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A RANDOMIZED CLINICAL TRIAL COMPARING GENERAL EXERCISE, McKENZIE TREATMENT AND A CONTROL GROUP IN PATIENTS WITH NECK PAIN

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Seventy-seven patients with neck pain in the primary health care were included in a prospective, randomized clinical trial and randomly assigned to general exercise, McKenzie treatment, or a control group. Seventy patients completed the treatment; response rate 93% at 12-month follow-up. All three groups showed significant improvement regarding the main outcomes, pain intensity and Neck Disability Index, even at 12-month follow-up, but there was no significant difference between the groups. In all, 79% reported that they were better or completely restored after treatment, although 51% reported constant/daily pain. In the McKenzie group compared with the control group, a tendency toward greater improvement was noted for pain intensity at 3 weeks and at 6-month follow-up, and for post-treatment Neck Disability Index. Significant improvement in Distress and Risk Assessment Method scores was shown in the McKenzie group only. The three groups had similar recurrence rates, although after 12 months the McKenzie group showed a tendency toward fewer visits for additional health care. The study did not provide a definite evidence of treatment efficacy in patients with neck pain, however, there was a tendency toward a better outcome with the two active alternatives compared with the control group.

Key words: randomized clinical trial, neck pain, physiotherapy, McKenzie treatment, active exercise, primary health care, impairment, disability.

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INTRODUCTION

There is little evidence that physiotherapeutic interventions is effective for patients with neck pain (1–3), mainly because such have not been studied in enough detail. Reviews of randomized clinical trials focused on patients with neck pain (1–3) have shown positive effects of active physiotherapy, electromagnetic therapy, manipulation, and mobilization. However, the information presented in those reviews was based on a very small number of investigations for each treatment modality, thus it is difficult to utilize the results in a clinical setting. Moreover, the results were almost solely concerned with impairment outcomes, and the effects of the different treatments on disability outcomes have not been elucidated (2). Further randomized trials are clearly warranted.

General exercise is a common form of physiotherapy treatment in primary care for patients with musculoskeletal disorders, such as neck discomfort, and is accepted as one standard form of practice among others. Moreover, randomized trials have shown that active exercise has a positive effect on neck pain (4–6). However, several review studies (1–3) have shown that most studies of this type have been of poor quality, and they have often combined general exercises with other treatment modalities, hence it is difficult to draw any conclusions about the impact of general treatment on neck pain in particular.

The McKenzie method (7) was introduced in Sweden in 1985 and came to be frequently used in the 1990s as a treatment modality for patients with mechanical problems of the spine. Today, physiotherapists in primary care often employ this procedure as both a diagnostic tool and a treatment model. The method has a highly trust among physiotherapists (8, 9), but there is little scientific evidence that McKenzie treatment is effective for patients with neck pain. To our knowledge, randomised clinical trials involving patients with neck pain and comparing the McKenzie method with other treatment modalities have not been reported in the literature, with the exception of one study on patients with whiplash-associated disorders (10). In the indicated investigation, active mobilization consistent with the McKenzie principles was compared with a standard protocol that included information along with advice and instructions. The results show that active mobilization reduced pain more than standard treatment. We can conclude that there is an obvious need for studies evaluating commonly used treatment strategies for patients with neck pain.

Our aim was to do a comparison between general exercise, McKenzie treatment and a control group for patients with neck pain. We considered both short-term and 1-year outcome.

MATERIAL AND METHODS

Design

A prospective, randomized clinical trial was conducted with the

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alternatives general exercise, McKenzie treatment, and a control group. The main criterion for eligibility was that a physiotherapist could provoke the neck pain for which the patient was seeking care. The study was approved by the Ethics Committee of the Faculty of Health Sciences, Linköpings University.

The study sample was recruited from three different physiotherapy units in primary health care and from a private physical therapy practice in the county of Östergötland, Sweden, from March 1996 to December 1998.

All patients with neck pain visiting the physiotherapy units were given information regarding the study and its goal, and they were told that participation was voluntary and that they could withdraw at any time. The information we provided the patients related that there is limited evidence of the efficacy of different kinds of treatment for neck pain, and that our aim was to evaluate three different treatment methods, one of which is considered, but has not been proven, to be less effective than the other two.

To determine what proportion of all patients with neck complaints were actually included in our study, we recorded all patients aged 18–65 years presenting with neck complaints at the physiotherapy units. After testing the inclusions and exclusions criteria, the included patients were randomized into one of the three treatment groups by drawing sealed envelopes out of a box.

The inclusion criteria were neck pain with or without radiation that could be provoked by a physiotherapist, and an age of 18–65 years. Each patient was subjected to four manual pain-provoking tests, and, if at least one of the four was positive, the subject was included in the study. The tests were chosen because they are considered to provoke different anatomical pain-sensitive structures in the neck. The following four tests were used: (a) a single movement of active flexion of the neck or extension with retraction of the neck; (b) sustained flexion, extension with retraction, or rotation of the neck for a maximum of 2 minutes; (c) test for the foramina intervertebralia; (d) the upper limb tension test. It has been suggested that the latter two tests provide high sensitivity and specificity (11).

Two hundred and forty patients with neck complaints were visiting the physiotherapy units during the study period (Fig. 1). Sixty-two of those patients declined to participate, mainly due to lack of time ($n = 49$). Other explanations for non-participation were: request of a specific treatment modality, primarily an intervention with previously positive result; financial reasons. The majority of the patients declined before the randomization procedure; only four refused to participate after randomization, due to lack of time ($n = 1$) or vacation ($n = 1$), or because they could not accept the treatment given in the group to which they were randomized ($n = 2$).

Outcome measurements

We used both subjective and objective measurements, although the results of the latter are not in focus in this article. For the subjective measurements, a questionnaire was administered on four occasions: before beginning treatment, directly after the treatment period, and subsequently 6 and 12 months after the date treatment was started. The questionnaire included items on background data and different aspects of pain, function, general health, and psychosomatic and depressive signs. In addition, pain intensity and frequency were registered each week during the treatment period.

Background data covered age, sex, life-style factors such as smoking and exercise habits, job satisfaction, similar problems and experience of treatment during the previous 5 years, duration of current episode, and duration of sick leave (12).

Pain intensity was recorded using a visual analogue scale (VAS, in millimetres) (13) with the end points 0 (no pain) and 100 (unbearable pain); pain frequency on a 5-point scale; and use of painkillers on a 4-point scale (12). Measures of function were sick leave and the Neck Disability Index (NDI) (14). NDI is a modification of the original Oswestry Low Back Pain Disability Questionnaire (15), and it consists of a 10-item condition-specific self-report measure. The items pertain to pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation, with the aim of illustrating the impact on the activities of daily living and social life. Each item is rated on a 6-point scale (0–5), thus NDI scores can vary from 0 to 50. The results are recalculated and are expressed on a scale ranging from 0% (no pain or difficulties) to 100% (maximum pain or difficulty for all items) (15). Inasmuch as some Swedes do not have a driver's licence or own a car, we modified the item "driving" to include the alternative "no car or driver's license", which was chosen by 12 patients. According to Stratford (16), a change of 5 points in the test results is considered as a clinically important change.

General health was measured using a 6-point scale and on a VAS (in millimetres) with the end points 0 (best imaginable) and 100 (worst imaginable) (12).

We used the Modified Somatic Perception Questionnaire (MSPQ) (17) and the Modified Zung Depression Index (modified Zung) (18) to measure psychosomatic and depressive symptoms. The two instruments were combined according to the Distress and Risk Assessment Method (DRAM) (19), resulting in four different categories: normal, at risk, distressed-depressive, and distressed-somatic.

Before treatment was initiated, the patients registered their expectations of treatment on a 4-point scale; after treatment, they reported on fulfilment of their expectations (12). Also after treatment, subjective assessment of treatment efficacy was done using a 7-point scale (ranging from completely restored to much worse), and satisfaction with care was rated on a 4-point scale (very good to very bad). Moreover, the patients were asked if they thought they had been treated with an effective or a less effective method. Recurrence of the same problem (never, once, several times, always) was measured at each follow-up, and health care consumption was determined at 6- and 12-month follow-up. The questionnaire administered after treatment included the following open question: "What would you do if your problem were to recur?" In addition, the physiotherapists recorded the number of treatment sessions for each patient and rated treatment efficacy on a 7-point scale (completely restored to much worse).

Treatments

The general exercises were aimed at the neck and shoulders and were intended to increase cervical movement, and the endurance and strength of the cervical muscles through active movements. The therapists could choose patient-specific exercises from a predetermined set of exercises compiled through a consensus among the physiotherapists. The number of repetitions and amount of resistance were started on a pain-free level and were increased throughout the treatment period. The patients had two treatment sessions a week for 8 weeks (4). In addition, they followed a standard home-exercise protocol. (The exercise program, in Swedish, may be ordered from the authors.)

The McKenzie method, or mechanical diagnosis and therapy, is a system to classify/diagnose and to treat based on mechanical and symptomatic reactions on loading (repeated specific movements) (7). The physiotherapist follows the McKenzie protocol but chooses the type of exercises, the number of treatment sessions and home exercises to suit the individual patients. The purpose of the McKenzie method is to reduce pain and increase functional ability, and to give patients knowledge of self-treatment in case of recurrence. In our study, the treatment period was limited to 8 weeks.

The control group received ultrasound administered at the lowest intensity possible and with the indicator lights on. The ultrasound was applied bilaterally to the superior portion of m. trapezius (7 minutes on each side). The physiotherapists were allowed to provide common information about neck problems comparable to what is usually available to the general public, but no patient-specific instructions were given. A limited program including arm motions was given as home-exercises.

Five physiotherapists were involved in the study. They had a median of 23 years of experience, mainly in primary health care. They were all using the studied treatment modalities in their daily work. The exercises in the general exercise group are fundamental knowledge among physiotherapist and, furthermore, all had completed at least part C course of the McKenzie education program.

Study sample

Ninety-five patients were excluded before randomization on the basis of the following exclusion criteria: had received physiotherapeutic or chiropractic treatment during the past 3 months ($n = 29$); showed evidence of an affected nerve root, seen as signs associated with sensibility, muscle strength, and reflexes ($n = 16$); exhibited whiplash

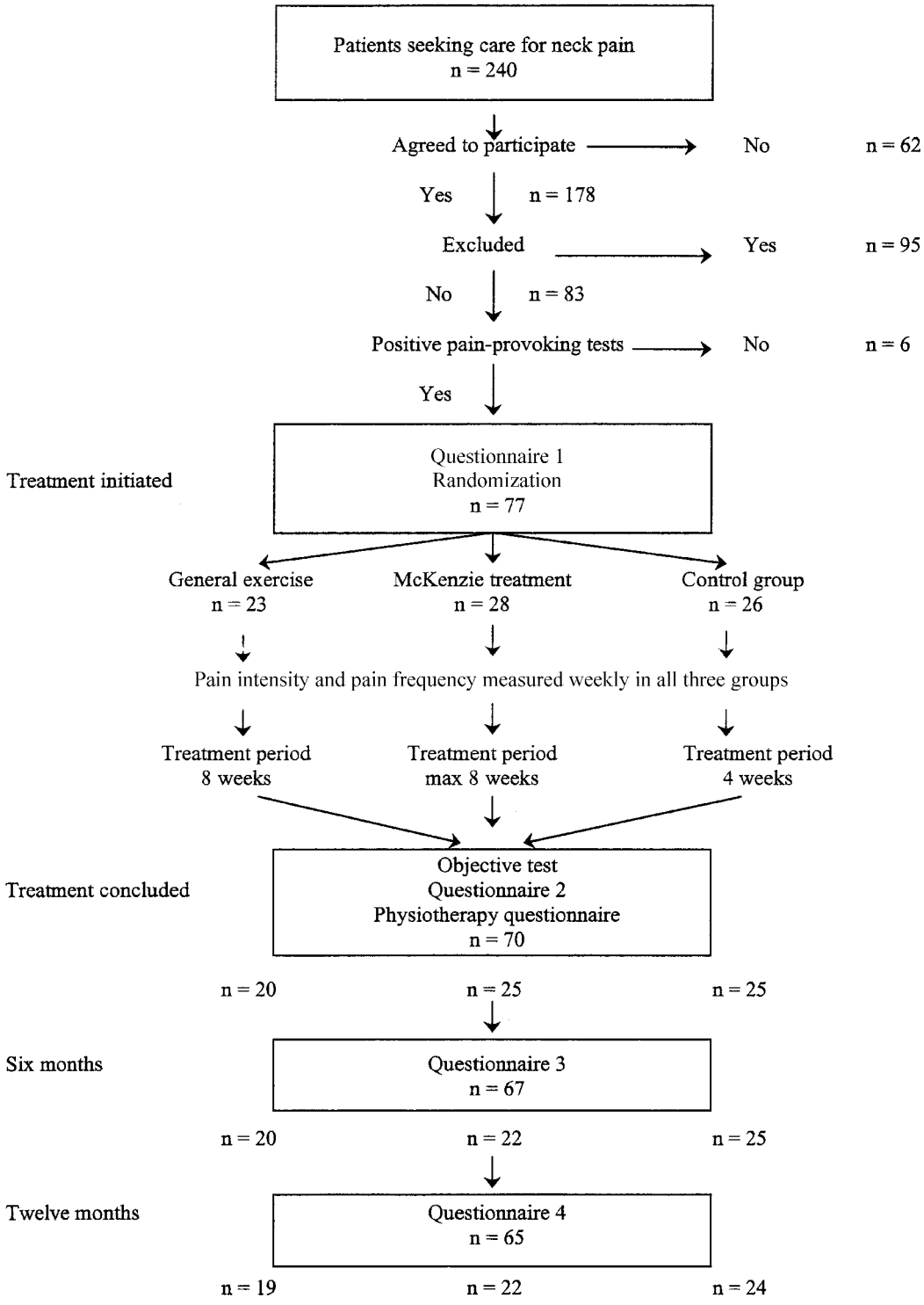

Fig. 1. Flowchart of the randomized study.

symptoms after trauma within the past 6 months, and the symptoms were associated with consistent neck pain or ongoing insurance litigation ($n = 7$); suffered from other diseases ($n = 19$); had been involved in an accident less than 10 days previously ($n = 19$); unable to understand Swedish ($n = 5$). Six patients were excluded because they were negative in the pain-provoking test.

Accordingly, a total of 77 patients were included in the study and randomly assigned to the general exercise group ($n = 23$), the McKenzie group ($n = 28$), and the control group ($n = 26$). Drop out during the treatment period was equally distributed between the three groups and occurred as follows: in the general exercise group, due to symptoms of affected nerve root at the second visit ($n = 1$) and active withdrawal ($n = 2$); in the McKenzie group, due to active ($n = 2$) and unmotivated ($n = 1$) withdrawal; in the control group, due to frequent cancellations

Table I. *Background data and characteristics of neck-pain (NP) patients according to treatment groups. Values represent numbers of patients (%) unless otherwise stated*

	General exercise ($n = 20$)	McKenzie treatment ($n = 25$)	Control group ($n = 25$)
Mean (SD) age in years	46.8 (8.5)	45.4 (11.3)	42.6 (12.1)
Gender: women	16 (80)	18 (72)	19 (76)
Smokers (yes)	6 (32)	7 (28)	2 (8)
Exercise regularly: ≥once a week	15 (75)	16 (64)	21 (84)
Work full-time	10 (50)	13 (52)	13 (52)
Satisfied with job	17 (89)	23 (96)	20 (83)
Mean years (SD) since first NP episode	10.1 (6.2)	6.6 (3.9)	8.3 (7.8)
Similar problems during previous 5 years	14 (70)	11 (44)	14 (56)
Treatment for previous problems	11	9	6
Expectation: be completely restored	14 (70)	18 (72)	16 (64)
Duration of current episode			
≤1 week	2 (10)	1 (4)	0 (0)
1–4 weeks	7 (35)	9 (36)	7 (28)
≥1 > 3 months	5 (25)	5 (20)	3 (12)
≥3 months	6 (30)	10 (40)	15 (60)
Duration of sick leave, $n = 22$			
≤1 week	4	2	0
1–4 weeks	4	6	3
≥1 month	1	1	1

($n = 1$). Consequently, a total of 70 patients (general exercise $n = 20$, McKenzie group $n = 25$, control group $n = 25$) were included in the analysis. Initially, there were no differences between the drop outs and the patients who completed the treatment period with respect to sick leave, pain intensity, pain frequency, duration of current episode, well being, similar problems during the previous five years, or earlier treatment due to the same problem. However, the drop outs had a higher NDI score ($p < 0.01$) mean (SD) 49% (14) and general health ($p < 0.01$) mean (SD) 52 mm (30). The response rate was 96% at 6-month and 93% at 12-month follow-up.

Background data and characteristics of the patients are presented in Table I, and the initial outcome variables in Tables II–IV. Initially, there were no significant differences in any of the variables between the three groups.

Analysis

Changes within groups were tested by Wilcoxon's sign rank test or paired sign test. To detect any differences inbetween the three groups, we used χ^2 tests (e.g. in regard to the proportions of patients on sick-leave and using pain killer), and Kruskall-Wallis. For analysis of the follow-up values for pain intensity, pain frequency, general health and NDI the mean change was analysed. The weekly assessments of pain intensity and frequency were analysed using repeated measures of ANOVA. In case of missing weekly assessment data on pain intensity and frequency, we assumed that the patient had not improved and used the latest assessment values. The Mann-Whitney *U*-test was used to detect differences, as mean change, in further two-group analyses. Spearman's rank correlation was used to analyse correlation.

RESULTS

Pain frequency, measured weekly, decreased during the first 4 weeks ($p < 0.001$), and there were no differences in improvement between the groups (Table III). The improvement reported after treatment remained at the 6- and 12-month follow-up for all groups, and there was even further improvement in pain frequency in the general exercise and the McKenzie groups at 6 months.

After treatment, each group showed significant improvement in the two main outcome variables, pain intensity and NDI score (Tables III, IV).

All groups improved significantly in pain intensity during the first 4 weeks ($p < 0.0001$) (Table III). The improvement was maintained at the assessments after treatment and at 6- and 12-month follow-up, with no further improvement. Three-group analysis revealed no significant differences between the groups on any assessment occasion. Further analysis by two-group comparison indicated significantly greater improvement in the McKenzie group than in the control group at 3-week and 6-month follow-up ($p < 0.05$). No other significant differences were recorded.

All three groups improved significantly in NDI during the treatment period ($p < 0.01$–0.001) (Table IV), but showed no further significant improvements during the period between, after treatment and 6- or 12-month follow-up. Three-group analysis revealed no differences for any of the follow-up periods. In additional two-group analysis, the only difference detected was greater post-treatment improvement in the McKenzie group than in the control group ($p < 0.05$), and this difference tended to be maintained at 6 months ($p = 0.08$). No differences were found between the groups at 12-month follow-up. A change of 5 points (=10%) or more from before to after treatment was noted for 60–63% of the general exercise and the McKenzie group compared with 37% of the control group.

Considering the other outcome variables, significant improvements were noted within groups during the period before and after treatment in regard to use of pain killers ($p < 0.01$–0.05) except for the control group, sick leave due to neck pain ($p < 0.01$–0.05) except for the general exercise group (Table II). Significant improvement in general health ($p < 0.01$) and in DRAM ($p < 0.05$) was observed for the McKenzie group only. The initial value for well-being was high in all groups, with no

Table II. *Data on outcome variables before and after treatment according to treatment groups of neck-pain (NP) patients. Values represent numbers of patients (%) unless otherwise stated*

	Before treatment			After treatment		
	General exercise	McKenzie treatment	Control group	General exercise	McKenzie treatment	Control group
Pain						
Use of pain killers						
(several times a day—daily)	6 (30)	6 (24)	8 (32)	1 (5)	2 (8)	2 (8)
Pain localization						
Neck	6 (30)	11 (44)	11 (44)	6 (32)	13 (52)	12 (50)
Shoulder and/or arm	0	3 (12)	2 (8)	2 (11)	3 (12)	0
Neck and arm	14 (70)	11 (44)	12 (48)	11 (58)	9 (36)	12 (50)
Sick leave						
Sick leave due to NP	9 (45)	9 (36)	4 (16)	4 (20)	4 (16)	3 (12)
Sick leave due to other reasons	1 (5)	3 (12)	4 (16)	0	2 (8)	6 (25)
Health						
Well being: very well-rather well	19 (95)	25 (100)	22 (88)	16 (80)	24 (96)	21 (91)
General health, mm VAS, mean (SD)	32 (18)	33 (19)	30 (20)	23 (23)	23 (17)	21 (17)
Psychosomatic and depressive						
DRAM*						
Normal	10 (56)	14 (58)	10 (42)	13 (72)	17 (71)	10 (42)
At risk	6 (33)	7 (29)	11 (46)	5 (28)	6 (25)	13 (54)
Distressed, depressive	0	1 (4)	1 (4)	0	1 (4)	1 (4)
Distressed, somatic	2 (11)	2 (8)	2 (8)	0	0	0

* DRAM = Distress and Risk Assessment Method.
General exercise, $n = 20$, McKenzie treatment $n = 25$, control group $n = 25$, except for DRAM: general exercise $n = 18$; McKenzie $n = 24$; control $n = 24$.

significant change after treatment. No statistically significant differences in any of the outcome variables could be seen between the three groups directly after treatment or at 6- and 12-month follow-up.

There were no differences between the three groups concerning self-reported effect of treatment as well as the physiotherapists assessment of effect, and 79% of the study population reported that they were better or completely restored. The correlation between the patients and the physiotherapists assessment was $r = 0.73$. The majority of the patients were satisfied with the care, the alternatives good or very good were chosen by 90% of the study population (n.s.). Seven patients were not satisfied: two in the general exercise group, one in the McKenzie group, and four in the control group. Furthermore, 76% of the patients rated their expectations as totally or partly fulfilled (n.s.). There were no significant differences between the groups as to whether they thought that the treatment was effective or less effective, 77% of the study population considered their treatment effective.

Due to the study design, the number and length of the treatment sessions differed. The general exercise group had a mean (SD) of 13 (3) sessions and a mean treatment period of 55 (15) days; corresponding values are 7 (2) and 31 (20) for the McKenzie patients, and 8 (1) and 30 (5) for the control group.

Considering the open question about what to do in case of a recurrence, 30 patients indicated that they would contact a

Table III. *Pain intensity (VAS) mm mean (SD), and pain frequency (continuous—daily),* n. *(%) before the treatment, weekly during 3 weeks, directly after the treatment period, and at 6- and 12-month follow-up in the three patient groups*

	Before treatment	After 1 week	After 2 weeks	After 3 weeks	After treatment	6-month follow-up	12-month follow-up
Pain intensity, mm VAS (SD)							
General exercise	56 (23)	38 (21)	35 (24)	31 (22)	27 (26)*	23 (26)	30 (27)*
McKenzie treatment	53 (23)	40 (20)	24 (19)	18 (19)	19 (18)	21 (17)**	26 (23)**
Control group	47 (23)	34 (18)	25 (17)	24 (20)	21 (20)*	27 (23)	25 (24)*
Pain frequency as continuous—daily, *n* (%)							
General exercise	19 (95)	19 (95)	13 (65)	10 (50)	10 (53)*	7 (35)	9 (47)*
McKenzie treatment	22 (88)	23 (92)	16 (64)	11 (44)	14 (56)	6 (27)***	6 (27)***
Control group	20 (80)	17 (68)	15 (60)	15 (60)	11 (46)*	14 (56)	11 (46)*

General exercise $n = 20$, McKenzie treatment $n = 25$, control group $n = 25$
* Data missing for 1 patient. ** Data missing for 2 patients. *** Data missing for 3 patients.
There are some differences between the treatment groups in regard to the length of time elapsing between the assessments "after 3 weeks" and "after treatment", and between "after treatment" and "6-month follow-up".

Table IV. *Neck disability index (NDI) before and after the treatment period and at 6- and 12-month follow-up. Values represent NDI % mean, (SD)*

	Before treatment	After treatment	6-months follow-up	12-months follow-up
General exercise ($n = 20$)	33 (16)	21 (16)	17 (17)	18 (17)
McKenzie treatment ($n = 25$)	30 (12)	16 (12)	15 (12)**	18 (14)**
Control group ($n = 25$)	27 (14)	19 (13)	18 (15)*	16 (15)*

* Data missing for 1 patient.
** Data missing for 2 patients.

physiotherapist (highest percentage in the McKenzie group); 10 answered that they would contact a physician (higher percentage in the general exercise and control groups); one patient would seek an alternative therapist (general exercise group); and two said that they would rely on self treatment (McKenzie group). Eleven patients did not specify what type of professional they preferred, but indicated that they would use primary care or occupational health services. Six answered that they did not know (general exercise and control group equally), and 9 patients did not answered the question at all (equal distribution between the groups). There was no significant difference between the groups in regard to the rate of recurrence at 6 and 12 months. At the 1-year follow-up, 64% in the general exercise group reported more than one recurrence, corresponding values are 69% for the McKenzie group, and 75% for the control group. Eleven patients used health care during the treatment period, most often administered by a physician, usually on one or two occasions. In all, the studied patients had 24 appointments (15 of the 24 in the general exercise group) to the health care during the treatment period. The consultation pattern for the first 6 months and the second 6 months is presented in Table V. The patients had a total of 136 visits to a physiotherapist during the period after treatment up to the 12-month follow-up; these appointments were made by 12 patients, 6 of which belonged to the control group.

DISCUSSION

The main finding of our study is that there were no differences between the three groups at 12 months follow-up. However, in the short term, McKenzie treatment was more favourable than general exercise and the control group, with a more rapid improvement in pain intensity during the first 3 weeks.

Other investigations using an active approach to treat neck-pain patients have achieved similar short-term improvements but no difference between the treatment groups at long-term follow-up (4, 6 20). Jordan et al. (4) compared intensive training, physiotherapy, and manipulation in a randomized study involving patients with chronic neck pain and found that all groups improved in all primary-effect parameters, and these improvements were maintained at 12-month follow-up, with no differences between the groups. David et al. (20) used inclusion and exclusion criteria that were similar to ours, except they mentioned a duration of neck pain >6 weeks. David and colleagues observed improvement in both groups but no difference at 6 months between acupuncture and other physiotherapeutic interventions. These studies, like several other investigations, did not include a placebo or a control group, hence the observed improvements may simply have been the result of time.

Differences between groups are often observed at short-term

Table V. *Consumption of additional health care during different measurement periods. Values represent numbers of patients unless otherwise stated*

	General exercise $n = 20$				McKenzie treatment $n = 22$				Control group $n = 24$			
Consultation pattern	PT	Dr	Other	Total	PT	Dr	Other	Total	PT	Dr	Other	Total
Total 0–6 months												
Patients*	1	4	3	6	2	3	1	5	4	6	3	9
Number of visits*	7	11	11	29	22	5	1	28	39	11	26	76
(range)	(7)	(1–4)	(1–8)		(10–12)	(1–2)	(1)		(1–28)	(1–5)	(4–18)	
Mean no. of visits				4.8				5.6				8.4
Median no. of visits				4.5				2.0				2.0
Total 6–12 months												
Patients*	2	1	4	5	2	3	1	5	5	1	2	7
Number of visits*	7	8	58	73	11	5	2	18	50	1	13	64
(range)	(2–5)	(8)	(5–35)		(1–10)	(1–3)	(2)		(1–30)	(1)	(3–10)	
Mean no. of visits				14.6				3.6				9.1
Median no. of visits				10.0				1.0				7.0

PT = physiotherapists; Dr = physicians; other = chiropractor or alternative therapy.
* Some of the patients consulted more than one health-care professional.

but not at long-term follow-up. Various interventions and events occurring during the follow-up period may have an impact that is beyond the control of the researchers and can therefore interfere with the long-term results and perhaps obliterate differences. On the other hand, in a shorter perspective, it is necessary to consider the possibility of natural recovery, which has been reported for low back pain (21, 22) but, to our knowledge, not for neck pain. In our study, the intensity of neck pain decreased throughout the treatment period in all three groups. This might reflect the natural recovery, which could be expected to be most marked during the first week, as we observed in all groups. A slight difference in the pattern of recovery was noted during the following weeks that is, the McKenzie group continued to improve through the 3 weeks, although no difference was noted between the groups in a longer perspective. Pain frequency also decreased over the treatment period, but 51% of the study population still reported that they had continuous or daily pain after the treatment period was finished. The risk for long-standing problems and chronicity of neck pain has been confirmed in previous studies (23, 24).

Further health care consumption might indicate poor treatment outcome. We found no significant differences between the groups with respect to recurrence rates at either 6- or 12-month follow-up, although there was a tendency that the McKenzie group used health care less frequently, especially during the period 6–12 months. During the 12 months period, 30% of the study population consumed additional health care, which agrees with results published by Wright et al. (25). We regard this as a low level of additional consumption, especially when comparing with low back disorders. Andersson et al. (26) noted greater use of primary health care by patients with low back pain than by those with neck–shoulder pain, in relation to reported prevalence.

Randomized clinical trials (RCTs) are considered as the most reliable studies. Unfortunately, it is difficult to implement such studies in clinical settings, because they are time consuming and includes high demands in addition to the ordinary work load for the involved physiotherapists. To increase the size of our study population, we attempted to recruit additional physiotherapy units, but further units were not able to participate. Another reason was that the involved physiotherapists should have at least C-course of the McKenzie education program, which was not the case for many physiotherapists in the county at that time.

A large number of the patients declined participation prior to randomization. They were asked to take part in our study before any of the exclusions criteria were tested, thus some of those who declined probably would have been excluded on the basis of one or more exclusions criteria.

We chose one impairment and one disability outcome, pain intensity and NDI, respectively, as the main outcomes. There is little evidence of treatment efficacy for patients with neck pain measured on a disability level (2), hence it is important to determine if physiotherapy treatments have any effect on different levels. The NDI has been validated and found to have high internal consistency and high test–retest reliability (14). Studies have reported NDI rates of 35–39% (14, 16), which is slightly higher than the value of 30% noted in our investigation. This difference may be explained by the fact that whiplash injury was included in the cited studies but not in ours. Using the definition that a change of 5 points or more in NDI is considered as a clinically important change (16), 60–63% of the patients in the general exercise and the McKenzie group but only 37% in the control group achieved a goal of clinical relevant change. Unfortunately, there seems to be no consensus regarding how to categorize individuals with the NDI, which makes it difficult to compare the results of different studies (14, 16). Categorizing our NDI values as recommended for the Oswestry score indicates that initially 26% had minimal disability (NDI score $<20\%$), whereas only 2% had a pain intensity <20 mm (VAS). This might imply that the main reason our study population sought care was to achieve a reduction in pain, although the treatments improved both outcomes, but had a greater impact on pain intensity. Corresponding values after treatment were 63% with an NDI score $<20\%$ and 57% with pain intensity <20 mm.

DRAM has been reported to be the best psychometric predictor of low back pain (27). In a population study of musculoskeletal pain and depression, Rajala et al. (28) found that one of the most common regions of pain during the previous 12 month was the neck, and that depressed individuals had a higher rate of neck pain than those not suffering from depression, measured using the Zung Self-Rating Depression Scale. Moreover, psychological distress and psychosomatic problems have been reported to be predictors of neck pain (29).

In our study, 8 patients were initially considered to be distressed, and these subjects accounted for the significant improvement in DRAM. More precisely, the following was noted for the indicated 8 patients on the second assessment occasion: 7 moved to the normal or the at-risk category, and one (in the McKenzie group) changed from the distressed-somatic to the distressed-depressive category. In addition, 1 patient in the control group moved from the at-risk to the distressed-depressive category. According to Main et al. (19), the DRAM was designed as a screening procedure for referral for multidisciplinary treatment, in order to reduce unsatisfactory outcome of simple physical treatment. Main and colleagues also stated that highly distressed patients require more than physical treatment modalities, and that changes in distress depend on success or failure of surgery; in other words, moving from the at-risk and distress categories to a classification of normal can be regarded as a good outcome. On the basis of that, the improvement in DRAM seen in our study seems to represent a good result, especially for the general exercise and the McKenzie group (70% categorized as normal after treatment) compared with the control group (42% categorized as normal).

Our study has not provided a definite evidence of treatment efficacy in patients with neck pain. However, we did find a tendency toward a better outcome with the two active alternatives compared with the control group. General exercise has been reported to yield a positive outcome in patients with

neck pain, but, to our knowledge, no such effect has been reported for the McKenzie method. Analyses of the objective measures, comparison of the subjective and objective measures, as well as the prognostic factors still remains to be investigated in the present study. An analysis of cost-effectiveness considering both the short- and long-term results are of importance as well, since there were some differences between the groups concerning the sloop of early recovery.

Despite our effort to recruit a homogeneous study sample by, among other things, using the pain-provoking test as an inclusion criterion, the lack of differences between the treatment groups, suggests that the sample was heterogeneous. Additional work is needed to more strictly define the inclusion criteria, for instance regarding duration of complaints, which has been reported to be a prognostic factor for neck pain (30). Subgroup analysis of duration of complaints was not feasible in the present study, due to the size of the study sample.

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