“Osteopathy as a promising short-term strategy for irritable bowel syndrome: A randomized controlled trial”

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Background:

The most popular therapeutical strategies are attempts to initiate positive changes in lifestyle and diet, phytotherapy, psychotherapy and drug treatment. The most commonly used types of drugs are Spasmolytics, low dose antidepressants and neurotransmitter agonists or antagonists. But they are typically accompanied by considerable side-effects. Because on one side there is no therapeutic gold standard, on the other side there is ample empiric evidence that an osteopathic treatment may be very helpful for patients with IBS, we aimed at scrutinizing our observation by means of proper scientific methods.

Objective:

Hypothesis underlying our study: A predefined osteopathic treatment can have specific improving effects on the symptoms of IBS

Material and Methods:

Study Design:

Prospective, randomized, controlled, patientblind study
Osteopathic treatment: a custom-tailored treatment of the actual dysfunctions in four predefined areas
Sham-treatment: osteopathic tests in predefined areas without therapeutical intention

Outcome Measures:

Primary outcome parameter: pain intensity measure by VAS
Secondary outcome parameters: frequency and intensity of distension, constipation, diarrhea and others measured by VAS / Likert scales

Results:

Flow Chart of Study

Main Outcome Parameter: Pain

Pain Reduction
Sham: 19%
Osteo: 75%

The changes in pain intensity were significantly different between the two groups as soon as two weeks after the second treatment.
The difference remained significant until the end of the study.

Secondary Outcome Parameters

The most popular therapeutical strategies are attempts to initiate positive changes in lifestyle and diet, phytotherapy, psychotherapy and drug treatment. The most commonly used types of drugs are Spasmolytics, low dose antidepressants and neurotransmitter agonists or antagonists. But they are typically accompanied by considerable side-effects. Because on one side there is no therapeutic gold standard, on the other side there is ample empiric evidence that an osteopathic treatment may be very helpful for patients with IBS, we aimed at scrutinizing our observation by means of proper scientific methods.

Summary

- Pain reduction was significantly more pronounced in the osteopathic group
- Improvement was slightly more pronounced in all four secondary outcome parameters in the osteopathic group
- Intra-group longitudinal changes were significant in all parameters from T5 on in the osteopathic group only
Material and Methods

Study Design:
- Randomized controlled trial
- Intervention Group: 3 osteopathic treatments between 12th and 34th week of gestation
- Custom-tailored treatment of the actual dysfunctions; two therapists
- Control Group: no osteopathic treatment during pregnancy

Outcome Measures:
- Primary outcome parameter: Length of delivery (hours)
- Secondary outcome parameters: Intensity of pain during delivery (NRS), mode of delivery, number and type of delivery complications, injuries, and the baby’s condition (Apgar-Score, umbilical artery pH-value)

Main inclusion/exclusion criteria:
- At least 18 years old, planned delivery in a hospital, women before 12th week of gestation, no somatic and psychic diseases, no previous abortion

Results

Duration of delivery

- Pain intensity during delivery decreased by 37% in the intervention group (52 percentage points on the Numeric Rating Scale NRS, compared to 82 percentage points in the control group; p < 0.005)
- Mode of delivery: 24 vaginal deliveries compared to 18 in the control group.
- The number of episiotomies showed no significance but decreased: 24 (71%) had no episiotomy in the osteopathic group, compared to 16 (51%) in the control group.
- The data regarding injuries and complications during delivery were more positive in the intervention group.
- 100% of the babies in the intervention group had normal or slightly acidic umbilical artery pH-values, compared to only 83% in the control group.

Summary

Three osteopathic treatments during pregnancy had a relevant impact on the length of delivery. The results were clinically relevant but not entirely statistically significant. Possible reasons could be the fact that there were some drop outs in the control group and that the sample size was not large enough. This outcome is encouraging for further research in this field especially in terms of prevention and whether complications during childbirth can be reduced through specific osteopathic treatment during pregnancy.
Osteopathic treatment of women with primary dysmenorrhoea: A randomized controlled trial

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2 German Academy of Osteopathy (AFO), Research Commission

Background
Primary dysmenorrhoea is the most common gynaecological problem. By definition the pain starts shortly after the menarche or a few years later. It occurs regularly shortly before or with the onset of bleeding and increases in intensity over the course of the following one to two days. There are many symptoms e.g. painful menstrual cramps, pain in the pelvis area, low back pain, headaches, vomiting and nausea.

Objective
To assess the effectiveness whether osteopathic treatments can have an influence on the intensity and duration of pain in women with primary dysmenorrhoea.

Material and Methods

Study Design:
- Randomized controlled trial
- Intervention Group: 5-6 osteopathic treatments during 4 monthly cycles
- Custom-tailored treatment of the actual dysfunctions; three therapists
- Control Group: untreated (waiting list design)

Outcome Measures:
- Primary outcome parameters: pain intensity (Numeric Rating-Scale NRS), duration (threshold value > 5)
- Secondary outcome parameters: Generic health status (SF-36), associated disorders, work disability (Sultan Scale), medication

Main inclusion/exclusion criteria:
- Medically diagnosed primary dysmenorrhoea, at least 14 years old,
- no pregnancy, no hormonal contraceptives

Results

Primary outcome parameter:

<table>
<thead>
<tr>
<th>Pain intensity and duration</th>
<th>Longitudinal changes</th>
<th>Between-group differences</th>
<th>Between-group difference, and 95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2 - T8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteopathic group (n=25)</td>
<td>4.6 ± 1.2</td>
<td>-0.1 ± 1.6</td>
<td>-2.6 (-1.7 to -3.6)</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Control group (n=28)</td>
<td>5.1 ± 2.9</td>
<td>-0.4 ± 1.6</td>
<td>-1.5 (-2.4 to -0.6)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Secondary outcome parameter:

Quality of life (SF-36, physical component summary PCS)

<table>
<thead>
<tr>
<th>Between-group differences</th>
<th>Longitudinal changes</th>
<th>Between-group difference, and 95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2 - T8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteopathic group (n=25)</td>
<td>5.1 ± 3.4</td>
<td>-2.2 ± 1.4</td>
<td>0.216</td>
</tr>
<tr>
<td>Control group (n=28)</td>
<td>4.7 ± 3.4</td>
<td>-1.9 ± 1.6</td>
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</tbody>
</table>

In the osteopathic group:
- 59% improvement for pain intensity
- 86% less duration of pain

In the control group:
- 15% improvement for quality of life (physical component summary, SF-36)
- 50% improvement of duration of associated disorders
- 66% improvement of absenteeism at work or school
- 79% reduction of medication (increase in the control group of 31%)

Summary

Five to six osteopathic treatments of the women with primary dysmenorrhoea over a period of four monthly cycles had a statistically significant and clinically relevant influence on the pain symptoms. Further studies are warranted, and the sustainability of the successful treatment should be monitored in a follow-up.
"Osteopathic treatment of low back pain during pregnancy. A randomized controlled trial."

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²German Academy of Osteopathy (AFO), Research Commission

Background:
Low back pain during pregnancy is a common problem. Epidemiologic data on the prevalence vary between 23% and 85%. A clear definition and classification of low back pain symptomatic for pregnant women does not exist. Two usual definitions which refer to pain symptomatology are: pregnancy-related pelvic girdle pain (PPP) for musculoskeletal pain in the pelvis area and pregnancy-related low back pain (PLBP) for pain in the lumbar region. Therapeutic interventions are limited because of pregnancy. Drug therapy is avoided with inherent problem.

Objective:
Can a series of osteopathic treatments on women with pregnancy related pain in the pelvic and/or lumbar area influence the pain symptomatology?

Material and Methods:
Study Design:
- A randomized controlled clinical trial based on a "waiting list design"
- Intervention group: 4 osteopathic treatments in weekly intervals.
- Osteopathy according to actual diagnosis
- Control group: Waiting time for 5 weeks

Outcome Measures:
- Main outcome measure: pain intensity (Visual Analogue Scale – VAS)
- Secondary outcome parameter: Impact of back pain on activities of daily life (Quebec back pain disability scale)

Main inclusion criteria:
- 20.-30. week of pregnancy, gynecological examination indispensable, first incidence of pain symptomatology in the time of pregnancy, VAS ≥ 3

Results:

Flow Chart of the study

Between-group difference of changes

<table>
<thead>
<tr>
<th>Longitudinal changes T1 to T5</th>
<th>Between-group difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention group n = 30</td>
<td>Control group n = 27</td>
<td></td>
</tr>
<tr>
<td>Pain intensity (VAS-Score)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.4 ± 2.4</td>
<td>-0.3 ± 1.9</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Disability (Quebec Score)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.1 ± 16.6</td>
<td>-8.4 ± 10.4</td>
<td>&lt;0.0005</td>
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</tbody>
</table>

Pain intensity (Visual analogue scale)

<table>
<thead>
<tr>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
<th>T5</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.6</td>
<td>6.5</td>
<td>6.4</td>
<td>6.4</td>
<td>6.4</td>
</tr>
<tr>
<td>5.8</td>
<td>5.9</td>
<td>5.8</td>
<td>5.8</td>
<td>5.8</td>
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</tbody>
</table>

Disability (Quebec - Score)

<table>
<thead>
<tr>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
<th>T5</th>
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<tbody>
<tr>
<td>6.4</td>
<td>6.4</td>
<td>6.4</td>
<td>6.4</td>
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<tr>
<td>6.4</td>
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<td>6.4</td>
<td>6.4</td>
</tr>
</tbody>
</table>

Summary:
- Four osteopathic treatments over a period of five weeks led to a statistically significant and clinically relevant improvement of pain symptoms.
- Additionally there was an improvement of the activities of daily life.
- Osteopathic interventions may be a promising therapeutic regimen for pregnant women with pain in the pelvic and/or lumbar area.
“Osteopathic treatment of patients with chronic non-specific neck pain: A randomized controlled trial”

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Background:
Chronic non-specific neck pain (CNP) is a common, often disabling condition which presents with inconsistent aetiology, pathology and symptoms and still lacks a reliable therapeutic standard. The primary symptom, permanent pain of unclear origin, and the resulting complaints represent a substantial health problem. It seems that an improvement of pain symptomatology is possible with physiotherapy (exercises, manipulation, and mobilization). Empiric evidence suggests that osteopathic interventions might be effective in alleviating CNP symptoms.

Objective:
To assess whether a series of osteopathic treatments is superior to physiotherapy concerning the pain of patients with chronic non-specific neck disorders.

Material and Methods:

Study Design:
- Randomized controlled trial, including a three-month follow-up.
- Control Group: Physiotherapy, on average 18 treatment sessions over a nine-week period.

Outcome Measures:
- Primary outcome parameters: pain intensity (Visual Analogue Scale - VAS), duration, and frequency (Likert Scale)
- Secondary outcome parameters: Generic health status (SF-36), activities of daily living (Nordic questionnaire)

Main inclusion criteria:
- Medically diagnosed chronic neck disorder, persisting at least 3 months, VAS ≥ 40%, age between 20 and 50 years

Results:

Flow chart of study
163 patients assessed for eligibility
60 patients randomized
Assignment to intervention group n = 31
Assignment to control group n = 29
2 drop outs
29 analyzed data
60 patients randomized

Primary outcome parameter:
1.) Between-group differences: VAS - Scores

<table>
<thead>
<tr>
<th></th>
<th>Control group (n=29)</th>
<th>Osteopathy group (n=29)</th>
<th>Between-group difference, and 95% CI</th>
<th>p - value</th>
</tr>
</thead>
<tbody>
<tr>
<td>actual pain</td>
<td>21.3</td>
<td>11.3</td>
<td>10.0 (5.2 to 14.7)</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>average pain</td>
<td>29.5</td>
<td>20.6</td>
<td>8.9 (2.8 to 15.0)</td>
<td>0.005</td>
</tr>
<tr>
<td>maximum pain</td>
<td>22.6</td>
<td>15.0</td>
<td>7.6 (2.2 to 12.9)</td>
<td>0.013</td>
</tr>
</tbody>
</table>

2.) Within-group longitudinal changes: Average pain (VAS-Scores, SD)

<table>
<thead>
<tr>
<th></th>
<th>Begin of treatment W0</th>
<th>End of treatment W11</th>
<th>Intra-group Diff. and 95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteopathic group (n=29)</td>
<td>41.9 ± 14.4</td>
<td>20.5 ± 14.7</td>
<td>(11.9 to 26.8)</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Control group (n=29)</td>
<td>45.1 ± 8.7</td>
<td>29.7 ± 10.9</td>
<td>(15.4 to 18.8)</td>
<td></td>
</tr>
</tbody>
</table>

Secondary outcome parameter:
Quality of life (SF-36):

<table>
<thead>
<tr>
<th></th>
<th>Bodily health Control group (n=29)</th>
<th>Control group (n=29) - Osteopathic group (n=29) - 95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.)</td>
<td>14.5 ± 5.4</td>
<td>14.5 to 2.2</td>
<td>&lt;0.0006</td>
</tr>
<tr>
<td>2.)</td>
<td>14.5 ± 5.4</td>
<td>12.8 to 16.1</td>
<td></td>
</tr>
</tbody>
</table>

Summary

- Five osteopathic treatments over a 10-week period could have a clinically relevantly more pronounced influence on pain and quality of life in patients with chronic neck pain than physiotherapy.
- These results confirm findings of a previous study (Bischoff et al., 2002), strengthening the evidence that a series of osteopathic treatments may be an appropriate therapy for patients suffering from chronic neck pain.

Pain intensity: Average pain
(Visual analogue scale)

Pain intensity: Average pain
(mean, 95% CI)

Control Group:
34% improvement on average pain intensity, 31% improvement on Quality of life, Follow up after 3 months: 22% worsening on pain intensity

Intervention Group:
54% improvement on average pain intensity, 8% worsening on pain intensity
**Development of a study protocol in osteopathic clinical research on an osteopathic approach for patients with late whiplash syndrome (LWS)**

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3 German Institute for Health Research (DIG)
4 German Academy of Osteopathy (AFoO), Research Commission

**Background**
Whiplash is a common injury associated with motor vehicle accidents and causes chronic pain, disability, activity limitations, and often psychological distress. The clinical sequelae and manifestation resulting from this trauma six months after the accident is defined as late whiplash syndrome (LWS), and describes symptoms like somatic dysfunction, pain, disability, as well as psychological and psychosocial factors.

**Systematic Literature Review of the latest relevant literature on LWS**
For the development of this study protocol a systematic literature research was carried out first to identify and collect studies from the last 10 years which give some clinical indication of the latest research on LWS. Literature analysis was based on a comprehensive search of published materials on the whiplash syndrome complex, including clinical trials, systematic reviews, meta-analyses, and guidelines published between 1999 and 2009 in Medline, Embase, the Cochrane Library, and other important databases.

**Main results:**
- **Classification:** Whiplash injury of the cervical vertebrae is signified by a physical acceleration and deceleration trauma.
- **Epidemiology:** In Germany 18 to 25% of patients suffering from whiplash injury still have problems up to one year after the original incident.
- **Symptoms:** The most common symptoms are pain and stiffness in the neck region.
- **Diagnosis:** In contrast to most other injuries, the structure of the trauma following a whiplash injury is largely unclear.
- **Therapy:** A lot of research has been done about the effect of treatment options of LWS that cover a wide range of conservative care. But a rational evidence-based approach is absent, and there is no gold standard for the management of affected patients.

**Systematic Literature Review of trials on LWS concerning methodological implications**
In Neck pain related to neurological treatment of WAD or LWS were evaluated concerning methodological aspects potentially relevant for the protocol development, e.g.,

**Outcome measurements:** The most common outcome variables were pain intensity (32.8%), followed by disability (21.5%) and ROM (17.2%). In 77% of the cases the subjective perceived pain intensity was obtained using a numerical (NRS) or visual analogue scale (VAS). The Neck Disability Index (NDI) was used in 45% of the cases for disability-related functional impairment. The Whiplash Disability Questionnaire (WDQ) is a validated modified 13-item version of the NDI.

**Systematic Literature Review on osteopathic treatment of patients with LWS**
The aim of this literature review was to identify and extract osteopathic intervention studies from the past 10 years. The studies were clearly concerned with the treatment modality “osteopathic treatment” or “OMT” in whiplash syndrome. The were no results of osteopathic clinical trials found in peer reviewed journals.

**Conclusion**
Patients who visit an osteopathic practitioner are often suffering from the sequelae of an injury, especially after road traffic accidents. It is remarkable about conventional treatment methods generally result in no discerning improvement with these patients. Empirical evidence has shown that osteopathic treatment has positive effects on late whiplash syndrome.

**Study protocol**

**Primary objective:** The main objective of the study is to determine the effect of test-dependent osteopathic treatments on patients with whiplash injury-related disability in comparison to “watchful waiting.”

**Secondary objectives:** Reduction of pain intensity, improvement in quality of life, correlation of psychological factors with LWS, frequencies of areas of osteopathic dysfunction, reduction of medication, association between psychological factors and the target symptoms, lasting positive effects of osteopathic treatment.

**Study design:** The study is designed as a 2-armed, randomized, controlled, evaluator blind, multi-center trial, which compares osteopathic treatment with a waiting list group (untreated). Follow-up after 3 and 6 months. The study follows the standards of the Declaration of Helsinki and the ICH-GCP Guideline for Good Clinical Practice. The study protocol is subject to an IRB review. Subjects will be randomly assigned to one of the two groups: Osteopathic intervention group and untreated group.

**Inclusion criteria:**
- Ages eligible for study: 18 years to 65 years.
- Whiplash injury with rear-end collisions from 6 months to 10 years ago.
- Actual symptoms intensity must exceed 30% on the VAS.
- Symptoms must be as a result of the motor vehicle collision.

**Exclusion criteria:**
- Undergoing treatments like physical therapy, manual therapy, chiropractic spinal manipulation, acupuncture within the past 3 months, undergoing osteopathic treatment within the past 6 months.
- Regular intake of corticosteroid medication and ongoing treatment with anticoagulants.
- A pending insurance claim, involvement in current litigation or a pending pension application.
- Pregnancy, Osteoarthritis of the cervical spine, cervical radiculopathy or myelopathy, vascular insufficiency, fibromyalgia, inflammatory disorders, infectious diseases, malignancy, calcium metabolism disorders, circulatory disorders of the A. vertebrale.
- Severe trauma/skeletal injury/fractures in the previous 3 months.

**Setting / patients:**
- Research centers in osteopathic practices (primary care setting).
- Each osteopath will be required to have successfully completed the highest possible level of osteopathic education in their country.
- Number of subjects: 140 (70/70), according to sample size calculation.
- Number of centers: at least 8 osteopathic research centers should collaborate.
- Number of therapists: at least 10 osteopaths should conduct the treatments.

**Primary outcome measure:**
Whiplash related disability (measured by the WDQ)

**Secondary outcome measures:**
- Pain intensity (VAS), quality of life (SF-12 Health Survey), psychosocial factors (BDI), medication (medication diary), osteopathic dysfunctions (examination forms: SOE, SDAP).

**Osteopathic intervention:** The treatment follows osteopathic principles according to the test-dependent dysfunctions which will be evaluated for each treatment session.

**Conclusion:**
This study protocol outlines the rationale and suitable design of a randomized controlled trial to determine osteopathic treatment effectiveness in patients with LWS.
“Do osteopathic treatments have an influence on the symptoms of patients with chronic abacterial prostatitis/chronic pelvic pain syndrome?”

A randomized controlled trial

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2German Academy of Osteopathy (AFO), Research Commission

Background

Prostatitis is the most frequent urological complaint diagnosed in men under 50. As bacteria are found in less than 5% of all cases, one is dealing chiefly with chronic abacterial prostatitis. The symptoms seem to be multifactorial so that conventional therapies rarely lead to an improvement.

Objective

The aim of this study was to examine whether osteopathic interventions may be effective in alleviating the symptoms of chronic abacterial prostatitis/chronic pelvic pain syndrome (CAP/CPPS).

Methods

The study was carried out in an osteopathic practice. The patients recruited were referred by urologists and through newspaper articles. The osteopathy group received a total of 5 treatments over a period of 8 weeks, at one-week intervals for three weeks and with an interval of up to 3 weeks at the end. The osteopathic dysfunctions were diagnosed and treated individually. The sham treatment of the control group consisted of a programme of exercises.

Main outcome parameters | Instruments
--- | ---
Lower urinary tract symptoms (LUTS) | International prostatic symptom score (IPSS)
Chronic pelvic pain (CPP) | National index of Health-chronic prostatitis syndrome index (NIH-CPSI)
Quality of life | Quality of life instrument of the IPSS (QoL)

Results

IPSS

Group: Osteopathic group vs Control group

<table>
<thead>
<tr>
<th>Inter-group difference</th>
<th>T0 –T5 (95% CI)</th>
<th>6-weeks follow-up (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPSS (0-35)</td>
<td>8.9 (4.7 to 13.1)</td>
<td>1.2 (-0.05 to 2.4)</td>
</tr>
<tr>
<td>P&lt;0.0005</td>
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<td></td>
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</tbody>
</table>

NIH-CPSI

Group: Osteopathic group vs Control group

<table>
<thead>
<tr>
<th>Inter-group difference</th>
<th>T0 –T5 (95% CI)</th>
<th>6-weeks follow-up (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH-CPSI (0-43)</td>
<td>12.8 (7.9 to 17.6)</td>
<td>4.1 (1.9 to 6.3)</td>
</tr>
<tr>
<td>P&lt;0.0005</td>
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</table>

Quality of Life

Group: Osteopathic group vs Control group

<table>
<thead>
<tr>
<th>Inter-group difference</th>
<th>T0 –T5 (95% CI)</th>
<th>6-weeks follow-up (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QoL (0-6)</td>
<td>2.5 (1.5 to 3.4)</td>
<td>0.3 (-0.1 to 0.8)</td>
</tr>
<tr>
<td>P&lt;0.0005</td>
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</tbody>
</table>

The positive effects of the osteopathic treatment sustained regarding the follow-up assessments 1 year after the study.

Conclusion

A series of osteopathic interventions seems a promising therapeutic regimen for CAP/CPPS sufferers. Further studies will have to demonstrate whether these findings are reproducible.