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Intensive dynamic training for females with chronic neck/shoulder pain. A randomized controlled trial

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Objectives: To compare the clinical effectiveness of an intensive three-month training programme with a less intensive programme on females suffering from chronic neck/shoulder pain.
Study design: A prospective observer-blinded clinical trial including 12-month pretreatment follow-up.
Setting: Patients were referred to the Departments of Rheumatology and Physical Medicine at Hvidovre Hospital by their general practitioners. Training was undertaken at a satellite clinic for physiotherapy of Hvidovre Hospital.
Subjects: Female patients aged 18–65 years suffering from chronic neck/shoulder pain for a minimum of six months.
Intervention: Patients were examined by a physician in order to exclude serious diseases. They were then randomized to either an intensive neck/shoulder training programme or a programme of lesser intensity but of similar duration.
Main outcome measures: Scales measuring pain and activities of daily living (ADL) were used, and strength and endurance measurements of the cervical and shoulder muscles were carried out at baseline and completion of the study. Follow-up measurements were carried out by postal questionnaire at 6 and 12 months after inclusion, and included pain, ADL and treatment satisfaction measurements.
Results: Seventy-seven patients were included in the trial, of whom 27 (69%) completed the intensive programme and 25 (61%) the lighter programme. Forty-one (>80%) completed the follow-up questionnaires. The patients in the two groups did not differ with regard to age, pain, ADL scores and physical measurements prior to training. Patients in both groups that completed the trial demonstrated statistically significant improvements in nearly all of the outcome measurements at completion. ADL scores maintained statistical significance at 12 months in both groups, but pain scores were only significantly improved in the intensive group at 12 months follow-up. There was no statistically significant difference between groups regarding pain or ADL, but overall 50% of all patients showed improvement.
Conclusions: The type of low-tech dynamic training used in either of our two programmes resulted in both subjective and objective improvements in patients suffering from chronic neck/shoulder pain, but there were no statistically significant differences in outcome between the two approaches. The subjective improvements were maintained throughout the follow-up period.

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Introduction

Spinal pain is one of the more frequent causes of sick leave in Denmark.[1] To date, research has primarily focused on low-back pain patients despite the fact that neck pain is as prevalent as low-back pain.[2,3] This is probably because low-back pain frequently leads to disability pensions while neck pain reduces the patients' quality of life, but rarely results in longer periods of sick leave. Epidemiological studies have demonstrated that risk factors for the development of neck/shoulder pain include female gender, age, stress levels and static work postures, particularly with elevated extremities.[2–4]

As is the case with low-back pain patients, clinical findings in neck/shoulder pain patients are rarely definitive and often only include stiff, tender muscles and reduced motion even after thorough clinical examination.[5–7]

These similarities between neck and low-back pain[7] inspired us to carry out a rehabilitative trial utilizing the same principles (low-tech, group training) as those shown to be successful in the rehabilitation of low-back pain patients[8–10] and in the treatment of workers suffering from neck/shoulder symptoms.[5] The current trial was designed to compare the clinical effectiveness of two types of training on chronic neck/shoulder patients

Methods

All general practitioners in the referral area of our hospital received a written invitation to refer female patients with chronic neck/shoulder pain to our department for examination and eventual inclusion to our study (Figure 1). Only female patients were included due to the greater frequency of neck/shoulder symptoms in this gender and due to differences in neck strength measurements between males and females. A list of inclusion and exclusion criteria was included in the invitation (see Appendix 1). After referral from their general practitioners, patients were examined by a rheumatologist to determine whether the inclusion criteria were met. Following this patients underwent strength and endurance measurements of the cervical and shoulder muscles and filled out the questionnaires. They were then randomized (by drawing a number out of an envelope) to either the intensive training programme or the lighter programme. These programmes were carried out in groups. Sessions were approximately of one and a half hours duration with a frequency of three times per week (total 36 sessions both groups). The difference between training programmes was the dosage of the intervention. The programmes are described below and individual exercises are illustrated in Figure 2.

Light training

Sessions began with hot packs for 14 min. This was followed by stationary bicycling and the stretching of relevant muscle groups for 15 min. There were six exercises for the neck and shoulder muscles. These were carried out once in each session and included 20 repetitions of each exercise.

Intensive training

Sessions began with bicycling and the stretching of relevant muscle groups (10 min). There were seven exercises for the neck and shoulder area. Each exercise was carried out with 20 repetitions per round and five rounds were carried out in each session. Additionally, shoulder exercises were carried out with increasing resistance.

Outcome measurements

Pain was measured with two 11-point box scales measuring pain at the moment, and the average level of pain in the preceding 14 days (total 0–20 points).[11] In addition, the intake of pain-relieving medication was reported as yes or no.

Activities of daily living (ADL) were measured using a newly developed disability scale (see Appendix 2), based upon a validated low-back pain rating scale.[12] This has demonstrated good reliability and validity.[13] Pain and ADL questionnaires were filled out at baseline, after three months of training and 6 and 12 months after baseline (total 0–40 points).

Maximal voluntary isometric contraction of the flexors and extensors of the cervical spine were tested with strain-gauge equipment (Figure 3).[14,15] This measuring system has demonstrated

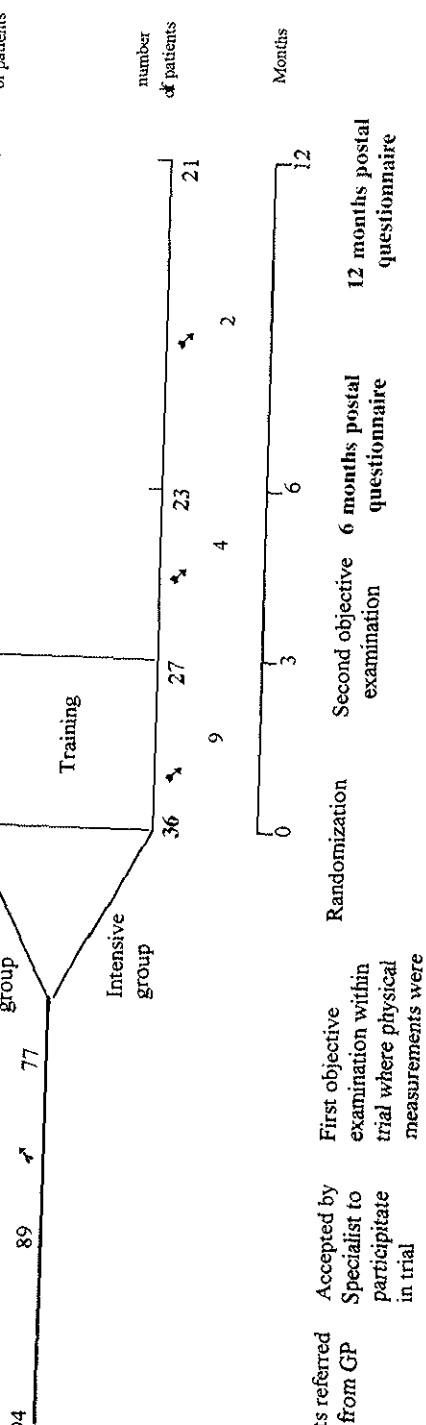

Figure 1 Flow chart showing routing through the trial

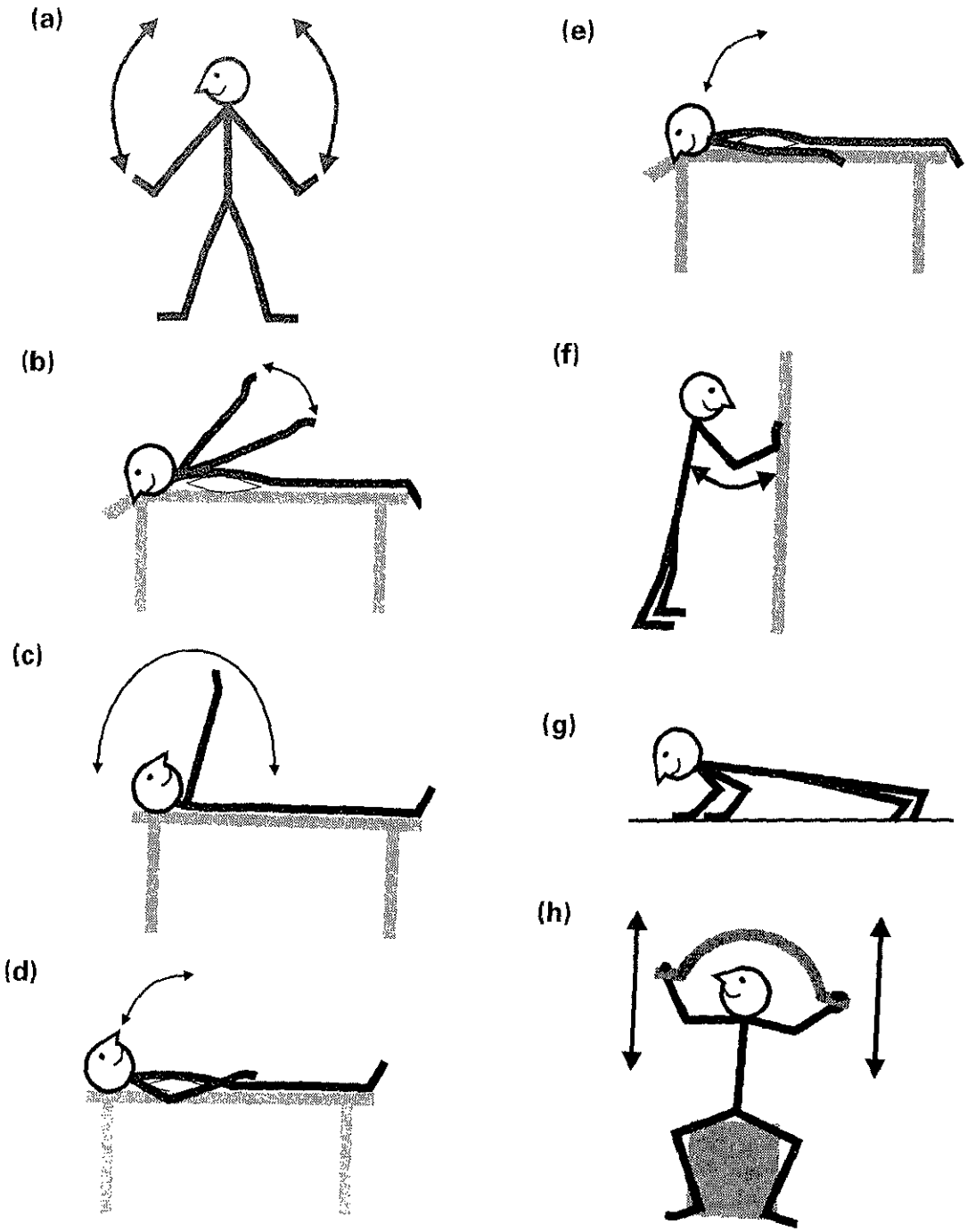

Figure 2 *Exercises used in the training programme.* A = light group; B = intensive group (a) Arm abduction: A and B (with increasing load). (b) Shoulder retraction: A and B (with increasing load). (c) Arm swing: A and B (with increasing load). (d) Neck extension: A and B. (e) Neck flexion: A and B. (f) Push-away: A. (g) Push-up: B. (h) Lateral pull-down: B.

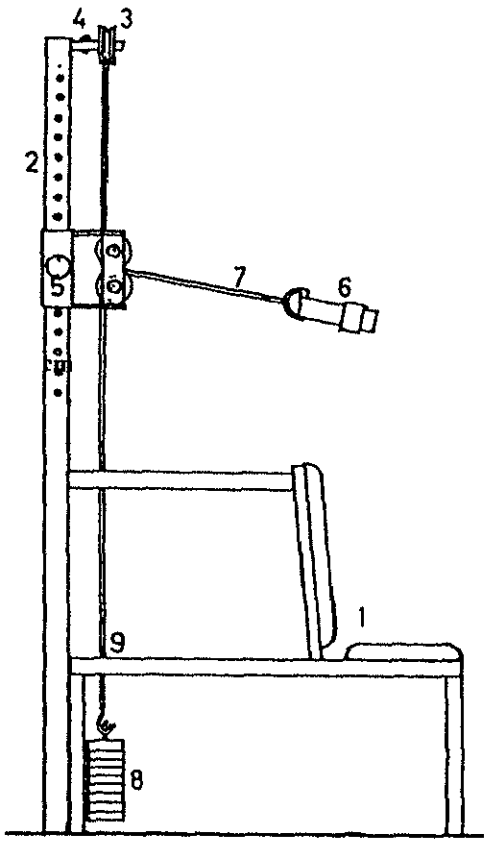

Figure 3 Dynanometer for measuring strength and endurance of neck muscles. (1) Seat, (2) measuring column; (3) pulley, (4) strain gauge cell (connected to a four-channel writer); (5) pulley system; (6) head strap; (7) tension line; (8) weight stack; (9) traction string. Subjects sat on the seat, first with their back to the column, allowing measurement of neck flexion. Then they changed position so that the chest was leaning on the chairback to obtain extension measurements. Maximum voluntary contraction (MVC) and isometric endurance (IE) at 60% of MVC were recorded. MVC was measured in kiloponds and later converted to Newton-metres (Nm). IE was measured in seconds. Tests of MVC and IE were performed with a starting position of 15° flexion.

good reliability.[15] Measurements are presented in Newton-metres (Nm). Isometric endurance of these muscle groups was tested using 60% of the values obtained during maximal strength measurements and measured in seconds. Isometric endurance of the shoulder muscles was measured with patients holding a 2 kg weight with arms stretched out perpendicularly from the shoulders. Time was measured in seconds and the test stopped if movement of more than 5 cm was registered.[8] Strength and endurance measurements were carried out at baseline and after three months of training.

Statistical methods

Standard nonparametric statistics were employed. Wilcoxon's rank sum test was used for the comparative paired statistical tests (i.e. within group) and Mann–Whitney *U*-tests were used for unpaired comparative analysis. Fisher's exact test was used to compute overall success rates. A 20% improvement from baseline values was considered to be clinically relevant.

Results

Ninety-four patients were referred to our department. Eighty-nine of these fulfilled the inclusion criteria, but only 77 attended the entrance examination and were actually included in the figure (Figure 1). Mean age was 39 years (range 18–61) with symptoms lasting for median 48 months (range 6–348). Forty-one were randomized to the light training of whom 25 (61%) completed treatment, and 36 were randomized to the intensive training programme of whom 27 (75%) completed treatment. Reasons for not completing the trial are given in Table 1. Six- and 12-month follow-up postal questionnaires were completed by 20 (80%) in the lightly trained group at both intervals and by 23 (85%) and 21 (78%) in the intensive group, respectively.

The patients in the two groups did not differ with regard to age, pain, use of pain-relieving medication, ADL scores and in physical mea-

Table 1 Reasons for not completing the trial

	Light training	Intensive training
Signs of nerve root pressure	0	0
Worsening of symptoms	3	3
Sickness not related to neck/shoulder pain	3	2
Not enough time to come to treatment	7	3
No information given	3	1
Total	16	9

surements prior to the training.

In both groups patients improved significantly with regard to objective parameters at conclusion (Table 2), but no statistically significant difference between groups could be demonstrated. Regarding ADL, median scores improved by 25% (from 16 to 12) in the light group at conclusion, and stayed at this level for the rest of the observation period (Figure 4). In the intensive group the median ADL score improved by 38% (from 16 to 10) and remained at this level. Pain scores decreased by 25% (from 12 to 9) after training in the light group, but returned to baseline values at the 6- and 12-month postal questionnaire (Figure 5). In the intensive group pain scores decreased by 20% (from 12 to 10) at conclusion and improved even further at the 6-month interval to 33% lower than at baseline (from 12 to 8). After 12 months the gains declined to a 20% improvement over baseline values (Figure 5). In accordance with this, more patients in the intensive group discontinued their intake of pain-relieving medication after training than patients in the less intensive group (Figure 6). Despite these differences within the groups, we could not demonstrate any statistically significant difference between the groups at any time (probability values ranged from 0.07 to 0.99).

The overall success rate was 50% at conclusion and 60% one year after inclusion (Table 3). There were no statistically significant differences between groups.

A subgroup of analysis of the patients that did not complete the study as opposed to those that did, demonstrated that these persons were younger (median age 33 compared to 41 years for the patients who completed the training; p-value 0.002). They did not use pain-relieving medication on a daily basis, and they had greater maximal extensor strength (16.66 Nm versus 13.72 Nm; $p = 0.03$). This may indicate that their neck/shoulder problem did not warrant such a substantial intervention as the one offered.

Table 2 The change in objective measurements in both groups from baseline

		Before training	After training	% increase	*Probability of* difference between groups post training
MVC extension	A	13.7 Nm (10.5–17.7)	16.7 Nm (11.8–19.2)	+22%	0.06
	B	17.7 Nm (12.2–20.6)	22.5 Nm (14.7–24.1)	+27%*	
MVC flexion	A	12.7 Nm (9.0–14.7)	18.4 Nm (12.7–19.6)	+44%*	0.82
	B	14.7 Nm (9.8–17.2)	18.6 Nm (11.8–20.6)	+26%*	
IE extension	A	80 s (30–152)	99 s (40–140)	+24%	0.46
	B	91 s (30–190)	121 s (60–212)	+32%	
IE flexion	A	44 s (21–80)	59 s (22–106)	+34%*	0.55
	B	30.5 s (22–50)	67 s (46–106)	+120%*	

*$p < 0.05$ in Wilcoxon–Pratt (assessing change within the group, not between).
A (light group) and B (intensive group). Median values for maximal voluntary contraction (MVC) in Newton metres (Nm) and isometric endurance (IE) in seconds. Figures in brackets represent the 90% confidence interval. Probabilities for difference between the two groups at completion after Mann–Whitney U-test are shown in the last column.

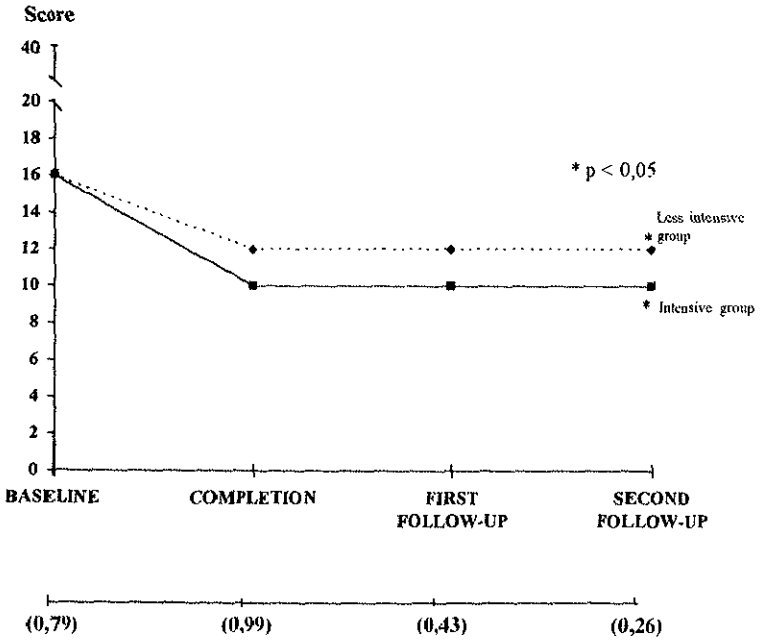

Figure 4 Median values for ADL in the light group and intensive group. The line beneath the figure shows the corresponding *p*-values in the Mann–Whitney *U*-test for comparison of groups.

Discussion

Research of the past decade has shown that treatment interventions that activate patients with low-back pain result in superior treatment results than passive treatment strategies.[16,17] Treatment concepts for low-back pain patients that focus on activating patients through training as well as delegating responsibility to patients for their own well-being, have become popular in both the United States and Scandinavia.[18,19] The duration of training interventions (minimum 2–3 months) has been shown to be of extreme importance, as has the training dosage.[8–10,15,16,19–21] There has been much less research on neck/shoulder patients, probably because the economic impact of neck/shoulder pain is less than that of low-back pain, and only a few trials have been published. The results of these trials[4,5] as well as the theory that we could transfer training concepts from low-back pain patients to neck/shoulder pain patients, formed the foundation for the training programmes used in this trial.

Both of the tested training programmes resulted in improved physical measurements after three months of training. Maximal strength gains are similar to those seen in other studies involving the neck muscles[15] and our improvements in relative endurance are similar to low-back training protocols.[16] The lack of statistical difference between groups may be due to the fact that both groups improved with regard to pain and that this was probably reflected in the objective measurements.

Scores for ADL also improved in both groups and were maintained at the 12-month questionnaire. Relative gains were were similar to those seen in low-back pain patients.[9] With regard to pain, the intensive group demonstrated greater improvement since they maintained a lower pain level throughout the observation period as opposed to the less intensive group whose values returned to baseline levels after six months. Despite these differences we could not demonstrate any statistically significant difference between groups at any interval.

Could this be because we were only recording the natural history of neck/shoulder pain? We do not believe this to be the case as the patients in our trial had chronic neck/shoulder pain with a median duration of 48 months at baseline, and most of them had been through various kinds of treatment including traditional physiotherapy and were using pain-relieving medication on a

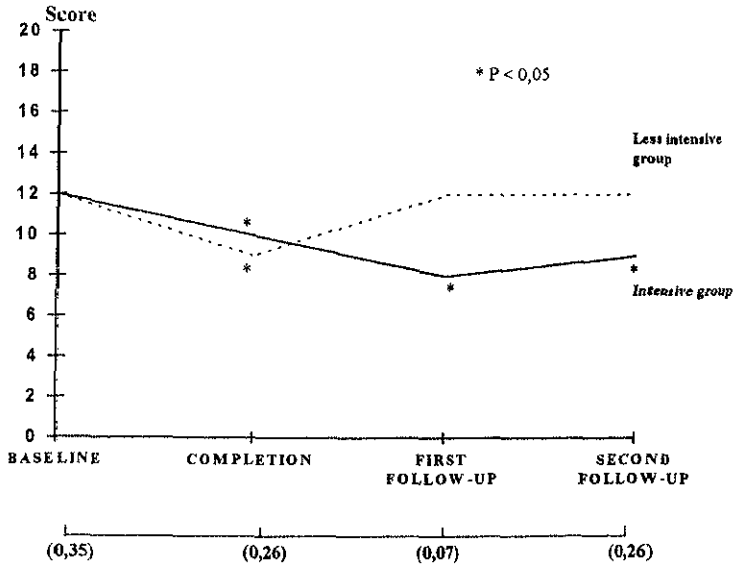

Figure 5 Median values for pain in the light group and intensive group measured by 2 × 11-point box scale. The line beneath the figure shows the corresponding *p*-values in the Mann–Whitney *U*-test for comparison of groups.

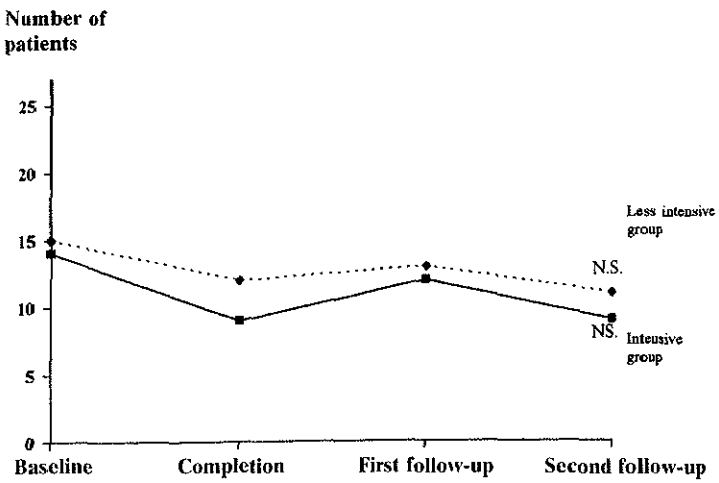

Figure 6 Number of patients using pain-relieving medication within the light and intensive groups.

Table 3 Patient satisfaction in the light trained group (A) and the intensively trained group (B)

	Completion		First follow-up		Second follow-up	
	A	B	A	B	A	B
Very satisfied	7 (28%)	4 (16%)	3 (15%)	4 (18%)	4 (22%)	5 (25%)
Satisfied minor complaints	4 (16%)	13 (46%)	8 (40%)	10 (43%)	6 (28%)	5 (25%)
Satisfied some trouble	8 (32%)	5 (19%)	2 (10%)	4 (17%)	1 (6%)	5 (25%)
Unchanged	6 (24%)	5 (19%)	7 (35%)	5 (22%)	8 (38%)	6 (31%)
Deteriorated	0%	0%	0%	0%	1 (6%)	0%

daily basis. Could a lack of difference between groups have been avoided by including more patients? Probably not. The risk of committing a type two error in our setting was less than 5%, when choosing a minimal relevant difference at 20% from baseline to conclusion.

We think the reason should be sought in the fact that there was too little difference between the design of the two programmes. In our setup we were only able to increase resistance progressively in the shoulder muscles. This was not possible for the neck muscles (because we wanted to avoid using high-tech equipment), and except for the number of repetitions the dosage for the neck muscles was the same for both groups.

Sixty per cent of the patients in both groups reported no or only minor symptoms 12 months following treatment. We believe this result to be of importance in that we were unable to find any other randomized trials involving chronic neck/shoulder patients that have demonstrated a positive long-term effect. The reason for this long-term effect remains speculative. Training programmes such as ours probably work at different levels.

In addition to gains in strength, endurance and co-ordination, patients come to believe that they are capable of much more than they previously thought possible. This change of attitude towards their problem may have a considerable and lasting effect.[22]

Our trial is weakened by the large percentage of dropouts. The most frequently given reason for not completing the trial was lack of time, thus indicating that there was a disparity between the magnitude of the problem as seen from the patient's perspective and the duration of the intervention (one and a half hours, three times a week for three months).

Please recall that 12 of the patients did not show up for the initial examination after being referred to our department (Figure 1) and that out of 25 dropouts 10 claimed that they could not find time for the training and four never gave any information about why they discontinued training. We had scheduled training sessions after working hours, but it was obviously a problem for many patients to manage training as well as go to work and look after their families. In our study only 5% of patients were on sick leave in contrast to the 50–100% of patients on sick leave or seeking pensions in many low-back pain trials.[8,9,23] The compliance in the Swedish trial[5] that among others, inspired us to design the training programme as we did, was also considerably higher but training in this study was carried out at the workplace during working hours.

Only three patients in each group did not complete the trial due to increased pain. None were found to have signs of nerve root involvement or any other serious complications. We did not find it ethically correct to include a control group that was either untreated or treated with traditional physiotherapy because many of our patients had already undergone this type of intervention as well as other treatments.

In conclusion, the training programmes utilized in this trial demonstrated positive and lasting clinical gains on the majority of the chronic neck/shoulder patients included in this trial. Due to the fact that there was no control group we cannot objectively determine whether the success of our interventions was simply due to time. Side-effects were rare and not severe. The trial also demonstrates that satisfactory results can be

obtained without employing advanced equipment. The benefit seen was not related to the intensity of treatment.

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Appendix 1 – Inclusion and exclusion criteria

Inclusion criteria

1) Female subjects aged 18–65 years
2) Neck/shoulder pain of a minimum of six months duration
3) Residence within short distance to the hospital

Exclusion criteria

1) X-ray of the cervical spine revealing underlying disease (cancer, spondylolithesis, fracture, etc.)
2) Positive foramen compression test
3) Clinical signs of acute nerve root compression
4) Previous surgery or major trauma to the cervical spine
5) Any known inflammatory joint disease
6) Headache dominating over neck pain
7) Typical migraine
8) Any somatic disease which would make carrying out a training programme difficult
9) Any psychosocial problems which would make carrying out a training programme difficult, such as drug or alcohol abuse etc.

Exclusion after randomization

1) The development of clinical signs indicative of nerve root compression
2) The inability to carry out the full training programme after six sessions
3) More than 30% absence from training sessions

Appendix 2 – Activities of daily living (ADL) questionnaire

	Yes	Can give problems	No
1) Can you sleep at night without neck pain interfering?	☐	☐	☐
2) Can you manage daily activities without neck pain reducing your activities?	☐	☐	☐
3) Can you manage daily activities without help from others?	☐	☐	☐
4) Can you manage putting on your clothes in the morning without taking more time than usual?	☐	☐	☐
5) Can you bend over the washing basin in order to brush your teeth without getting neck pain?	☐	☐	☐
6) Do you spend more time than usual at home because of neck pain?	☐	☐	☐
7) Do you remain in bed longer than usual due to neck pain?	☐	☐	☐
8) Do you feel that neck pain has influenced your emotional relationship with your nearest family?	☐	☐	☐
9) Have you had to give up contact with other people during the past two weeks due to neck pain?	☐	☐	☐
10) Do you feel that neck pain will influence your future?	☐	☐	☐