Study on the effectiveness of a test-dependent osteopathic treatment for women with persistent post partum back pain. A randomized controlled trial

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Objective: To investigate whether a series of test-dependent osteopathic treatments has a positive effect on persistent non-specific post partum back pain.

Design: Randomized controlled trial using a “waiting list design”.

Materials and methods: Forty women (average age 34.5 y) with non-specific back pain post partum participated in the study. Back pain had to be present for at least three but not longer than 24 months, associated with pregnancy or birth. Twenty women were randomly allocated to the treatment group and twenty to the control group. The treatment group received four osteopathic treatments over an eight-week period. The women in the control group remained untreated during this period. A follow-up was conducted six weeks after completion of treatment. At any treatment session, actually diagnosed osteopathic dysfunctions were treated according to the principles of osteopathy. The main outcome measures were a) pain intensity as measured on a visual analogue scale (VAS), and b) changes in the activities of daily living (ADL) as measured with the Oswestry Pain Questionnaire (OPQ).

Results: Mean between group differences of longitudinal changes of pain intensity as well as of the OPQ were statistically significant (-45.7, 95% CI= -33.8 to -57.6, p < 0.001, and -17.7, 95% CI= -11.6 to -23.8, p < 0.001). In the treatment group the intensity of the pain measured on the VAS decreased from 68.3 to 20.6, which corresponds to an improvement of 70% (95% CI= -36.5 to -58.8, p < 0.001). No changes were observed in the control group (2.0, 95% CI= -6.6 to 2.7, p = 0.383). Similar results were observed for ADL. In the intervention group, the OPQ improved on average by 17.4 points, which corresponds to 62% (95% CI= -11.8 to -23.0, p < 0.001) as opposed to no changes in the control group (0.4 points, 95% CI= -2.5 to 3.1, p=0.808). A sensitivity analysis did not reveal any tested external factor to have a noticeable impact on these findings. In the follow-up 6 weeks after the end of treatment, a further improvement of the symptoms was noted in the treatment group.

Conclusion: In this study a series of test-dependent osteopathic treatments for women with persistent, non-specific backache post partum resulted in a clinically relevant improvement of pain symptoms, and a reduction of ADL impairments. If these findings are confirmed, serial osteopathic treatments may mean new hope to women suffering from severe pain.
Do osteopathic treatments improve the symptoms of headache and/or sinus pressure in patients with chronic rhino sinusitis (CRS)? A randomized controlled trial

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Objective: To investigate whether osteopathic treatments improve the symptoms of headache and/or sinus pressure in patients with chronic rhino-sinusitis (CRS).

Design: Randomized controlled trial with an “untreated” control group (waiting list design)

Material and methods: Out of a total of 61 patients with an established diagnosis of CRS complaining of symptoms of headache and/or sinus pressure, thirty-one were randomized to the intervention group and received five osteopathic treatments at intervals of two weeks. Thirty patients served as controls and were not treated for 10 weeks. Consecutively they received 5 osteopathic treatments at two week intervals. A follow-up was conducted four months after completion of treatment. Main outcome measures were headache and/or sinus pressure as rated on a numeric rating scale (NRS). Overall symptomatology was assessed using the Sinonasal Assessment Questionnaire (SNAQ-11). Treatment was given based on actual individual findings.

Results: A direct comparison between the osteopathic and control groups using the primary parameter of “intensity of headache and/or sinus pressure” produced a statistical significance in favour of the osteopathic group The inter-group differences of changes were 1.7 for the NRS (95% CI=-0.1 to -3.2, p=0.039) and 1.8 (95% CI=-0.3 to -3.3, p=0.002) respectively. During the course of the study headache severity dropped from 3.2 to 1.7 on the NRS (95% CI=-0.37 to -2.60, p=0.011,) in the intervention group, equivalent to a reduction of 47%. Sinus pressure improved from 3.7 to 2.1 (95% CI=-0.61 to -2.55; p=0.002) equivalent to a reduction of 43%. In the control group symptoms remained unchanged. Similar inter-group and within-group changes were observed for the SNAQ-11. A sensitivity analysis did not reveal any tested external factor to have a noticeable impact on these findings. A follow-up of 51 patients four months after completion of the last patient’s treatment confirmed the sustainability of the treatment method with an additional slight improvement in the results.

Conclusion: The positive evidence for the effectiveness of osteopathic treatments for patients with CRS found by this study is promising. Five osteopathic treatments within an eight-week period seem to have caused a clinically relevant relieve of the overall symptomatology and of pain in CRS. If these results can be replicated by other RCTs, a series of osteopathic treatments may prove to be an effective intervention producing sustainable results in patients with CRS.
Osteopathic treatment of somatoform autonomic dysfunctions of the cardiovascular system. A randomized controlled trial.
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Introduction: Functional cardiovascular dysfunctions are among the most common complaints, with patients often reporting strong cardiovascular symptoms even though no apparent organic problems can be diagnosed in medical examinations.

Objective: The main objective of this study was to assess the effectiveness of a series of osteopathic treatments on patients suffering from cardiovascular somatoform autonomic dysfunctions (SAD).

Materials and Methods: Thirty-six patients (average age 48.9 years) reporting symptoms of cardiovascular SAD but without any manifest problem requiring treatment by a cardiologist were enrolled into the study. By means of external randomisation 19 patients were assigned to the intervention group, 17 patients to the control group. The intervention group received five osteopathic treatments in intervals of two weeks. The patients of the control group did not receive any treatment during the same time range of 10 weeks (“waiting list design”). Primary outcome parameters were the patients' self-evaluation of their physical symptoms and changes in those symptoms as measured with the SOMS-7 questionnaire (Screening for Somatoform Symptoms). Secondary outcome parameters were intensity of the heart-related symptoms (assessed by means of a visual analogue scale) and frequency of occurrence (Likert-Scale) as well as quality of life (SF-36) and osteopathic dysfunctions. Osteopathic dysfunctions in the visceral, parietal and craniosacral systems were recorded on the day of treatment in accordance with the individual diagnoses of the patients and were treated based on osteopathic principles.

Results: The comparison of changes between groups revealed clinically relevant improvements in the osteopathic group for the main outcome parameter SOMS. The between-group difference of changes of the SOMS-7-SSC Score (somatization symptom count) was -3.6 (95% CI = -1.5 to -7.6, p=0.005), respectively -15.5 (95% CI = -9.3 to -26.4, p<0.005) of the SOMS-7-SSI Score (somatization severity index). In the intervention group the SOMS-7-SSC Score dropped from 22.2 to 18.1 (95% CI = -6.8 to -1.3; p=0.006) and the SOMS-7-SSI Score from 46.4 to 29.7 (95% CI = -23.6 to -9.7; p<0.005). In the control group no changes were observed during that time. The intensity of heart-related symptoms (68% to 20%) and the frequency (3.3 to 0.8) decreased. Physical health state (SF-36) improved in the intervention group from 35 to 42 (95% CI = 2.9 to 9.9; p=0.001) and mental health state from 39 to 44 (95% CI = 0.6 to 8.5; p=0.03). The three-month follow-up showed that the improvement in the intervention group remained stable regarding to all outcomes.

Conclusion: Five osteopathic treatments over a period of ten weeks led to clinically relevant positive changes of the symptoms of cardiovascular SAD. Further studies are warranted, extending the focus on reproducibility.
Osteopathic treatment of women suffering from urinary incontinence following an injury to the perineum during delivery. A randomized controlled trial

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Objective: The main objective of this study is to evaluate whether an osteopathic treatment in addition to the current standard therapy (“pelvic floor muscle training”) can improve the overall quality of life of women suffering from urinary incontinence following an injury to the perineum during delivery.

Design: Evaluator-blind randomized controlled trial.

Materials and methods: Sixty women (average age 37.5 years) diagnosed by their gynecologists as suffering from urinary incontinence took part in the study. By means of external randomisation 30 women were assigned to the intervention group, 30 women to the control group. The intervention group received four osteopathic treatments in intervals of three weeks. Both groups received usual instructions on how to do pelvic floor muscle training at home, and were advised to perform those exercises on a regular basis for the entire time of participation in the trial (12 weeks). Osteopathic dysfunctions in the visceral, parietal and cranio-sacral systems were recorded on the day of treatment in accordance with the individual diagnoses of the patients and were treated based on osteopathic principles. Primary outcome parameter was a condition-specific outcome instrument, the King's Health Questionnaire (KHQ).

Results: The total score of the KHQ could only be measured for about 40 patients because of some missing values of the other 20 patients. In the intervention group the symptom-specific quality of life had significantly improved by the end of treatment from 34 to 19 points on the KHQ (95% CI=8.6 to 21.4, p< 0.0005). The improvement in the control group was less pronounced (31 to 22 points, 95% CI=2.6% to 16.6%, p=0.011). The direct comparison of both groups, however did not reveal a statistically significant superiority of the additional intervention (Inter-group difference of longitudinal changes 5.5 points, 95%CI=--3.7% to 14.6%, p=0.24). To allow evaluation of the total number of 60 patients two secondary analyses were carried out, with missing values replaced either by the average value or the worst value of the group. In both of these exploratory analyses the total score of the KHQ revealed statistically significant superiority of the addition of an osteopathic treatment.

Conclusion: Four osteopathic treatments in intervals of three weeks in addition to pelvic floor muscle training had a statistically significant influence on the symptom-specific quality of life of women with urinary incontinence following an injury of the perineum, suggesting superiority of an additional osteopathic therapy as opposed to the standard therapy of “pelvic floor muscle training” alone. An osteopathic treatment series seems to be a suitable therapeutic method in the treatment of women with urinary incontinence following perineal injury.
**Do osteopathic treatments influence the lower urinary tract symptoms (LUTS) in patients with benign prostatic syndrome (BPS)? A randomized controlled trial.**

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**Objective:** To evaluate whether osteopathic treatment influences the symptom severity in men with lower urinary tract symptoms (LUTS) defined as an International Prostate Symptom Score (IPSS) >8 associated with Benign Prostatic Syndrome (BPS).

**Study design:** Randomized controlled trial including a follow-up three months succeeding the last osteopathic session.

**Methods:** 64 men aged between 41 and 69 years (average age 58.5 ± 8 years) with urological diagnosed BPS and LUTS participated in the study. By means of external randomization 34 men were allocated to the osteopathic group and 30 to the control group. In the osteopathic group case histories and osteopathic examination were followed by four osteopathic treatments at intervals of two weeks. The custom tailored treatment based on osteopathic principles. The patients of the control group did not receive any treatment during the study period. Primary outcome parameter war the symptom severity level measured by the IPSS. The secondary outcome parameter “disease-specific Quality of Life (QoL)” was assessed by means of the Quality of Life Item of the IPSS and the parameter “erectile dysfunction and its impact on sexuality” by the International Index of Erectile Function (IIEF). According to an intention-to-treat analysis the available data of one dropped-out patient in the osteopathic group were utilized by last observation carried forward (LOCF).

**Results:** The inter-group comparison of changes revealed statistically significant improvement in support of the osteopathic treated group for the main outcome parameter “symptom severity level” difference of means = -5.6; 95% CI: -7.7 to -3.5; p<0.0005). IPSS improved in the osteopathic group by 38.5% (difference of means = -7.4; 95% CI: -9.1 to -5.8; p<0.0005) and in the control group by 10% (difference of means = -1.8; 95% CI: -3 to -0.6; p=0.004). The results related to the secondary parameters presented clinically relevant positive effects too. At baseline 2 men (6%) were satisfied with their current QoL, at the end of the study period 19 men (58%) were “delighted to mostly satisfied”. Erectile function improved in the osteopathic group by 11% (difference of means = 2.2; 95% CI: 0.5 to 4; p=0.01). In the control group no changes were recorded. The follow-up showed that the results of all outcomes in the intervention group remained stable respectively continued to improve.

**Conclusion:** Four osteopathic treatments over a period of eight weeks led to clinically relevant positive changes of urological symptom severity level in men suffering from LUTS associated with BPS. Further studies are warranted extending the focus on further hypotheses related to the subject of male lower urinary tract symptoms.