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Treatment of myofascial trigger-points with ultrasound combined with massage and exercise – a randomised controlled trial

Arne N. Gam*, Susan Warming, Lone Hørdum Larsen, Bente Jensen, Ola Høydalsmo, Ingelise Allon, Bente Andersen, Niels E. Gøtzsche, Marelis Petersen, Birgitte Mathiesen

Department of Rheumatology, Bispebjerg Hospital, University of Copenhagen, Lyngholmvej 53, 2720 Vanløse, Denmark

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Abstract

The effect of treatment with ultrasound, massage and exercises on myofascial trigger-points (MTrP) in the neck and shoulder was assessed in a randomised controlled trial. The outcome measures were pain at rest and on daily function (Visual Analogue Scale, VAS), analgesic usage, global preference and index of MTrP. Long-term effect for treatment and control groups was assessed after 6 months using a questionnaire. The patients were randomised to three groups. The first group was treated with ultrasound, massage and exercise (A), the second group with sham-ultrasound, massage and exercise (B), while the third group was a control group (C). The duration of the study was 6 weeks. Treatment was given twice a week from the second to the fifth week. The number and index of MTrPs were recorded at each treatment session in groups A and B but only at entry as well as end of study in group C. VAS and analgesic usage was recorded in all three groups throughout the study period. Six months after the last treatment session a questionnaire was send to the patients. A total of 67 patients were included. Nine patients dropped-out during the study, which left 58 patients that could be included in the final analysis. Twenty patients were randomised to group A, 18 to group B and 18 to group C. A significant reduction in index were found between treatment groups (A and B) and control group (C), but no difference between group A and B. VAS scores, analgesic usage or global preference showed no difference between group A, B or C. The patients in the group C were offered treatment (ultrasound, massage, exercise) after the 6 weeks treatment period. At the questionnaire after 6 month 44 (87%) of the 52 patients from all three groups who had treatment responded. Sixty-four percent answered that they had had good or some effects, 68 percent were still doing the exercise programme and 17 percent had received other forms of therapy after they had completed the study. No difference between groups given ultrasound or sham ultrasound were found. It is concluded that US give no pain reduction, but apparently massage and exercise reduces the number and intensity of MTrP. The impact of this reduction on neck and shoulder pain is weak.

Keywords: Ultrasound; Ultrasonic; Massage; Exercise; Physiotherapy; Neck and shoulder; Electro-thermotherapy; Trigger-points; Myofascial trigger-points; Myositis; Localised fibromyalgia; Randomised controlled trial

1. Introduction

Ultrasound therapy has achieved recognition as a suitable method in physical medicine in treatment of acute and chronic musculoskeletal disorders. Ultrasound consists of sound waves with a frequency of more than 20 000 Hz/s, well beyond the range of human hearing. The sound waves are absorbed differently in tissue with low and high protein content. Experimental studies have shown that it is possible to heat deeper structures, such as joints, muscle and bone, with ultrasound (Bender et al., 1953; Gersten, 1953; Lehmann et al., 1968). Despite extensive research into the mechanism of how ultrasound works, no conclusive explanation of the suggested beneficial effect of ultrasound has been found.

Two basic diagnostic features of myofascial trigger-points (MTrP) are local tenderness and alteration in consistency. Attempts to characterise the pathology of MTrP have been disappointing (Gerwin, 1994; Goddard et al., 1994; Granges and Littlejohn, 1993; King and Goddard, 1994). The clinical diagnose, however, based on local tenderness, alteration in consistency and 'jump sign' (patient vocalisa-

* Corresponding author. E-mail: arnegam@dadlnet.dk

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tion or withdrawal) have shown to be acceptable with regards to interrater reliability (Fisher, 1988). At the present it is still unknown if MTrP is purely secondary to joint and bone disorders or exist as a single disorder (Dreyfuss et al., 1994; Sluka, 1996; Friedman and Nelson, 1996).

Based on these findings we decided to carry out a study addressing the following questions:

Has ultrasound combined with massage and exercise any effect on neck and shoulder pain?

Does ultrasound, massage and exercise reduce the number of trigger-points, consistency and tenderness?

2. Method

The study was approved by the local ethical committee. During a period from January 1st to December 1st 1995 all patients referred to the department of rheumatology at Bispebjerg Hospital out-patient clinics were asked to participate in trial if they meet the following criteria.

2.1. Inclusion criteria

1. Age between 18 and 60.
2. Trigger-points in the neck and shoulder region and having a duration more than 3 months with an intensity disturbing normal daily activity.
3. Reproduction of the patients pain complaints by palpation of trigger-points.
4. The number of trigger-points less than 10.
5. The patients should be capable of following the demands inherent in the trial.
6. Correct daily recorded Visual Analogue Scales (VAS) for pain at rest and on normal daily function a week before entrance in study.

2.2. Exclusion criteria

1. Signs of cervical discus prolapse, systemic disorder or migraine.
2. Changes in medication or other treatments 3 weeks prior to entrance.
3. Pregnancy.

2.3. Flow in study

The total duration of the study for each patient was 6 month. After a clinical examination by one of the physicians participating in trial, the patients that fulfilled the inclusion criteria were invited to participate in the trial, verbal as well as written information was given to the patients. The patients were then randomised by the envelope method to either massage, exercise with ultrasound (A) or sham-ultrasound (B) or to a control (C) group given no treatment. After 1 week the treatment groups were given the first treatment session. If the registration cards were correctly filled out the patient was included in the study. The treatment period was 4 weeks with two sessions per week, giving a total of eight treatment sessions. The ultrasound treatment was carried-out such that neither the physician, the physiotherapist nor the patient knew whether it was ultrasound or sham-ultrasound. The code was broken after data-analysis.

2.4. Outcome measures

The physician palpated the number of MTrP and marked the size, consistency and tenderness on a drawing, using a score from 0 to 3:0 indicating increased consistency but where palpation produced no pain; 1, increased consistency but the patient indicated only pain after being asked; 2, increased consistency and the patient spontaneously expressed pain; 3, increased consistency and the patient withdraw from the palpation (jump sign). An index-score was made from the sum of the scores at each treatment session. The total number of MTrP and index-scores were used as effect variables.

One week before entrance in the study the patients daily recorded the pain level on a VAS-scale (rest and normal daily activity (function)) and daily analgesic usage as type and number of tablets per day. The VAS-scale was 10 cm long with no anchors between the ends, which were indicated by 1 (no pain) and 10 (unbearable pain) (Carlsson, 1983; Scott and Huskisson, 1979).

At each session the number, size and tenderness of MTrP were palpated and registered by the physiotherapists by the same method as the physician at inclusion. After each session the registrations cards were collected by a person without connection to the trial. The same procedure was used with the VAS-scale and analgesic usage registration after each treatment week.

To test the blinding procedure the treating physiotherapist was asked at the last treatment session, if they thought the patient had received treatment with ultrasound or sham ultrasound. The patients were asked the same question at the final examination.

At final examination the patient was asked whether the treatment had been satisfying (global preference). After 6 months the patients received a follow-up questionnaire regarding long term effect of the treatment.

2.5. Treatments

Six physiotherapists participated in the trial. All physiotherapists had experience in treating these kind of symptoms. Prior to the study all physiotherapists received instruction and training in procedures used in the study.

At each treatment the physiotherapist palpated the region by using Kieblers test and palpation. The MTrP (number, size and tenderness) were recorded as described previously.

Ultrasound and then massage were applied to a maximum of the five most tender trigger-points followed by a standar-

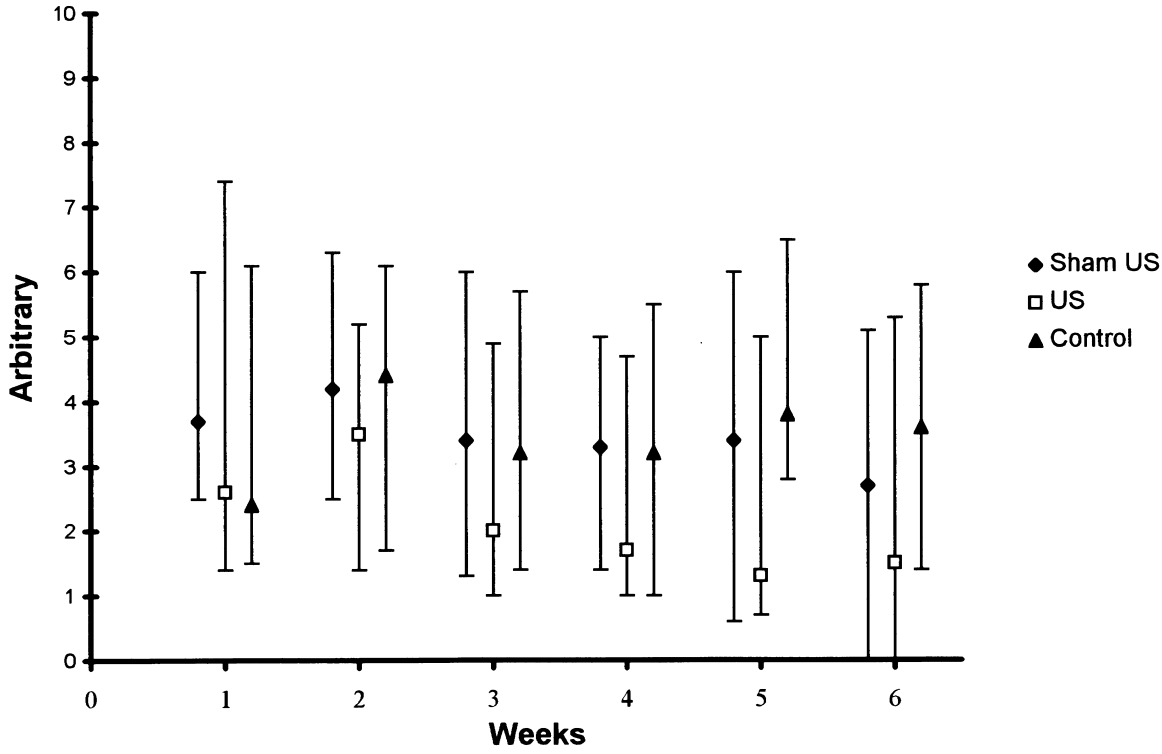

Fig. 1. Visual analog scale at rest given as median and 25th and 75th percentiles.

dised exercise programme. The exercise programme was also handed out to the patients for home training.

Before treatment Sonogel was applied on the skin covering the area of the MTrP, the soundhead applied and then the apparatus switched on. The physiotherapists were instructed to keep the soundhead in contact and at right angles to the skin at all times.

The frequency was 100 Hz, pulse = 2:8 and the intensity was 3 W/cm^2. The treatment time was 3 min per soundhead. The radiation area was 0.8 cm^2. The treatment was applied with circular movements. The total given dose varied depending on how many MTrP that were found with maximum treatment time of 15 min.

Initially after the ultrasound the patient received massage consisting of transverse frictions on the MTrP followed by myofascial technique applied on the involved muscle-groups. The maximum duration of this was 10 min.

The home training programme for the neck/shoulder region consisted of six exercises focusing on strength and mobility for the neck and shoulder region. The programme also included stretching of the involved muscle groups.

The patient was carefully instructed in and carried out the whole exercise programme the first two times at the clinic. At subsequent treatment-sessions the patients' home training programme was examined and the exercises which the patient found difficult were reinstructed. At the first two sessions 30 min were spent on the exercise programme. The following 3 weeks a maximum of 15 min were used on the exercise programme together with the physiotherapist. The patients were asked to do the exercise programme at home once a week.

2.6. Apparatus

The ultrasound equipment was delivered by the firm Kebo Care (former Enraf Nonius) and consisted of three identical apparatus of the type Sonopuls 590 with six soundheads. Three soundheads were active and three were sham. The six soundheads looked identical and could not be distinguished when handled in the normal way. At each apparatus had one active soundhead and one sham. During the study all apparatus were controlled every 3rd month by the producer.

2.7. Control group

The control group recorded pain level (VAS-scales) and analgesic usage throughout the 6 weeks. At the final consultation they were offered treatment (ultrasound, massage, exercise). Only data on patients that accepted treatment was included in the results of the questionnaire at 6 months.

2.8. Statistic

With a sample-size of 16 patients (SD of 3.0, type 1 and 2 errors of 5% and 10%, respectively) the smallest significant difference would be 2.5 on a VAS-scale. Statistical analysis

Table 1
Inclusion data

Treatment group	Sham ultrasound No. 22			Active ultrasound No. 18			Control group No. 18		
	50	25	75	50	25	75	50	25	75
Age (years)	42	33	48	39.5	28.5	52.3	38.5	30.7	42.3
Duration (months)	7.5	3	12	4	1.4	15	12	4.8	24
MTrP	4	2.8	6	4	3	6	5.5	4	7
Index	10	5	13.5	11.5	5	15.3	12.5	9.8	16.3

Data at inclusion. Median = 50, percentiles 25 and 75. A Mann–Whitney test showed no significant difference at inclusion.

was done using the PC program SPSS. Non-parametric statistical tests was used.

3. Results

The total of 67 patients were initially included in the trial, but nine dropped out during the study for the following reason: one was suspected for having a cervical discusprolaps, one was hospitalised for a gynaecological disorder, the rest did not show up to the treatment sessions. Data for the patients included are given in Table 1. The data at inclusion were tested for homogeneity using Mann–Whitney test for independent data and no significant difference was found between drop outs and included patients.

Fifty-eight patients were included in the final analysis of the study. Eighteen received active ultrasound treatment (A), 22 sham treatment (B), and 18 in the control group (C). Data at inclusion is given in Table 1. No statistical significant difference were found between the groups in respect to age, duration of symptoms, gender, number of trigger-points or index at entry.

At all times no significant differences were found in the pain-scores (VAS) at rest and on function between group A, B and C. Results are given in Figs. 1 and 2.

There were no differences found between the groups in analgesic usage at all times. The majority of the patients did not use analgesic. Distinction was not made between non-steroid anti-inflammatory drugs (NSAID) and paracetamol, only the total number of tablets were used. In Fig. 3 the data of the analgesic usage is shown.

The result of MTrP- and index scores showed a significant reduction in the number and tenderness of MTrP for groups A and B, at the end of the study, compared to group

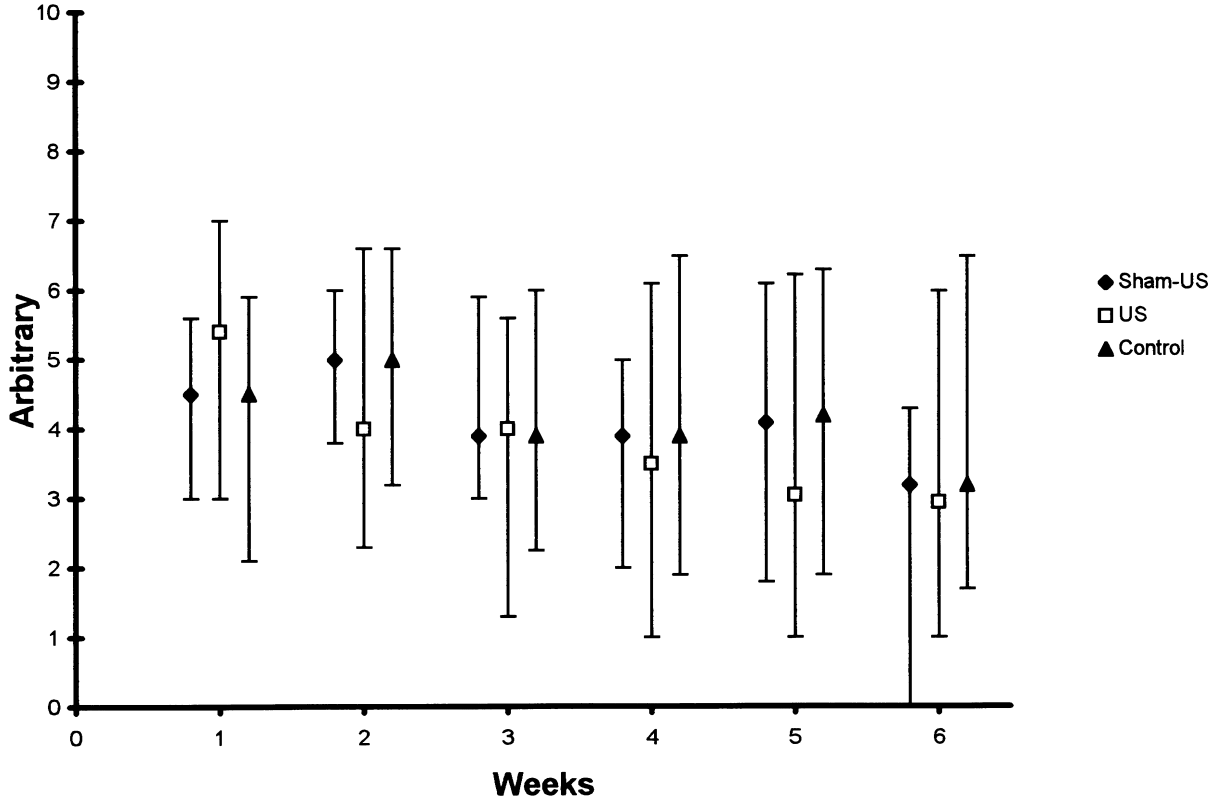

Fig. 2. Visual analog scale on function given as median and 25th and 75th percentiles.

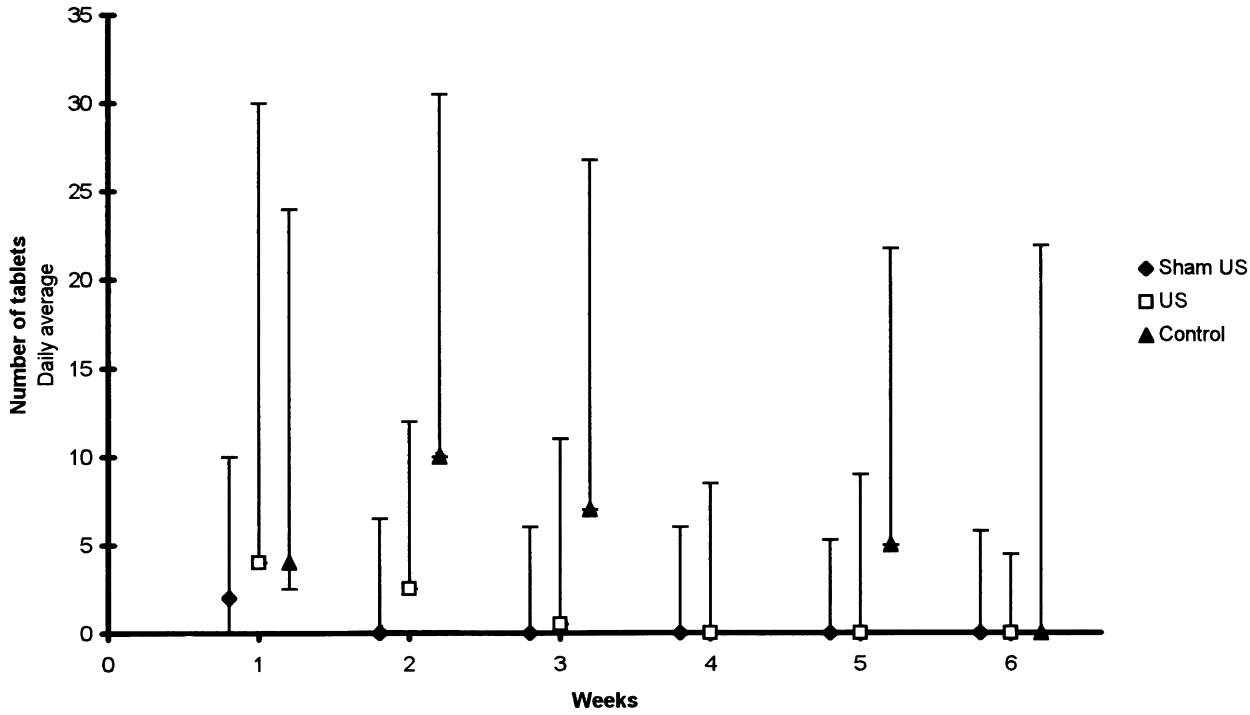

Fig. 3. Analgesic usage given as median and 25th and 75th percentiles.

C ($P < 0.05$). Results are given in Figs. 4 and 5.

In the above, the Kruskal–Wallis one-way ANOVA test was used.

No difference between groups A and B were found in global preference (Pearson's test). In group A, 14 responded with good effect, four no effect and four did not know. In group B, 13 responded good effect, four no effect and one did not know.

The blinding was tested by asking the physiotherapists at the last treatment session and the patients at the final examination, if they thought the treatment had been active (A) or not (B), there was found to be no difference (Pearson's test), indicating that the blinding was sufficient. Results are shown in Table 2.

Forty-four patients responded on the 6-month follow-up questionnaire, which is 75% of the total number of patients included. From the control group 12 patients had treatment and only these were included in the data, which gives a

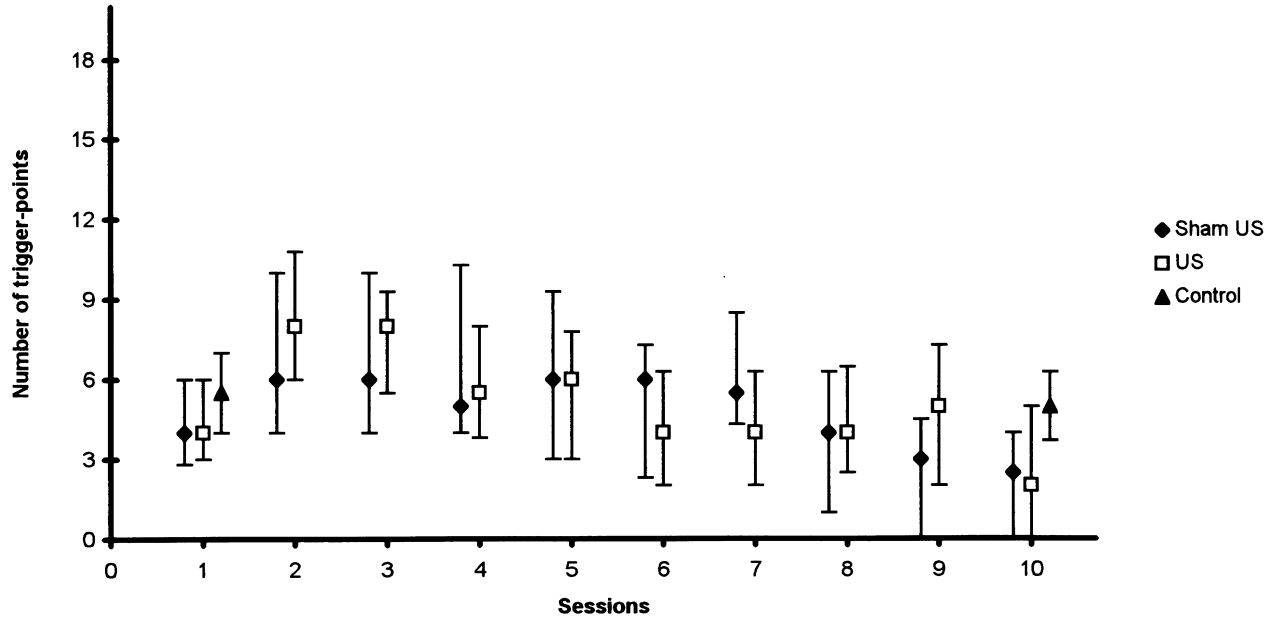

Fig. 4. Trigger-points given as median and 25th and 75th percentiles ($P < 0.05$).

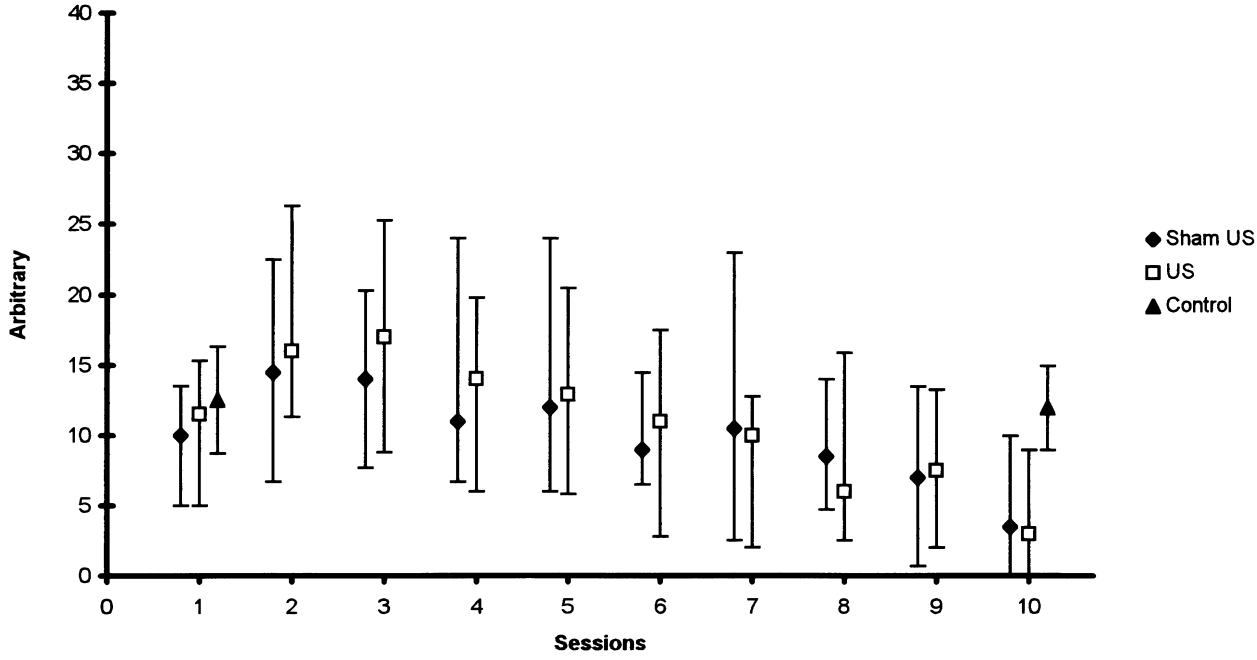

Fig. 5. Index scores given as median and 25th and 75th percentiles ($P < 0.05$).

response rate on 88% of those who were given treatment. No difference between the groups given ultrasound or sham were found (Kruskal–Wallis one-way ANOVA test). Sixty-four percent of the patients said that they got a good or some effect from the treatment (Table 3). Sixty-eight percent of the patients were still doing the given exercise programme after 6 months (Table 4). Six patients (17%) had received other forms of therapy in the period.

4. Discussion

This study showed that the treatment groups (massage, exercise) had a reduction of number and intensity of myofascial trigger-points (MTrP) compared with a control group, but no difference in ultrasound (US) versus sham with respect to reducing pain assessed by analgesic usage, visual analogue scale (VAS) on function and at rest.

Neck and shoulder pain is common, with a estimated point prevalence of nearly 13% and a lifetime prevalence of 50% (Bovim et al., 1994; Horal, 1969). Different conservative management of mechanical neck pain have been tested with conflicting results and at the present no treatment strategy is generally accepted (Aker et al., 1996).

US is being used in physical medicine to relieve pain and joint immobility. Many papers have been published on the issues of the effect of ultrasound in musculoskeletal disorders, but a published meta-analysis (Gam and Johanssen, 1995) found no documentation that US can relief pain. The literature was generally of poor quality and only one randomised controlled trial (RCT) (Falconer et al., 1992) tested the effect of US in facilitating exercise by increasing joint mobility and relieving pain. In this study, no differences were found between the two groups treated either with ultrasound or sham-ultrasound combined with exercise with respect to range of motion, reduction in pain, or gait velocity.

Two controlled studies treating myofascial pain dysfunction with electrotherapy (Roman, 1960; Talaat et al., 1986),

Table 2
Test of blinding procedure

Treatment given Physiotherapist impression	A No	B No	Treatment given Subject impression	A No	B No
Ultrasound	8	13	Ultrasound	12	9
Sham US	11	1	Sham US	3	5
Don't know	3	4	Doń know	7	4
Total	22	18	Total	22	18

Impression of which treatment was given as indicated by the physioterapists and patients compared with treatment actually given (A, active ultrasound; B, sham-ultrasound). Pearson's test non-significant.

Table 3
Global preference after 6 months

Effect	Treatment A	Treatment B	Control
Good	5 (23)	4 (22)	0
Some	5 (23)	5 (27)	9 (50)
Little	5 (23)	3 (17)	1 (0,5)
No	3 (14)	4 (22)	0
Total	18	16	10
Missing data	4 (18)	2 (11)	8 (44)*

Data given as number of subject (no. 58). *Six subjects in the control group received no treatment, two because they were spontaneously symptom-free. Numbers given in parentheses are percentages of the total number of subjects included in the group.

Table 4
Exercise frequency after 6 months

Treatment	Sham-US	US	Control
Daily	4	1	3
Weekly	8	7	6
Rare	1	1	1
Never	5	7	0
Total	18	16	10
Missing data	4	2	8*

Exercise frequency after 6 months. *Six subjects received no treatment, two because they were spontaneously symptom free.

including US, found significant effect in reducing pain. The problem with these studies was that they gave no information about where the US was given and that the outcome measures used had low validity (5- and 4-graded rank scales).

More promising results have been obtained by treating neck and shoulder pain with strength (power) training, alone or in combination with passive physiotherapy (Levoska and Keinnen-Kiukaanniemi, 1993; Berg et al., 1994; Ylinen and Ruuska, 1994). In the study of Levoska and Keinnen-Kiukaanniemi female industrial workers with neck and shoulder complaints were treated with either active physiotherapy (muscle training) or passive physiotherapy (surface heat, massage, stretching). The conclusion was in favour of active physiotherapy with better effect on neck and shoulder pain immediately after treatment and a reduction in cephalagy at 1-year follow-up.

The over-all conclusion of the present study is that US give no pain reduction, but apparently massage and exercise reduces the number and intensity of MTrP, but this reduction had little impact on the patients neck and shoulder complaints. The result of the follow-up questionnaire showed that only six patients had received additional treatment 6 months after completing the study.

Studies are necessary to evaluate the best way to handle neck and shoulder pain, including investigations into the importance of sufficient patient information about different aspects of neck and shoulder pain (Keefe, 1996).

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