Randomized Controlled Trial of Pulsating Cupping (Pneumatic Pulsation Therapy) for Chronic Neck Pain

Holger Cramer[a]   Romy Lauche[a]   Claudia Hohmann[a]   Kyung-Eun Choi[a]   Thomas Rampp[a]
Frauke Musial[a,b]   Jost Langhorst[a]   Gustav Dobos[a]

[a] Chair of Complementary and Integrative Medicine, University of Duisburg-Essen, Germany
[b] The National Research Center in Complementary and Alternative Medicine (NAFKAM), Department of Community Medicine Faculty
  of Health Science, University of Tromsø, Norway

Summary

Background: Pneumatic pulsation therapy may combine the effects of cupping therapy and massage. This study investigated the effect of pneumatic pulsation therapy on chronic neck pain compared to standard medical care. **Methods:** 50 patients (79.15% female; 46.17 ± 12.21 years) with chronic nonspecific neck pain were randomized to treatment group (TG; n = 25) or control group (CG; n = 25). The TG received 5 pneumatic pulsation treatments over a period of 2 weeks utilizing a mechanical device. Treatment was applied as a combination of moving and stationary pulsating cupping. Main outcome measure was pain intensity in pain diaries (numerical rating scale). Secondary outcome measures included functional disability (NDI), quality of life (SF-36), and pain at motion. Sensory thresholds, including pressure pain threshold, were measured at pain-related sites. **Results:** After the intervention, significant group differences occurred regarding pain intensity (baseline: 4.12 ± 1.45 in TG and 4.20 ± 1.57 in CG; post-intervention: 2.72 ± 1.62 in TG and 4.44 ± 1.96 in CG; analysis of covariance: p = 0.001), NDI (baseline: 25.92 ± 8.23 and 29.83; post-intervention: 20.44 ± 10.17 and 28.83; p = 0.025), and physical quality of life (baseline: 43.85 ± 7.65 and 41.66 ± 7.09; post-intervention: 47.60 ± 7.93 and 40.49 ± 8.03; p = 0.002). Further significant group differences were found for pain at motion (p = 0.004) and pressure pain threshold (p = 0.002). No serious adverse events were reported. **Conclusion:** Pneumatic pulsation therapy appears to be a safe and effective method to relieve pain and to improve function and quality of life in patients with chronic neck pain.

Zusammenfassung

Hintergrund: Schröpfen und Massage haben sich als wirksam in der Behandlung chronischer Nackenschmerzen erwiesen. In dieser Studie wurde die Effektivität der Pneumatischen Pulsationstherapie, die als Kombination beider Verfahren betrachtet wird, im Vergleich zur Standardtherapie bei chronischen Nackenschmerzen untersucht. **Methoden:** 50 Patienten (79,15% weiblich; 46,17 ± 12,21 Jahre) mit chronischen unspezifischen Nackenschmerzen wurden in eine Behandlungsgruppe (BG; n = 25) und eine Kontrollgruppe (KG; n = 25) randomisiert. BG-Patienten wurden in einem Zeitraum von 2 Wochen insgesamt fünfmal mit Pneumatischer Pulsationstherapie, einer Kombination aus pulsierender Schröpfkopfmassage und pulsierendem Schröpfen, behandelt. Die Pulsation wurde mit Hilfe eines medizinischen Gerätes erzeugt. Hauptzielkriterium war Schmerzintensität, die mit Hilfe eines Schmerztagebuchs (numerische Rating-Skala) erfasst wurde. Nebenzielparameter waren funktionelle Einschränkungen (NDI), Lebensqualität (SF-36) und Bewegungsschmerz. Im schmerzhaften Bereich wurden sensorische Messungen, inklusive der Erfassung der Druckschmerzschwelle, durchgeführt. **Ergebnisse:** Nach der Intervention fanden sich signifikante Gruppenunterschiede bezüglich Schmerzintensität (vor Intervention: 4,12 ± 1,45 in der BG und 4,20 ± 1,57 in der KG; nach Intervention: 2,72 ± 1,62 in der BG und 4,44 ± 1,96 in der KG; Kovarianzanalyse: p = 0,001), NDI (vor Intervention: 25,92 ± 8,23 und 29,83; nach Intervention: 20,44 ± 10,17 und 28,83; p = 0,025) und körperbezogener Lebensqualität (vor Intervention: 43,85 ± 7,65 und 41,66 ± 7,09; nach Intervention: 47,60 ± 7,93 und 40,49 ± 8,03; p = 0,002). Weitere signifikante Gruppenunterschiede traten beim Bewegungsschmerz (p = 0,004) und der Druckschmerzschwelle (p = 0,002) auf, ein Zeichen für eine verringerte Hyperalgesie. Schwere unerwünschte Ereignisse traten nicht auf. **Schlussfolgerung:** Pneumatische Pulsationstherapie scheint eine sichere und effektive Methode zur Behandlung chronischer Nackenschmerzen darzustellen. Zukünftige Studien sollten etwaige Langzeitwirkungen untersuchen.

Holger Cramer
Klinik für Naturheilkunde und Integrative Medizin
Knappschafts-Krankenhaus, Kliniken Essen-Mitte, Am Deimelsberg 34a
45276 Essen, Germany
Tel. +49 201 174-25054, Fax -25000
h.cramer@kliniken-essen-mitte.de

Introduction

Neck pain is a common ailment in industrialized countries, afflicting about 40% of adults in a given year [1]. Each year about 10% of adults suffer from chronic neck pain [2], up to 11% of adults report that their activities are limited [3], and about 5% are significantly disabled by neck pain [4]. Thus, neck pain represents an important socioeconomic burden to society.

Degenerative changes of the cervical spine are poorly correlated with the severity of symptoms [5]. Rather, chronic neck pain is clearly associated with psychological [6, 7], social, and occupational factors [6, 8]. Thus, most patients are diagnosed as having nonspecific neck pain, which is not attributed to degenerative changes or injuries [9]. Stress, anxiety, and postural deficits cause increased muscle tonicity and pain, which individuals sustain by adopting relieving postures [10]. Chronic pain and muscle spasm may cause irritation of the local innervation and alter regional and central pain processing [11]. This may result in regional hypersensitivity to noxious stimuli such as pressure or heat [12, 13].

The standard treatment for patients with chronic neck pain is pain medication [14], but more than half of the patients seek complementary treatments [15]. However, there is limited evidence of effectiveness for complementary as well as for conventional treatments [16, 17]. Therapies involving exercises, manual therapy, or massage are most effective for patients with neck pain [16].

One complementary method used to treat musculoskeletal conditions is cupping. A method of traditional medicine widely used in Asian, Middle Eastern, and European countries, cupping utilizes a glass or bamboo cup or a mechanical device to create suction on the skin and underlying tissue [18]. With dry cupping the cups are applied to the intact skin, while with wet cupping the skin is incised before the cups are applied [18].

Wet cupping appears to be effective in treating low back pain [19], brachialgia paresthetica nocturna [20], and carpal tunnel syndrome [21], while a recent pilot study has indicated that dry cupping may help alleviate chronic neck pain [22].

A newly developed modification of dry cupping designed to combine the effects of cupping with those of massage is pneumatic pulsation therapy. This method utilizes a mechanical device that produces a pulsating vacuum instead of one of stable negative pressure [23]. Cupping [18] and massage [24] are both thought to increase regional blood flow. This might normalize the pathological low blood flow in musculoskeletal disorders, such as neck pain [25]. However, no scientific literature on pneumatic pulsation therapy is available.

This trial compared the effects of a series of 5 pneumatic pulsation therapy treatments with that of standard medical care in alleviating chronic nonspecific neck pain. It was hypothesized that patients receiving pneumatic pulsation therapy would have greater improvements in pain intensity, functional disability, and quality of life.

Methods

Design

This was a randomized unblinded clinical trial. Patients were randomized, one by one, to the treatment group (TG) or the control group (CG) using randomly varying block lengths. Software was used to create random numbers. Randomization was carried out by means of sequentially numbered, sealed opaque envelopes, prepared by the study coordinator, who was neither involved in treatment nor evaluation. At baseline assessment, patients filled out questionnaires relating to their neck pain, and sensory threshold measurements were taken. Over the next 2 weeks the TG patients received 5 pneumatic pulsation therapy treatments, while CG patients continued with self-directed standard medical care. Both groups were asked to record in a daily diary the intensity of their neck pain, medical care they received, and pain medication they had taken. Patients attended a post-intervention assessment 2.5 weeks after baseline assessment. The institutional ethics committee of the medical institutions at the University of Duisburg-Essen approved the study protocol. All study patients gave their informed consent in writing before randomization.

Patients

Study patients were recruited by means of a press release and initially screened via a standardized telephone interview. Potential participants were then seen by a study physician, who took their medical histories and performed the physical examinations. To be included in the study, patients (male or female) needed to be 18–75 years old and to have had nonspecific neck pain for at least the previous 3 months. The mean pain intensity had to be at least 4 on an 11-level numerical rating scale (NRS), with '0' meaning 'no pain' and '10' meaning 'worst pain imaginable'.

Exclusion criteria included radicular syndrome, congenital deformity of the spine, spinal stenosis, inflammatory rheumatic disease, active oncologic disease, major depression, insulin-dependent diabetes mellitus, and pregnancy. Patients were not included if they had had invasive treatment of the spine within the previous 4 weeks or spinal surgery within the previous 12 months. Since pneumatic pulsation therapy exposes the treated area of skin and tissues to shear and strain, patients were excluded if they were taking oral steroids or anticoagulants or if they had hemophilia or a skin condition in the area to be treated. In addition, patients who had started a new treatment for neck pain within the previous month or were planning to start a new treatment within the next month were excluded.

Interventions

Pneumatic Pulsation Therapy

Patients in the TG received 5 semi-standardized pneumatic pulsation treatments [23] over a period of 2 weeks, 1 treatment every 3–4 days.

Treatment was performed using a Pneumatron® 200S (Pneumed GmbH, Idar-Oberstein, Germany). With this mechanical device, pulsating electromechanical suction is applied to 1–4 glass (ø 6–56 mm) or silicone (ø 16–130 mm) cups that can be placed on the area of skin to be treated. Reduction of pressure (adjustable between –0.01 and –0.8 bar) and atmospheric pressure itself are alternated by a fixed frequency of 200 cycles/min, causing the skin and subdermal tissues under the cup to oscillate.

Each treatment session consisted of 2 steps:

Examination: The patients, who lay prone on a massage table with their neck/shoulder region bared, were examined to evaluate muscle tension and myofascial trigger points. Those areas where manual pressure and lifting of the skin caused the most discomfort were chosen for treatment.

Treatment: Arnica massage oil (Weleda AG, Schwäbisch Gmünd, Germany; ingredients: sunflower oil, olive oil, *arnica montana* extract,

betula alba leaf extract, and natural essential oils) was applied to the neck and shoulder region. A 38-mm diameter glass cup was placed on the skin and was stroked over the painful region in sweeping movements. Negative pressure intensity was adjusted according to the patient's sensitivity to elicit the sensation of strong but comfortable oscillation. Normally, 50–70% of maximal pressure reduction (corresponding to an absolute pressure of approximately 0.60–0.44 bar) was chosen. Mainly the trapezius, levator scapulae, and semispinalis capitis muscles were treated for 10–15 min depending on the location and intensity of the individual's pain.

Next, 4 stationary 130-mm diameter silicone cups were placed on the trapezius muscle. Again, negative pressure intensity was adjusted to the patient's sensitivity. The cups were removed after 5–10 min.

Standard Medical Care

Treatment in the CG was not regulated, but patients continued self-directed standard medical care (SMC) with their general practitioner or orthopedist. In Germany, SMC for neck pain mainly comprises physiotherapy, sports activities, and analgesics as needed [26]. Patients were allowed to use all such treatments, but no complementary therapies, e.g., acupuncture or homeopathy. Patients were asked not to change their treatment regimen during the course of the study and to record pain medications and other treatments for neck pain in their diaries. Control patients were waitlisted and offered to receive the same treatment as the TG when the trial was concluded.

Outcome Measures

Primary Outcome Measure

Patients recorded the intensity of their neck pain in a daily diary for 7 days prior to randomization and 18 days after randomization. Pain intensity was assessed 3 times a day (in the morning, at midday, in the evening) on an 11-level NRS. The pretreatment ratings (the 7 days prior to randomization) were averaged and served as the baseline measurement of neck pain intensity. Since the intervals of time between treatments differed (1 treatment every 3–4 days), pain ratings after each treatment were averaged using all 3 ratings on treatment day and on each day following treatment day until the day preceding the next treatment.

Secondary Outcome Measures

Pain at motion: Patients were asked to successively carry out 6 different movements of their heads (flexion, extension, lateral flexion right/left, and rotation right/left) and to rate the intensity of pain induced by each motion on a 10 cm visual analog scale (VAS) [27].

Neck-related function and health-related quality of life: Functional disability was measured using the neck disability index (NDI) [28], a 10-item reliable instrument to measure limitations in the activities of daily living due to neck pain. Scores may range from 0–100 with higher ratings indicating poorer function. Health-related quality of life was assessed using the short form 36-health survey questionnaire (SF-36) [29], a 36-item reliable instrument to assess 8 dimensions of general health (physical functioning, physical role functioning, bodily pain, general health perceptions, vitality, social role functioning, emotional role functioning, and mental health) and 2 sum scores (physical and mental). Scores may range from 0–100 with higher ratings indicating a better quality of life. Perceived change in health status was recorded on an unscaled item.

Sensory Measurements

Pressure pain threshold, mechanical detection threshold, and vibration detection threshold were measured a) at the site of maximal pain, which the patient indicated on a pain diagram, and verified by physical examination, and b) in an adjacent region, 1–2 cm outside the painful area. Thresholds determined at 2 control sites, the right hand and foot, served as measures of intra-observer reliability.

Measurements were performed according to the quantitative sensory testing protocol [30]. Pressure pain threshold was measured using an electronic algometer (Somedic Sales AB, Hörby, Sweden) with a 1 cm^2 circular probe. Pressure was applied at a rate of 50 kPa/s to the neck, to the thenar eminence, and over the abductor hallucis muscle. The patients pressed a switch to indicate when the sensation changed from pressure alone to pressure and pain. The pressure applied at that point in time was recorded. It was stressed to the patients that their pain threshold was being measured, not their pain tolerance. The log-transformed arithmetic mean of 3 threshold determinations was calculated for each test site [30]. The intra-observer reliability (Pearson's r) was 0.71 for the hand and 0.70 for the foot.

Mechanical detection threshold was measured with a set of von Frey filaments (Somedic Sales AB) that exert forces between 0.26 and 1,080 mN. The threshold was determined by the method of limits, whereby the stimulus intensity is decreased until the patient can no longer perceive the touch and is then increased until the patient first perceives the touch again. Five series of descending and ascending stimulus intensities were made. The final threshold was the log-transformed geometric mean of these 5 series [30]. The intra-observer reliability was r = 0.70 for the hand and r = 0.60 for the foot.

To measure the vibration detection threshold, a Rydel-Seiffer tuning fork (64 Hz, 8/8 scale) was placed over a bony prominence (a spinal process, the ulnar styloid process, or the medial malleolus) and patients were instructed to report when the sensation of vibration ceased. The arithmetic mean of 3 threshold determinations was calculated [30]. The intra-observer reliability was r = 0.81 for the hand and r = 0.80 for the foot.

Statistical Analysis

The study was powered to detect an effect size of the primary outcome measure of 0.87, which was estimated based on the findings of a pilot study on dry cupping in chronic neck pain [22]. To detect this effect with 80% power and a 2-sided α of 0.05, a sample of 44 patients was needed. To account for possible dropouts, a sample of 50 patients was chosen.

All outcome measures were analyzed based on the intention-to-treat population. Missing data were replaced by carrying the last observation forward. Neck pain intensity (pain diaries) was analyzed with a repeated-measures analysis of covariance (ANCOVA) [31], which took 'time' as the within-subject factor, 'group' as a between-subject factor, and the baseline measure as a linear covariant. All other parametric outcome criteria were analyzed with univariate ANCOVAs with 'group' as a between-subject factor and the respective baseline value as a linear covariant. The SF-36 'change in health status' was analyzed by means of the Mann-Whitney U-test.

A p value of <0.05 was considered statistically significant for all statistical tests. P values were adjusted for multiple testing according to Bonferroni, i.e., for pain intensity with 5 post-hoc tests and for SF-36 with 10 subtests. For primary outcome measure, effect size (Cohen's d) was calculated as the group difference in post-treatment pain intensity, divided by the pooled standard deviation, subtracted by the group difference in baseline pain intensity, and divided by the pooled standard deviation.

Results

Patients

Between August 2009 and July 2010, 109 patients were screened for eligibility, of whom 59 were ineligible. The most common reasons for exclusion were minor neck pain,

Cramer/Lauche/Hohmann/Choi/Rampp/ Musial/Langhorst/Dobos
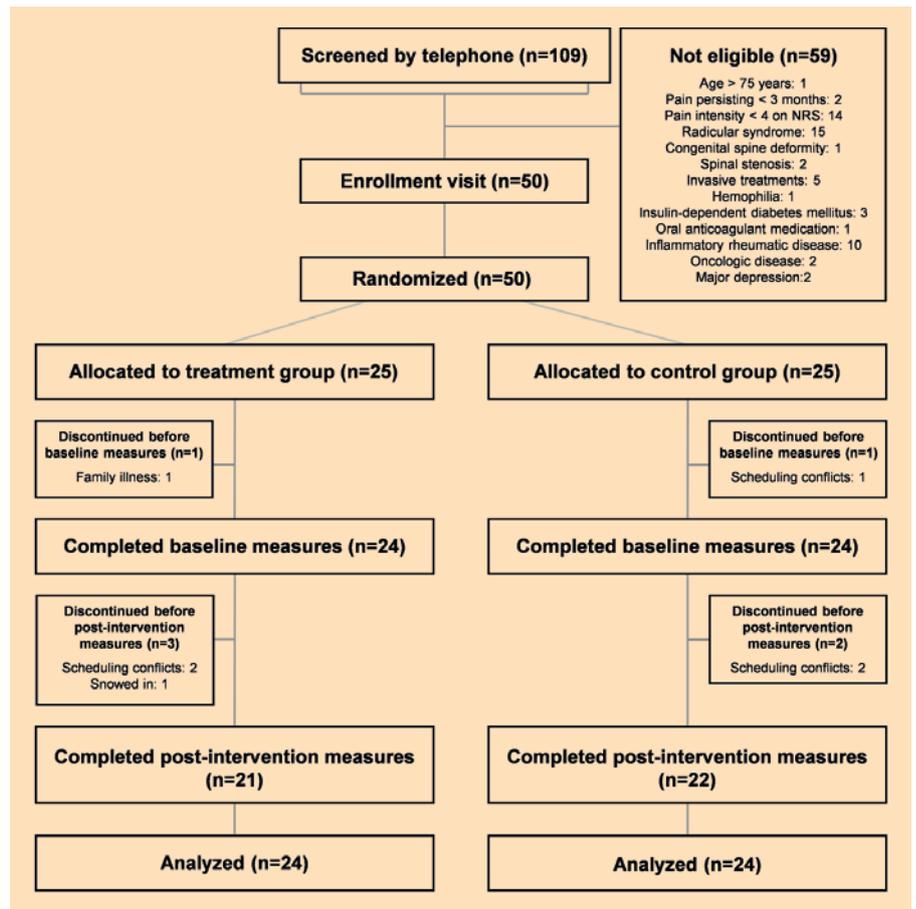
Fig. 1. Participant flow diagram.

radicular syndrome, and inflammatory rheumatic diseases (fig. 1). Of the remaining 50 patients, 25 were randomized to the TG and 25 to the CG. One patient in each group discontinued the study before baseline assessment. Three patients in the TG and 2 patients in the CG were lost to follow-up. Since statistical analyses were based on the intention-to-treat population, missing values for patients completing baseline assessment but discontinuing before post-intervention assessment were replaced by carrying the last observation forward.

No significant differences between groups at baseline were found in demographic characteristics, neck pain characteristics, or treatment expectations (table 1).

During the 7 days prior to randomization, the TG patients used a mean of 0.13 ± 0.29 of the defined daily dose (DDD) [32] of an analgesic and the CG patients used a mean of 0.09 ± 0.13 of the DDD. During the treatment period, the mean daily use of pain medication fell to 0.07 ± 0.17 (–49.4%) of the DDD in the TG and to 0.07 ± 0.11 (–21.9%) of the DDD in the CG (p = 0.735). Prior to randomization, TG patients received 0.21 ± 0.72 physiotherapy treatments (PT) per week and patients in the CG received 0.17 ± 0.38 PT per week. During the treatment period, TG patients received 0.13 ± 0.49 PT and CG received 0.24 ± 0.63 PT per week (p = 0.474).
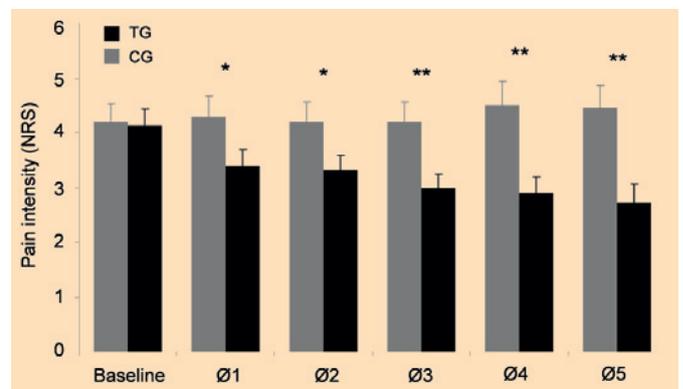
Fig. 2. Mean ratings of perceived pain intensity (+SEM) for the treatment group (TG) and the control group (CG). Mean pretreatment ratings (baseline) and mean ratings following each treatment (Ø1–Ø5) are depicted. P values from Bonferroni corrected post-hoc tests are indicated as: *p < 0.01; **p < 0.002.

Outcome Measures

Primary Outcome Measure

A repeated measurement ANCOVA of pain intensity revealed a significant group × time interaction (p = 0.038). At baseline, the mean pain intensities were 4.12 ± 1.45 and 4.20 ± 1.57 for the TG and the CG, respectively. After the first treat-

Table 1. Means (± SD) of baseline characteristics

	TG (n = 24)	CG (n = 24)	Group difference (95% CI)	p value
Demographic characteristics				
Age	44.46 ± 10.79	47.88 ± 13.50	–3.53 (–10.52; 3.68)	0.34
Women / men	83.3% / 16.7%	75% / 25%	N/A	0.48
Neck pain characteristics				
Duration, months	107.04 ± 101.84	107.17 ± 87.18	–0.13 (–55.21; 54.96)	1.00
Pain intensity[a]	4.12 ± 1.45	4.20 ± 1.57	–0.07 (–0.99; 0.85)	0.88
Functional disability	25.92 ± 8.27	29.17 ± 9.65	2.59 (–8.47; 1.97)	0.22
Bothersomeness[b]				
VAS	4.45 ± 2.17	4.18 ± 1.90	0.28 (–0.91; 1.46)	0.64
Days/month	1.40 ± 2.27	1.40 ± 2.21	0.00 (–1.30; 1.30)	1.00
Treatments previously used, %				
Spinal operations	4.2	0.0	N/A	0.32
Pain medication	75.0	66.7	N/A	0.53
Treatment expectation (VAS)[c]	8.03 ± 1.68	7.49 ± 1.98	0.54 (–0.53; 1.61)	0.32

[a]Mean pretreatment pain intensity in the pain diary.
[b]Patients were asked to rate the average bothersomeness on a 10 cm VAS and to rate how many days they were seriously bothered by their neck pain the previous three month.
[c]Patients were asked to rate their expectations of the pneumatic pulsation therapy on a 10 cm VAS scale from 0 = 'not effective at all' to 10 cm = 'most effective'.
TG = Treatment group; CG = control group; VAS = visual analog scale.

Table 2. Baseline scores, post-intervention scores and treatment effects on pain at motion, functional disability and health-related quality of life (SF-36). Means (± SD) are shown

	TG		CG		Group difference	p value[a]
	Baseline	post-intervention	baseline	post-intervention	(95% CI)	
Pain at motion (sum)	24.84 ± 11.93	16.73 ± 11.57	22.05 ± 8.74	26.15 ± 10.00	–11.22 (–16.24; –6.20)	*<0.001*
Pain at motion (maximum)	6.00 ± 2.38	3.52 ± 2.65	5.29 ± 1.90	5.03 ± 2.18	–1.90 (–3.16; –0.63)	*0.004*
Functional disability	25.92 ± 8.23	20.44 ± 10.17	29.17 ± 9.65	28.83 ± 11.94	–5.78 (–10.80; –0.76)	*0.025*
SF-36 subscales						
Physical functioning	81.25 ± 13.37	85.42 ± 12.68	77.29 ± 11.79	74.79 ± 15.28	7.22 (1,92; 12,51)	0.009
Physical role functioning	52.08 ± 36.80	76.04 ± 33.36	46.88 ± 41.25	44.79 ± 42.97	28.32 (9.73; 46.91)	*0.004*
Bodily pain	43.92 ± 13.78	56.88 ± 17.86	44.33 ± 14.98	43.29 ± 18.41	13.83 (4.42; 23.24)	*0.005*
General health perceptions	66.48 ± 18.23	71.15 ± 19.39	62.54 ± 15.52	60.74 ± 19.41	4.02 (–2.92; 10.96)	0.249
Vitality	53.65 ± 14.20	60.10 ± 18.16	53.33 ± 17.24	53.33 ± 18.28	6.53 (–1.43; 14.49)	0.105
Social functioning	75.52 ± 21.01	87.50 ± 20.19	80.21 ± 17.65	79.69 ± 23.83	11.00 (0.50; 21.50)	0.041
Emotional role functioning	71.01 ± 36.66	77.78 ± 37.64	65.28 ± 43.38	60.42 ± 41.36	13.43 (–6.83; 33.69)	0.188
Mental health	65.83 ± 17.37	71.33 ± 19.48	65.67 ± 18.68	69.00 ± 18.24	2.18 (–3.47; 7.83)	0.441
SF-36 component scores						
Physical	43.85 ± 7.65	47.60 ± 7.93	41.66 ± 7.09	40.49 ± 8.03	5.80 (2.34; 9.27)	*0.002*
Mental	46.79 ± 9.97	49.83 ± 11.66	47.48 ± 12.21	48.07 ± 11.65	2.01 (–2.62; 6.64)	0.386

[a]Italic p values indicate significant group differences.
P values for SF-36 subscales and component scores were adjusted for multiple testing. P values < 0.005 were considered statistically significant.
TG = Treatment group; CG = control group.

ment, the mean pain intensity fell to 3.39 ± 1.42 (–17.8%) in the TG and increased to 4.29 ± 1.74 (+2.1%) in the CG (p = 0.008). This effect was maintained until the end of the treatment period. After the 5th treatment, the mean intensity was 2.72 ± 1.62 (–34.1%) in the TG and 4.44 ± 1.96 (+5.7%) in the CG (Cohen's d = 0.9; p = 0.001) (fig. 2).

Secondary Outcome Measures
Pain at motion: Pain at motion decreased more in the TG than in the CG (table 2). The mean pain intensity (sum score over all head movements) decreased by 32.7% in the TG and increased by 18.6% in the CG. The mean maximum pain intensity (the head movement eliciting the most intense pain

Cramer/Lauche/Hohmann/Choi/Rampp/
Musial/Langhorst/Dobos

Table 3. Means (± SD) for mechanical detection, pressure pain and vibration detection thresholds at baseline and post-intervention

	TG		CG		Group difference	p value[a]
	baseline	post-intervention	baseline	post-intervention	(95% CI)	
Site of maximal pain						
Mechanical	0.46 ± 0.45	0.55 ± 0.43	0.57 ± 0.47	0.54 ± 0.47	0.10 (–0.08; 0.28)	0.287
Pressure	2.41 ± 0.15	2.46 ± 0.15	2.36 ± 0.16	2.34 ± 0.15	0.08 (0.03; 0.13)	*0.002*
Vibration	5.90 ± 1.48	5.51 ± 1.53	5.50 ± 1.36	5.53 ± 1.40	–0.11 (–0.79; 0.57)	0.745
Adjacent region						
Mechanical	0.33 ± 0.42	0.31 ± 0.37	0.44 ± 0.63	0.37 ± 0.55	–0.07 (–0.32; 0.18)	0.581
Pressure	2.44 ± 0.20	2.47 ± 0.19	2.41 ± 0.18	2.36 ± 0.16	0.09 (0.04; 0.14)	*<0.001*
Vibration	5.85 ± 1.51	5.35 ± 1.85	5.25 ± 1.54	5.08 ± 1.45	–0.25 (–0.86; 0.36)	0.414

[a]Italic p values indicate significant group differences.
TG = Treatment group; CG = control group.

Fig. 3. Mean pressure pain thresholds in lg(kPa) (+SEM) at baseline and after the intervention. Measures for the site of maximal pain (left) and the adjacent region (right) are depicted. P values < 0.01 are indicated by 2 asterisks (**) and p values < 0.001 by 3 asterisks (***).
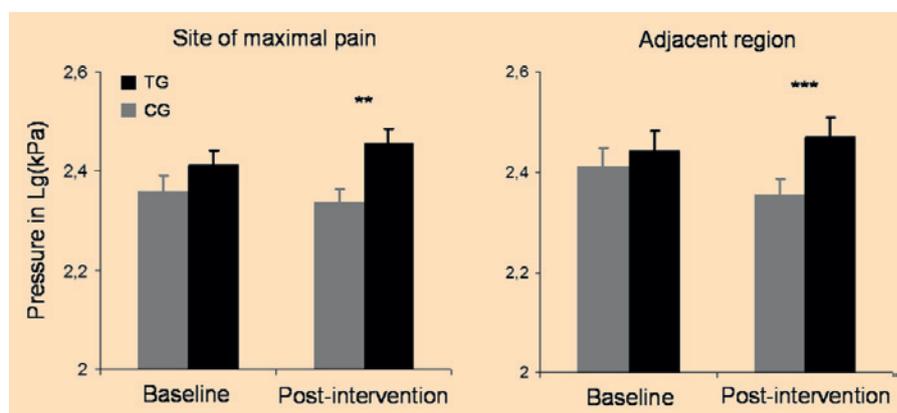
at baseline) decreased by 41.3% for the TG and by 4.9% for the CG.

Neck-related function and health-related quality of life: NDI improved significantly in the TG compared to the CG (table 2). Analyses of SF-36 scores revealed that physical role function, bodily pain, and the physical component score improved more in the TG than in the CG (table 2). Under 'change in health status' significantly more patients in the TG than in the CG rated their health to be better after treatment (p < 0.001).

Sensory measurements: At the end of the trial, pressure pain thresholds at the site of maximal pain and in the adjacent region had increased significantly more in the TG than in the CG (table 3; fig. 3).

No significant group differences were found in mechanical and vibration detection thresholds (table 3).

Correlation Analysis

There was a significant negative correlation between post-treatment pain intensity and pressure pain threshold at the site of maximal pain (r = –0.34; p = 0.025), and a trend for the adjacent region (r = –0.29, p = 0.053), as well as a significant correlation with functional disability (r = 0.52, p < 0.001).

Safety

There were no serious adverse events. Minor adverse events in the TG included muscle soreness for 1–2 days (n = 2), minor hematoma at the treated site for 2 days (n = 1) and increased neck pain for 1–5 h (n = 2).

Discussion

Chronic neck pain is very prevalent in industrialized countries [1]. Since conventional treatments for chronic neck pain have limited evidence [16, 17], patients often request complementary therapies [15]. Massage [33, 34] and cupping [22] appear to be beneficial in treating neck pain. Since pneumatic pulsation therapy is designed to combine the effects of cupping and massage [23], positive effects on chronic neck pain can be assumed. In this trial the effects of pneumatic pulsation therapy was compared with that of standard medical care in alleviating chronic nonspecific neck pain.

Upon completion of the trial, patients in the TG, who had received 5 pneumatic pulsation treatments over a period of 2 weeks, reported a significant decrease in the intensity of their neck pain at rest and at motion and significantly less

functional disability than patients in the CG, who had received standard medical care alone. According to the criteria of Dworkin et al. [35], these reductions in both measures are clinically relevant. Furthermore, increases in pressure pain thresholds were greater in patients in the TG, indicating that their pain sensitivity had decreased. The physical dimensions of quality of life, i.e., physical role function, bodily pain, and the physical component score, improved to a greater extent in the TG than in the CG. Post-treatment pain intensity was correlated with functional disability and sensitivity to pain.

The results of this study are unlikely to be due to the pain medication taken or the physiotherapy received, their use in the 2 groups being comparable and in general limited, i.e., less than 1 DDD/week and less than 1 PT/month. Thus, it is unlikely that the symptomatic improvements associated with study treatments represent a simple add-on effect.

Since degenerative changes in the cervical spine are common in asymptomatic persons as well as in patients with neck pain [5], nonspecific neck pain is thought to be mainly caused by muscular problems. Muscle spasm can cause pain by stimulating mechanosensitive nociceptors or by compressing local blood vessels, leading to ischemic pain [24]. Sustained stimulation of peripheral nociceptors can initiate and maintain sensitization of nociceptor or spinal neurons [11], and nervous tissue may become locally inflamed when blood vessels become compressed [12]. Both mechanisms are thought to induce hypersensitivity to noxious stimuli [11], reflected in lower pressure pain thresholds in patients with chronic neck pain [12, 13].

The physiological effects of low-amplitude oscillation of the skin and underlying tissues have not yet been investigated. However, petrissage, the manual lifting and kneading of muscle tissue, has been shown to decrease neuromuscular excitability [36, 37]. Massage is thought to utilize this inhibitory effect to reduce muscle spasm [24]. Moreover, petrissage locally increases muscle circulation [38]. Pneumatic pulsation therapy, lifting and kneading muscle tissue by means of a pulsating vacuum, may induce similar inhibitory effects, reduce muscle spasm, and increase muscle circulation. Thereby, nociceptor stimulation and local ischemia are reduced, and neck pain, functional disability, and pressure pain hypersensitivity would be decreased.

Since the topical application of arnica has been shown to reduce musculoskeletal pain [39, 40], it may also have contributed to the pain relief found in this study.

The results of this trial are in line with those of trials on the effects of massage in treating chronic neck pain, although massage was incorporated as only 1 component of multimodal interventions in many trials [41]. However, in 2 trials massage was the sole intervention: a home program of trigger point massage reduced the intensity of neck pain and increased the pressure pain threshold in patients with chronic neck pain [33]. The application of Swedish and clinical massage techniques reduced functional disability and symptom bothersomeness in patients with chronic neck pain [34].

A recent pilot study found that dry cupping had more favorable effects on chronic neck pain than being simply on a waiting-list for that treatment [22]. Moreover, in a trial of wet cupping for carpal tunnel syndrome in which neck pain was also measured, cupping was more effective than the topical application of heat in relieving neck pain [21].

A limitation for this study is that the 2 groups are not completely comparable. Since increased attention received from the therapists by the TG patients was not controlled for, nonspecific effects may have played a role in the apparent effects of pneumatic pulsation therapy. However, a systematic review of the nonspecific effects of repeated sham treatments (3–12 applications) on mild to moderate chronic neck pain (3–5 cm VAS) found small to medium average effect sizes, with several studies reporting virtually no effect at all [42]. Therefore, the large effect (Cohen's d = 0.9) of pneumatic pulsation therapy on pain intensity found in this study can hardly be completely accounted for by nonspecific effects. A further limitation is the rather mild baseline pain intensity. Pain intensities reported by the patients in this study were at the lower end of the inclusion criteria scale. Some patients even fell below the required pain intensity of 4 on the NRS. This can be regarded as a possible source of bias, since patients might have exaggerated their complaints during screening to ensure inclusion into the study. Due to the mild baseline pain intensity, any absolute reduction of pain intensity also had to be small. However, in trials of different types of massage for neck pain, baseline pain intensity was comparably low (2.6–5.7 cm VAS), and the effect size of pain relief was lower (d = –0.01–0.75) [27, 33, 41, 43]. Another limitation is the lack of a long-term follow-up.

The strengths of this trial include that patients' pain intensities were monitored daily and that psychophysical measurements were also taken. Pressure pain threshold is less likely to be influenced by patient subjectivity than other aspects of their pain. Thus, the reduction of hypersensitivity cannot easily be explained by nonspecific effects. All psychophysical measurements had satisfactory to good intra-observer reliability in this study.

In conclusion, pneumatic pulsation therapy appears to be a safe and effective method to alleviate pain and to enhance function and quality of life in patients suffering from chronic neck pain. The long-term effects of this treatment and comparisons with other treatments such as traditional cupping or massage should be investigated in future studies.

Disclosure Statement

Cramer/Lauche/Hohmann/Choi/Rampp/
Musial/Langhorst/Dobos

References

1 Fejer R, Kyvik KO, Hartvigsen J: The prevalence of neck pain in the world population: a systematic critical review of the literature. Eur Spine J 2006; 15:834–848.

2 Makela M, Heliovaara M, Sievers K, Impivaara O, Knekt P, Aromaa A: Prevalence, determinants, and consequences of chronic neck pain in Finland. Am J Epidemiol 1991;134:1356–1367.

3 Palmer KT, Syddall H, Cooper C, Coggon D: Smoking and musculoskeletal disorders: findings from a British national survey. Ann Rheum Dis 2003; 62:33–36.

4 Côté 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;23:1689–1698.

5 Matsumoto M, Fujimura Y, Suzuki N, Nishi Y, Nakamura M, Yabe Y, Shiga H: MRI of cervical intervertebral discs in asymptomatic subjects. J Bone Joint Surg Br 1998;80:19–24.

6 Hogg-Johnson S, van der Velde G, Carroll LJ, Holm LW, Cassidy JD, Guzman J, Côté P, Haldeman S, Ammendolia C, Carragee E, Hurwitz E, Nordin M, Peloso P; Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders: The burden and determinants of neck pain in the general population: results of the Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders. Spine 2008;33:39–51.

7 Linton SJ: A review of psychological risk factors in back and neck pain. Spine 2000;25:1148–1156.

8 Côté P, van der Velde G, Cassidy JD, Carroll LJ, Hogg-Johnson S, Holm LW, Carragee EJ, Haldeman S, Nordin M, Hurwitz EL, Guzman J, Peloso PM; Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders: The burden and determinants of neck pain in workers: results of the Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders. Spine 2008;33:60–74.

9 Binder AI: Cervical spondylosis and neck pain. BMJ 2007;334:527–531.

10 Vlaeyen JWS, Linton SJ: Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. Pain 2000;85:317–332.

11 Treede RD, Rolke R, Andrews K, Magerl W: Pain elicited by blunt pressure: neurobiological basis and clinical relevance. Pain 2002;98:235–240.

12 Johnston V, Jimmieson NL, Jull G, Souvlis T: Quantitative sensory measures distinguish office workers with varying levels of neck pain and disability. Pain 2008;137:257–265.

13 La Touche R, Fernández-de-Las-Peñas C, Fernández-Carnero J, Díaz-Parreño S, Paris-Alemany A, Arendt-Nielsen L: Bilateral mechanical-pain sensitivity over the trigeminal region in patients with chronic mechanical neck pain. J Pain 2010;11:256–263.

14 Borghouts J, Janssen H, Koes B, Muris J, Metsemakers J, Bouter L: The management of chronic neck pain in general practice. A retrospective study. Scand J Prim Health Care 1999;17:215–220.

15 Wolsko PM, Eisenberg DM, Davis RB, Kessler R, Phillips RS: Patterns and perceptions of care for treatment of back and neck pain: results of a national survey. Spine 2003;28:292–297.

16 Hurwitz EL, Carragee EJ, van der Velde G, Carroll LJ, Nordin M, Guzman J, Peloso PM, Holm LW, Côté P, Hogg-Johnson S, Cassidy JD, Haldeman S; Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders: Treatment of neck pain: noninvasive interventions: results of the Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders. Spine 2008;33:123–152.

17 Peloso PMJ, Gross A, Haines T, Trinh K, Goldsmith CH, Burnie SJ; Cervical Overview Group: Medicinal and injection therapies for mechanical neck disorders. Cochrane Database Syst Rev 2007; 18:CD000319.

18 Chirali IZ: Traditional Chinese Medicine – Cupping Therapy. London, Churchill Livingstone, 2000.

19 Farhadi K, Schwebel DC, Saeb M, Choubsaz M, Mohammadi R, Ahmadi A: The effectiveness of wet-cupping for nonspecific low back pain in Iran: a randomized controlled trial. Complement Ther Med 2009;17:9–15.

20 Lüdtke R, Albrecht U, Stange R, Uehleke B: Brachialgia paraesthetica nocturna can be relieved by 'wet cupping' – results of a randomised pilot study. Complement Ther Med 2006;14;247–253.

21 Michalsen A, Bock S, Lüdtke R, Rampp T, Baecker M, Bachmann J, Langhorst J, Musial F, Dobos GJ: Effects of traditional cupping therapy in patients with carpal tunnel syndrome: a randomized controlled trial. J Pain 2009;10:601–608.

22 Lauche R, Cramer H, Choi K, Rampp T, Saha F, Dobos GJ, Musial F: The influence of a series of five dry cupping treatments on pain and mechanical thresholds in patients with chronic non-specific neck pain – a randomised controlled pilot study. BMC Complement Altern Med 2011;11:63.

23 Dobias D: Pneumatische Pulsationstherapie – Teil eines multimodalen Behandlungskonzeptes bei Schmerzen. Prax Mag 2003;11:6–11.

24 Weerapong P, Hume PA, Kolt GS: The mechanisms of massage and effects on performance, muscle recovery and injury prevention. Sports Med 2005;35:235–256.

25 Larsson R, Oberg PA, Larsson SE: Changes of trapezius muscle blood flow and electromyography in chronic neck pain due to trapezius myalgia. Pain 1999;79:45–50.

26 Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin (DEGAM): Nackenschmerzen. DEGAM-Leitlinie Nr. 13, Stand Juni 2009. Düsseldorf, omikron publishing, 2009.

27 Irnich D, Behrens N, Molzen H, König A, Gleditsch J, Krauss M, Natalis M, Senn E, Beyer A, Schöps P: Randomised trial of acupuncture compared with conventional massage and 'sham' laser acupuncture for treatment of chronic neck pain. BMJ 2001;322:1574–1578.

28 Vernon H, Mior S: The Neck Disability Index: a study of reliability and validity. J Manipulative Physiol Ther 1991;14:409–415.

29 Bullinger M, Kirchberger I: SF-36 Fragebogen zum Gesundheitszustand. Göttingen, Hogrefe; 1998.

30 Rolke R, Baron R, Maier C, Tölle TR, Treede RD, Beyer A, Binder A, Birbaumer N, Birklein F, Bötefür IC, Braune S, Flor H, Huge V, Klug R, Landwehrmeyer GB, Magerl W, Maihöfner C, Rolko C, Schaub C, Scherens A, Sprenger T, Valet M, Wasserka B: Quantitative sensory testing in the German Research Network on Neuropathic Pain (DFNS): standardized protocol and reference values. Pain 2006;123:231–243.

31 Vickers AJ, Altman DG: Statistics notes: analysing controlled trials with baseline and follow up measurements. BMJ 2001;323:1123–1124.

32 WHO Collaborating Centre for Drug Statistics Methodology: Guidelines for ATC Classification and DDD Assignment 2010. Oslo, World Health Organisation, 2009.

33 Hanten WP, Olson SL, Butts NI, Nwicki AL: Effectiveness of a home program of ischemic pressure followed by sustained stretch for treatment of myofascial trigger points. Phys Ther 2000;80:997–1003.

34 Sherman KJ, Cherkin DC, Hawkes RJ, Miglioretti DL, Deyo RA: Randomized trial of therapeutic massage for chronic neck pain. Clin J Pain 2009;25:233–238.

35 Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick C, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport BA, Rauschkolb C, Revicki DA, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S: Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain 2008;9:105–121.

36 Morelli M, Seaborne D, Sullivan S: H-reflex modulation during muscle massage of human triceps surae. Arch Phys Med Rehabil 1991;72:915–919.

37 Sullivan SJ, Williams LR, Seaborne DE, Morelli M: Effects of massage on alpha motoneuron excitability. Phys Ther 1991;71:555–560.

38 Hovind H, Nielsen S: Effect of massage on blood flow in skeletal muscle. Scand J Med Sci Sports 1974;6:74–77.

39 da Silva AG, de Sousa CP, Koehler J, Fontana J, Christo AG, Guedes-Bruni RR: Evaluation of an extract of Brazilian arnica (Solidago chilensis Meyen, Asteraceae) in treating lumbago. Phytother Res 2010;24:283–287.

40 Widrig R, Suter A, Saller R, Melzer J: Choosing between NSAID and arnica for topical treatment of hand osteoarthritis in a randomised, double-blind study. Rheumatol Int. 2007;27:585–591.

41 Ezzo J, Haraldsson BG, Gross AR, Myers CD, Morien A, Goldsmith CH, Bronfort G, Peloso PM; Cervical Overview Group: Massage for mechanical neck disorders: a systematic review. Spine 2007;32: 353–362.

42 Vernon H, Humphreys BK, Hagino C: The outcome of control groups in clinical trials of conservative treatments for chronic mechanical neck pain: a systematic review. BMC Musculoskelet Disord 2006;7:58.

43 Gam AN, Warming S, Larsen LH: Treatment of myofascial trigger-points with ultrasound combined with massage and exercise – a randomised trial. Pain 1998;77:73–79.