Does osteopathic treatments improve the symptoms of headache and/or head-pressure in patients with Chronic Rhinosinusitis (CRS)?

A randomized controlled trial

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Background

- CRS is one of the most widespread chronic diseases.
- Inflammations of the mucosa of the nose as well as of the paranasal sinus are among the 3 most frequent human diseases.
Present therapy of CRS

- **Drugs therapy:**
  Antibiotics, Corticosteroids, Antihistamines, etc.

- **Surgical therapy:**
  Functional endoscopic surgery of paranasal sinus (FESS)

- **Alternative therapies:**
  Herbal compounds
  Acupuncture treatment
  Nasal saline irrigation
Objective

Primary question

Do osteopathic treatments improve the intensity and frequency of headache and/or the head-pressure in patients with Chronic Rhinosinusitis (CRS)?

Secondary question

Do osteopathic treatments improve the symptomatic of CRS as a whole?
The appropriate choice of the study design always depends on the objective being investigated.

When proving an effect of an intervention today, the randomized controlled trial (RCT) is the gold standard.

For the chosen objective the effectiveness of an osteopathic treatment should be assessed: a pragmatic trial (versus the efficacy and an explanatory trial).

For an appropriate sham-treatment the mode of action of the index treatment has to be known.
Study design II

Standard intervention: Evidence of Efficacy?

- NO
  - New efficacious? NEW vs. PLACEBO (SHAM)
  - New effective? NEW vs. UNTREATED

- YES
  - New intervention: Evidence of Effectiveness?
    - NO
      - New effective? STANDARD + NEW vs. STANDARD
    - YES
      - New better? NEW vs. STANDARD
Study design III

- **Randomized controlled trial** with follow up four months after end of treatments

- **Two groups:**
  - **Intervention group:** 5 osteopathic treatments at two week intervals
  - **Control group:** “untreated” control group for 10 weeks („waiting-list-design“). Consecutively 5 osteopathic treatments
Eligibility criteria

**Inclusion criteria:**
- minimum age of 18 years
- diagnosed CRS by a physician
- headache/ head pressure for > 1 year
- headache or head-pressure above the level of 3 on the numeric-rating scale (NRS) from 0-10

**Exclusion criteria:**
- due to the profession (e.g. varnisher, chemistry)
- seasonal (hay fever, allergy to pollen)
- systemic disease (e.g. asthma)
- migraine
Outcome measures

Primary outcome measure
The intensity and frequency of headache and/or head pressure subjectively felt by the patient.
Measuring instrument: Numeric rating scale (NRS) 0-10

Secondary outcome measure
Total pathology of CRS
Measuring instrument: Sinonasal assessment questionnaire (SNAQ-11)
Osteopathic findings and intervention

- **Osteopathic findings**
  - cranial: standardized record of findings
  - visceral: standardized record of findings
  - parietal: „black-box-examination“

- **Evaluation system of the dysfunctions**
  
  
  0 = not affected/ full mobility
  1 = slightly affected / limited mobility
  2 = strongly affected / blocked

- **Intervention**  
  Osteopathic treatment, specific to the individual findings of the patient
<table>
<thead>
<tr>
<th>Time points</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
<th>T5</th>
<th>T6</th>
<th>T7</th>
<th>T8</th>
<th>T9</th>
<th>T10</th>
<th>T11</th>
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</thead>
<tbody>
<tr>
<td><strong>OSTEOPATHIE GROUP</strong></td>
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<tr>
<td>Scan of the NRS and/or SNAQ</td>
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<tr>
<td>Treatment</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>CONTROL GROUP</strong></td>
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<td>Treatment</td>
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<tr>
<td>Time of waiting</td>
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<tr>
<td>Scan of the NRS and/or SNAQ</td>
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<td></td>
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</tr>
<tr>
<td>Period in Weeks</td>
<td>0</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>8</td>
<td>10</td>
<td>12</td>
<td>14</td>
<td>16</td>
<td>18</td>
<td>20</td>
</tr>
</tbody>
</table>

O 1. Follow-Up

O 2. Follow-Up
101 patients assessed for eligibility

40 patients excluded

61 patients randomized

31 patient allocated to osteopathic treatment group

31 analyzed data

1. Follow-Up (n=31)

30 patients allocated to waiting list group

29 analyzed data (1 drop out)

26 patients treated in the waiting list group (3 drop outs)

1. Follow-Up (n=26)

2. Follow-Up (n=57) 51 complete data
## Base-line characteristics

<table>
<thead>
<tr>
<th></th>
<th>Intervention group (n=31)</th>
<th>Control group (n=29)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>age</strong></td>
<td>44.8 ± 12.8</td>
<td>42.1 ± 12.5</td>
<td>0.420</td>
</tr>
<tr>
<td><strong>gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>men</td>
<td>12</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>women</td>
<td>19</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td><strong>Duration (years)</strong></td>
<td>14.1 ± 12.2</td>
<td>11.0 ± 7.9</td>
<td>0.253</td>
</tr>
<tr>
<td><strong>actual headache (NRS)</strong></td>
<td>3.1 ± 2.6</td>
<td>3.2 ± 2.6</td>
<td>0.928</td>
</tr>
<tr>
<td><strong>actual head-pressure (NRS)</strong></td>
<td>3.7 ± 2.5</td>
<td>4.2 ± 2.3</td>
<td>0.817</td>
</tr>
<tr>
<td><strong>SNAQ-11</strong></td>
<td>71.1 ± 22.4</td>
<td>65.2 ± 24.9</td>
<td>0.551</td>
</tr>
</tbody>
</table>
## Results

### Inter-group differences (NRS-Scores)

<table>
<thead>
<tr>
<th></th>
<th>Longitudinal changes T1 to T5</th>
<th>Between-group difference, and 95 % CI</th>
<th>p - value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group (n=29)</td>
<td>Osteopathic group (n=31)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>actual headache intensity</td>
<td>-0.2</td>
<td>1.5</td>
<td>1.7 (-0.1 to -3.2)</td>
</tr>
<tr>
<td>actual head-pressure</td>
<td>-0.2</td>
<td>1.6</td>
<td>1.8 (-0.3 to -3.3)</td>
</tr>
<tr>
<td>Frequency of headache</td>
<td>-0.4</td>
<td>2.6</td>
<td>3.0 (-1.2 to -4.8)</td>
</tr>
<tr>
<td>Frequency of head-pressure</td>
<td>-0.1</td>
<td>3.0</td>
<td>3.1 (-1.3 to -4.8)</td>
</tr>
</tbody>
</table>
Results
Within-group longitudinal changes (NRS-Scores)

<table>
<thead>
<tr>
<th></th>
<th>Begin of treatment (T1)</th>
<th>End of treatment (T5)</th>
<th>Intra-group difference, and 95% CI</th>
<th>p - value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Actual headache</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteopathic group</td>
<td>3.2</td>
<td>1.7</td>
<td>1.5 (0.4 to 2.6)</td>
<td>0.011</td>
</tr>
<tr>
<td>Control group</td>
<td>3.2</td>
<td>3.4</td>
<td>-0.2 (1.0 to -1.3)</td>
<td>0.760</td>
</tr>
<tr>
<td><strong>Actual head pressure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteopathic group</td>
<td>3.7</td>
<td>2.1</td>
<td>1.6 (0.6 to 2.6)</td>
<td>0.002</td>
</tr>
<tr>
<td>Control group</td>
<td>4.2</td>
<td>4.4</td>
<td>-0.2 (1.0 to -0.4)</td>
<td>0.682</td>
</tr>
<tr>
<td><strong>Frequency headache</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteopathic group</td>
<td>5.6</td>
<td>3.0</td>
<td>2.6 (1.5 to 3.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Control group</td>
<td>4.3</td>
<td>4.7</td>
<td>-0.4 (-1.9 to 1.1)</td>
<td>0.601</td>
</tr>
<tr>
<td><strong>Frequency pressure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteopathic group</td>
<td>6.2</td>
<td>3.2</td>
<td>3.0 (1.7 to 4.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Control group</td>
<td>6.4</td>
<td>6.5</td>
<td>-0.1 (-1.3 to 1.2)</td>
<td>0.956</td>
</tr>
</tbody>
</table>
Results

Analysis of the relevant disorders
Time dependent comparison within the groups

Osteopathic group:
improvement 55%
Control group:
Worsening 2%

Osteopathic group:
improvement 57%
Control group:
Improvement 6%
### Results

#### Secondary parameters

**SNAQ-11: Total symptomatic of CRS, within group longitudinal changes**

<table>
<thead>
<tr>
<th></th>
<th>Begin of treatment (T1)</th>
<th>End of treatment (T5)</th>
<th>Intra-group difference, and 95% CI</th>
<th>p - value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteopathic group</td>
<td>71.2</td>
<td>34.9</td>
<td>36.3 (27.1 to 45.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Control group</td>
<td>65.2</td>
<td>52.1</td>
<td>13.1 (-1.5 to 27.7)</td>
<td>0.076</td>
</tr>
</tbody>
</table>

Improvement in the osteopathic group: 51%

**Osteopathic dysfunctions:**

- Structures of the paranasal sinuses most frequently involved (e.g. Maxilla, Os ethmoidale, Os frontale, Os sphenoidale and Os occipitale)
- Visceral and parietal findings much less
Results
Analysis of reproducibility and sustainability of the trial

First Follow-up: 4 weeks after the last treatment of each patient
Second Follow-up: about 2.5 years from the begin of the study

SNAQ-11: Total symptomatic of CRS

<table>
<thead>
<tr>
<th></th>
<th>Begin</th>
<th>End</th>
<th>First Follow-up</th>
<th>Second Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteopathic group (n=27)</td>
<td>71.2</td>
<td>34.9</td>
<td>31.5</td>
<td>32.6</td>
</tr>
<tr>
<td>Treatment of the „waiting“ group</td>
<td>66.1</td>
<td>40.7</td>
<td>35.4</td>
<td>37.1</td>
</tr>
</tbody>
</table>
Conclusion

- 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.

- The positive evidence for the effectiveness of osteopathic treatments for patients with CRS found by this study is promising.
Acknowledgement

- We thank the organizing committee for inviting us to this Conference.

- We thank the German Association of Osteopaths (VOD) for financial support.
Thank you for your attention

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References:
Ergebnisse

Quantitative Analyse der osteopathischen Dysfunktionen
Mittelwerte

Summe der Bewertungen (0/1/2) der gefundenen Dysfunktionen (n=57, Mittelwerte, Skala= 0 bis 114)