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Third Prize

A Blinded Randomized Clinical Trial of Manual Therapy and Physiotherapy for Chronic Back and Neck Complaints: Physical Outcome Measures

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ABSTRACT

In a blinded randomized clinical trial, we compared the effectiveness of manual therapy, physiotherapy, (continued) treatment by the general practitioner (GP), and a placebo therapy (detuned ultrasound and detuned short wave diathermy) for patients (n = 256) with chronic nonspecific back and neck complaints. The physical outcome measures (spinal mobility and physical functioning) are presented for 3, 6 and 12 wk follow-up. Manual therapy showed a faster and larger improvement in physical functioning compared to the other three therapies. The changes in spinal mobility among the four study groups appear to be small and show no consistent pattern. (J Manipulative Physiol Ther 1992; 1:16–23)).

Key Indexing Terms: Clinical Trials, Randomized, Physical Therapy, Back, Neck, Pain.

INTRODUCTION

It has been estimated that some 80% of all people experience back problems during their active life (1, 2). Neck problems are less frequently reported, but also constitute a major health problem. In most cases, no underlying pathology can be established and the causes of the complaints remain unknown (1, 3). The majority of patients with acute back pain recover within a few weeks, often with the help of bed rest, analgesics and advice about posture and exercises (4). Within a few months, the complaints disappear in about 90% of the cases (5, 7). There is, however, a relatively high recurrences rate.

We know of about 35 randomized clinical trials investigating the efficacy of manipulation and mobilization for back and neck complaints (8). Unfortunately, the results of these studies are inconsistent and interpretation is often difficult due to methodological flaws. In most of these studies only a small number of patients were included and measurement involved subjective judgments while not blinded. In this article, we present the results of a randomized clinical trial in which we tried to avoid these flaws and in which we compare manual therapy, physiotherapy, treatment by the general practitioner and a placebo treatment for patients with chronic back and neck complaints. We focus on two physical outcome measures which are assessed by a blinded research assistant: physical functioning and spinal mobility. Physical functioning is operationally defined as the ability of patients to perform active lumbar, thoracic and cervical movements. This was chosen as a relatively objective outcome measure (9, 10). Spinal mobility is generally considered to be an objective outcome measure for evaluating progress in patients with back pain (10–12), and was, therefore, measured in our study as well. Elsewhere, the results on severity of the complaints, global perceived effect, pain and functional status are reported (13).

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METHODS

Selection of the Patients

Patients were selected by general practitioner (GPs) during a 2-yr period (January 1988 to December 1989). Due to an initially low admission rate, we expanded the recruitment activities by repeated advertisements in the local press. Potential subjects were seen by one research assistant, who was an experienced physiotherapist and manual therapist. The research assistant performed a physical examination and did the final check with respect to the admission criteria. Criteria for inclusion were pain or self-reported limited range of motion in the back or neck for at least 6 wk. Criteria for exclusion were suspicion of underlying pathology (e.g., malignity, osteoporosis, herniated disc), treatment with physiotherapy or manual therapy for back or neck complaints received during the previous 2 yr, pregnancy, language problem or inability to reproduce the complaints by active or passive movements during physical examination. Eligible patients completed the informed consent by signing a letter. Subsequently, randomization was carried out by a second research assistant using a list of random numbers.

Treatments

The following four treatments were included: a) physiotherapy such as exercises, massage and physical therapy modalities (heat, electrotherapy, ultrasound, shortwave diathermy); b) manual therapy, which consisted of manipulative techniques (manipulation and mobilization of the spine) according to the directives of the Dutch Society for Manual Therapy); c) continued treatment by the general practitioner (n = 40), which consisted of prescription of medication (analgesics, nonsteroidal anti-inflammatory drugs), advice about posture, home exercises, participation in sports, (bed)rest, etc.; d) placebo treatment, which consisted of a physical examination and subsequently detuned shortwave diathermy (10 min) and detuned ultrasound (10 min) carried out by the participating physiotherapists. The sessions of the placebo treatment were scheduled at 2 times a wk for a period of 6 wk. Both the manual therapists (n = 7) and the physiotherapists (n = 8) participating in the study were selected by their professional organizations (the Dutch Society for Manual Therapy and the Royal Dutch Society for Physiotherapy).

All therapists (except for the placebo treatment) were free to choose from their usual therapeutic domain within some explicitly formulated limits (e.g., no manipulative techniques could be performed by the physiotherapists). All treatments were given for a maximum duration of 3 months. After 6 wk, the patients had the opportunity to discuss the results of the treatment with their GP and to decide whether to continue, change or stop the treatment.

Follow-up, Outcome Measures and Blinding

Follow-up measurements were carried out at 3, 6 and 12 wk after randomization. Primary outcome measures were the severity of the complaint, global perceived effect, pain and functional status (13, 14). In the research protocol, physical functioning and spinal mobility were chosen to be the most important secondary outcome measures (14). Both were measured by the research assistant who was unaware (blind) of the treatment assignment of the patients at the time of all follow-up measurements. Physical functioning was defined as the ability of patients to perform active spinal movements. Patients with neck complaints performed a standardized set of cervical movements (flexion, extension, lateral flexion, and rotation). Patients with back complaints performed a similar set of trunk movements. This included forward flexion, extension, lateral flexion and rotation of the trunk with the patient in sitting and standing positions. These movements were followed by trunk forward flexion while the patient was standing on one leg (right and left leg alternately) and the other leg is bent in the hip and knee joint toward the trunk (patient is supported by the research assistant). After these movements, patients were asked to stand on one leg (right and left leg alternately). Finally, in a sitting position, they had to put one leg over the other (right and left leg alternately).

At baseline, the research assistant noted, for each patient, the movements (maximally three) for which the patient reported the most severe pain or a limitation of the range of motion (ROM). In addition, the research assistant scored the severity of the pain (or of the limitation of the ROM) for these movements on a 10-point scale (1 = minimal severity, 10 = maximal severity). During the follow-up measurements, the movements chosen at baseline were reassessed by the research assistant, who again scored the severity of the pain or the limitation of the ROM. The research assistant had no information about previous severity scores. The physical functioning score was calculated by counting the severity scores of all (maximally three) the movements at issue divided by the number of movements.

Spinal mobility was measured by the research assistant with the use of an inclinometer (Cybex EDI 320).

The reproducibility of spinal measurements with the EDI 320 appeared to be satisfactory in a previous study (15). Table 1 presents the three spinal movements we assessed. At baseline and the three follow-up measurements, the patients performed these movements two times consecutively. The mean of these two measurements was taken as the ROM at the moment at issue. Cervical movements were performed by all patients with neck complaints. Forward spinal flexion was performed by all patients with back pain.

Statistical Analysis

For both outcome measures, we calculated the differences between the follow-up scores and the baseline score for the individual patients. The four study groups were compared for their mean improvement in physical functioning and spinal mobility at 3, 6 and 12 wk after randomization. Furthermore, cumulative distributions of the improvement scores for physical functioning were calculated. Group differences and 90% confidence intervals were calculated for 6 wk follow-up using a linear regression model. In this model we entered the following prognostic indicators: localization and duration of the main complaint, the baseline physical functioning score, age and recruitment status (GP or advertisement). We first present a 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 this, we present an alternative analysis with the purpose of adjusting for missing values and patients who changed from the assigned therapy. In this analysis we substitute 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 substitute the last measurement for patients with missing values with the score of the last measurement available. The analyses were carried out with BMDP version 1988 (16).

TABLE 1. Movements between extremes of the path of motion* and position of the inclinometer

Movement	Position Inclinometer	Position Patient
1 Cervical forward flexion	Os Nasale	Sitting
2 Cervical lateral flexion	Os Temporale Processus Zygomaticus	Sitting
3 Spinal forward flexion	T1	Standing

* Movement 3: from anatomical to extreme position.

RESULTS

Study Sample and Prognostic Comparability

A total of 256 patients were included and randomly assigned to the study treatments. 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.

After 12 wk follow-up, 23 patients (9%) had dropped out. Table 3 shows the cumulative drop-out rate for

TABLE 2. Baseline characteristics of the study population

Characteristic	Manual Therapy	Physiotherapy	Placebo Therapy	General Practice	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 physical functioning score (10-point scale)	5.9	5.8	5.7	5.7	5.8
Range of motion (degrees)					
Cervical anteflexion	113	112	117	116	115
Cervical lateroflexion	60	61	64	62	62
Spinal forward flexion (T1)	133	126	129	127	129

TABLE 3. Cumulative number of drop-outs (and total number of missing values of measurement by blinded research assistant) at follow-up after 3, 6 and 12 wk

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

each group at the 3, 6 and 12 wk follow-up. The reasons given for dropping out were inconvenience and lack of time (n = 10), problems with filling in questionnaires (n = 3), complaints having disappeared (n = 2; one in physiotherapy group, one in GP group), no benefit of treatment (n = 2; in GP group), pregnancy (n = 1) and personal reasons or no reason given (n = 5). In addition, a number of people did not show up for the physical measurements by the research assistant (mainly because of lack of time).

Blinding and Compliance with Treatment

Patients could not be blinded for referral to a physiotherapist, a manual therapist or a 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" (the phrase used in the informed consent document). At 6 wk, half of the patients (n = 32) in the GP group answered affirmatively, against 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.

Table 4 shows the number of treatments, session time and duration of treatment for the four study groups. The manual therapy group received considerably fewer treatments (mean number of treatments is 5.4) than the physiotherapy group (mean number of treatments is 14.7). Most patients in the GP group paid only a single visit to their GP.

Besides drop-outs (Table 3) and patients who changed from the assigned therapy (switch-overs) (Table 5), all patients in the physiotherapy group, manual therapy group and placebo group received the assigned therapy, while four patients in the GP group did not visit the GP. According to the study protocol (for ethical reasons), patients could change therapy at 6 wk after randomization. Table 5 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. Between the 6 and 12 wk follow-up, a considerable number of patients in the placebo and GP groups changed from the assigned therapy.

Outcome

Table 6 lists the results of the outcome measures. All four groups showed an increasing mean improvement of physical functioning (rated by the blinded research assistant) at the three follow-up measurements. The improvement for the manual therapy group was larger than for the other groups at all follow-up measurements. Physiotherapy, placebo therapy and treatment by the GP showed similar results at the 3 and 12 wk follow-ups. At 6 wk the physiotherapy scores were slightly better than the placebo therapy and the treatment by the GP.

The mean changes in spinal mobility appear to be small and show no consistent pattern. The maximal mean increase in ROM was 9° (cervical flexion in the

TABLE 4. Mean number of treatments, session time and duration until 12 wk follow-up. The medians are given in parentheses

	Number of treatments	Session time	Duration
		min	*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 GP consisted usually of a single visit by the patient at the general practice.

TABLE 5. Cumulative number of deviations from the allocated therapy at follow-up.

Treatment	3	6	12
		wk	
Manual therapy	1 inj	1 inj	1 inj 2 physio 1 spec
Physiotherapy			1 man th
Placebo therapy	7 physio	9 physio	15 physio 2 man th 2 spec
GP	3 physio 1 man th	4 physio 1 man th 1 sportm	7 physio 4 man th 2 cesar/mensendieck
		2 spec	1 HNP operation 1 hospitalisation 1 spec 2 alt med 1 sportm

inj, injection by GP; physio, physiotherapy; man th, manual therapy; spec, referral to specialist; alt med, treatment with alternative medicine; sportm, sport massage.

TABLE 6. Improvement on physical functioning and change in range of motion at 3, 6, and 12 wk follow-up in the intention-to-treat analysis

Outcome measure	3	6	12
		wk	
Mean (SD) improvement on physical functioning (10-point scale)			
Manual therapy (n = 53)*	2.3 (2.1)	3.5 (1.9)	4.0 (2.3)
Physiotherapy (n = 54)	1.6 (1.9)	3.1 (1.8)	3.2 (2.0)
Placebo therapy (n = 51)	1.6 (2.2)	2.6 (2.3)	3.4 (2.3)
General Practitioner (n = 44)	1.7 (2.1)	2.4 (2.6)	3.4 (2.2)
Cervical flexion: patients with neck complaints			
Mean (SD) change of range of motion: cervical forward flexion (degrees)			
Manual therapy (n = 23)	−2 (16)	3 (14)	4 (16)
Physiotherapy (n = 22)	0 (16)	2 (18)	4 (15)
Placebo therapy (n = 18)	5 (20)	5 (13)	9 (15)
General practitioner (n = 21)	−7 (20)	−11 (23)	−7 (21)
Mean (SD) change of range of motion: cervical lateroflexion (degrees)			
Manual therapy (n = 23)	2 (9)	2 (10)	1 (11)
Physiotherapy (n = 22)	1 (10)	0 (9)	3 (10)
Placebo therapy (n = 18)	−3 (8)	−1 (8)	2 (8)
General practitioner (n = 21)	−2 (7)	−3 (9)	−3 (10)
Spinal flexion: patients with back complaints			
Mean (SD) change of range of motion: spinal flexion at T1 (degrees)			
Manual therapy (n = 36)	0 (10)	−2 (12)	−2 (15)
Physiotherapy (n = 31)	−1 (12)	4 (13)	6 (13)
Placebo therapy (n = 39)	−4 (11)	−3 (9)	0 (10)
General practitioner (n = 30)	3 (10)	0 (14)	0 (18)

* Number of patients after 6 wk follow-up. After 3 and 12 wk the numbers may vary slightly because of missing values.

placebo group), and the maximal decrease in ROM was 11° (cervical flexion in the GP group). In most cases, however, the mean changes in ROM varied between 0° and 5°. The standard deviations indicate the large variation for this outcome measure between the patients in each group. Cervical extension and lateral flexion to the right, and spinal flexion measured at L1 are not presented because these results were almost identical to the ones presented.

Figure 1 is a graphic presentation of the cumulative distribution of the improvement scores of physical functioning of the four study groups at 6 wk follow-up. On the abscissa the reader can choose the preferred cutoff point of the improvement score, and read the proportion of patients of the four study treatments with at least that score on the ordinate. For example, respectively, 36% in the GP group, 43% in the placebo group, 54% in the physiotherapy group and 62% in the manual therapy group had an improvement score of three points or more. In general, curves which lay more in the direction of the right upper corner of this figure indicate a more favorable outcome. In all four study groups, most patients improved between zero and six points. Only a small percentage in each study group showed an improvement of six points or more. The manual therapy group showed the best outcome for patients with improvement scores of less than six points, whereas the GP group showed the lowest improvement. The cumulative distributions of physiotherapy and placebo therapy were in between.

Table 7 shows the magnitude of the group differences and the 90% confidence intervals at 6 wk follow-up. When the value "zero" is not included in the confidence interval, the group difference is statistically significant at 5% level (one-sided test). Only the difference between manual therapy and treatment by the GP was statistically significant. Group differences were also calculated at 3 and 12 wk. At 3 wk, all differences between manual therapy and the other three groups were statistically significant. The difference with physiotherapy was 0.8 (0.2, 1.4), and with placebo therapy and treatment by the GP both 0.7 (0.1, 1.3). All other contrasts were not statistically significant. At 12 wk there appeared to be no statistically significant differences between the four groups.

Alternative Analysis

In this study, the results in the placebo group and GP group (especially beyond 6 wk) of the intention-to-treat analysis may be biased due to drop-outs, missing values and contamination. Therefore, we also present an analysis in which we assume that patients who

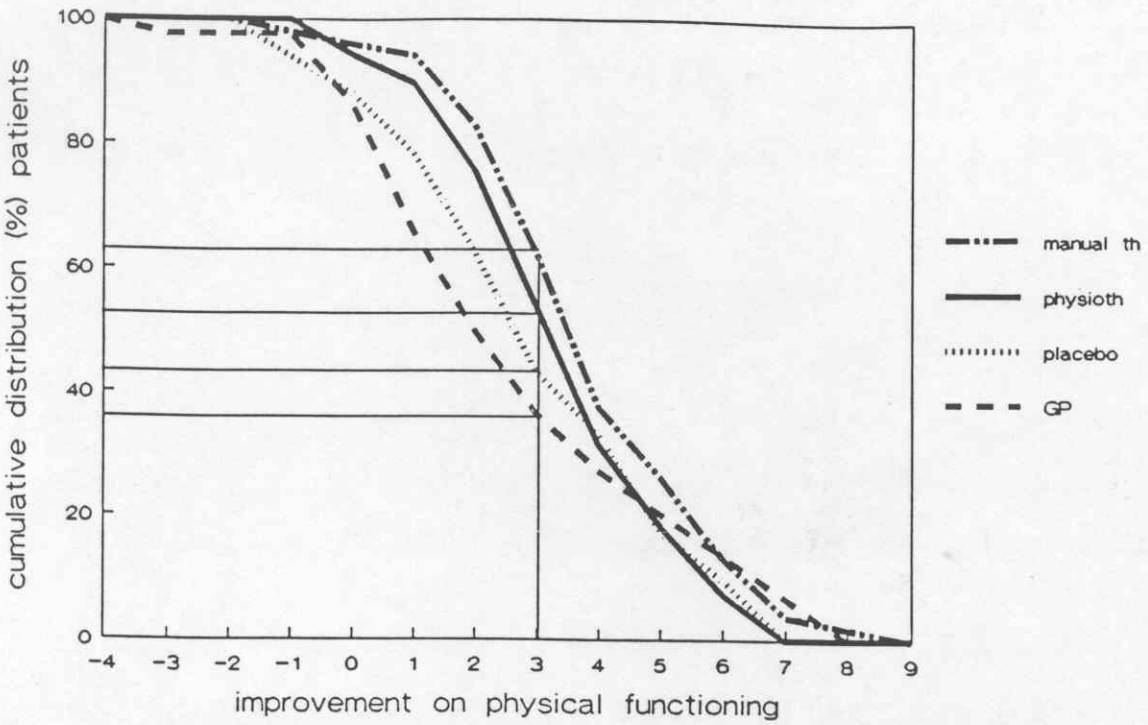

Figure 1. Improvement on physical functioning at 6 wk follow-up (intention-to-treat analysis).

TABLE 7. Group differences (90% confidence limits) for mean improvement of physical functioning at 6 wk: intention-to-treat and alternative analysis

	Physiotherapy	Placebo therapy	GP
Intention-to-treat analysis			
Manual therapy	0.5 (−0.1, 1.1)	0.6 (−0.1, 1.2)	1.3 (0.7, 1.9)
Physiotherapy		0.3 (−0.4, 0.9)	0.6 (−0.1, 1.3)
Placebo therapy			0.7 (−0.1, 1.4)
Alternative analysis			
Manual therapy	0.5 (0.0, 1.1)	1.2 (0.6, 1.9)	1.3 (0.7, 1.9)
Physiotherapy		0.8 (0.2, 1.4)	0.7 (0.1, 1.3)
Placebo therapy			0.1 (−0.6, 0.8)

dropped out, had a missing value or changed therapy did not improve since the last follow-up measurement available. The main underlying assumption for this analysis is that patients probably stop or change therapy because they do not (expect to) benefit (anymore) from the assigned therapy. The results of this alternative analysis is presented in Table 8.

The underlying assumptions for the alternative analysis appeared to affect the placebo group and GP group the most. Manual therapy continued to show the best results at all follow-up measurements. The differences between manual therapy and physiotherapy, on the one hand, and placebo therapy and treatment by the GP, on the other hand, turned out to be larger than the intention-to-treat analysis at 6 and 12 wk. This pattern is also clearly visible in the graphic presentation (Figure 2). The differences between manual therapy and physiotherapy, on the one hand, and the placebo therapy, on the other hand, were statistically significant at 6 wk (Table 7). At 12 wk, these differences could still be demonstrated.

TABLE 8. Improvement on physical functioning at 3, 6 and 12 wk follow-up in the alternative analysis

Outcome measure	3	6	12
		wk	
Mean (SD) improvement on physical functioning (10-point scale)			
Manual therapy	2.1 (2.1)	3.1 (2.1)	3.6 (2.4)
Physiotherapy	1.3 (1.8)	2.7 (2.0)	2.9 (2.2)
Placebo therapy	1.0 (1.9)	1.7 (2.3)	2.1 (2.4)
General practitioner	1.3 (2.0)	1.8 (2.4)	2.3 (2.5)

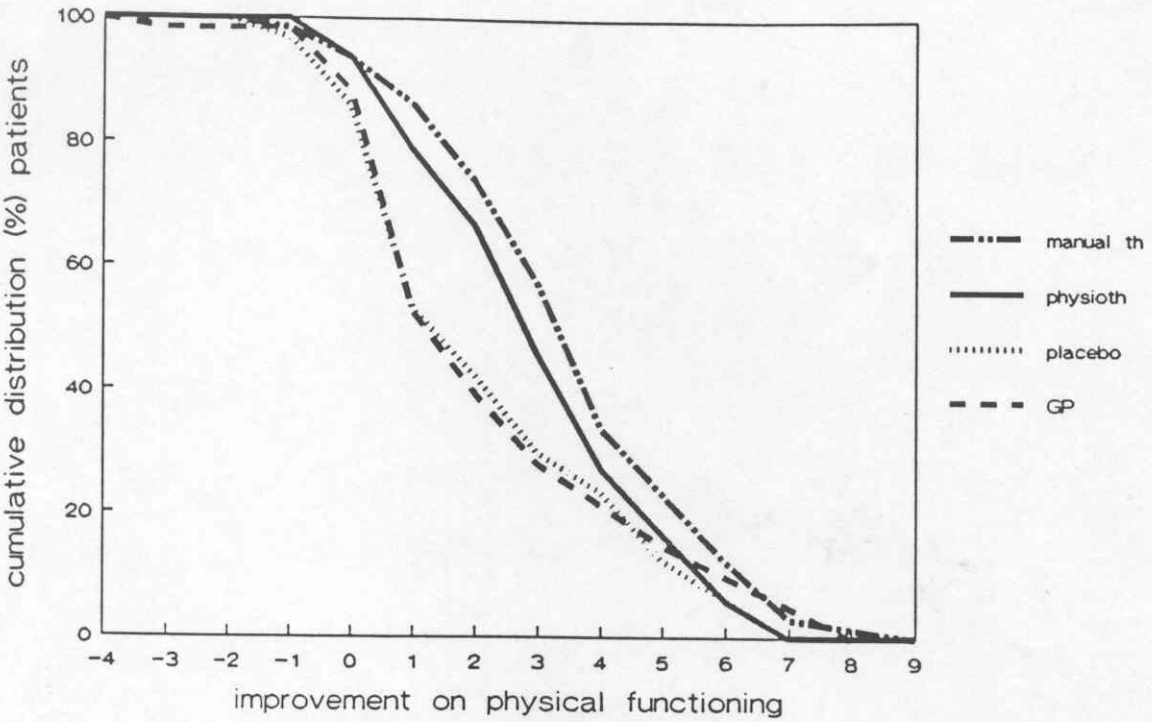

Figure 2. Improvement on physical functioning at 6 wk follow-up (alternative analysis).

DISCUSSION

Manual therapy showed a faster and larger improvement in physical functioning, as measured by the blinded research assistant, than the other three therapies. At 3 wk, the difference between manual therapy and the other three therapies was statistically significant, whereas at 6 wk this was the case only for the contrast between manual therapy and treatment by the GP. At 12 wk, there appeared to be no statistically significant differences in the intention-to-treat analysis. Although the patients in all four study groups showed a mean improvement in physical functioning, this patient was not found for the change in mean spinal mobility measured with the Cybex EDI 320. Considering the total range of motion of the movements measured at baseline, the mean changes at follow-up were all relatively small in the four study groups. These findings indicate that the improvement in physical functioning occurred relatively independently of changes in range of motion of the spinal movements. Generally, spinal range of motion is considered to be an objective and relatively reproducible measure (17, 18). However, it might not be very suitable for measuring progress of patients with chronic back and neck complaints (19, 20).

The outcome of physical functioning supports to a large extent the findings of the primary outcome parameters of this clinical trial (improvement on the main complaint and global perceived effect), which indicated a favorable outcome for both manual therapy and physiotherapy compared to treatment by the GP or the placebo treatment (13). The main difference is that, especially after 3 wk follow-up, manual therapy appeared to improve physical functioning more than physiotherapy.

An intention-to-treat comparison is most valid when the drop-out rate (and number of missing values) is low and there is no contamination. In this study, however, the results, especially at 12 wk follow-up, might be biased substantially due to switch-overs. Particularly in the placebo group and GP group, a considerable number of patients changed from the assigned therapy to (mainly) physiotherapy and manual therapy. Furthermore, the number of drop-outs and missing values were the highest in the placebo group and the GP group. We dealt with these problems 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 a deterioration. Readers can choose the analysis they prefer for drawing conclusions. We believe that the intention-to-treat analysis overestimates the efficacy of the placebo therapy and treatment by the GP, especially at 12 wk follow-up. On the other hand, the alternative analysis might lead to some underestimation of the effect of the placebo therapy and treatment by the GP.

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