3, 6, and 12 weeks follow-up. Both physiotherapy and manual therapy decreased the severity of complaints more and had a higher global perceived effect compared to continued treatment by the general practitioner. Differences in effectiveness between physiotherapy and manual therapy could not be shown. A substantial part of the effect of manual therapy and physiotherapy appeared to be due to nonspecific (placebo) effects. [Key words: randomized clinical trial, manipulation, physical therapy, back pain, neck pain].

BACK AND NECK complaints occur frequently in Western countries, and it is estimated that some 80% of all persons in the West experience back problems during their active life.[11,22] Neck problems are less frequently reported, but they constitute a major health problem as well. In most cases, no underlying pathology can be established and the causes of the complaints remain unknown.[11,21] The majority of patients with acute low-back pain recover within a few weeks, often with the help of bed rest, analgesics, and advice about posture and exercises.[23] Within a few months, the complaints disappear in about 90% of the cases.[4,11,24–26] When the complaints do not disappear, the general practitioner (GP) will often refer these patients to a physiotherapist for treatment with massage, exercise, and physical therapy modalities (eg, electrotherapy, ultrasound, short wave diathermy). Other patients are referred to a manual therapist for manipulative treatment.

Despite the widespread use of physiotherapy for back and neck complaints, its effectiveness has rarely been investigated in adequate randomized clinical trials.[18] The effectiveness of manipulation and mobilization of the spine for back and neck complaints has been investigated in a number of trials[19]; however, these studies often show methodologic flaws. Common problems are the small size of the study population, the criteria for selecting patients, the operationalization of the manipulative techniques, and the absence of blinded outcome measurements.[2,6,14,19] We present a randomized clinical trial that tries to avoid these flaws and that focuses on the relative quantification of the effectiveness of manual therapy and physiotherapy for patients with nonspecific back and neck complaints lasting for at least 6 weeks.

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METHODS

Selection of the Subjects. Potential subjects with pain or self-reported limited range of motion in the back or neck region were selected by 40 GPs during a 2-year period (January 1988–December 1989). Due to a low admission rate of patients in the early stage of the trial, we expanded the recruitment activities by repeated advertisements in the local press, informing patients about the possibility of participating in the study. Patients showing interest were asked to contact their GP, who checked the admission criteria. Subsequently, an appointment was made with the research assistant, who was also an experienced physiotherapist (AHME) and manual therapist. The research assistant performed a physical examination and did the final check with respect to the admission criteria.

The purpose of these criteria was to select a relatively homogeneous group of patients suitable for treatment with both physiotherapy and manual therapy and also continued care by the GP. Patients had to have been in pain or to have endured self-reported limited range of motion in the back or neck for at least 6 weeks. Criteria for exclusion were suspicion of underlying pathology (eg, malignity, osteoporosis, herniated disc). Candidates were also excluded if they had received physiotherapy or manual therapy for their back or neck complaints during the previous 2 years, were pregnant, were unable to speak and read Dutch, or if their complaints turned out not to be reproducible by active or passive movements during physical examination.

Patients completed the informed consent by signing a letter explaining all relevant information about the study, including the 25% chance of receiving a "treatment which professionals expected to provide no effect." The relevant variables in the history and physical examination were recorded, and the patients filled out a number of questionnaires (pain and functional status) to complete the baseline measurements. The study protocol was approved by the ethical committee of the University Hospital.

Treatment Assignment. Randomization per stratum took place by the use of a list of random numbers. Prestratification by localization of the complaints (back, neck), age (younger than 40 years, 40 years and older), and residence (four regions) was carried out to further prevent unequal distributions among the treatment groups. Within each stratum, the random assignment was performed within blocks of eight to ensure approximately equal numbers in the treatment groups. Depending of the outcome of the randomization, the patient went to their own GP, to a

physiotherapist (for physiotherapy or placebo therapy), or to a manual therapist.

Except for the placebo therapists, all therapists were free to choose from their usual therapeutic domain within some explicitly formulated limits (eg, no manipulative techniques were performed by the physiotherapists). All treatments were given for a maximum of 3 months:

1. Physiotherapy consisted of exercises, massage, and physical therapy modalities. The majority of the patients in this group received exercises and massage (exercises and massage only [10%], or in combination with heat [44%]); the remainder received these in combination with electrotherapy (12%) or with heat and electrotherapy (9%). A minority of the patients received exercises without massage only (3%), in combination with heat (9%), or in combination with electrotherapy (5%). Finally, 5% of the patients received massage only, and 3% received massage in combination with heat.
2. Manual therapy consisted of manipulative techniques (manipulation and mobilization of the spine) according to the directives of the Dutch Society for Manual Therapy. Both the manual therapists (n = 7) and the physiotherapists (n = 8) participating in the study were selected by their respective professional organizations (the Dutch Society for Manual Therapy and the Royal Dutch Society for Physiotherapy).
3. Continued treatment by the GP (n = 40) consisted of prescription of medication (eg, analgesics, nonsteroidal anti-inflammatory drugs), advice about posture, home exercises, participation in sports, bed rest, and other treatment modalities.
4. Placebo treatment consisted of a physical examination and subsequently detuned short-wave diathermy (10 minutes) and detuned ultrasound (10 minutes) carried out by a physiotherapist (n = 8). These treatment sessions were scheduled two times per week for a period of 6 weeks.

After 6 weeks, the patients returned to their GP with a written report from the manual therapist of physiotherapist in order to discuss the results and to decide whether to continue, change, or stop the treatment. The therapists registered the content, frequency, and duration of the therapy given to the patients.

Follow-up, Outcome Measures, and Blinding. Follow-up measurements (physical examination and questionnaires) were carried out at 3, 6, and 12 weeks after randomization. The follow-up measurement taken at 3 weeks was included to detect short-term effects. The follow-ups at 6 and 12 weeks were expected to provide the maximal benefit of the treatments included.

Measures of effect were chosen in sequence of importance:

1. Severity of complaints was measured by a blinded research assistant on a 10-point scale (0 = no severity, 10 = maximal severity). The score of the severity was based on an anamnesis and a physical examination. This physical examination consisted of a protocol of active and passive movements. During all follow-up measurements, the research assistant was unaware of the treatment to which the patients were assigned.
2. Global perceived effect was measured by self-assessment on a six-point scale (1 = no benefit, 6 = maximal benefit).
3. Pain was rated on a six-point subscale of pain severity according to the West Haven-Yale Multidimensional Pain Inventory (WHYMPI) (0 = no severity, 6 = maximal severity).[17]
4. Functional status was measured according to the Sickness Impact Profile.[1]

Spinal mobility and physical functioning were also measured. Furthermore, measurements at the 6-month and 1-year follow-up examinations were included to detect long-term effects and recurrences of the complaints. These results will be presented in a separate study.

Prognostic Information. Information on prognostic variables was collected mainly to assess whether the randomization has been successful. The following information was obtained:

- History of current complaints (eg, localization, duration, severity) and demographic information;
- Range of motion of the spine and measurements of active and passive movements by physical examination;
- General health status as measured with the Hopkins Symptom Check List (HSCL)[3];
- Compliance and additional treatment measured by a written questionnaire;
- Treatment regimen, duration, and frequency recorded by the therapists and GPs.

Statistical Analysis. A protocol for the data analysis was written before the results were available. Comparability of baseline measurements among the four study groups was assessed critically. To determine the severity of the complaint, pain, and functional status we calculated the difference between the follow-up score and the baseline score for each individual patient. These scores can thus be regarded as indicators of improvement (or deterioration). The four study groups were compared for their mean improvement scores at the 3-, 6-, and 12-week follow-up. Furthermore, cumulative distributions of the improvement scores of severity of the main complaint, and global perceived effect at 6-week follow-up, were calculated.

One-way analysis of variance was used for each outcome measure. Group differences and 90% confidence intervals were calculated for the 6-week follow-up. In addition, we calculated group differences and confidence intervals using a linear regression model. The purpose of this model was to estimate group differences adjusted for small differences at the baseline for important prognostic indicators. Another reason was to enlarge the precision of the point estimates of the group differences. In this model, we entered the following prognostic indicators: localization and duration of the main complaint, the baseline score of the outcome measure at issue, age, and recruitment status (GP or advertisement).

We present one statistical analysis according to the "intention-to-treat" principle. Thus, all patients remain in the group to which they were assigned by randomization. This includes drop-outs (as far as they participated in the effect measurements), patients with low compliance, and patients who changed from the assigned therapy.

In addition to the intention-to-treat analysis, we present an alternative analysis in order to adjust for missing values and patients who changed from the assigned therapy. In this analysis, we substituted the outcomes at follow-up of patients who changed from the assigned therapy with the score of the last measurement before changing therapy. Similarly, we substituted the last measurement for patients with missing values. The analyses were carried out with a statistical software package (Biomedical Computer Programs P-series, version 1988, University of California, Berkeley).[7]

RESULTS

Study Sample

There were more than 1,500 responses to the recruitment activities. Most persons responded to the publicity in the local newspapers. The majority were not eligible for reasons such as not fulfilling the admission criteria, no persisting interest in participating, or the fact that their GP did not participate in the study. In total, 424 persons were invited for an appointment with the research assistant to check their eligibility, of which 168 persons were excluded. The most common reasons for exclusion were suspicion of prolapse of the disc (n = 43), complaints that turned out not to be reproducible during physical examination (n = 39), prior treatment (for present complaint) with physiotherapy or manual therapy within the previous 2 years (n = 24), and complaints that were of less than 6 weeks' duration (n = 19). Finally, 256 patients were enrolled and randomly assigned to the study treatments: 65 to manual therapy, 66 to physiotherapy, 64 to the placebo therapy, and 61 to the GP.

After the 12-weeks follow-up examination, 23 patients (9%) had dropped out. Table 1 shows the cumulative dropout rate for each group at the 3-, 6-, and 12-week follow-up. The reasons given for dropping out were inconvenience and lack of time (n = 10); problems with the questionnaires (n = 3); complaints having disappeared (n = 2; one in

Table 1. Cumulative Number of Dropouts (and Total Number of Missing Values of the Measurement by the Blinded Research Assistant) at Follow-Up After 3, 6, and 12 Weeks

Treatment	3 Weeks	6 Weeks	12 Weeks
Manual therapy	1 (4)	1 (11)	3 (8)
Physiotherapy	2 (10)	4 (11)	5 (12)
Placebo therapy	5 (14)	6 (13)	8 (16)
General practitioner	4 (14)	6 (17)	7 (20)

the physiotherapy group, one in the GP group); no benefit of treatment (n = 2; both in the GP group); pregnancy (n = 1); and personal reasons or no reason given (n = 5). In addition, a number of persons failed to attend the physical measurement by the research assistant (mainly because of lack of time). However, they usually did fill out the written questionnaires and could therefore be included in those analyses for outcome measures for which their data were not missing.

Prognostic Comparability

Table 2 shows the demographic and clinical characteristics of the patients who were included in the study. Comparability for the main prognostic variables, such as duration, severity, localization of the complaints, and age, seems to be satisfactory.

For patients with back or neck complaints, the median duration of the present episode was 1 year. (For the 48 patients with back and neck complaints, the median duration of back complaints was 1.5 years and and the median duration for neck complaints was 1 year). Of all patients, 52% had at some time received physiotherapy for their current complaint and 11% had received manual therapy (but not in the previous 2 years).

Blinding and Compliance with Treatment

Patients could of course not be blinded for referral to the physiotherapist, manual therapist, or GP. However they were blinded for the placebo therapy. Patients were asked whether they thought they received "the treatment which professionals would expect to provide no effect." At 6 weeks, one half of the patients (n = 32) in the GP group answered affirmatively vs. 22 in the placebo group, 15 in the manual therapy group, and 9 in the physiotherapy group. The variation across the study groups seems to suggest that the placebo therapy was not systematically unmasked by the patients who were actually treated in that group.

Besides dropouts (Table 1) and patients who changed from the assigned therapy (switch-overs) (Table 3), all patients in the physiotherapy group, manual therapy group, and placebo group received the assigned therapy. Apart from the dropouts (Table 1) and switch-overs (Table 3), four patients in the GP group did not visit the GP. Table 4 shows the number of treatments, session time, and duration of treatment for the four study groups. As was expected, the manual therapy group received considerably fewer treatments than the physiotherapy group. Patients in the GP group mostly paid only a single visit to their GP.

Contamination Bias

Table 3 presents the cumulative frequency of the deviations of the allocated therapy. It appears that contamination mainly occurred in the placebo group and in the GP group. Seven patients in the placebo group received physiotherapy before the 3-week follow-up: one due to an administrative error, one due to unmasking of the placebo by the patient, and five because the therapist unfortunately decided that giving a placebo was not appropriate for the patient in question. Four patients in the GP group received physiotherapy or manual therapy before the

Table 2. Baseline Characteristics of the Participants

Characteristic	Manual Therapy	Physiotherapy	Placebo Therapy	General Practitioner	All Subjects
No.of subjects	65	66	64	61	256
Selected through advertisement (%)	75	64	60	62	68
Mean age (yr)	43	42	43	43	43
Gender (% female)	54	48	52	38	52
Localization of complaints (%)					
Back	55	54	62	53	56
Neck	20	32	22	26	25
Back and neck	25	14	16	21	19
Median duration of present episode of complaints (wk)					
Patients with back or neck complaints (n = 208)	52	52	52	45	52
Patients with back and neck complaints (n = 48)					
Back	78	26	92	78	79
Neck	91	26	65	52	52
Mean severity:					
main complaint	7.0	7.0	6.8	6.8	6.9
Previous treatment (%)					
Physiotherapy	58	45	58	48	52
Manual therapy	12	18	5	10	11
Alternative medicine	14	18	9	20	15
Specialist	17	18	22	18	19
Mean ordinal pain score: subscale WHYMPI (severity)	3.0	2.8	3.1	2.9	3.0
Mean initial SIP score					
Overall	5.3	5.8	5.6	4.8	5.4
Physical dimension	3.2	3.3	4.2	2.4	3.3
Psychosocial dimension	4.9	5.7	5.3	5.0	5.2
Mean HSCL score					
Psychological dimension	7.3	6.3	6.2	7.0	6.7
Somatic dimension	5.6	5.2	5.8	5.3	5.5
Total	28.1	25.0	25.6	25.5	26.1

HSCL = Hopkins Symptom Check List; SIP = Sickness Impact Profile; WHYMPI = West Haven-Yale Multidimensional Pain Inventory.

Table 3. Cumulative Number of Deviations from the Allocated Therapy at Follow-Up

Treatment	*3 Weeks*	*6 Weeks*	*12 Weeks*
Manual therapy	1 inj	1 inj	1 inj (painkiller) 2 physio 1 spec
Physiotherapy			1 man th
Placebo therapy	7 physio	9 physio	15 physio 2 man th 2 spec
General practitioner	3 physio 1 man th	4 physio 1 man th 1 sport mas 2 spec	7 physio 4 man th 2 cesar/mensendieck 1 HNP operation 1 hospitalization 2 spec 2 alt med 2 sport mas

alt med = treatment with alternative medicine; HNP = hernia nuclei pulposi; inj = injection by general practitioner; man th = manual therapy; physio = physiotherapy; spec = referral to specialist; sport mas = sports massage.

3-week follow-up: one because the patient did not want treatment by the GP, one because the GP carried out manual therapy himself, and two because the GP thought that a referral was more appropriate. At the 6-week follow-up, these figures appeared to be slightly higher. Between the 6- and 12-week follow-up, a considerable number of patients in the placebo and GP group changed from the assigned therapy. Although not desirable, according to the study protocol (for the ethical reasons), patients could change therapy at 6 weeks after randomization. In the physiotherapy group (one patient received manual therapy) and manual therapy group (two patients received physiotherapy and one was referred to a specialist), these changes occurred considerably less often.

Primary Outcomes

Table 5 lists the results of the primary outcome measures. The trend is that all four study groups show an increasing improvement at three follow-up measurements. The improvement of the main complaint (rated by the blinded research assistant) for both the manual therapy group and physiotherapy group is larger than in the GP group at the 3- and 6-week follow-up. The placebo group also shows a larger improvement than the GP group, but smaller than the manual therapy and physiotherapy groups. At the 12-week follow-up, all four study groups showed the largest improvement, but the differences among the study groups have almost entirely disappeared.

The assessment by the patient of global perceived effect (1 = no benefit, 6 = maximal benefit) shows similar results. All study groups show an increasing effect. Both the manual therapy and physiotherapy groups show the highest mean scores at 3 and 6 weeks. There are no differences between these two study groups. At 3 and 6 weeks, the placebo group had a mean score just below that of the manual therapy and the physiotherapy groups, but at 12 weeks, the mean scores were about equal. The GP group showed the lowest mean scores at all follow-up measurements.

Table 4. Mean Number of Treatments, Session Time, and Duration Until the 12-Week Follow-Up

	No. of Treatments	*Session Time (min)*	*Duration (wk)*
Manual therapy	5.4 (6)	41 (40)	8.9 (9)
Physiotherapy	14.7 (14)	35 (30)	7.8 (8)
Placebo therapy	11.1 (12)	29 (30)	5.8 (6)
General practitioner*	—	—	—

*(Continued) treatment by the general practitioner consisted usually of a single visit by the patient at the general practice.

Note: Medians are given in parentheses.

All four study groups showed an increasing mean improvement for pain severity (subscale WHYMPI, range 0–6) at the follow-up measurements. The improvements were small, however, and there appears to be no statistically significant difference among the four study groups ($P > .7$ at all follow-up measurements according to one-way analysis of variance).

The magnitude of the improvement on daily functioning measured by the Sickness Impact Profile (physical dimension) is very small for all four study groups. On a scale from 0 to 100, the improvement appears to be one point at the 3-week follow-up and about 2 points at the 12-week follow-up. There were no statistically significant differences among the four study treatments ($P > .3$ at all follow-up measurements according to one-way analysis of variance).

Figures 1 and 2 are graphic presentations of the cumulative distributions to the improvement scores of the four study groups at the 6-week follow-up. On the abscissa, one can choose the preferred cutoff point of the score and read the proportion of patients of the four study treatments with at least that score on the ordinate. For example, Figure 1 shows that 32% in the GP group, 47% in the placebo group, and more than 60% in the manual therapy and physiotherapy groups, respectively, had an improvement score of 3 points or more. In general, higher curves indicate a more favorable outcome. In all four study groups, most patients improved between 0 and 6 points (on a 10-point scale). A small percentage (10–15%) in each study group showed an improvement of 6 points or more. The manual therapy and physiotherapy groups showed the best outcome of the patients with improvement scores of less than 6 points. In these two study groups, the cumulative distribution of the improvement scores was almost identical. The cumulative distribution of the GP group was the lowest for almost all improvement scores. The placebo group showed results that were in between.

Figure 2 shows the cumulative distribution of the benefit scores at the 6-week follow-up examination. Again, the distributions of the manual therapy and physiotherapy groups were almost identical. The GP group showed the lowest outcome at all benefit scores. The placebo group had a score that was in between, but relatively close to the scores of the "real" treatments.

Table 5. Improvement in Main Complaint, Global Perceived Effect, Pain, and Functional Status at the 3- 6-, and 12-week Follow-Up in the Intention-to-Treat Analysis

Outcome measure	*3 Weeks*	*6 Weeks*	*12 Weeks*
Mean (SD) improvement in main complaint (10-point scale)			
Manual therapy	2.3 (2.1)	3.4 (2.1)	4.0 (2.6)
Physiotherapy	2.0 (2.3)	3.4 (2.4)	3.8 (2.3)
Placebo therapy	1.7 (2.6)	2.7 (2.4)	3.8 (2.6)
General practitioner	1.3 (2.3)	2.0 (3.1)	3.9 (2.6)
Mean (SD) global perceived effect (6-point scale)			
Manual therapy	2.5 (1.5)	3.4 (1.7)	3.4 (2.0)
Physiotherapy	2.6 (1.6)	3.3 (1.6)	3.7 (1.7)
Placebo therapy	2.1 (1.4)	2.8 (1.6)	3.3 (1.9)
General practitioner	1.6 (1.0)	1.9 (1.3)	2.2 (1.7)
Mean (SD) improvement in severity of pain (6-point scale)			
Manual therapy	0.4 (1.3)	0.6 (1.5)	0.8 (1.7)
Physiotherapy	0.4 (1.3)	0.6 (1.4)	0.9 (1.5)
Placebo therapy	0.3 (1.3)	0.6 (1.7)	1.1 (1.7)
General practitioner	0.2 (1.0)	0.4 (1.4)	0.9 (1.6)
Mean (SD) improvement in functional status (100-point scale)			
Manual therapy	0.9 (3.1)	1.8 (3.0)	1.6 (2.9)
Physiotherapy	1.2 (3.3)	1.3 (3.8)	1.9 (3.8)
Placebo therapy	1.1 (4.4)	1.3 (3.6)	2.2 (5.1)
General practitioner	1.1 (2.7)	0.7 (2.9)	0.8 (4.7)

Table 6 shows the magnitude of the group differences and the 90% confidence intervals at the 6-week follow-up examination. When the value 0 is not included in the confidence interval, the group difference can be regarded as statistically significant at the 5% level (one-sided test).

The estimates presented were carried out with a linear model; however, these adjusted group differences differed only marginally from the crude estimates with regard to the magnitude of the differences and the precision of the point estimates.

The difference between manual therapy and physiotherapy is small and not statistically significant. The differences between manual therapy and physiotherapy on the one hand and placebo therapy on the other hand are not statistically significant with regard to the improvement of the main complaint. However, there appears to be a trend in favor of manual therapy and physiotherapy. Regarding the global perceived effect, the differences are statistically significant. All differences between manual therapy and physiotherapy one the one hand and the GP group on the other hand appear to be highly statistically significant.

Group differences were also calculated at 3 and 12 weeks. Regarding improvement of the main complaint, there was a statistically significant difference at 3 weeks only between the manual therapy group and the GP group (0.9; 0.3, 1.5) and between the physiotherapy group and the GP group (0.7; 0.2, 1.5). At 12 weeks, there were no longer any significant differences.

With regard to global perceived effect, all contrasts with the GP group were statistically significant at 3 weeks as well as at 12 weeks, whereas all other contrasts were not statistically significant.

Alternative Analysis

An intention-to-treat comparison is most valid when the dropout rate, as well as number of missing values, is low and there is no contamina-

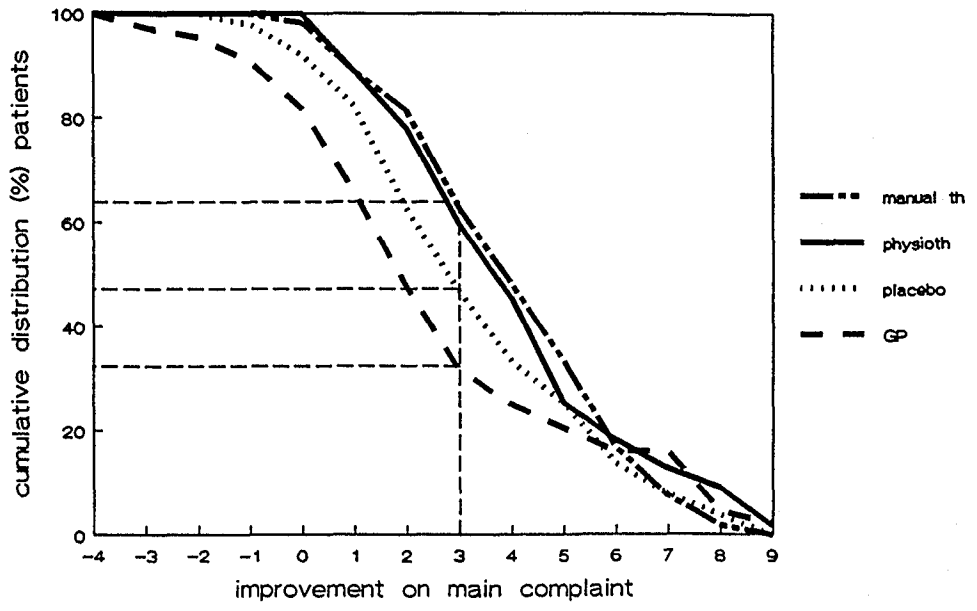

Fig 1. Improvement on main complaint at 6-week follow-up (intention-to-treat analysis).

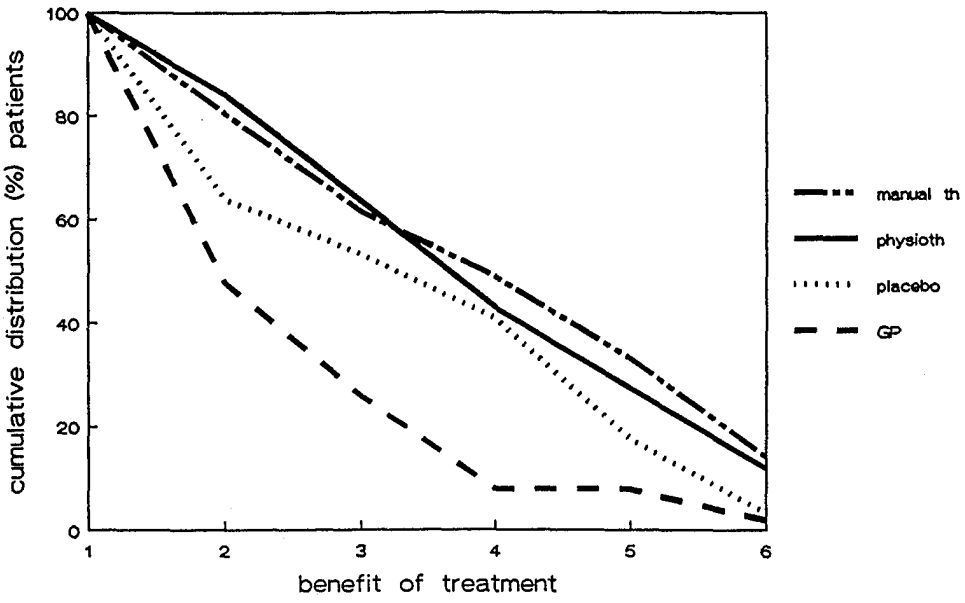

Fig 2. Global perceived effect at 6-week follow-up (intention-to-treat analysis).

tion bias. In this study, however, the results in the placebo group and GP group (especially after 12 weeks) of the intention-to-treat analysis may be biased because of dropouts, missing values, and contamination. Therefore, we also present an analysis in which we assume that patients who dropped out, changed therapy, or had a missing value did not improve since the last follow-up measurement. The main underlying assumption for this analysis is that patients probably change therapy because they no longer expect to benefit from the assigned therapy. The results of this alternative analysis are presented for improvement on main complaint and global perceived effect in Table 7.

The underlying assumptions for the alternative analysis appear to affect the placebo group and GP group most. The differences between manual therapy and physiotherapy on one hand and between placebo therapy and treatment by the GP on the other appear to be larger at 3 and 6 weeks. This pattern is apparent in the graphic presentations (Figures 3–4). With regard to the improvement of the main complaint, the differences between manual therapy and placebo therapy and between physiotherapy and placebo therapy appear to be statistically significant at 6 weeks (Table 6). At 12 weeks, these differences still appear to exist.

DISCUSSION

The pragmatic comparison made in this trial indicates a more favorable outcome for treatment with manual therapy or physiotherapy vs. treatment by the GP. This conclusion is based on the greater improvement of the main complaint assessed by the blinded research assistant at the 3- and 6-week follow-up examinations, and a larger perceived effect by self-assessment at all follow-up measurements. In contrast to the other treatment groups, however, the patients in the GP group did not receive a "new" treatment (ie, referral). The patients in the GP group may therefore have thought that they were less well off and therefore could have had a sort of "negative" placebo effect. This idea is supported by our finding that the placebo therapy (detuned ultrasound and detuned short-wave diathermy) showed better results than treatment by the GP.

There was no difference in effectiveness between manual therapy and physiotherapy for all outcome measures at all follow-up measurements. However, the number of treatments (visits) was considerably less for the manual therapy group, and this might be regarded as a considerable advantage.

Table 6. Group Differences (90% Confidence Limits) at 6 Weeks: Intention-to-Treat and Alternative Analysis

	Physiotherapy	*Placebo Therapy*	*General Practitioner*
Intention-to-Treat Analysis			
Mean improvement			
Main complaint			
Manual therapy	0.1 (−0.6, 0.8)	0.4 (−0.3, 1.1)	1.2 (0.4, 2.1)
Physiotherapy		0.4 (−0.3, 1.2)	1.2 (0.3, 2.0)
Placebo therapy			0.8 (0.0, 1.7)
Mean global			
Perceived effect			
Manual therapy	0.2 (−0.3, 0.8)	0.7 (0.2, 1.2)	1.7 (1.2, 2.2)
Physiotherapy		0.5 (0.0, 1.0)	1.4 (0.9. 1.9)
Placebo therapy			0.9 (0.5, 1.4)
Alternative analysis			
Mean improvement			
Main complaint			
Manual therapy	0.2 (−0.4. 0.9)	1.1 (0.5, 1.8)	1.4 (0.7, 2.1)
Physiotherapy		1.1 (0.4, 1.7)	1.5 (0.5, 2.0)
Placebo therapy			0.3 (−0.4, 1.0)
Mean global			
Perceived effect			
Manual therapy	0.4 (−0.1, 0.9)	1.2 (0.7, 1.6)	1.9 (1.5, 2.4)
Physiotherapy		0.8 (0.3, 1.3)	1.5 (1.1, 2.0)
Placebo therapy			0.8 (0.4, 1.2)

Table 7. Improvement on Main Complaint and Global Perceived Effect at the 3-, 6-, and 12-Week Follow-Up in the Alternative Analysis

Outcome Measure	*3 Weeks*	*6 Weeks*	*12 Weeks*
Mean (SD) improvement on Main complaint (10-point scale)			
Manual therapy	2.1 (2.1)	3.0 (2.3)	3.8 (2.6)
Physiotherapy	1.7 (2.2)	3.0 (2.5)	3.4 (2.6)
Placebo therapy	1.1 (2.2)	1.8 (2.3)	2.3 (2.5)
General practitioner	1.0 (2.1)	1.5 (2.7)	2.4 (3.0)
Mean (SD) global effect (6-point scale)			
Manual therapy	2.4 (1.5)	3.4 (1.7)	3.4 (2.0)
Physiotherapy	2.4 (1.6)	3.1 (1.7)	3.5 (1.8)
Placebo therapy	1.8 (1.3)	2.3 (1.6)	2.5 (1.9)
General practitioner	1.4 (0.8)	1.6 (0.9)	1.7 (1.3)

The median duration of the present episode of back and neck pain of 1 year is rather high. However, this figure must be interpreted with some caution. Patients were asked to estimate the duration of the current attack, but the start of this attack is often not clear, eg, when there is a continuous complaint but the intensity varies over time. Thus, a reliable estimate of the duration of the current attack seems difficult to obtain.

The choice of an appropriate placebo treatment that was trusted by the patients and that had no specific effects was difficult. Placebo or sham manipulation, exercises, or massage, although desirable, did not appear to be practically feasible. Therefore, we chose detuned ultrasound and short-wave diathermy as the next best solution. The patients in the placebo group responded remarkably well. Although the improvement of the main complaint (intention-to-treat) in the physiotherapy and manual therapy group was consistently better than in the placebo group at 3 and 6 weeks, the differences were not statistically significant at the conventional 5% level. The comparison of placebo therapy vs. physiotherapy and manual therapy thus reveals that a substantial part of the

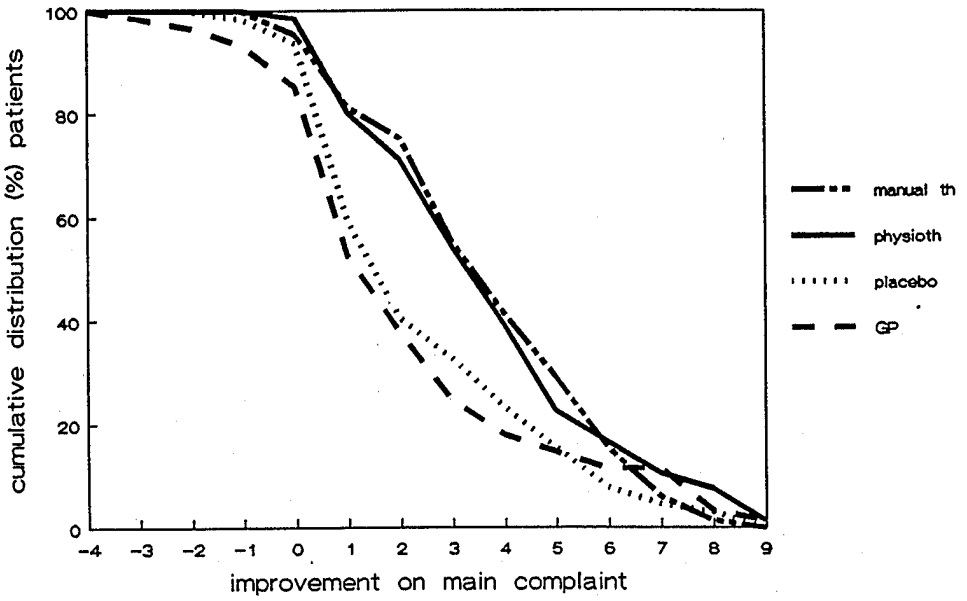

Fig 3. Improvement on main complaint at 6-week follow-up (alternative analysis).

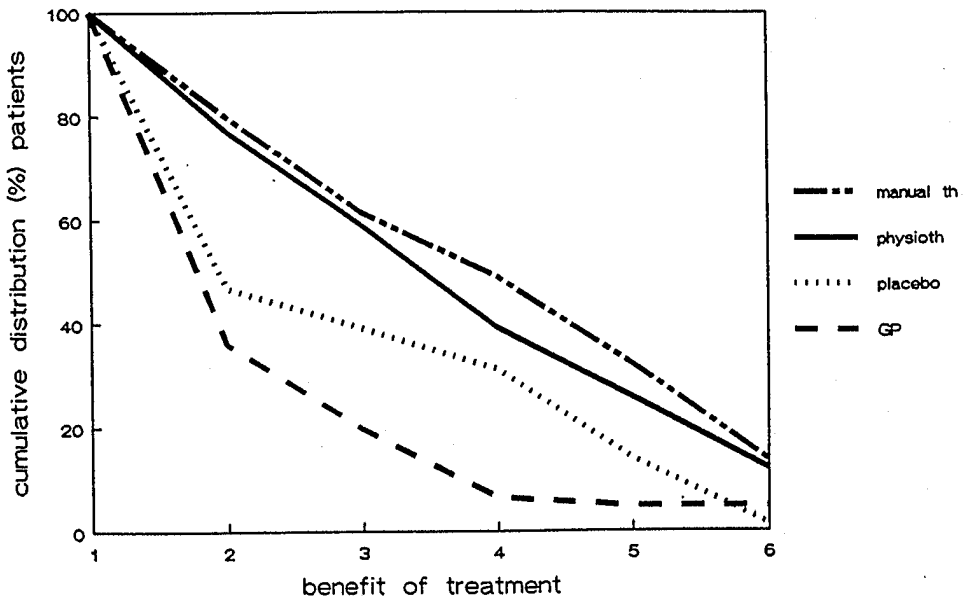

Fig 4. Global perceived effect at 6-week follow-up (alternative analysis).

effect of referral for physiotherapy or manual therapy may be explained by nonspecific effects of the referral (eg, extra attention).

When designing this trial, we had chosen the Sickness Impact Profile as an instrument for measuring functional status.[20] This health status questionnaire has been used previously in back pain trails.[5,10] In this new trial, however, the scores of the patients at baseline were only slightly higher than in a general population, thus leaving not much room for improvement in daily functioning. The use of this instrument in clinical trials with patients comparable to those in this study might not be very suitable. The same holds for the use of the WHYMPI. Although we used only the subscale pain severity, this instrument (its present name is the Multidimensional Pain Inventory) does not seem to be very responsive to changes in severity of complaints that obviously occurred in the trial and that were very easily measured by the blinded research assistant.

We presented two analyses of the data. In general, we believe that an intention-to-treat analysis is the most valid approach for analyzing the results of a clinical trial. In this particular trial, however, the results especially at the 12-week follow-up might be biased substantially because a number of patients in the placebo and GP groups changed from the assigned therapy to mainly physiotherapy and manual therapy. Furthermore, the number of dropouts and missing values were highest in the first two groups. This can be regarded as an outcome measure in itself. The treatments in groups with many patients who change therapy and many dropouts are probably less effective. We dealt with this contamination bias by substituting the results at follow-up with the last available measurement before changing therapy to physiotherapy or manual therapy or before having a missing outcome. Thus, we assumed no further improvement after these moments for the patients involved. This means that for these patients we ignored the general trend of improvement over time, but also ignored the possibility of deterioration among these patients. Readers can choose their own analysis for drawing conclusions. We believe the intention-to-treat analysis overestimates the efficacy of the placebo therapy and treatment by the GP, especially at the 12-week follow-up. However, the alternative analysis might lead to an underestimation of the effect of the placebo therapy and treatment by the GP.

Further analysis of the data will be carried out to explore whether there are subgroups of patients (eg, back patients and neck patients separately) in which different treatment effects occurred. The results of other randomized trials investigating the effectiveness of manipulative techniques are controversial.[19] Some investigators did not find a beneficial effect of manipulative techniques over physiotherapy, corset or analgesic tablets,[8] minimal massage, low-level electrostimulation,[13] short-wave diathermy and detuned short-wave diathermy.[12] Other investigators demonstrated better short-term results with manipulation over soft tissue massage,[16] mobilization,[15] microwave diathermy, and isometric abdominal exercises.[9] However, these findings usually were found for patients with acute complaints, whereas we studied patients with subacute and chronic problems.

We conclude that it seems useful to refer patients with nonspecific back and neck complaints lasting for at least 6 weeks for treatment with physiotherapy or manual therapy. Patients also responded remarkably well to the placebo therapy. This does not alter this conclusion, however, but suggests the importance of the nonspecific effects of a referral. Although this phenomenon needs further study and is not yet fully understood, the possibility that nonspecific effects (eg, extra attention) could produce improvement should be considered in the approach and treatment of patients with back and neck complaints.

REFERENCES

1. Bergner M, Bobbitt RA, Carter WB, Gilsen BS: The sickness impact profile. Med Care 19:787–805, 1981
2. Brunarski DJ: Clinical trials of spinal manipulation: A critical appraisal and review of the literature. J Manipulative Physiol Ther 7:243–249, 1984
3. Derogatis LR, Lipman RS, Rickels K, Uhlenhuth EH, Covi L: The Hopkins symptom checklist, a self-report symptom inventory. Behav Sci 19:1–151, 1974
4. Deyo RA: Conservative therapy for low back pain. JAMA 250:1057–1062, 1983
5. Deyo RA: A controlled trial of transcutaneous nerve stimulation (TENS) and exercise for chronic low back pain. N Engl J Med 322:1627–1634, 1990
6. Di Fabio RP: Clinical assessment of manipulation and mobilization of the lumbar spine—a critical review of the literature. Phys Ther 66:51–54, 1986
7. Dixon WJ, Brown MB, Engelman L, Hill MA: BMDP statistical software manual. Berkeley, University of California Press, 1988
8. Doran DJM, Newell DJ: Manipulation in treatment of low back pain: a multicentre study. Br Med J 2:161–164, 1975
9. Farrell JP, Twomey LT: Acute low back pain: comparison of two conservative treatment approaches. Med J Aust 1:160–164, 1982
10. Follick MJ, Smith TW, Ahern DK: The sickness impact profile: A global measure of disability in chronic low back pain. Pain 21:67–76, 1985
11. Frymoyer JW: Back pain and sciatica. N Engl J Med 318:291–300, 1988
12. Gibson T, Grahame R, Harkness J, et al: Controlled comparison of short-wave diathermy treatment with osteopathic treatment in non-specific low back pain. Lancet 1:1258–1261, 1985
13. Godfrey CM, Morgan PP, Schatzker J: A randomized trial of manipulation for low back pain in a medical setting. Spine 9:301–304, 1984
14. Greenland S, Reisbord LS, Haldeman S, Buerger AA: Controlled clinical trials of manipulation: A review and a proposal. J Occup Med 22:670–676, 1980
15. Hadler NM, Curtis P, Gillings DB, Stinnett S: A benefit of spinal manipulation as adjunctive therapy for acute low back pain: A stratified controlled trial. Spine 12:703–705, 1987
16. Hoehler GK, Tobis JS, Buerger AA: Spinal manipulation for low back pain. JAMA 245:1835–1838, 1981
17. Kerns RD, Turk DC, Rudy TE: The West Haven-Yale Multidimensional Pain Inventory (WHYMPI). Pain 23:345–356, 1985
18. Koes BW, Bouter LM, Beckerman H, Heijden van der GJMG, Knipschild PG, Physiotherapy exercises and back pain: A blinded review. Br Med J 302:1572–1576, 1991
19. Koes BW, Assendelft WJJ, Heijden van der GJMG, Bouter LM, Knipschild PG: Spinal manipulation and mobilization for back and neck pain: A blinded review. Br Med J (In press)
20. Koes BW, Bouter LM, Knipschild PG, et al: The effectiveness of manual therapy, physiotherapy and continued treatment by the general practitioner for chronic non-specific back and neck complaints. J Manipulative Physiol Ther (In press)
21. Nachemson A: Towards a better understanding of low back pain. Rheum Rehabil 14:129–143, 1975
22. Nachemson A: The lumbar spine: An orthopaedic challenge. Spine 1:59–71, 1976
23. Nachemson A: A critical look at the treatment for low back pain. Scand J Rehabil Med 11:143–147, 1979
24. Spitzer WO, Leblanc FE, Dupuis M: Scientific approach to the assessment and management of activity-related spinal disorders. Spine (Suppl 1)7:1–59, 1987
25. Waddell G: A new clinical model for the treatment of low-back pain. Spine 12:632–644, 1987
26. White AA, Gordon SL: Synopsis: workshop on idiopathic low-back pain. Spine 7:141–1499, 1982

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