Effect of Therapeutic Exercise and Sleeping Neck Support on Patients with Chronic Neck Pain: A Randomized Clinical Trial

ANTOINE HELEWA, CHARLES H. GOLDSMITH, HUGH A. SMYTHE, PETER LEE, KATHY OBRIGHT, and LARRY STITT

ABSTRACT. ***Objective.*** To investigate the effects of therapeutic exercises and sleeping neck support contoured pillows on patients with chronic neck pain.

Methods. Using a factorial design in a prospective clinical trial, participants were equally allocated at random to 4 treatment groups in the study: (1) placebo control, of hot or cold packs and massage; (2) sleeping neck support pillow and placebo; (3) active neck exercises and placebo; and (4) combined exercise and sleeping neck support pillow and placebo. Participants were treated by physical therapists over a 6 week period and assessed by masked independent assessors at 0, 3, 6, 12, 24 weeks, and 12 months, with the 12 week assessment being the primary decision time. The primary outcome measure was the Northwick Park Neck Pain Questionnaire (NPQ).

Results. For the 128/151 (85%) participants tested at 12 weeks, the NPQ descriptive statistics of count, mean (standard deviation) were: Initial: 128, 31.0 (11.3) at Week 12; All: 128, 18.5 (11.6); Control: 34, 18.6 (10.0); Pillow: 32, 21.5 (13.1); Active neck exercises: 29, 20.1 (11.6); and Combined: 33, 14.1 (10.6). Factorial analysis of variance showed that the main effects of Exercise ($p = 0.146$) and Pillow ($p = 0.443$) were not statistically significant; but the interaction of Exercise plus Pillow ($p = 0.029$) was statistically significant and clinically meaningful.

Conclusion. Treatment by physiotherapists trained to teach both exercises and the use of a neck support pillow achieved the most favorable benefit for participants with chronic neck pain; either strategy alone was not more effective than a control regimen. Time was an important cofactor. (First Release Nov 1 2006; J Rheumatol 2007;34:151–8)

Key Indexing Terms:
NECK PAIN THERAPY EXERCISE CONTOURED PILLOW
RANDOMIZED CLINICAL TRIAL FACTORIAL DESIGN

Neck pain with limitation of mobility is common. The course is generally self-limiting, and symptoms in the majority of cases resolve in days or a few weeks. Episodes that do not resolve in 2 months after onset may become chronic problems and, apart from pain, can result in major loss of function, with related costs.

At the second international meeting of the Cochrane Collaboration at McMaster University in 1994, a systematic analysis of prior studies of neck pain was presented, and a model design was proposed. An expanded version was published in 1996[1], and 2 full reviews in 2004[2,3]. All of these studies (and others) have influenced our discussions.

In earlier studies of the prevalence of neck pain in university staff and faculty, in London, Ontario, we found 8% of subjects interviewed had neck pain at the time of initial contact, and in that same group, 12% reported neck pain during a 5 year followup[4]. Historical studies gave similar estimates of point prevalence[5,6]. A recent postal survey found much higher figures, with point prevalence of 22.2% and lifetime prevalence of neck pain of 66.7%, estimates that the authors suggest may be too high[7]. Clinically important disability resulted in 4.6%.

Therapeutic trials have been assessed systematically in Cochrane Reviews. A 1996 report[1] included 24 randomized clinical trials, and concluded that, "there is little information

From the School of Physical Therapy, University of Western Ontario, London, Ontario; Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario; Department of Medicine, University of Toronto, Toronto, Ontario; and Department of Epidemiology and Biostatistics, University of Western Ontario, London, Ontario, Canada.

This study was conducted at the School of Physical Therapy, Elborn College, University of Western Ontario, London, Ontario; supported by a grant from the National Health Research Development Plan (Grant 6606-5681-403), Health Canada.

A. Helewa, MSc, Professor Emeritus; K. Obright, MSc, Professor, School of Physical Therapy; L.W. Stitt, MSc, Department of Epidemiology and Biostatistics, University of Western Ontario; C.H. Goldsmith, PhD, Professor Emeritus, Department of Clinical Epidemiology and Biostatistics, McMaster University, Father Sean O'Sullivan Research Centre, St. Joseph's Healthcare, Hamilton, Ontario; H.A. Smythe, MD, FRCPC, Professor Emeritus, University of Toronto; P. Lee, MD, FRCPC, Professor, Department of Medicine, University of Toronto, The Mount Sinai Hospital, Toronto, Ontario.

Address reprint requests to Dr. H.A. Smythe, University of Toronto, 2 Heathbridge Park, Toronto, Ontario, M4G 2Y6 Canada. E-mail: hasmythe@rogers.com

Accepted for publication August 15, 2006.

available from clinical trials to support many of the treatments for mechanical neck pain. In general, conservative interventions have not been studied in enough detail to assess efficacy or effectiveness adequately." More recent reports included 33 randomized trials, and found that, "The evidence did not favour manipulation [high velocity thrusts] or mobilization [low velocity] done alone or in combination with various other physical medicine agents; when compared to one another, neither was superior." Individual studies documented mild improvement, variously attributed to multimodal strategies, exercise, behavioral management, or other factors. "Factorial design would help determine the active treatment agent(s) within a treatment mix." The effect of time on outcome was not modeled in any of the analyses.

In the past decade, there has been a proliferation of neck support pillows recommended for patients with neck pain. In a recent prospective cohort study of neck supports by one of us (HAS), 47% of patients with C6–C7 level tenderness improved at first followup (median 8 months), with further improvement on second followup (median 18 months) in 63% of those with prior fibromyalgia (FM) and 84% of those without prior FM. A third followup (median 35 months) showed a satisfactory response in 80% of patients with previous FM and in 90% of patients without FM[8]. In another randomized crossover study of patients with chronic neck pain, 3 types of pillows were compared. A water-based pillow compared to the patients' regular pillow, or a roll pillow, was associated with greater pain relief and improved quality of sleep[9]. A 1998 study of 35 patients with FM, using 3 types of pillows in a series of n = 1 studies, showed no clinically important difference in objective outcomes in a 2 week period; however, most participants (62.9%) preferred the Shape of Sleep pillow[10] (Manutex Products, Mississauga, ON, Canada).

Our objective was to further evaluate the effects of therapeutic exercises with postural corrections, and sleeping neck support using contoured pillows, on patients with chronic neck pain.

MATERIALS AND METHODS

Design. We used a 2 × 2 balanced factorial design in a randomized clinical trial to compare the effects of neck and postural exercises, with a sleeping neck support pillow. Volunteers were screened and then allocated at random to one of 4 treatment arms. The 4 interventions were: (1) Active control: heat or cold plus superficial massage; (2) Control, plus instruction in using a sleeping neck support pillow (provided); (3) Control, plus active neck and postural exercises; and (4) Control, plus a neck support pillow, plus active neck and postural exercises. Balanced treatment-group allocation was done using randomly selected, randomly ordered blocks.

Blinding. The code was held in confidence by the research associate (LS). Assessments were carried out by independent assessors who were blinded to the treatment received. One of us (AH) made all decisions about patient eligibility for the trial. Once the patient was eligible, a research assistant opened the allocation envelope, hence concealing the randomization plan from the person making the eligibility decision.

Study population. Subjects who volunteered for the study were 18–70 years of age; with unresolved neck pain (with or without radiating symptoms in the upper limbs) of at least 2 months' but not more than 12 months' duration; on stable medical or other therapies; who comprehended English; lived in the Middlesex County of Southwestern Ontario; and who, after explanation, signed a consent form. Subjects with systemic inflammatory joint disease, neoplasms, infections, neurological disease, or other serious sources of disability were excluded. Author PL read radiographs to exclude those with cervical subluxation or spinal fracture or other major pathology.

Interventions. The following treatment maneuvers were provided by physical therapists assigned to the study.

1. Thermal modalities and massage. All participants received a moist hot or cold pack according to their preference, applied for 20 minutes to the back and side of the neck, and upper scapular area. Participants were also provided with a pack for home use, with instructions on safety. Effleurage massage consisted of soothing rhythmic superficial strokes lasting 5 minutes. Vigorous and deep massages, which may have effects similar to spinal mobilization or manipulation techniques, were avoided. These 2 modalities were considered an active control treatment.

2. Neck support. Participants in the second and fourth arms of the study received a neck support pillow to be used during sleep. Participants were instructed by the physiotherapist in the use of these pillows, given written instructions, and reviewed on subsequent visits. Reliable support to the low anterior neck throughout sleep was considered essential. Two types of pillows were randomly assigned equally in each arm. These were the Shape of Sleep and the Sissel Design AB Swedish foam pillow (Sissel Design AB, Svedala, Sweden). They were similar in design, but differed in firmness. Subject satisfaction was recorded[8].

3. Active exercise. Participants in the third and fourth arms of the study received a program of active neck and postural exercises.

The sitting posture, taught and reinforced by mirror feedback, was a relaxed mid-position, with the shoulders neither retracted nor protracted. Viewed from the side, the head is held with the ear above the shoulder. The exercises were performed twice daily, and designed for simplicity and minimal or no pain. They required no aids and little time (about 5 to 10 min). Manually resisted isometric exercises involved muscle groups acting on the head, neck, and shoulder girdles. Contraction of one muscle group was followed slowly and rhythmically by a contraction of its antagonist. Gradually, participants assumed responsibility by performing the exercises at home, preferably at the same time of day, to establish a daily routine. The exercise program was checked and reinforced in subsequent visits. Participants were to record pain or other difficulties resulting from the treatment maneuvers, using a diary sheet.

Participants were seen throughout the course of treatment by the same physical therapist. Treatment files were clearly identified for group assignment by color code and large print to prevent contamination. Treatments were scheduled at 2 visits per week for the first 3 weeks, one visit per week for the remaining 3 weeks, and one final followup visit at Week 10, to a total of 7 to 10 visits as determined by the physical therapists. Attendance at all physical therapy visits and scheduled assessments was recorded.

Outcome measures

The primary outcome measure was the Northwick Park Neck Pain Questionnaire (NPQ) score, measured at 12 weeks. Several secondary outcome measures were used, recorded on admission to the study and at predetermined time intervals.

1. The Northwick Park Neck Pain Questionnaire. The NPQ[11] is self-administered and was applied at 0, 3, 6, 12, 24, and 52 weeks. This instrument is a reliable, valid, and responsive measure of neck pain therapy, with 10 questions, that is simple and takes a few minutes to complete. Nine questions covering neck-related pain, sleep, and specific functions are scored 0 to 4, so that total raw scores may vary from 0 (no pain or dysfunction) to 36. The raw totals are divided by 36 and expressed as 0 to 100. A 10th question asked how current pain compared to that felt at the previous assessment (much better, slightly better, the same, slightly worse, much worse).

2. Study questionnaire. In addition to height and weight, this self-adminis-

tered questionnaire, developed by our group, obtained baseline information relating to the patient's demographic profile, history of illness, medication or surgery, and history of neck or arm pain or headaches. Information on lifestyle factors such as smoking, alcohol consumption, physical exercise, and activities and hobbies was also sought. A modified followup questionnaire was applied at 3, 6, 12, 24, and 52 weeks.

3. SF-36 Health Status Survey (Acute). The SF-36 Health Status Survey is a 36-question instrument that measures function, pain, emotional state, and general quality of life over the last month or week[12,13], validated in a variety of disease groups. It was self-administered at 0, 3, 6, 12, 24, and 52 weeks. From the 36 survey items, scores for 8 dimensions are calculated, each on a scale of 0 to 100. In addition, summary physical and mental component scores were derived from weighted means of the 8 dimensions. The values are transformed using means and standard deviations derived from large reference populations, to have a "normal" mean of 50 and a standard deviation of 10; lower values indicate worse symptoms[13].

4. Independent assessors' physical measures. At baseline, 3, 6, and 12 weeks, independent assessors measured grip strength and anterior neck muscle strength using a modified sphygmomanometer[14]. Anterior neck muscle strength[15] was measured using the same device. In a half-lying position at 45°, the patient was asked to raise the head from the bed, and flex and rotate against the resistance of the inflated bag for 5 seconds. These isometric holds were repeated to right and left. A visual analog scale (VAS) was used to record current pain. A 12-point modified tender point score[16] was used. The tender sites in the low anterior neck included in the American College of Rheumatology criteria for the classification of FM[17] were not used, because groups not receiving neck support during sleep were to remain unaware of the existence of these key sites.

The independent assessors were individuals without a medical background, specially trained by 2 authors (AH and HAS) to conduct specific measurements. They were selected on the basis of their interpersonal skills, previous work record, and accuracy of reporting. They were blinded to the intervention arm to which a particular patient had been allocated, and to the purposes and objectives of the study.

Cointerventions and contamination. During the 12 week intervention period, participants were asked not to change their dose or type of analgesic/antiinflammatory medication, if these were prescribed. If none was prescribed, participants were urged not to begin taking any new analgesic/antiinflammatory medications during the intervention period. Family physicians were notified of this trial requirement. Participants were also asked not to seek care from another health professional for neck or upper limb pain, back pain, or headaches. Participants whose designated interventions were contaminated were followed up as intent-to-treat participants.

Sample size. Sample size was computed for the planned primary outcome, the NPQ 12, assessed by 2 × 2 factorial analysis, for main effects and interactions. Our preliminary calculations assumed a standard deviation of 8.6[11], which was reviewed after recruitment of 83 participants. The new standard deviation was 11.96, with a 95% confidence interval of 10.4 to 14.1. Using the new standard deviation of 12.0%, a new sample size of 156 participants would have a power of 51% for differences of 4 (10%), 84% for 6 (15%), and 98% for 8 (20%). In the study of Leak, *et al*[11], the mean change in NPQ between 1 and 3 months in participants who judged themselves "slightly better" was 3.7, and "much better" was 7.8. This sample size was designed to detect factorial effects, but may not detect differences among the 3 treatment groups. We were able to randomize 151 participants and 128 completed 12 weeks, giving a 15% dropout rate.

Randomization. Blocks of 8 patients were randomly allocated to each of the 4 arms of the study, with an allocation ratio of 1:1:1:1, to ensure that one-quarter of patients were assigned to each arm. Random number lists were prepared and held by the research assistant. Stratification for possible prognostic factors such as age, sex, pain severity, and neck and arm pain was considered, but the evidence to justify their use was considered not conclusive.

Statistical analysis. Data for the trial were managed using SAS (v. 8.2) and JMP statistical packages (JMP v. 5.0.1.2; SAS Institute, Cary, NC, USA). Descriptive statistics were produced for all key baseline demographic variables and for the outcome variables at baseline and at 12 weeks, the primary decision time. Analysis of variance techniques were used to analyze the primary and secondary outcomes according to the stratified 2 × 2 factorial trial design. Probability values less than 5% were considered to be statistically significant. Least-square means and variances were analyzed by maximum likelihood techniques, with and without baseline NPQ values as covariates.

Subject safeguards. Ethical review of the study was conducted and approved by the Internal Review Board at the University of Western Ontario. Verbal consent was first obtained by the research assistant by telephone contact when patients initially volunteered to participate. Written informed consent was obtained at the baseline interview by the independent assessor. Participants were informed that they were free to leave the study at any time without loss of care. Confidentiality and freedom from assault were assured. The assessment procedures, interventions, and treatment risks involved were explained in full. Subject and data confidentiality were maintained by using both a respondent number, given to all subjects reviewed for eligibility, and a subject number, given to those participants who were admitted to the trial.

RESULTS

Of the 429 volunteers screened, 179 met eligibility criteria, and of those, 151 were allocated at random and entered into the trial (Figure 1). One subject listed as a protocol deviation saw another physiotherapist during the 12-week period. The 28 eligible volunteers who were not randomized were excluded for the following reasons: physician refused permission (3), subject refusal (24), or inappropriate treatment assignment (1; subject was assigned to a treatment group without being randomized). No other inconsistencies were found, suggesting high integrity of the randomization process. Thirty-seven participants were allocated to the placebo control group and 38 to each of the remaining 3 arms of the study. At 12 weeks, outcome measures were available on 128 participants, a loss to followup of 15% (Figure 1).

The 4 groups had similar baseline characteristics (Table 1).

Results are presented for the predefined outcome measure, NPQ at 12 weeks (NPQ 12) in Table 2, and graphically in Figures 2, 3, and 4. Only the 128 subjects who completed the 12-week assessment are included in these analyses. Clearly, the main effects of pillow or exercise alone are clinically unimportant and not statistically significant; the lines are parallel in Figure 2. The interaction between the 2 factors neck support and exercise supervised by a trained physiotherapist is shown by the lack of parallelism of the 2 lines in Figure 3; it is both statistically significant and clinically important.

Addition of NPQ 0 as a covariate increases the variance explained by the model (R^2 increased from 0.06 to 0.27), while reducing the root mean-square error (RMSE) from 11.38 to 10.09. Analysis including the data collected at 0, 3, and 6 weeks further increased the R^2 to 0.54, and reduced the RMSE to 8.63. These gains are achieved by identifying variances within individuals in the study, and by identifying effects due to time. Standard errors are further reduced by iteratively fitting a least-squares regression line to the dataset as a whole, using only 1 degree of freedom, assuming that the variances are similarly distributed at random within the groups.

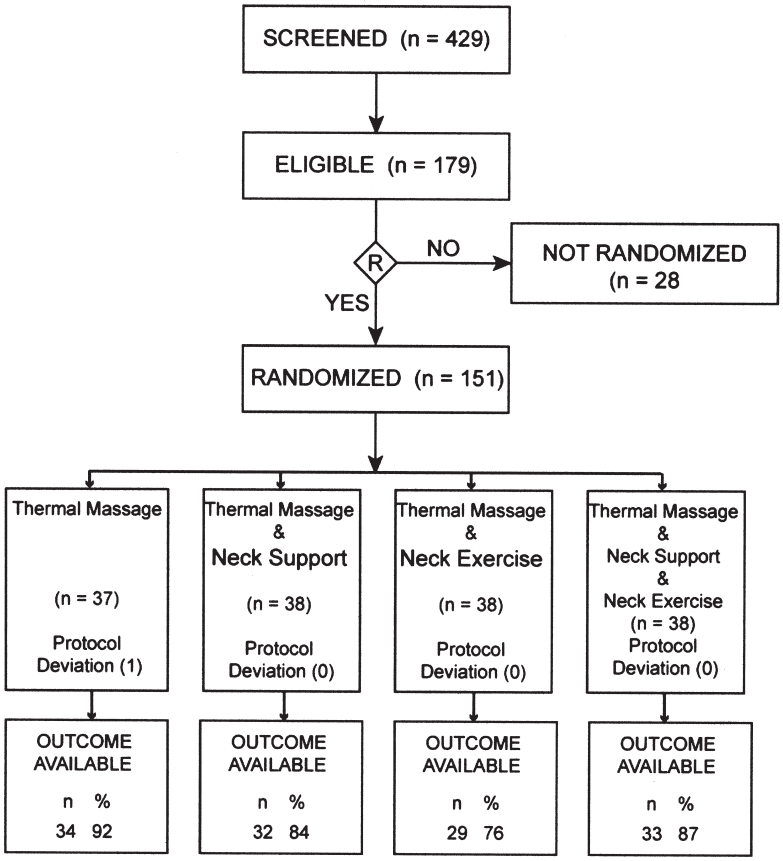

Figure 1. Population accepted, randomized for study, and followed 12 weeks.

Table 1. Demographics; characteristics of groups at baseline.

	Control, n = 37	Pillow, n = 38	Exercise, n = 38	Pillow + Exercise, n = 38	All, n = 151
Age, yrs, mean (SD)	53.1 (12.2)	51.6 (12.8)	47.6 (14.7)	47.1 (15.0)	49.8 (13.9)
Female, n (%)	22 (59.5)	25 (65.8)	27 (71.1)	16 (42.1)	90 (59.6)
Married, n (%)	28 (75.7)	28 (73.7)	26 (68.4)	20 (52.6)	102 (67.6)
Employment, n (%)					
Full-time	15 (40.5)	11 (29.0)	14 (36.8)	16 (42.1)	56 (37.1)
Part-time	3 (8.1)	4 (10.5)	4 (10.5)	6 (15.8)	17 (11.3)
BMI, kg/m^2					
Mean	26.4	28.3	25.9	28.6	27.2
> 30, %	21.6	31.6	18.4	34.2	28.5

BMI: body mass index.

The course through time during the period 0 to 12 weeks is summarized in Table 3 and Figure 4. Clearly, the effect of time is very much greater than the effect of the treatment strategies. The NPQ decreased in an almost straight-line fashion from a mean of 31.1 at baseline to 18.6 at 12 weeks (least-square means, which give equal weight to each group, while the arithmetic means give more weight to groups with larger sample sizes). The overall mean NPQ difference due to time was therefore 12.5 ($p = 0.0285$), as shown. The estimate of the interaction effect, contrasting control and pillow plus exercise groups, was 5.7, to a least-square mean of 14.1. The difference between the pillow plus exercise group and the others is suggestive by 6 weeks, and clear by 12 weeks (df 1,495; $F = 7.76$; $p = 0.0056$.) This improvement was maintained through 24 and 52 weeks (data not shown). There was little change in those evaluated at 52 weeks in the control, pillow, and exercise groups, with possible further improvement in the interaction group, to a least-square mean of 13.2.

The patients' perception of "clinically meaningful" change was indicated by the answers to the NPQ Question 10[11]. The change in mean NPQ score between 6 and 12 weeks was –4.2 in those who felt "Much better," –2.7 in those who were

Table 2. ANOVA, primary outcome measure, NPQ 12.

Model	Source
Y =	NPQ 12
A =	Pillow (Groups 2 and 4)
B =	Exercise (Groups 1 and 3)
A + B =	Pillow + Exercise (Interactions)

Analysis of Variance

Source	df	Sum of Squares	Mean Square	F Ratio	p
Model	3	1004.91	334.97	2.588	0.0561
Error	124	16052.96	129.46		
Total	127	17057.88			

Pillow, n = 65

Group	Least-Sq Mean	SE	Difference	Lower CL	Upper CL
No Pillow	19.94	1.28	2.76	–0.80	6.32
Pillow	17.18	1.26			
F ratio = 0.59, df 1,124, p = 0.4427					

Exercise, n = 62

Group	Least-Sq Mean	SE	Difference	Lower CL	Upper CL
No Exercise	20.02	1.24	2.93	–0.61	6.47
Exercise	17.09	1.28			
F ratio = 2.14, df 1,124, p = 0.1464					

Effect Estimates

Group	Estimate	SE	Lower 95%	Upper 95%	t Ratio	p
Intercept	18.60	1.01	16.61	20.60	18.46	< 0.0001
Control	0.02	1.71	–3.37	3.40	0.01	0.9927
Pillow	2.93	1.74	–0.52	6.38	0.77	0.4428
Exercise	1.54	1.80	–2.03	5.10	0.15	0.3957
Pillow + Exercise*	–4.48	1.73	–7.90	–1.07	–2.22	0.0285
*F ratio = 4.91, df 1,124, p = 0.0285						

NPQ: Northwick Park Neck Pain Questionnaire, SE: standard error, CL: confidence limit.

"Slightly better," and 0.72 in those reporting "no change." The 5 who were "worse" had increased NPQ scores averaging 10.5. The standard deviation of all scores was 9.0, reflecting wide variation among the self-reports.

The treatment effects may be underestimated because of floor effects. At baseline, the mean NPQ score was 31 (i.e., 3.1 on a 0 to 10 scale). At 12 weeks, 20 of the values were ≤ 6 (3 and 0 were the only other possibilities). Nine of these were in the pillow plus exercise group.

Secondary outcome measures. We also recorded data needed to evaluate sensitivity, time effects, and variance measures for other measures. Included were: neck strength, all 8 SF-36 scales and 2 summary scales[12,13], VAS pain, grip strength, and tender point counts and scores. The sensitivity of these measures to changes in the total group assessed between baseline and 12 weeks is shown in Table 4. Clearly, the NPQ performed best, followed by the Bodily Pain scale of the SF-36 and the VAS pain scale. Differences among treatment groups were statistically significant and clinically important only for the NPQ.

By all these measures, the baseline measures of severity were mild; the mean VAS pain was 2.8 on a 0 to 10 scale. Floor effects severely limited the value of many of the measures in this trial, measures that could be quite useful in other trials with more severely affected participants. Twenty-two of 128 subjects had zero VAS pain at 12 weeks; 9 of these were in the pillow plus exercise group.

Adverse events. No adverse events were reported despite use of a daily diary sheet, in which participants were to record pain or other difficulties resulting from the exercises and other therapies.

DISCUSSION

Primary outcomes. In this study, there was no measurable effect of exercise training alone, or sleeping neck support, as

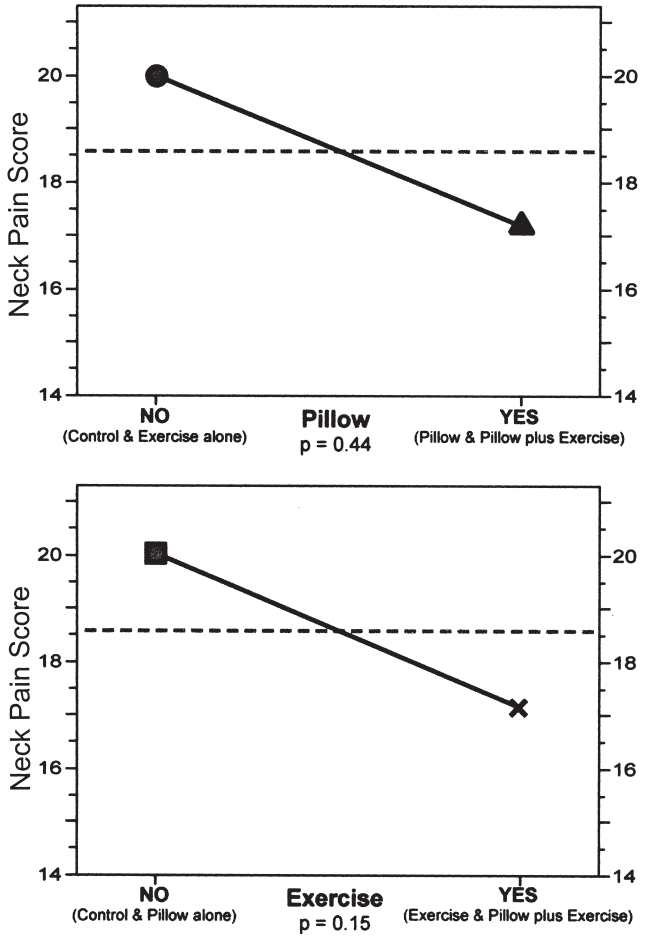

Figure 2. Main effects of Pillow and Exercise at 12 weeks. Broken line is the overall mean.

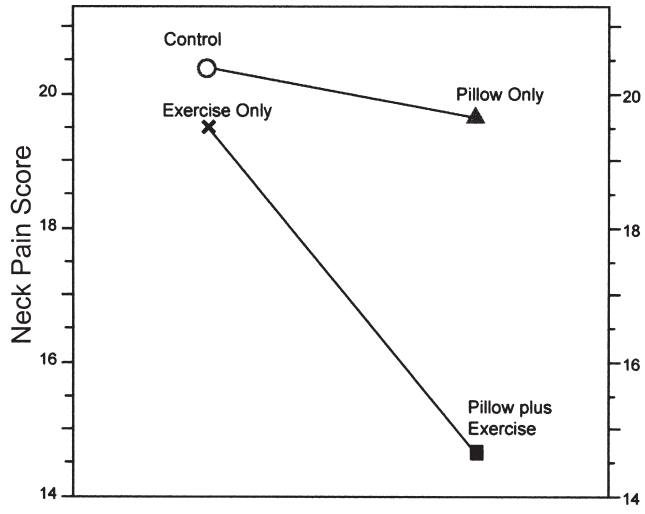

Figure 3. Interaction effects at 12 weeks ($p < 0.03$).

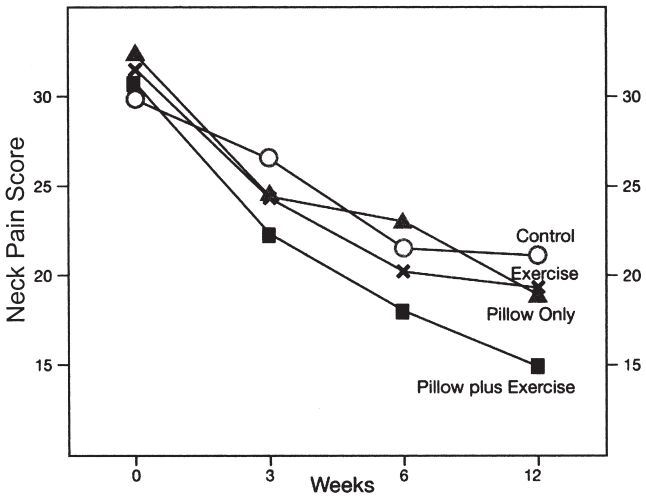

Figure 4. Effects through time ($p = 0.0056$ at 12 weeks for group 4 vs others).

compared with placebo, the 2 primary treatment factors; however, the interaction of physiotherapists and the neck support pillow was clinically important and statistically significant. The largest effect was time, a factor not commonly modeled in the studies covered in the Cochrane reviews.

Time and earlier studies. When the time effect was not explicitly modeled, benefit was often attributed to other time-consuming factors of interest to authors, such as exercise, multimodal therapies, or behavioral therapies. It must be stated that there is no acceptable evidence of benefit from any of these programs. It is also clear that acceptable evidence will only derive from fully modeled studies, usually 2 by 2 or similar fully factorial designs, also modeling for time.

Interaction effect. What was the nature of the interaction between the trained physiotherapists and sleeping neck support? In our protocol, we have termed it "exercise"; with pain relief from the pillow, exercise can be more effective. However, the pillow alone did not improve neck pain, and exercise alone did not improve neck strength.

An alternative explanation is more complicated. It relates to the major difficulties patients and health professionals have with referred pain, and therefore with neck and back problems in general. The brain is not equipped to identify the precise site of origin of pain arising from any of the deep structures in the body, and specifically from the vertebrae and attached structures in the lower neck. The brain places the pain in the back of the neck (and in other regions), but not in the deeply tender front of the lower neck. Knowledge of the precise site of origin, and the precise cause of the pain, dictates the precise treatment strategies. Our physiotherapists were trained to reinforce these otherwise unknowable tactics at each encounter.

Strengths and weaknesses of this study. The balanced factorial design and the modeling of time effects identified strategies that were ineffective, and strengthened the evidence for the use of neck support during sleep, directed to the tender low anterior cervical spine. Because these strategies cannot be

Table 3. Summary tables; time effects, Weeks 0 to 12. Data represent count, mean, standard deviation.

NPQ	Weeks			
	0	3	6	12
Control	34, 27.4, 9.2	34, 24.0, 10.6	33, 18.8, 9.4	34, 18.6, 10.0
Pillow	32, 35.0, 10	31, 27.3, 11.6	31, 26.1, 13.5	32, 21.5, 13.1
Exercise	29, 32.3, 12.5	29, 25.2, 11.7	28, 21.1, 13.3	29, 20.1, 11.6
Pillow + Exercise	33, 29.9, 12.5	33, 21.5, 11.7	31, 17.7, 11.6	33, 14.1, 10.6
VAS	**Weeks**			
	0	3	6	12
Control	34, 2.5, 1.7	34, 2.2, 1.8	33, 1.7, 1.7	33, 1.7, 1.6
Pillow	32, 3.6, 1.9	31, 3.2, 2.1	31, 2.3, 1.7	32, 1.9, 1.7
Exercise	29, 2.9, 2.4	29, 2.7, 2.2	28, 1.9, 1.8	25, 1.7, 1.4
Pillow + Exercise	33, 2.3, 1.6	33, 1.9, 1.5	31, 1.3, 1.2	32, 1.0, 1.3
SF-36	**Weeks**			
Bodily Pain	0	12		
Control	34, 43.8, 5.9	34, 50.0, 7.0		
Pillow	32, 41.1, 6.3	32, 48.5, 8.9		
Exercise	29, 42.8, 8.7	29, 48.7, 9.6		
Pillow + Exercise	33, 43.7, 7.4	33, 52.1, 6.5		

NPQ: Northwick Park Neck Pain Questionnaire.

Table 4. Secondary outcome measures ranked by sensitivity; all subjects, Week 12 minus Week 0.

Outcome Measure	Mean	df	SD	t Test	Prob > |t|
NPQ 12	–12.52	127	11.74	–12.06	< 0.0001
SF-36 body pain	7.01	127	8.90	8.91	< 0.0001
VAS pain	–1.25	121	2.12	–6.52	< 0.0001
Tender point count	–0.71	114	2.84	–2.69	0.0082
Tender point score	–1.13	114	4.96	–2.45	0.0160
Grip strength	12.33	121	64.38	2.11	0.0365
Neck strength	7.12	121	65.62	1.20	0.2329

NPQ: Northwick Park Neck Pain Questionnaire.

intuitively obvious to the patient, training by knowledgeable health professionals was essential.

In the patients studied, pain was relatively mild, and floor effects limited the ability to measure benefit. Our findings may not generalize to patients with FM or related severe chronic pain problems. Only one prospective and encouraging, but uncontrolled study[8] has been reported. Further studies are much needed.

Our results indicate that subjects with chronic neck pain should be treated by health professionals trained to teach both exercises and the appropriate use of a neck support pillow during sleep; either strategy alone will not give the desired clinical benefit. Trials should include a balanced factorial design, and analysis of time effects.

ACKNOWLEDGMENT

The contoured pillows used in this study were developed by Dr. H.A. Smythe, who holds the trademark for the Shape of Sleep brand.

REFERENCES

1. Aker PD, Gross AR, Goldsmith CH, Peloso P. Conservative management of mechanical neck pain: systematic overview and meta-analysis. BMJ 1996;313:1291-6.
2. Gross A, Bronfort G, Hoving J, Goldsmith C, Haines T, Aker P, Cervical Overview Group. Manipulation and mobilisation for mechanical neck disorders. In: The Cochrane Library, Issue 1, 2004. Oxford: Update Software.
3. Verhagen AP, Scholten-Peeters GG, de Bie RA, Bierma-Zeinstra SM. Conservative treatments for whiplash. Cochrane Database Syst Rev 2001;4:CD003338.
4. Helewa A, Goldsmith CH, Lee P, Smythe HA, Stitt L. The prevalence of neck pain in a university community. Phys Ther 1994;74 Suppl 5:S26.
5. Hult L. Cervical, dorsal and lumbar spinal syndromes. Acta Orthop Scand 1954;Suppl 16:1-76.
6. Lawrence JS. Disc degeneration: its frequency and relationship to symptoms. Ann Rheum Dis 1969;28:121-37.
7. Cote P, Cassidy JD, Carroll L. The Saskatchewan Health and Back Pain Survey. The prevalence of neck pain and related disability in Saskatchewan adults. Spine 1998;23:1689-98.

8. Smythe HA. The C6-7 syndrome — Clinical features and treatment response. J Rheumatol 1994;21:1520-6.
9. Lavin RA, Pappagallo H, Kuhlemeier KV. Cervical pain. A comparison of three pillows. Arch Phys Med Rehabil 1997;78:193-8.
10. Ambrogio N, Cuttiford J, Linekar S, Li L. A comparison of three types of neck support in fibromyalgia patients. Arthritis Care Res 1998;11:405-10.
11. Leak AM, Cooper J, Dyer S, Williams KA, Turner-Stokes L, Frank AO. The Northwick Park Neck Pain Questionnaire, devised to measure neck pain and disability. Br J Rheumatol 1994;33:469-74.
12. Ware JE, Kosinski M, Keller SD. SF-36 Physical and Mental Health Summary Scales; a user's manual. Boston: The Heath Institute; 1994.
13. Ware JE, Kosinski M. Health Assessment Lab, 1994. SF-36® physical and mental health summary scales: a manual for users of version 1. 2nd ed. Lincoln, RI: QualityMetric Incorporated; 2001.
14. Helewa A, Goldsmith CH, Smythe HA. Patient observer and instrument variation in the measurement of strength of shoulder abductor muscles in patients with rheumatoid arthritis using a modified sphygmomanometer. J Rheumatol 1986;13:1044-9.
15. Vernon HT, Aker P, Aramenko M, Battershill D, Alepin A, Penner T. Evaluation of neck muscle strength with a modified sphygmomanometer dynamometer: reliability and validity. J Manipulative Physiol Ther 1992;15:343-9.
16. Smythe HA, Buskila D, Gladman D. Performance of scored palpation, a point count, and dolorimetry in assessing unsuspected nonarticular tenderness. J Rheumatol 1993;20:352-7.
17. Wolfe F, Smythe HA, Yunus MB, et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia; report of the Multicenter Criteria Committee. Arthritis Rheum 1990;32:160-72.