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Strain—counterstrain to treat restrictions of the mobility of the cervical spine in patients with neck pain—A sham-controlled randomized trial☆,☆☆

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Summary
Objective: Strain—counterstrain is an osteopathic technique which is widely used for treating mobility restrictions in the neck. We aimed to investigate whether a single strain—counterstrain intervention is more effective than a sham intervention in improving restricted cervical range of motion in patients with neck pain.
Methods: 61 adult patients with neck pain and restricted cervical mobility were randomly allocated to receive either a single strain—counterstrain intervention or a sham treatment. After outcome measurement all patients received full individualized osteopathic treatment. Mobility of the cervical spine was measured by a blinded observer using the Cervical Range of Motion (CROM) tool. In addition, patients rated pain intensity and assessed the treatment effect. The main outcome measure was the sum of changes in mobility restriction (in %) after treatment compared to normal mobility.
Results: All patients completed the study. Mobility restriction decreased by 2.0% (SD 6.9%) in the group receiving strain—counterstrain treatment and 0.6% (SD 5.7%) in the group receiving sham treatment (mean difference 1.5%, 95% confidence interval −1.7 to 4.8%; $p = 0.35$). There were no significant differences between groups for secondary outcomes. After receiving the full osteopathic treatment the group initially receiving strain—counterstrain improved by another 4.2% (7.0%; $p = 0.003$) and the group initially receiving sham by another 5.6% (SD 6.8%; $p < 0.001$).
Conclusions: Strain—counterstrain as a single intervention did not have immediate effects on mobility and pain over a sham treatment. Future studies should probably focus on the investigation of full osteopathic treatment.

Introduction

Neck pain is a very common condition affecting about half of all individuals at some point during their life.[1] In most cases no clear pathology can be detected and the neck pain is considered non-specific.[2] A common finding in many patients with neck pain is a reduced cervical range of motion.[3] While evidence for their effectiveness is yet limited[4,5] osteopathic

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interventions are increasingly used by both physicians and other health care professionals for treating neck pain and other musculoskeletal pain.[6] Osteopathic treatment typically involves complex manual techniques to diagnose and treat somatic dysfunctions in the musculoskeletal system, inner organs and the nervous system.[6] Strain—counterstrain is one osteopathic technique which is widely used (often together with other osteopathic techniques) when treating pain and mobility restrictions in the neck. It involves passive body positioning, which is claimed to elicit immediate and prolonged reductions in tenderness at digitally tender points and to reduce pain and dysfunction associated with musculoskeletal conditions.[7] Due to its relatively gentle character it is considered a safe technique associated with lower risk than high-velocity manipulations.[7] A survey published in 2003 found that strain—counterstrain was the forth most commonly used manipulative technique among providers of osteopathy in the US.[8] The most common explanation for the effects of strain—counterstrain is that it influences aberrant neuromuscular activity mediated by muscle spindles, local circulation and inflammatory reactions.[9] Clinical research into the effects of strain—counterstrain has only begun to emerge in recent years (see[9] for a review).

To the best of our knowledge, randomized trials investigating the effects of strain—counterstain on the range of motion in patients suffering from neck pain have not been published. In the study described below we aimed to investigate whether a single strain—counterstrain intervention is more effective than a sham intervention in reducing the mobility restriction in patients with neck pain. In addition, we aimed to obtain preliminary data on whether changes of mobility are more pronounced after application of a full osteopathic treatment.

Methods

Design

The main part of the study was a randomized controlled trial with patients, the study assistant and outcome assessor (AB) blinded. The random sequence was created by the study methodologist (KL) using Research Randomizer (www.randomizer.org) with variable block sizes of 8, 10 and 12 (permuted block design). A student not involved in the study prepared sequentially numbered, opaque, sealed envelopes prepared according to the recommendations by Doig and Simpson.[10] After inclusion of a patient into the study by the treating physician (RK) the participant received a code number and went to the study assistant for the baseline measurement of cervical mobility (see below). After completion of the measurement the patient received the envelope with the corresponding code number and went back to the physician who opened the envelope and provided the allocated treatment (strain—counterstrain or sham intervention). After a second measurement all patients received a full individualized osteopathic treatment and were measured a third time. All patients provided written and oral informed consent. The study was approved by the ethics committee of the Medical Faculty of the Technische Universität München.

Patients

Patients were recruited in a large private general practice in Bavaria, Germany. To be included patients had to be between 18 and 65 years old, had to have an acute episode of non-specific neck pain and a blocking of cervical joints in the manual investigation. A blocking was identified finding an irritation-point and restriction of the range of motion in one or more cervical joints of the cervical spine. Most patient had recurrent or chronic complaints and had undergone a variety of diagnostic tests and therapeutic interventions in the past. Patients were excluded if manual therapy was contra-indicated (inflammation, trauma with injury of anatomic structures, severe osteoporosis, severe degenerative changes in the cervical spine, anomalies of the A. vertebralis, severe mental disorder) and if measurement with a magnetic device could have implied a risk for the patient.

Intervention

At inclusion into the study all patients were examined manually. Patients allocated to the intervention group then received a strain—counterstrain treatment according to the diagnostic findings. The affected body parts were positioned to the free direction contrary to the restriction. To activate neurophysiologic reflex mechanisms, this position was held for 90 s while the tender point was monitored by using the finger of the therapist in the position with the minimal tension of the tender point. Afterwards, a slow reposition to basic position was carried out.

To carry out the sham treatment, the finger of the therapist was placed at the height of C4 paravertebraly on the right hand side of the dorsal part and the head was rotated by 30° to the left to basic position without any flexion, extension or lateral flexion. This position was also held for 90 s. Afterwards, a slow reposition to basic position was carried out.

All treatments were performed by the first author, a general practitioner with additional qualifications in sports medicine and manual therapies. He has completed the full osteopathic curriculum (postgraduate) of the Deutsch-Amerikanische Akademie für Osteopathie (German-American Academy of Osteopathic Medicine) in cooperation with the Philadelphia College of Osteopathic Medicine (Certificate and Diploma Osteopathic Medicine, EROP Diploma Osteopathic Medicine TM) and has 8 years of experience in using osteopathic treatments.

After receiving the allocated treatment patients underwent a second measurement. Then all patients received the complex, individualized osteopathic intervention they would have received in routine practice outside the study. Depending on the individual situation various combinations of osteopathic techniques were added to the counterstrain treatment (for example, myofascial release, muscle energy technique, craniosacral treatment and high velocity low amplitude mobilization).

Measurements

At study entry patients were asked to fill in a questionnaire which included questions on age, sex, body size, weight,

seating habits, use of analgesics, constraints in everyday activities and work capacity due to neck pain in the last 6 weeks, the German versions of the Neck Pain and Disability Scales (NPDS),[11] of the Patient Health Questionnaire 9 (PHQ-9)[12] for detection of depressive disorders and of the Patient Health Questionnaire 15 (PHQ-15)[13] for detection of somatoform disorders. The NPDS comprises 9 items (each with a 5-point Likert scale) evaluating the intensity and consequences of neck pain. It includes a question on the intensity of current neck pain. Both after receiving the strain—counterstrain or the sham intervention and after receiving the individualized osteopathic interventions patients were again asked to rate the intensity of current neck pain and to assess the treatment effects and side effects. The full NPDS could not be used as an outcome as it mainly measures long-term effects.

The mobility of the cervical spine at study entry and after the first and the second intervention was measured with the CROM (cervical range of motion) device whose inter- and intra-observer-reliability has been shown repeatedly.[14,15] The measurement device is built up of a plastic frame which is put on like glasses and closed safe at the back of the head with a Velcro strip. Three goniometers arranged orthogonally to each other at the frame show the mobility of the patient's cervical spine. Flexion, extension and lateral flexion are registered with a gravity goniometer (the gauge block rotates concurrently with the patient's head while due to gravitation the weighted needle points perpendicular). The cervical rotation is measured by a magnetic compass combined with an artificial magnetic field. The artificial magnetic field is generated by a magnetic belt placed on the patient's shoulders and reinforces the natural magnetic field. The gauge blocks of the goniometers are divided into gaps of two degrees. All measurements were performed by the same study assistant (AB) trained before the study.

The main outcome measure for the confirmatory analysis was the difference between the sums of the percentage mobility restriction in the directions diagnosed as restricted in the manual examination at study entry divided by the number of restricted movements at baseline and after the first intervention. This relatively complex measure was used seeing that type and number of restricted directions vary among individual patients, and because the normal range of mobility varies for different directions. We expected it to be more sensitive to change than pain which is often only moderate in the patient population studied. Percentage restrictions for the single directions were calculated based on normal values reported in an empirical study.[16] The calculation of the main outcome measure is described in detail in Box 1.

Box 1
Calculation of the main outcome measure sum of changes (in %) in mobility restriction after treatment compared to normal mobility
Principle
In the first step of the calculation the percentage restriction before intervention of each direction was calculated. Based on an empiric investigation[15] for this purpose the normal mobility was assumed as: rotation right and left 85°; lateral flexion right and left 45°; flexion 70°; extension 80°. According to this, a restriction of 1° corresponds to the following percentage of normal mobility: Rotation right and left 1.18% ((1/85) × 100); lateral flexion 2.22% ((1/45) × 100); flexion 1.43% ((1/70) × 100); extension 1.25% ((1/80) × 100).
In the second step of the calculation the percentage restriction after intervention was calculated accordingly. In the last step of the calculation the percentage restriction after intervention was subtracted from the restriction before intervention.
Example (patient with a dysfunction at the height of C4, free direction: rotation left, lateral flexion left, flexion)
Test result before intervention (neutral zero method): rotation right/left: 70°—0°—85°; lateral flexion right/left: 40°—0°—45°; flexion/extension: 70°—0°—73°. This corresponds to the following restriction: rotation right 15° corresponding to 15 × 1.18% = 17.7%; lateral flexion right 5° corresponding to 5 × 2.22% = 11.1%; extension 7° corresponding to 7 × 1.25% = 8.7%. According to this, the sum of the percentage restrictions divided by the number of the affected directions is 37.5%: 3 = 12.5%.
We assume the following test result after intervention (neutral zero method): rotation right/left: 77°—0°—85°; lateral flexion right/left: 43°—0°—45°; flexion/extension: 70°—0°—80°. This corresponds to the following restriction after intervention: rotation right 8° corresponding to 8 × 1.18% = 9.4%; lateral flexion right 2° corresponding to 2 × 2.22% = 4.4%; extension 0° corresponding to 0 × 1.25% = 0.0%. According to this, the sum of the percentaged restrictions divided by the number of the affected directions is 13.8%: 3 = 4.6%.
In this example the main outcome measure results in 12.5—4.6% = 7.9%.

Statistics

As no previous studies on the treatment options tested and the outcome measure used were available, our results should be considered exploratory although we analyzed the study using a confirmatory approach. Based on a sample size calculation (two-sided test, $\alpha = 0.05$, Power = 0.8) using G*Power 3 assuming a standardized mean difference of 0.8 and assuming a drop-out rate of 10% we aimed at recruiting 60 patients. Findings were summarized using means, standard deviations, median, range, absolute numbers and percentages according to data type. The null hypothesis (no difference between strain—counterstrain and sham for the predefined main outcome measure) was tested using Student's *t*-test. We defined in advance that an additional analysis of covariance would be done in case of statistically significant or clinically relevant baseline differences. Differences between groups for secondary outcomes were tested using Student's *t*-test, the Mann—Whitney-*U*-test and the χ^2-test. Within-group differences were tested using the *t*-test for paired data. We did not adjust for multiple testing.

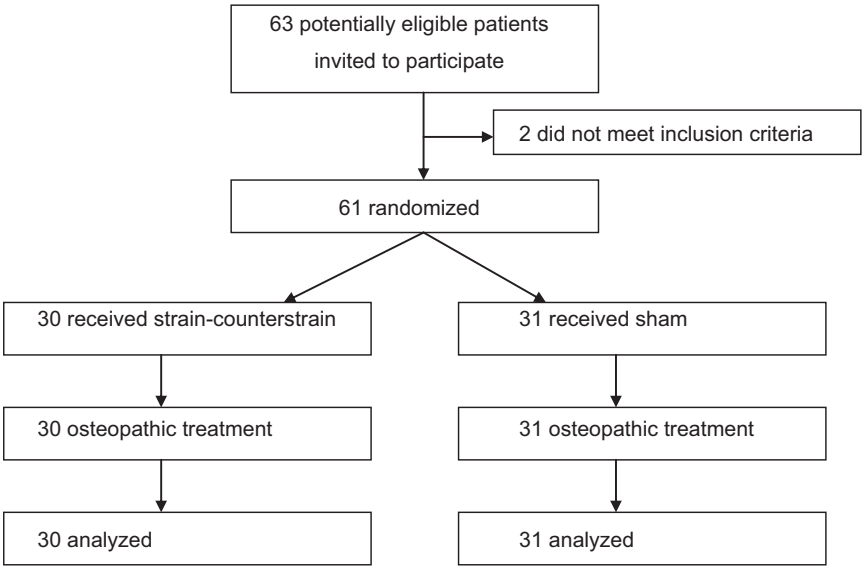

Figure 1 Flow chart.

Results

61 patients were recruited and randomized between February and August 2011 (see Fig. 1). All participants completed the study. Groups were well balanced for most variables (see Table 1 for patient characteristics and baseline values); however, patients in the sham group were considerably more often female and younger. Patients in the control group tended to have a slightly longer history of neck complaints and slightly less mobility restriction. According to the therapist the most frequent main mobility restriction was for rotation (in 54% of intervention and 58% of sham group subjects, respectively).

The mean percentage mobility restriction at baseline was 35.6% (SD 15.6%) in the intervention group and 33.0% (SD 17.1%) in the sham group. After strain—counterstrain treatment the restriction decreased by 2.0% (SD 6.9%) compared to 0.5% (SD 5.7%) after the sham intervention (difference between the groups 1.5%, 95%CI −1.7 to 4.8%, $p = 0.35$; Table 2). The results were similar ($p = 0.56$) if analysis of co-variance adjusting for baseline values, age and sex was used instead of a *t*-test.

The pain score decreased from a baseline of 2.2 (SD 1.2) to 1.6 (SD 1.1) in the intervention group and from 2.2 (SD 1.1) to 1.9 (SD 1.3) in the sham group ($p = 0.81$). No significant differences were found for the mobility restriction in the single directions or in the global assessment by patients (see Table 2).

In addition to the main comparison *between* groups after the first intervention we also analyzed changes over time *within* groups to investigate changes after the first intervention and after the full osteopathic treatment in an exploratory manner (Table 3). There were no statistically significant changes compared to baseline in both groups after the first intervention. After receiving the full osteopathic treatment the group initially receiving strain—counterstrain improved by another 4.2% (7.0) and the group initially receiving sham by another 5.6% (6.8%). The changes after the second intervention were significant compared to both baseline and the measurement after the first intervention. Pain was reduced significantly after the strain—counterstrain but not after the sham treatment; both groups reported significantly less pain after the second treatment (both compared to baseline and after the first intervention).

After the first intervention 4 patients in the strain counter-strain and 1 patient in the sham group reported mild transient adverse effects (pain apart from one verum patient reporting dizziness). During the second treatment 3 patients reported mild pain and one muscular hardening.

Discussion

In this patient- and evaluator-blinded randomized trial a single strain—counterstrain intervention did not have immediate effects over a sham intervention on mobility restriction or pain in patients with restricted cervical range of motion and neck pain. After receiving a full osteopathic treatment patients had significantly less mobility restriction and less pain.

Strengths of our trial include adequately concealed random allocation and the use of a reliable instrument to measure the range of cervical mobility. Patients and the outcome evaluator were blinded for the first comparison. There was no attrition and almost no missing data. The findings are highly consistent. Still, a number of limitations have to be kept in mind when interpreting our findings. The strain—counterstrain technique is typically used as one element of a more complex osteopathic treatment. Therefore, it is somewhat artificial to investigate it as a sole intervention. Yet, it is one important component which could be expected to specifically contribute to the overall effect of osteopathy. Finding a sham treatment for strain—counterstrain which is both credible and inactive is difficult. It cannot be ruled out that the sham technique used

Table 1 Patient characteristics and baseline values. Values are absolute numbers (percentages) and means (standard deviations).

	Strain—counterstrain $N = 30$	Sham $N = 31$
Women	18 (60%)	27 (87%)
Age in years	47.9 (10.1)	41.9 (10.4)
Body mass index	26.4 (4.6)	24.7 (3.9)
Hours sitting per day	5.2 (2.4)	4.8 (2.4)
Duration of complaints in months		
up to 1 month	6 (22%)	2 (7%)
2 to 12 months	8 (30%)	4 (14%)
13 to 60 months	4 (15%)	7 (24%)
over 5 years	9 (33%)	16 (55%)
Days with analgesics in the last 6 weeks	4.3 (8.0)	4.5 (7.4)
Days with disability in the last 6 weeks	7.8 (12.2)	6.3 (11.3)
Neck Pain Disability Scale	40.4 (17.9)	39.4 (18.1)
Intensity of pain (scale from 0 to 5)	2.2 (1.2)	2.2 (1.1)
Major depression acc. to PHQ-9	1 (3%)	4 (13%)
Minor depression acc. to PHQ-9	6 (20%)	5 (15%)
Somatoform disorder acc. to PHQ-15	9 (30%)	12 (23%)
Flexion in°	48.6 (17.0)	48.6 (12.7)
Extension in°	52.1 (15.2)	53.6 (15.5)
Lateral flexion left in°	27.2 (9.4)	32.6 (9.8)
Lateral flexion right in°	28.7 (7.8)	30.1 (7.7)
Rotation left in°	56.3 (12.1)	56.4 (14.6)
Rotation right in°	57.6 (10.2)	58.1 (13.8)

Table 2 Results — comparison between groups. Values are means (standard deviations) and absolute numbers (percentages).

	Strain—counterstrain $N = 30$	Sham $N = 31$	p-Value
Mobility restriction (%)			
Baseline	35.6 (15.6)	33.0 (17.1)	
After intervention 1	33.6 (13.6)	32.5 (16.0)	0.77
After intervention 2	29.4 (13.8)	26.9 (14.0)	0.49
Difference baseline — after intervention 1	2.0 (6.9)	0.5 (5.7)	0.35
Difference baseline — after intervention 2	6.2 (10.2)	6.1 (8.5)	0.94
Difference after interv. 1 — after interv. 2	4.2 (7.0)	5.6 (6.8)	0.45
Pain intensity (scale from 0 to 5)			
Baseline	2.2 (1.2)	2.2 (1.1)	
After intervention 1	1.6 (1.1)	1.9 (1.3)	0.33
After intervention 2	1.1 (1.1)	1.2 (1.2)	0.76
Patient assessment after intervention 1			
Much worse	—	—	
Slightly worse	1 (3%)	1 (3%)	
Unchanged	11 (37%)	17 (55%)	
Slightly better	16 (53%)	11 (36%)	
Much better	2 (7%)	2 (7%)	0.53
Patient assessment after intervention 2			
Much worse	—	—	
Slightly worse	—	—	
Unchanged	5 (17%)	3 (10%)	
Slightly better	16 (53%)	14 (45%)	
Much better	9 (30%)	14 (45%)	0.43

p-Values from Student's t-test (mobility restriction, pain intensity) or χ^2-tests (patient assessements).

Table 3 Results — within-group analyses. Values are means (standard deviations).

	Difference between means (SD)	*p*-Value
Mobility restriction (%)		
Strain—counterstrain group baseline — after intervention 1	2.0 (6.9)	0.12
Sham group baseline — after intervention 1	0.5 (5.7)	0.61
Strain—counterstrain group after intervention 1 — after interv. 2	4.2 (7.0)	0.003
Sham group after intervention 1 — after intervention 2	5.6 (6.8)	<0.001
Strain—counterstrain group baseline — after intervention 2	6.2 (10.2)	0.002
Sham group baseline — after intervention 2	6.1 (8.5)	<0.001
All patients baseline — after intervention 2	6.2 (9.3)	<0.001
Pain intensity (scale from 0 to 5)		
Strain—counterstrain group baseline — after intervention 1	0.7 (0.7)	<0.001
Sham group baseline — after intervention 1	0.3 (0.9)	0.08
Strain—counterstrain group after intervention 1 — after intervention. 2	0.4 (0.8)	0.007
Sham group after intervention 1 — after intervention 2	0.6 (0.9)	<0.001
Strain—counterstrain group baseline — after intervention 2	1.1 (1.1)	<0.001
Sham group baseline — after intervention 2	0.9 (1.0)	<0.001
All patients baseline — after intervention 2	1.0 (1.1)	<0.001

p-Values from *t*-tests for paired data.

in our study also had some minor activity; our results, however, do not suggest it had any relevant effects. Although a single trained rater did all mobility measurements using a device shown to be reliable and conditions were standardized as far as possible, the measurement of the cervical range of motion is also influenced by the patient's cooperation and concentration. Repeating the procedure three times might have effects on its own. In the sample size calculation we assumed a relatively large effect (0.8 standard deviations) as we considered our main outcome as a quite sensitive measure. The statistical power of our study was not sufficient to detect a small difference between the groups. The upper limit of our 95% confidence interval for the difference between the two groups is 4.8% for the main outcome measure. Such a difference could be considered clinically relevant. We only had about 50% power for detecting a difference of 3% (which we would not consider relevant) with the standard deviation observed. However, we think that the consistent lack of differences between the two groups in all outcomes makes it unlikely that we missed clinically relevant effects. Possibly our results would have been different if several sessions of strain—counterstrain treatments (or full osteopathic treatment) would have been compared to a sham intervention. We had considered such a study but it did not seem feasible in a single center setting. It seemed highly unlikely to us that a sufficient number of eligible patients would give consent to receiving only strain—counterstrain interventions or sham over a period of several weeks.

As stated in the introduction clinical research on strain—counterstrain as a sole intervention is still sparse and we are aware of only two small randomized trials testing it in patients with neck pain. Meseguer et al.[17] compared the immediate effects of a classical intervention and a modified strain—counterstrain intervention to a no treatment control group on pain threshold in 54 subjects presenting with mechanical neck pain. Both interventions significantly reduced the tenderness of tender points in the upper trapezius muscle compared to the control group. However there was no blinding and no sham control. Perreault et al.[18] did not find any significant differences on pain compared to a sham intervention after treatment and after 24 h in 20 subjects reporting upper trapezius pain but this study seems difficult to interpret due to relevant baseline differences, the very small sample size and the somewhat problematic use of a contra-lateral sham intervention. Two other small studies suggest that strain—counterstrain can reduce trigger point tenderness in other conditions.[19,20] Local pain was also reduced in one of these studies[19] while the other did not find effects on clinical pain and disability.[20] Recently, a randomized trial was published which could not show an additional effect of strain—counterstrain in combination with exercise over exercise alone in patients with acute low back pain.[21] In summary, concordant with the findings of our study these studies do not suggest that strain—counterstrain as a sole intervention has a major clinical specific effect.

The improvements after the second intervention seen in our study are difficult to interpret as there is no control group for this part of the study. Our simple pre-post analyses should be considered purely hypothesis-generating. Still, we think that our results suggest that the full osteopathic interventions might be more effective than the isolated strain—counterstrain intervention. Only few trials have investigated the effectiveness of complex osteopathic interventions in patients with neck pain beyond immediate effects. A trial in 60 neck pain patients by Nagrale et al.[22] found that an intervention combining strain—counterstrain with muscle energy techniques and ischemic compression reduced pain and disability at 2 and 4 weeks significantly more than muscle energy techniques alone. As this study did not include a sham control group the findings must be interpreted with caution. Schwerla et al.[23] reported a sham-controlled trial with 41 patients suffering from chronic neck pain. A series of individualized complex

osteopathic interventions reduced pain significantly compared to a sham-ultrasound control group. As this sham intervention differs considerably from osteopathy these findings, too, are not easy to interpret.

In conclusion, in this trial strain—counterstrain as a single intervention did not have immediate effects on mobility and pain over a sham treatment. Full osteopathic treatment seemed to have a more pronounced effect but this part of the study lacked a control group. Given the widespread use of osteopathy there is a clear need for further randomized trials. As strain—counterstrain is usually used together with other osteopathic techniques we would recommend that future trials preferably investigate combined osteopathic techniques which reflect interventions in routine practice.

Conflict of interest

None.

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