

Clinical Effectiveness of Osteopathic Treatment in Chronic Migraine: 3-Armed Randomized Controlled Trial

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Francesco Cerritelli, Liana Ginevri, Gabriella Messi, Emanuele Caprari, Marcello Di Vincenzo, Cinzia Renzetti, Vincenzo Cozzolino, Gina Barlafante, Nicoletta Foschi, Leandro Provincial: This study was carried out in the Department of Neurology of Ancona's United Hospitals, Ancona, Italy. This article has 54 references.

BACKGROUND FROM DAN MURPHY

The primary measurement outcome in this study is the *Headache Impact Test (HIT-6)*; below is the conclusion from the cited reference:

“Our study shows that the HIT-6 is a reliable and valid tool for measuring the impact of headache on daily life in both episodic and chronic migraine sufferers. Furthermore, the HIT-6 tool discriminates well between chronic migraine, episodic migraine and non-migraine patients. As a brief tool, the HIT-6 is easy to score and interpret, and can be readily integrated into clinical practice, or clinical studies of migraine patients. It may offer clinicians a practical and easy-to-implement tool to assist them with evaluating treatment effectiveness by obtaining input directly from the patient on aspects other than just the frequency of headache days.”

Yang M, Rendas-Baum R, Varon SF, Kosinski M; Validation of the Headache Impact Test (HIT-6™) across episodic and chronic migraine; *Cephalalgia*; 2011 Feb; 31(3): 357–367.

HIT scores range between 36-78 points. A sample of the **Headache Impact Test (HIT-6)** is found at the end of this Review.

KEY POINTS FROM THIS STUDY

1) “This osteopathic manipulative therapy trial is the largest ever conducted on migraine adult patients.” These authors assessed the effectiveness of manipulative treatment on 105 chronic migraine patients using:

- Headache Impact Test (HIT-6) questionnaire [main outcome measure]
- Drug consumption
- Days of migraine
- Pain intensity
- Functional disability

2) This is a randomized controlled trial. Patients received 8 treatments over a period of 6 months. Patients were randomly divided into three groups:

- Manipulation + medication therapy n=35
 - The manipulative techniques used in this study included myofascial release, treatment of ligamentous and membrane tensions, treatment of somatic dysfunctions, and treatment to asymmetries and imbalances in the pelvis and cranium.
- Sham manipulation + medication therapy n=35
 - The sham group received a false manipulation, in addition to drug care.
 - Sham therapy mimicked the manipulative care in terms of evaluation and treatment; it used light manual contact to “treat” the subject.
 - Both manipulative and sham therapy sessions lasted 30 minutes and were given weekly for the first two sessions, biweekly for the subsequent two, then monthly for the remained four sessions.
- Medication only n=35

3) “Migraine attacks are usually characterized by a unilateral and pulsating severe headache, lasting 4–72 hours, and are often associated with nausea, phono- and photophobia.”

4) “Migraine is a serious public health concern of considerable consequences to both the migraineur and society.”

5) The overall migraine prevalence in Europe is 10–15% of the population.

6) These authors make the following points pertaining to the etiology of migraine:

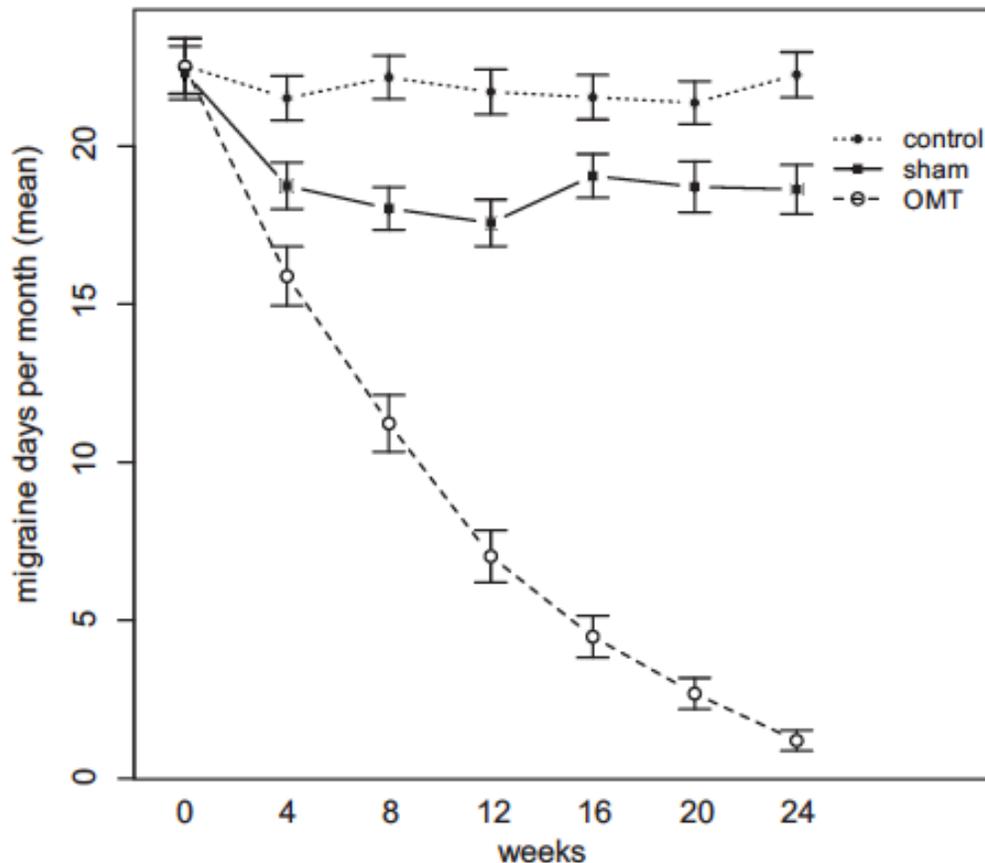
- In 20% of migraineurs, the attacks are anticipated by transient neurological symptoms, the aura.
- Migraine has a genetic etiology in about 50% of cases.
- Migraine etiology also has multifactorial epigenetic mechanisms.
- During a migraine attack, high levels of inflammatory cytokines are released causing neurogenic inflammation of the meninges and transmitting pain signals to the trigeminovascular system and autonomic nervous system nuclei.

- 7) Criteria considered for manipulative evaluation and treatment were:
- Alteration of tissue consistency
 - Asymmetry
 - Range of motion restriction
 - Tenderness
- 8) During migraine attacks, high levels of pro-inflammatory substances are released, altering neural autonomic pathways.
- 9) Manipulation influences the autonomic nervous system by producing a *parasympathetic effect*, and therefore, a “trophotropic tuning state.”
- 10) Manipulation is associated with a “reduction of pro-inflammatory substances.”
- 11) Manipulation in migraineurs could reduce the release of pro-inflammatory substances that have an effect on the autonomic nervous system function. “As a consequence, a cascade of biological and neurological events, potentially based on a rebalance of the abnormal activation of the habituation/sensitization mechanism, even between attacks, could occur resulting in an overall improvement of clinical outcomes.”

	Manipulation + Drugs	Sham Manip + Drugs	Drugs Only
Headache Impact Test (HIT-6)	Reduced by 8.74 points	Reduced by 6.62 points	Reduced by 2.32 points
Drug Consumption	Baseline 100% At 6 months 20% Reduction 80%	Baseline 100% At 6 months 32% Reduction 68%	Baseline 100% At 6 months 100% Reduction 0.0%
Days of Migraine Per Month	Baseline 22.5 At 6 months 1.2 Reduction 97%	Baseline 22.3 At 6 months 18.6 Reduction 17%	Baseline 22.5 At 6 months 22.3 Reduction 1%
Pain Intensity (0-4 scale)	Baseline 3 At 6 months 0 Reduction 100%	Baseline 3 At 6 months 2 Reduction 33%	Baseline 3 At 6 months 3 Reduction 0.0%
Functional Disability (0-4 scale)	Baseline 3 At 6 months 0 Reduction 100%	Baseline 3 At 6 months 2 Reduction 33%	Baseline 3 At 6 months 3 Reduction 0.0%

- 12) Manipulation “significantly reduced the frequency of migraine.”
- 13) At the end of the study period, there was a statistically significant difference on the overall HIT-6 score between the three groups; the manipulation group was statistically improved from control [drug only] and sham group.
- 14) “Considering migraine days per month, the three groups differed significantly at the end of the study period.”

- 15) Manipulation “significantly reduced the number of subjects taking medications.”
- 16) “No study participant reported any adverse effects of the [manipulation].”
- 17) “Migraine attacks, use of drugs, pain and disability scores were significantly reduced in the OMT group.”
- 18) “OMT showed a significant improvement in the migraineurs’ quality of life.”
- 19) Interestingly, the “sham group significantly reduced the HIT-6 score compared to the conventional [drug only] care. “The magnitude of the results suggests that the sham procedure may be clinically effective.” **[Important]**
- 20) The sham treatment used soft touch, which will induce responses at different levels of the central nervous system, reducing pain and improving well-being.
- 21) “The use of osteopathy [manipulative therapy] as an adjuvant therapy for migraine patients may reduce the use of drugs and optimize the clinical management of the patients.”
- 22) “The present study showed significant differences between OMT group compared to drug and sham groups, suggesting that OMT may be considered a clinically valid procedure for the management of patients with migraine.”



COMMENTS FROM DAN MURPHY

It is important to look at the numbers in the table and the graph in this Review.

Again, it is noteworthy that sham manipulation is superior to drug-only treatment for migraine.

Note that manipulation essentially eliminated migraine days per month, pain, disability, and reduced drug consumption by 80%.

Note that for the group assigned to taking drugs-only, there was essentially no reduction in migraine days per month, pain, disability, and no reduction in drug consumption.

My interpretation of this data is that it appears that manipulation is actually addressing the causative pathophysiology of migraine headache; in contrast, it appears that taking drugs is nothing more than temporary pain control with no benefit to the causative pathophysiological of migraine headache.

I remain perplexed as to why any healthcare delivery system would favor drugs for migraine (and many other pain syndromes) over mechanical therapy.

HIT-6™

HEADACHE IMPACT TEST

This questionnaire was designed to help you describe and communicate the way you feel and what you cannot do because of headaches.

To complete, please check one box for each question.

1. When you have headaches, how often is the pain severe?

Never Rarely Sometimes Very Often Always

2. How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?

Never Rarely Sometimes Very Often Always

3. When you have a headache, how often do you wish you could lie down?

Never Rarely Sometimes Very Often Always

4. In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?

Never Rarely Sometimes Very Often Always

5. In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?

Never Rarely Sometimes Very Often Always

6. In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities?

Never Rarely Sometimes Very Often Always

COLUMN 1
(6 points each)

COLUMN 2
(8 points each)

COLUMN 3
(10 points each)

COLUMN 4
(11 points each)

COLUMN 5
(13 points each)

To score, add points for answers in each column

Please share your HIT-6 results with your doctor.

Total Score: _____

Higher scores indicate
greater impact on your life.
Score range is 36-78.