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Myofascial Pain and Treatment

Osteopathic treatment of patients with shoulder pain. A pragmatic randomized controlled trial

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ABSTRACT

Background: Shoulder complaints are common in the general population. Typically, the diagnosis of a specific pathology is lacking. The objective of this trial was to evaluate the effectiveness of an osteopathic treatment in patients suffering from shoulder pain.

Methods: A pragmatic randomized controlled trial was conducted in patients with a history of shoulder pain of 6 weeks to 12 months, and a pain intensity level of at least 40% on the visual analogue scale (VAS). Participants were identified from the general population in Germany and allocated by means of external randomization to an intervention group or a control group. Patients in the intervention group received five osteopathic treatments at intervals of two weeks. Treatment was custom tailored and based on osteopathic principles. Controls received their osteopathic treatment after an 8-week untreated waiting period. Primary outcome parameters were pain intensity and frequency, measured by VAS and Likert Scales. Secondary outcome parameters were shoulder specific pain and disability (Shoulder Pain and Disability Index, SPADI), and quality of life (SF-36).

Results: A total of 70 patients aged 25–70 years (average age 45.6 ± 13.4 years) were included, 36 in the intervention group and 34 in the control group. The inter-group comparison of changes revealed clinically relevant improvements in favor of the intervention group for the main outcome parameters maximal pain intensity (VAS: between group difference of means 41.5; 95% CI: 34.6 to 48.3; $p < 0.005$) and average pain intensity (VAS: between group difference of means 40.4; 95% CI: 33.2 to 47.5; $p < 0.005$). The proportion of participants with a low frequency of pain increased in the osteopathic group only (from 7 to 34 vs. 9 to 6 in the control group, $p = 0.006$), and the number of patients with a high frequency decreased in the osteopathic group only (from 29 to 2 vs. 25 to 28, $p < 0.0005$). Shoulder specific pain and disability also improved. The follow-up assessment in the intervention group showed further improvements.

Conclusions: Five osteopathic treatments over a period of eight weeks led to statistically significant and clinically relevant positive changes of pain and disability in patients suffering from shoulder pain.

1. Introduction

(*epidemiology*) Non-traumatic shoulder pain is a common problem in the general population with a peak prevalence of about 30% in individuals aged 55–64 years, and a peak incidence of around 8% in individuals 45–60 years of age (Vincent et al., 2017). A previous systematic review found prevalence rates ranging from 7% to 26% for point prevalence, and up to 67% for lifetime prevalence (Luime et al., 2004). The large range in the prevalence rates was referred to the use of different definitions of the condition in the literature. Frequently, shoulder pain is not a short-time, self-limiting problem. An overview on shoulder disorders points out that of all new episodes presenting to primary care, approximately 50% apparently resolve within 6 months, while about 40% may

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persist for up to 12 months (Van der Heijden, 1999). Shoulder disorders account for more than 14% of all general practice encounters, being third (after back and neck pain) among musculoskeletal reasons for primary care consultations (Rekola et al., 1993).

(*definitions*) Shoulder pain is being defined as pain localized in the region of the deltoid muscle, acromioclavicular joint, superior part of the trapezoid muscle, and scapula (Murphy and Carr, 2010). Considerable disability may result from shoulder pain with notable impact on quality of life (Sun et al., 2015). Pain (and pain-related stiffness) in the shoulder may negatively affect ability to work and/or the ability to carry out household and leisure-time activities, burdening both patients and society (Luime et al., 2004). Radiation of pain into the arm may occur, and, in consequence, range of motion of the upper arm or shoulder-girdle may be affected. Shoulder pain is often associated with impaired sleep, thus negatively affecting mood, concentration, and performance (Tekeoglu et al., 2013).

(*etiology*) The four most common causes of shoulder pain and disability in primary care are described as rotator cuff disorders, glenohumeral disorders, acromioclavicular joint disease, and referred neck pain (Buchbinder et al., 2003). Bloom et al. (2012) stated in a Cochrane Review that shoulder pain is most commonly caused by a) rotator cuff disease, b) pressure on the tendons by the overlying bone (also called impingement syndrome), and c) adhesive capsulitis (also called frozen shoulder, stiff painful shoulder or periarthritis of the shoulder). Shoulder pain can also accompany hemiplegia that results from a stroke (Singh and Fitzgerald, 2010).

(*diagnosis*) Problems associated with the diagnosis of shoulder pain include lack of recognized diagnostic criteria, poor specificity of commonly used clinical tests, and frequent co-existence of multiple shoulder pathologies (Hegadus et al., 2008; Hanchard et al., 2013; Gismervik et al., 2017). Therefore the term 'non-specific shoulder pain' is commonly used, in clinical practice as well as in clinical trials (Peek et al., 2015). A review from 2008 identified more than a dozen "diagnostic labels" (descriptive terms with particular focus on e.g. etiology or core symptoms) to define study populations in clinical trials. Because an obvious lack of uniformity in diagnostic labeling of shoulder pain was identified, the authors suggested to "direct future research towards undivided populations with "general" shoulder pain" (Schellingerhout et al., 2008).

(*treatment*) There are many commonly used treatments for shoulder disorders, including physiotherapy modalities, non-steroidal anti-inflammatory drugs, glucocorticosteroid injections, oral steroids, manipulation under anesthesia, acupuncture or surgery. Whilst some interventions seem to be efficacious, overall there is limited evidence regarding the efficacy of these interventions (Green et al., 1998, 2005). Corticosteroid injections are a commonly used modality in treating shoulder pain irrespective of the underlying etiology. While a reasonable number of randomized controlled trials exist, small sample sizes, variable methodological quality and heterogeneity in terms of population studied, as well as injection modality employed preclude reliable evidence to date to guide treatment. Subacromial corticosteroid injection for rotator cuff disease and intra-articular injection for adhesive capsulitis may be beneficial although their effect may be small and not well-maintained (Buchbinder et al., 2003; Xiao et al., 2017). Regarding manual and manipulative therapy to the shoulder and shoulder girdle, a review found that there is fair evidence for the treatment of a variety of common rotator cuff disorders, shoulder disorders, adhesive capsulitis, and soft tissue disorders (Brantingham et al., 2011).

(*osteopathy*) There is little experimental research on osteopathic treatment approaches to shoulder pain, because - in our daily practice we feel that osteopathic treatments for shoulder pain leads to a great satisfying result. Only one published RCT for the osteopathic treatment of shoulder pain could be found in the literature (Knebl et al., 2002). In an unpublished thesis of Hettasch and Bube (2009) osteopathic treatment appeared to be effective in the treatment of shoulder pain.

Accordingly, the aim of this study was to evaluate the (perceived) effectiveness of an osteopathic treatment in a randomized controlled trial of patients suffering from shoulder pain, pain intensity and pain frequency as primary outcomes.

2. Methods

The present study was designed as a pragmatic randomized controlled trial with a thorough osteopathic physical examination at the beginning of any treatment session to determine the consecutive custom-tailored treatment of actual dysfunctions in the intervention group. Subjects randomized to the control group remained osteopathically untreated for eight weeks ("waiting list").

(Ethics) In Germany, up to now only studies carried out by physicians are subject to approval by one of two institutional ethics committees (and will be accepted for review), installed by the medical faculties of German universities and state medical associations, respectively. Therefore, approval for the study protocol of this study had to be sought elsewhere and was obtained from the Research Ethic Committee of the German Academy of Osteopathy (AFO), which had been founded as a (necessary) substitute. The present study meets the standards of the Declaration of Helsinki and the Good Clinical Practice guidelines. Our study adheres to CONSORT guidelines. Informed consent was obtained from all participants before enrollment.

(Setting) Three osteopaths (TH, MK and TS) carried out the study in their (private) practices in Germany. All of them are experienced "Heilpraktiker" (the only medical profession in Germany approved to treat patients without supervision/delegation of a physician, with particular emphasis on complementary and alternative medicine), had successfully completed 6 years of osteopathic training (approximately 1500 h), and had successfully passed a final clinical exam (thus representing the highest possible standard of osteopathic training in Germany).

(Recruitment and Randomization) Participants were recruited from the general population in three German cities between 2010 and 2012. Invitation to participate was spread through word of mouth, and information flyers were displayed in surgeries, clinics and pharmacies. Interested individuals could apply via telephone, where they were interviewed and checked for inclusion criteria. Patients were included if they were aged between 25 and 70 years and had been suffering from shoulder pain around the glenohumeral joint, the acromioclavicular joint, the sternoclavicular joint and/or the sub-acromial and scapular-thoracic connections for a minimum of six weeks and a maximum of one year and if they had already presented to a physician with their problem. In addition, perceived average shoulder pain intensity within the previous week had to be rated more than 40 points on a 100-point visual analog scale (VAS). On demand pain medication was allowed. General exclusion criteria were any of the following diagnoses as determined by a physician before study enrollment: operations on shoulder or thorax; fractures of shoulder, sternum or clavicle; dislocation of shoulder during the last six months; adhesive capsulitis or frozen shoulder; rupture of the rotator cuff; rheumatoid arthritis; peripheral palsy of upper extremity; acute inflammatory process; neoplasms; disorders of the central nervous system; and 3rd or 4th degree osteoarthritis of the shoulder joints.

Participants were randomly allocated to two groups: an intervention group that received proper osteopathic treatment, and a control group, which remained untreated during the study period

but received osteopathic treatment in an identic way eight weeks later. The assignment to the groups was performed externally by the German Institute for Political Science and Sociology, University of Bonn, Germany, where a computer-generated randomization list with variable block lengths of 4–8 was held (block lengths were not revealed to any party involved in the trial) (Altman and Bland, 1999). Participants' allocation to the respective groups was revealed only after date of birth and initials had been conveyed by telephone, and documented in the original randomization list.

(Outcome Measures) The main outcome was shoulder pain (intensity and frequency). A standard VAS was used to measure the quantity of self-perceived pain. At the beginning of each visit subjects were requested to place a mark between left (0%, no pain) and right (100%, worst possible pain) margins of the VAS for worst pain, and average pain within the previous week for assessment of intensity of pain. To assess frequency of shoulder pain in the previous week, a Likert Scale (never, rarely, occasionally, frequent, always) was used.

Secondary outcome parameters included shoulder specific pain and disability determined by the "Shoulder Pain and Disability Index" (SPADI) (Breckenridge and McAuley, 2011) and health-related quality of life assessed by the generic SF-36 questionnaire (Bullinger, 1995). A validated German version of SPADI is available. This German version is a practicable, reliable and valid instrument, and has been recommended for the self-assessment of shoulder pain and function (Angst et al., 2007). The SPADI contains 13 items that assesses two domains; a 5-item subscale that measures pain and an 8-item subscale that measures disability (Breckenridge and McAuley, 2011). For the data evaluation, the sum of the response points is divided by the maximum achievable score of the questions answered and multiplied by 100. SF-36 is a commonly used generic questionnaire that has been validated in German and for which standard values are available (Bullinger, 1995). Average intake of medication during the study period was recorded. Furthermore, the osteopathic dysfunctions were documented in an examination form.

(Intervention) Osteopathic practitioners use their understanding of the relationship between structure and function to optimize the body's self-regulation and self-healing capabilities. This approach to patient care and treatment is based on the concept that a human being is a dynamic functional unit, in which all parts are interrelated and that possesses its own self-regulatory and self-healing mechanisms. Two essential components of osteopathic health care are the structural evaluation of the patient for diagnosis and an array of manipulative techniques for treatment (WHO, 2010).

The aim of the structural examination is to locate somatic dysfunctions that may contribute to the clinical presentation of the patient. Diagnostic criteria for somatic dysfunctions are focused on tissue texture abnormalities, asymmetry of bony landmarks, restriction of motion and tenderness or soreness to examiner pressure (Kappler and Jones, 2003).

Osteopathic practitioners use a wide variety of therapeutic manual techniques to improve physiological function and restore homeostasis that has been altered by somatic dysfunction (WHO, 2010). They assess and treat the 'whole person', rather than just focusing on specific symptoms or illnesses (OIA, 2014). According to the principles of osteopathy, the location of dysfunction will not be restricted to the area of the shoulder joint alone; dysfunctions can arise and be diagnosed in the whole body, on a parietal, visceral or cranial level. At every osteopathic treatment session, only those structures for which actual osteopathic findings (dysfunctions) are present will be treated.

According to the Glossary of Osteopathic Terminology (Kappler and Jones, 2003), osteopathic manipulative treatment (OMT) typically involves an eclectic range of manual techniques, which may include articulatory treatments, balanced ligamentous tension, cranial treatments/osteopathy in the cranial field/cranial osteopathy, counterstain treatments, direct treatments, facilitated positional release treatments, high-velocity low-amplitude (thrust) treatment, indirect treatments, integrated neuromusculoskeletal release, ligamentous articular strain, muscle energy treatments, myofascial release treatments, soft tissue treatments, and visceral manipulative treatments. Treatment may include lifestyle advice and bio-psychosocial approaches as part of patient management.

(Study Groups) At the first consultation (T0), inclusion and exclusion criteria were checked, and eligible patients were randomized into one of the two groups after having received comprehensive information about the study and having signed a consent form. Participants in the osteopathic group received a series of five osteopathic examinations and treatments delivered at intervals of 2 weeks, lasting 40–60 min each. Treatments were scheduled at weeks 0 (T1), 2, 4, 6 and 8 (T5). Before each visit (baseline T1 to T5) and 2 weeks after the last visit (T6, which was the primary end point of the trial), participants completed the VAS, the Likert Scale and the SPADI. Health-related quality of life was assessed by the generic SF-36 questionnaire at baseline, 4 weeks, and 10 weeks. In the osteopathic group a follow-up evaluation was carried out 8 weeks after the end of the study (T7); the VAS, Likert, SPADI and SF-36 were filled out again.

At each visit, the patient received a comprehensive examination according to osteopathic principles. For documentation purposes, a standardized examination form was used by all three practitioners. This form was also important to monitor changes of dysfunctions over the course of treatment. In keeping with the principles of osteopathy, there was no pre-defined, standardized treatment protocol; each osteopath was free to decide which techniques to use, but those applied had to be documented in detail.

At the baseline visit (T1), control participants were required to fill out the VAS, the Likert Scale, the SPADI and the SF-36 questionnaire. The osteopath then told them that they would be placed on a waiting list for osteopathic treatment to be scheduled 8 weeks later. At 8 weeks, the control participants filled out all assessment instruments for the second time, and five free osteopathic treatments were offered to them.

In both groups, on-demand pain medication was allowed (which was documented in a diary). During the study period participants were asked not to seek any additional treatment for their problem (i.e., physical therapy or other complementary treatment approaches).

(Statistical Analysis) The sample size was calculated using the response rates and variances of the main outcome measures from the trial of Hettasch and Bube (2009). According to common standards in clinical trials, the type I error was set at 0.05, and type II error, 0.2 (i.e., a power of 80%). Pain intensity was used to determine the sample size. The trial was designed to be able to detect an overall clinically important difference in changes of 20% points with assumed SDs of 20, equivalent to an effect size of 0.72. The sample size calculation estimated that 64 participants would be required. We decided to aim for 35 participants in each group to account for potential additional variation as well as drop outs.

For the purpose of the study, only data of the osteopathic treatment period of the intervention group, and the waiting period of the control group were used for statistical analysis. All statistical evaluations were performed with PASW Statistics (version 17; SPSS Ltd). Results of the descriptive analysis at baseline are reported as means and standard deviations. Differences between groups at baseline were examined using unpaired two-sided t-tests. In the confirmatory analysis, longitudinal changes of different aspects of the main outcome in the course of treatment (i.e., between baseline

and end of treatment) were compared between both groups by unpaired, 2-sided t-tests. For all comparisons, $p < 0.05$ was considered statistically significant, and 95% CIs were calculated for all point estimates. The confirmatory analysis was performed as intention-to-treat analysis with last observation carried forward for dropouts.

3. Results

Eighty-three patients responded to some form of invitation, and, after an initial telephone interview, 70 patients fulfilled all relevant inclusion criteria and were included in the study: 36 in the intervention group and 34 in the control group. None of the participants dropped out, and thus data of all 70 patients were included in the analysis (Fig. 1 shows the flow of subjects through the trial). Clinical and demographic characteristics were similar in both groups at baseline (see Table 1 for details).

(Primary Outcome Measures) At baseline, the parameters average and worst pain intensity were similar in both groups. In the osteopathic group, average pain intensity (VAS) decreased from 57.3 ± 15.5 before treatment (T1) to 19.2 ± 11.4 at the end of therapy (T6), and worst pain (VAS) from 73.6 ± 13.5 at T1 to 28.2 ± 14,6 at T6 (Table 3). In the control group, no changes were observed in the corresponding time period (Table 3). The mean difference of longitudinal changes over the study period (T1 − T6) was −40.4 (95%CI: 33.2 to −47.5, $p < 0.0005$) for average pain intensity, and −41.5 (95%CI: 34.6 to −48.3, $p < 0.0005$) for worst pain in favor of the osteopathic group (Table 2). In the osteopathic group, pain frequency improved for 33 patients (3 patients remained unchanged, there was no deterioration). In the control group, pain frequency remained unchanged for 21 patients, only 8 patients improved (Fig. 2). Dichotomization of the Likert scale (pain frequencies never, rarely, sometimes = low frequency and often, always = high frequency) revealed significant differences in favor of the osteopathic intervention ($p = 0.006$ [Fisher exact test] for low frequency, and $p < 0.0005$ for high frequency (Table 3). During the 8 weeks' follow-up period (T6 to T7), the average pain intensity showed a continuing trend to improve in the intervention group (Fig. 3).

(Secondary Outcome Measures) Similar between and within group changes were observed for shoulder specific pain and disability (SPADI questionnaire: mean difference of changes −27.2, 95%CI: 19.3 to −31.1, $p < 0.0005$) (Table 2), which corresponds to an improvement of 59% in the intervention group. Concerning quality of life, the mean physical component score of the SF-36 changed from 41.7 to 46.5 in the osteopathic group ($p < 0.005$) (Table 3). There were no significant differences present between groups in the SF-36 mental component score. The evaluation of the osteopathic examination patterns revealed where osteopathic dysfunctions were most frequently encountered. Most frequently, osteopathic dysfunctions were diagnosed in the area of the respiratory diaphragm (70% of patients), at the thoracic spine (67%), and in the area of the glenohumeral and acromioclavicular joints. No serious adverse events or adverse reactions were reported during the treatment period. Occasionally, patients reported on some tiredness on the day of treatment.

4. Discussion

(Literature) Shoulder pain is common in the general population, yet for several reasons very often the etiology remains unclear. In a recent systematic review, Lange et al. identified a lack of high-quality studies evaluating inter-rater as well as intra-rater reliability of specific physical examination tests for the diagnosis of shoulder pathologies, and reliability measures differed markedly between included studies hindering proper cross-study comparisons (Lange et al., 2016). There are a lot of systematic reviews including several Cochrane reviews investigating different therapies for treating shoulder pain [e.g. Buchbinder et al., 2003; Green et al., 2003; Green et al., 2005; Green et al., 2006; Singh and Fitzgerald, 2010), but there is still limited evidence regarding the efficacy and/or clinical effectiveness of these interventions.

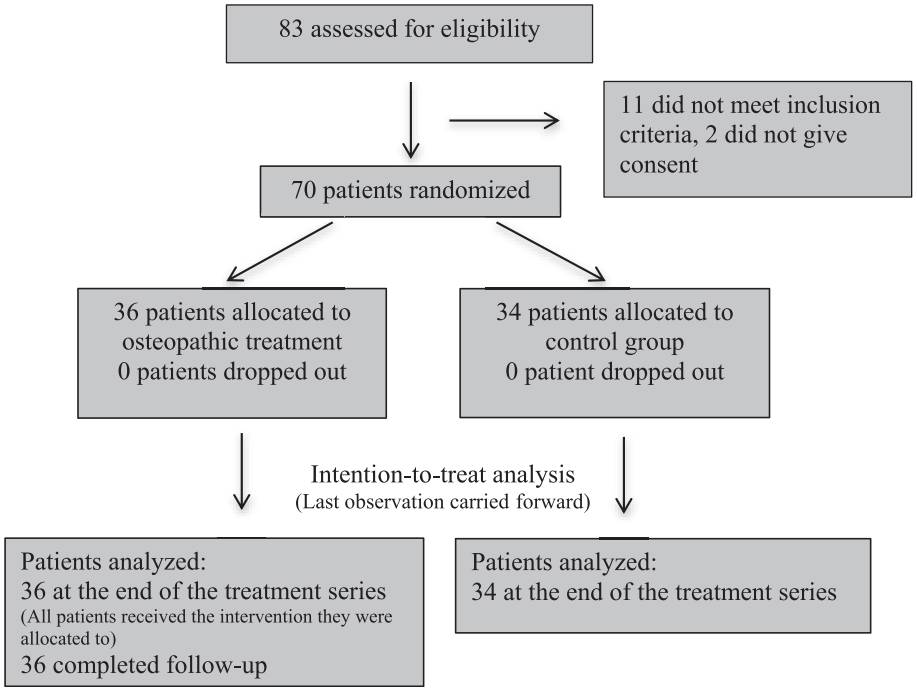

Fig. 1. Flow of subjects through the trial.

Table 1
Baseline characteristics of study patients.

Characteristics	Osteopathic group (n = 36)	Control group (n = 34)	p - value
Mean age ± SD, years	45.7 ± 13.5	45.6 ± 13.5	1.0
Gender (n): men	16	15	
women	20	19	1.0
Shoulder pain (VAS 0–100)			
Average pain intensity (Mean ± SD)	57.3 ± 15.5	59.7 ± 9.8	.4
Worst pain intensity (Mean ± SD)	73.6 ± 13.5	73.1 ± 12,3	.8
Likert-Scale			
Pain frequently last week (n)	14	14	.5
Pain constantly last week (n)	15	11	
SPADI-Score (0–100)	48.6 ± 23.2	45.4 ± 17.6	.5
SF-36 scale scores			
Physical components (PCS)	41.7 ± 7.1	41.4 ± 6.4	.8

SD, standard deviation.

Table 2
Inter-group differences; comparison of mean values of both groups between Baseline and end of treatment.

Mean ± SD	Longitudinal changes Baseline − end of treatment		Difference of longitudinal changes, and 95% CI	p - value
	Osteopathic group (n = 36)	Control group (n = 34)		
Pain intensity VAS (0–100)				
Average pain	−38.1 ± 18.1	2.3 ± 10.8	−40.4 (−33.2 to −47.5)	<.0005
Worst pain	−45.4 ± 16.5	−3.9 ± 11.4	−41.5 (−34.6 to −48.3)	<.0005
SPADI-Score	−28.5 ± 22.2	−1.3 ± 6.9	−27.2 (−19.3 ± 31.1)	<.005

SD, Standard deviation; CI, confidence interval.

Table 3
Within-group longitudinal changes.

Mean ± SD Osteopathic group n = 36 Control group n = 34	Baseline (T1)	End of treatment (T6)	Difference of longitudinal changes, and 95% CI	p value
Pain intensity (VAS), Average pain				
- osteopathic group)	57.3 ± 15.5	19.2 ± 11.4	−38.1 (−32.0 to −44.2)	<.005
- control group	59.7 ± 9.8	62.0 ± 13.3	2.3 (−1.5 to 6.1)	.2
Worst pain				
- osteopathic group	73.6 ± 13.5	28.2 ± 14,6	−45.4 (−51 to −39.8)	<.005
- control group	73.1 ± 12,3	69.2 ± 14,5	−3.9 (0 to −7.9)	.05
SPADI-Score				
- osteopathic group	48.6 ± 23.2	20.1 ± 17.8	−28.5 (−21.0 to −36.0)	<.005
- control group	45.4 ± 17.6	44.1 ± 17.8	−1.3 (1.1 to −3.7)	.30
Quality of Life (SF-36)				
Physical components (PCS)				
- osteopathic group	41.7 ± 7.1	46.5 ± 8.5	4.8 (2.6–7.1)	<.005
- control group	41.4 ± 6.4	43.5 ± 6	2.1 (0.4–3.8)	.02
	Baseline (T1)	End of treatment (T6)	Changes in pain frequency	p value
Pain frequency (high/low)				
- osteopathic group)	29/7	2/34	Low: $X^2 = 9.92$;	$p = 0.006$
- control group	25/9	28/6	High: $X^2 = 18.33$;	$p < 0.00005$

SD, Standard deviation; CI, confidence interval, X^2 = Chi square (p-values calculated with Fisher exact test).

(Study design) This study aimed to examine the effectiveness of a series of osteopathic treatments compared to “no intervention” for patients suffering from “shoulder pain”. We used a pragmatic approach to assess the effectiveness of an osteopathic treatment delivered in normal clinical practice, reflecting the real-life situation of individuals either deliberately seeking treatment or not (Resch, 1998; Witt, 2009) (i.e., perceived effectiveness of a series of treatment sessions rather than efficacy of particular osteopathic techniques). Results may therefore be of significant external validity (Hotopf, 2002; Califf, 2005).

Shoulder pain symptoms remained stable during the 8-week waiting period in the control group, confirming that participants' shoulder pain problems were in fact predominantly chronic in nature.

For patients in the control group, participation may not have been associated with a major disadvantage while they were on the waiting list, because they were in conscious anticipation of the benefit of five free osteopathic treatments after 8 weeks.

(Methods) To exclude degenerative processes as the only/prevailing pathology, an upper age limit of 70 years was chosen for participation. A history of the shoulder problem of 6 weeks to a maximum of one year was determined as an inclusion criterion to exclude acute stage shoulder pain (with a good proportion of short-time self-limiting cases) as well as chronically modified and thus

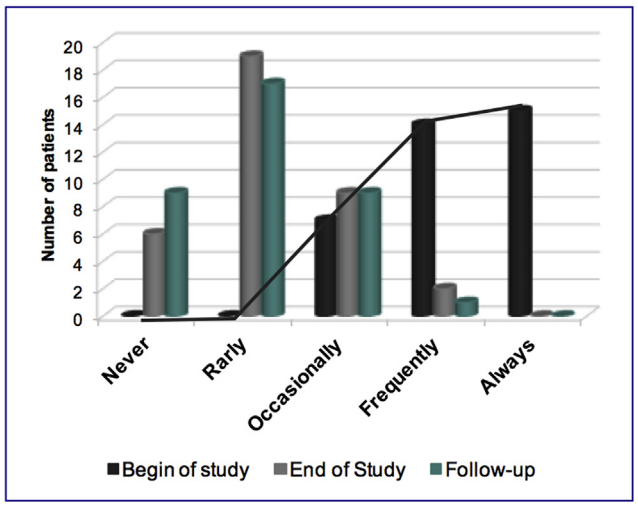

Fig. 2. Pain frequency of shoulder pain in the intervention group on a 5-point Likert Scale at the beginning, end of study and follow up.

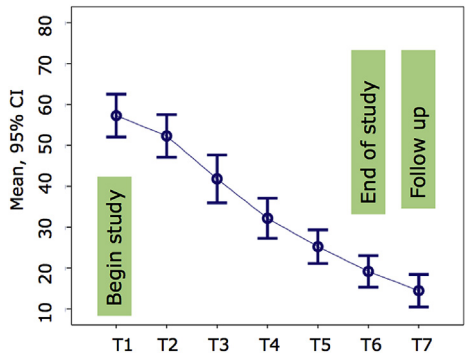

Fig. 3. Intensity of average shoulder pain on a 100% visual analog scale (VAS) in the intervention group from study start (T1) to follow up (T7). Error bars represent 95% CIs.

often structurally altered, compensated shoulder pain patients. The lack of change of severity of pain in the untreated control group confirms the assumption that this core inclusion criterion worked successfully. Two aspects of pain, which may matter most for patients with the problem under study, i.e. pain intensity and pain frequency, were used as main outcome parameters. Visual analogue scales are a widely used, easy to perform, reliable and valid instrument to quantify perceived aspects of pain and has been shown to be highly responsive to clinical changes (Price et al., 1983; Choiniere and Amsel, 1996; Grotle et al., 2004). The Shoulder Pain and Disability Index (SPADI) was used, because it is highly responsive to changes of the symptoms, and, in addition, is easy for patients to fill in. Paul et al. (2005) carried out a cross sectional comparison of four shoulder questionnaires. All of them showed a similar overall validity and patient acceptability, but SPADI was the quickest to complete and SPADI and SRQ (Shoulder Rating Questionnaire) were most responsive to change. An assessment of the extent of range of movement (ROM) was intentionally not included, because of a lack of evidence concerning the strength of the association of respective changes to patients perceived effectiveness.

In the case of a negative outcome in clinical trials concerned with manual therapy or other interventions directly delivered by a therapist there is no way to determine whether the therapy or the therapist may be the reason for ineffectiveness, if there is just one person/center delivering the therapy. In order to test the treatment approach and not the therapist, this study was performed in the form of a "best practice" multicenter trial (three well-trained and experienced osteopaths performed the treatments) with randomization stratified by therapist. Fig. 4 shows the decrease of the average pain intensity for each of the three therapists featuring satisfactory homogeneity to assume that the trial successfully quantifies the therapeutic potential of the osteopathic approach under the given circumstances, and that randomization was successful. Emphasis had been placed on external randomization and (stratified) random allocation via a renowned institution neutral to the subject under study to reliably preclude any type of accidental or intentional manipulation (McPherson and Campbell, 2009).

(osteopathic) Unlike in biomedicine, where decisions on what to treat and how to treat are typically based on the diagnosis of a disease or pathological condition that *a priori* determines a set of manual techniques "for the condition", osteopaths rather treat dysfunctions identified and considered relevant during a thorough physical examination, carried out at every session. Thus, each person receives an individualized ("made-to-measure") treatment tailored to actual findings. In the actual study, a detailed examination form was used that allowed for a comprehensive and precise documentation of all tests, test results, and consecutive treatment decisions, and gave a good overview of osteopathic dysfunctions identified in the present cohort of patients with shoulder pain.

(Results) Baseline data showed that "worst shoulder pain intensity" as well as "average shoulder pain intensity" were indeed both significant (over 70% and close to 60% on the VAS, respectively), indicating a serious and clinically relevant level of pain. After the eight weeks' treatment period with five custom-tailored osteopathic treatments, pain intensity had dropped to clinically moderate levels of less than 30% (effect size = 2.92) and less than 20% (effect size = 2.71), for worst and average pain intensity, respectively. This may be due to the fact that all effects – not only the specific effect of an osteopathic treatment as discussed above - are included.

Secondary outcome parameters corroborate these findings. Similar between-group and within-group changes were observed for frequency of pain, the SPADI-Questionnaire, and the SF-36. During the 8 weeks follow up period, no "rebound effect" was observed for pain intensity and frequency, but rather a trend for further decrease. This seems to indicate that the nature of the osteopathic intervention may better be described as "disease modifying" than "primarily symptomatic".

Documentation of on-demand self-medication had been determined in the study protocol, but was used only by few participants. It is well established that on-demand medication may be a relevant co-factor with an inherent tendency to narrow the difference in efficacy of different therapeutic approaches in different arms of the trial. The fact that we were not successful in documenting medication comprehensively precluded an analysis of its role as a co-factor. As a result, the difference in outcomes between the two arms of the trial may lead to a tendency of underestimating the true treatment effect.

The results of this study are in line with the study of Hettasch and Bube (2009) which included a total of 41 patients with shoulder pain. Study design (untreated control group), outcome measurements and number of osteopathic treatments were very similar, as were the results observed in association with an osteopathic treatment. In the treatment group, pain intensity as measured on the VAS had decreased from 63.3 to 20.0.

As compared to a trial of efficacy, however, certain differences apply concerning the interpretation of the results The fact that this study aimed at quantifying perceived effectiveness of an osteopathic treatment in patients who deliberately seek help from an osteopath implies that a) both patient as well as therapist must be

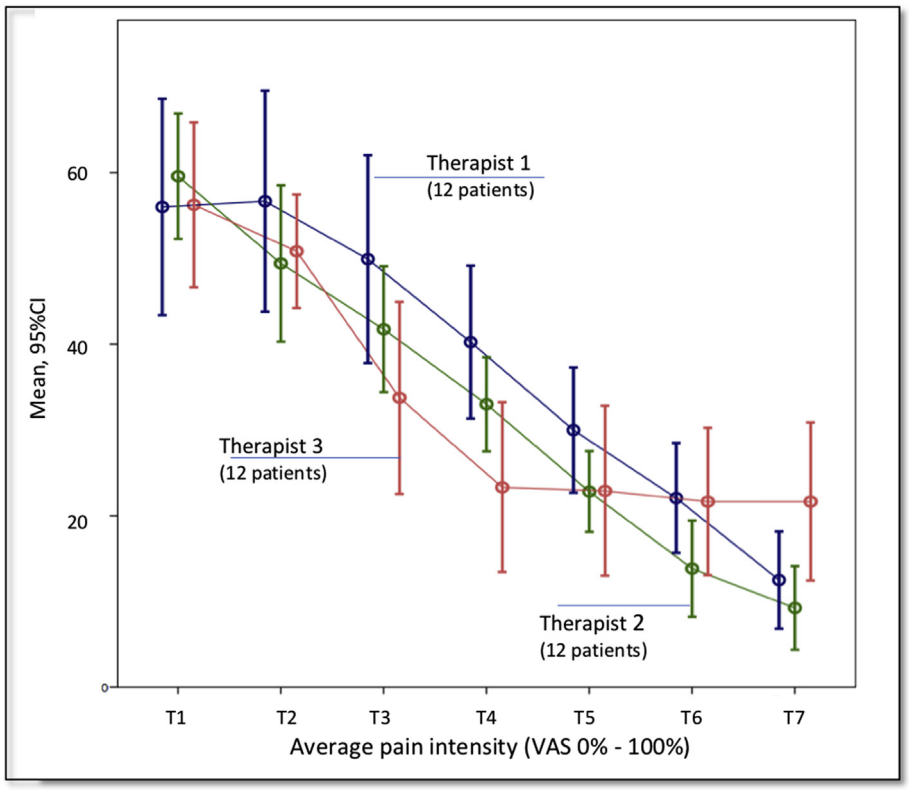

Fig. 4. Intensity of average shoulder pain on a 100% visual analog scale (VAS) in the intervention group from study start to follow up; results for each therapist in detail. Error bars represent 95% CIs.

fully aware of the circumstances and b) outcomes associated with a realistic ("real life") choice are subject to comparison (i.e. to seek versus not to seek help from an osteopath). This context rules out blinding any of the two stakeholders at the inevitable expense that various non-specific effects as, for instance, expectation, cannot be controlled for. For the research question under study, however, excluding any essential component expected to reliably occur during the treatment period would bias the results rather than prevent from bias.

In keeping with the study concept that focusses on the patients' perspective the instruments for assessing outcome (VAS and SPADI) are self-assessment instruments. Nevertheless, in the given context it cannot be ruled out that patients may feel obligated to positively (over-) estimate ratings of changes. Hence, we cannot exclude that this may have influenced ratings in one way or another. In the meantime, we would favor a procedure where the evaluator is blinded.

Concerning patient expectations, a major negative impact of allocation into the control group does not seem to be very likely, given the fact that participation provided a reliable perspective of receiving a (free!) osteopathic treatment within a reasonable timeframe. In general, the waiting list design that formally aims at establishing an "untreated" control group provides a concrete perspective for participants in this group to receive the same active intervention within a foreseeable time period anyway. With close to 4200 records (query performed in March 2018) in a Medline search for "waiting lists" as a major MeSH term (PubMed syntax: "Waiting Lists"[MeSH Major Topic]), over 7000 records for the term as a free text and a steadily increasing incidence (from 10 records in the year 1980 to about 450 records per year in recent years) is has indeed proved as a valid methodological tool in clinical research.

One inherent limitation of the waiting list design is that the follow up can only be carried out for the intervention group (because after end of the treatment period the control group is turning into a second treatment group). Thus, notions concerning observations in the follow up period do not fulfill the criteria of a randomized controlled trial, but must be considered as uncontrolled observational (within group) data. If, however, respective observations are available for the former control group, valuable conclusions on the reproducibility of the observations can be derived.

5. Conclusion

In conclusion, our study is the first to provide firm evidence that a series of five osteopathic treatments over a period of eight weeks might be beneficial for patients suffering from shoulder pain. Further studies might extend the focus on the different underlying pathologies (e.g., frozen shoulder or impingement syndrome), and are warranted to corroborate the findings, not least by extending follow-up to test whether changes observed in this study may be indicative of recovery in the long term.

Ethics approval and consent to participate

Positive approval in June 2011 from the Research commission of the German Academy of Osteopathy, Römerschanzweg 5, 82131 Gauting, Germany.

https://www.osteopathie-akademie.de.

Written informed consent was obtained from all participants before enrollment.

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Authors' contributions

FS, TH, MK, and TS contributed to the design and planning of the research. TH, MK, and TS carried out the osteopathic treatments and the data collection. MR was involved in the analysis of results. FS and KLR drafted the manuscript. All authors were involved in the critical revision of the manuscript.

Clinical relevance

- Non-traumatic shoulder pain is a common problem in the general population
- Problems associated with the diagnosis of shoulder pain include lack of recognized diagnostic criteria. Therefore the term 'non-specific shoulder pain' is commonly used, in clinical practice as well as in clinical trials
- Whilst some interventions seem to be efficacious, overall there is limited evidence regarding the efficacy of these interventions
- Five osteopathic treatments over a period of eight weeks might be beneficial for patients suffering from shoulder pain

Trial registration

German Clinical Trials Register: DRKS00013106, registration date 10.23.2017, retrospectively registered. https://www.drks.de/drks_web/setLocale_EN.do.

Declaration of competing interest

None.

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Not applicable.

References

Altman, D.G., Bland, J.M., 1999. Statistics notes: how to randomise. BMJ 319, 703–704.
Angst, F., Goldhahn, J., Pap, G., Mannion, A.F., Roach, K.E., Siebertz, D., Drerup, S., Schwyzer, H.K., Simmen, B.R., 2007. Cross-cultural adaptation, reliability and validity of the German shoulder pain and disability Index (SPADI). Rheumatology (Oxford) 46 (1), 87–92.
Bloom, J.E., Rischin, A., Johnston, R.V., Buchbinder, R., 2012. Image-guided versus blind glucocorticoid injection for shoulder pain. Cochrane Database Syst. Rev. 8, CD009147.
Brantingham, J.W., Cassa, T.K., Bonnefin, D., Jensen, M., Globe, G., Hicks, M., Korporaal, C., 2011. Manipulative therapy for shoulder pain and disorders: expansion of a systematic review. J. Manip. Physiol. Ther. 34 (5), 314–346. Jun.
Breckenridge, J.D., McAuley, J.H., 2011. Shoulder pain and disability Index (SPADI). J. Physiother. 57 (3), 197.
Buchbinder, R., Green, S., Youd, J.M., 2003. Corticosteroid injections for shoulder pain. Cochrane Database Syst. Rev. (1), CD004016.
Bullinger, M., 1995. German translation and psychometric testing of the SF-36 Health Survey: preliminary results from the IQOLA project. Int. Qual. Life Assess. Soc. Sci. Med. 41, 1359e66.
Califf, R.M., 2005. Simple principles of clinical trials remain powerful. J. Am. Med. Assoc. 293, 489–491.
Choiniere, M., Amsel, R., 1996. A visual analogue thermometer for measuring pain intensity. J. Pain Symptom Manag. 11 (5), 299–311.
Gismervik, S.Ø., Drogset, J.O., Granviken, F., Rø, M., Leivseth, G., 2017. Physical examination tests of the shoulder: a systematic review and meta-analysis of diagnostic test performance. BMC Muscoskel. Disord. 18 (1), 41. Jan.
Green, S., Buchbinder, R., Glazier, R., Forbes, A., 1998. Systematic review of randomised controlled trials of interventions for painful shoulder: selection criteria, outcome assessment, and efficacy. BMJ 316 (7128), 354–360. Jan 31.
Green, S., Buchbinder, R., Hetrick, S., 2003. Physiotherapy interventions for shoulder pain. Cochrane Database Syst. Rev. (2), CD004258.
Green, S., Buchbinder, R., Hetrick, S., 2005. Acupuncture for shoulder pain. Cochrane Database Syst. Rev. 18 (2), CD005319. Apr.
Green, S., Buchbinder, R., Glazier, R., Forbes, A., 2006. Interventions for shoulder pain. Cochrane Database Syst. Rev. (4), CD001156.
Grotle, M., Brox, J.I., Vollestad, N.K., 2004. Concurrent comparison of responsiveness in pain and functional status measurements used for patients with low back pain. Spine (Phila Pa 1976) 29 (21), e492–e501.
Hanchard, N.C., Lenza, M., Handoll, H.H., Takwoingi, Y., 2013. Physical tests for shoulder impingements and local lesions of bursa, tendon or labrum that may accompany impingement. Cochrane Database Syst. Rev. 30 (4), CD007427. Apr.
Hegadus, E., Good, A., Campbell, S., 2008. Physical examination tests of the shoulder: a systematic review with meta-analysis of individual tests. Br. J. Sports Med. 42, 80–92.
Hettasch, J., Bube, J., 2009. Osteopathic Treatment of Patients with Shoulder Pain. A Randomized Controlled Trial [Thesis]. German Academy of Osteopathy. Abstract only. Available through. http://www.osteopathic-research.com.
Hotopf, M., 2002. The pragmatic randomised controlled trial. Adv. Psychiatr. Treat. 8, 326–333.
Kappler, R.E., Jones, J.M., 2003. Osteopathic considerations in palpatory, diagnosis, and manipulative treatment. In: Ward, R.C. (Ed.), Foundations of Osteopathic Medicine, second ed. Lippincott Williams & Wilkins, Philadelphia. 2003.
Knebl, J.A., Shores, J.H., Gamber, R.G., Gray, W.T., Herron, K.M., 2002. Improving functional ability in the elderly via the Spencer technique, an osteopathic manipulative treatment: a randomized, controlled trial. J. Am. Osteopath. Assoc. 102 (7), 387–396. Jul.
Lange, T., Matthijs, O., Jain, N.B., Schmitt, J., Lützner, J., Kopkow, C., 2016. Reliability of specific physical examination tests for the diagnosis of shoulder pathologies: a systematic review and meta-analysis. Br. J. Sports Med. 1–9, 0.
Luime, J.J., Koes, B.W., Hendriksen, I.J., Burdorf, A., Verhagen, A.P., Miedema, H.S., et al., 2004. Prevalence and incidence of shoulder pain in the general population; a systematic review. Scand. J. Rheumatol. 33 (2), 73–81.
McPherson, G., Campbell, M., 2009. Methods of randomization. In: Gad, S.C. (Ed.), Clinical Trials Handbook. John Wiley & Sons, New Jersey, 2009.
Murphy, R.J., Carr, A.J., 2010. Shoulder pain. BMJ Clin. Evid. 2010, 1107. Published online.
OIA, 2014. Global Osteopathic Reports. https://oialliance.org/resources/oia-status-report. (Accessed 15 November 2018).
Paul, A., Lewis, M., Shadforth, M.F., Croft, P.R., Van Der Windt, D.A., Hay, E.M., 2005. A comparison of four shoulder-specific questionnaires in primary care. Ann. Rheum. Dis. 63 (10), 1293–1299.
Peek, A.L., Miller, C., Heneghan, N.R., 2015. Thoracic manual therapy in the management of non-specific shoulder pain: a systematic review. J. Man. Manip. Ther. 23 (4), 176–187. Sept.
Price, D.D., McGrath, P.A., Rafii, A., Buckingham, B., 1983. The validation of visual analogue scales as ratio scale measures for chronic and experimental pain. Pain 17 (1), 45–56.
Rekola, K.E., Keinanen-Kiukaanniemi, S., Takala, J., 1993. Use of primary health services in sparsley populated country districts by patients with musculoskeletal symptoms: consultations with a physician. J. Epidemiol. Commumity Health 47, 153–157.
Resch, K.L., 1998. Pragmatic randomised controlled trials for complex therapies. Forschende Komplementärmed. 5, 136–139.
Schellingerhout, J.M., Verhagen, A.P., Thomas, S., Koes, B.W., 2008. Lack of uniformity in diagnostic labeling of shoulder pain: time for a different approach. Man. Ther. 13 (6), 478–483. Dec.
Singh, J.A., Fitzgerald, P.M., 2010. Botulinum toxin for shoulder pain. Cochrane Database Syst. Rev. 9, CD008271.
Sun, Y., Chen, J., Li, H., Jiang, J., Chen, S., 2015. Steroid injection and nonsteroidal anti-inflammatory agents for shoulder pain: a PRISMA systematic review and meta-analysis of randomized controlled trials. Medicine (Baltim.) 94 (50), e2216, 5 Dec.
Tekeoglu, I., Ediz, L., Hiz, O., Toprak, M., Yazmalar, L., Karaaslan, G., 2013. The relationship between shoulder impingement syndrome and sleep quality. Eur. Rev. Med. Pharmacol. Sci. 17 (3), 370–374. Feb.
Van der Heijden, G.J., 1999. Shoulder disorders: a state-of-the-art review. Bailliere. Best Pract. Res. Clin. Rheumatol. 13, 287–309.
Vincent, K., Leboeuf-Yde, C., Gagey, O., 2017. Are degenerative rotator cuff disorders a cause of shoulder pain? Comparison of prevalence of degenerative rotator cuff disease to prevalence of nontraumatic shoulder pain through three systematic and critical reviews. J. Shoulder Elbow Surg. 26 (5), 766–773.
WHO, 2010. Benchmarks for Training in Osteopathy. http://www.who.int/medicines/areas/traditional/BenchmarksforTraininginOsteopathy.pdf. (Accessed 15 November 2018).
Witt, C.M., 2009. Efficacy, effectiveness, pragmatic trials: guidance on terminology and the advantages of pragmatic trials. Forsch. Komplementmed 16 (5), 292–294.
Xiao, R.C., Walley, K.C., DeAngelis, J.P., Ramappa, A.J., 2017. Corticosteroid injections for adhesive capsulitis: a review. Clin. J. Sport Med. 27 (3), 308–320. May.