



# Clinical effectiveness of osteopathic treatment in chronic migraine: 3-Armed randomized controlled trial



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## KEYWORDS

Osteopathic manipulative treatment;  
Headache;  
Pain;  
Sham therapy;  
Disability;  
Drug;  
HIT-6

## Summary

**Objective:** To assess the effectiveness of OMT on chronic migraineurs using HIT-6 questionnaire, drug consumption, days of migraine, pain intensity and functional disability.

**Design:** 3-Armed randomized controlled trial setting: all patients admitted in the Department of Neurology of Ancona's United Hospitals, Italy, with a diagnosis of migraine and without chronic illness, were considered eligible for the study.

**Interventions:** Patients were randomly divided into three groups: (1) OMT + medication therapy, (2) sham + medication therapy and (3) medication therapy only. Patients received 8 treatments in a study period of 6 months.

**Main outcome measures:** Changing from baseline HIT-6 score.

**Results:** 105 subjects were included. At the end of the study, ANOVA showed that OMT significantly reduced HIT-6 score (mean change scores OMT–conventional care:  $-8.74$ ; 95% confidence interval (CI)  $-12.96$  to  $-4.52$ ;  $p < 0.001$  and OMT–sham:  $-6.62$ ; 95% CI  $-10.85$  to  $-2.41$ ;  $p < 0.001$ ), drug consumption (OMT–sham: RR = 0.22, 95% CI 0.11–0.40; OMT–control: RR = 0.20, 95% CI 0.10–0.36), days of migraine (OMT–conventional care:  $M = -21.06$ ; 95% CI  $-23.19$  to  $-18.92$ ;  $p < 0.001$  and OMT–sham:  $-17.43$ ; 95% CI  $-19.57$  to  $-15.29$ ;  $p < 0.001$ ), pain intensity (OMT–sham: RR = 0.42, 95% CI 0.24–0.69; OMT–control: RR = 0.31, 95% CI 0.19–0.49) and functional disability ( $p < 0.001$ ).

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*Conclusions:* These findings suggest that OMT may be considered a valid procedure for the management of migraineurs.

The present trial was registered on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) (identifier: NCT01851148).

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## Introduction

Migraine is a serious public health concern of considerable consequences to both the migraineur and society. The overall migraine prevalence in Europe is approximately 10–15%.<sup>1,2</sup> Although migraine is considered a benign disorder, the annual cost of migraine-related lost productivity is extensive.<sup>3–5</sup>

The International Classification of Headache Disease (ICHD-II, 2004) ranks headache in primary and secondary forms. Furthermore the ICHD-II divided migraine into episodic and chronic according to the number of days per month (cut-off of 15 days).

Migraine attacks are usually characterized by a unilateral and pulsating severe headache, lasting 4–72 h, and are often associated with nausea, phono- and photophobia. In at least 1 out of 5 subjects, the attacks are anticipated by transient neurological symptoms, described as aura.

Migraine etiology has been proved to be genetic (up to 50% of cases),<sup>6</sup> but multifactorial epigenetic mechanisms may be outlined.

From a neurophysiological prospective, there is accumulating evidence to support that the central sensitization plays a critical role in migraine pathogenesis.<sup>7,8</sup> This has been proved by studies showing a functional alteration of key centers in the central nervous system (CNS), in particular the trigeminovascular nuclei.<sup>6,9–14</sup>

As far as the neurogenic inflammation of meninges is considered, high level of cytokines is released during migraine attacks<sup>13,14</sup> that in turn activates specific neural pathways transmitting pain signals to the trigeminovascular system and vegetative nervous system (VNS) nuclei.<sup>15,16</sup> This condition may predispose to VNS dysfunctions which have been suggested to be one of the causes of headache.<sup>11</sup>

Therefore, dysfunctional nervous structures, inflammatory condition and functional alteration of the VNS may be responsible for the pain and contribute to migraine pathophysiology.

Recent studies provided information about the possible association between manual therapies in particular osteopathic manipulative treatment (OMT) and its effects on migraine. Voigt et al. carried out an RCT showing the effects of OMT on migraineurs' quality of life. The author claimed a significant improvement in the quality of life parameters as well as a reduction of pain.<sup>17</sup>

Another piece of research evaluated the effects of OMT in patients with headaches. Patients who received 8–12 osteopathic sessions showed a significant reduction of pain and frequency of attacks.<sup>18</sup>

In 2006 Anderson and Seniscal compared the effects of OMT to progressive muscular relaxation exercises on patients with tension-type headache. Subjects who underwent both treatments, showed significant improvement on

joint and myofascial stiffness and reduction of pain compared to exercise only.<sup>19</sup>

Despite the number of studies conducted, evidence to support the effectiveness of OMT on chronic migraine remains elusive. Thus the present study aimed to test the effectiveness of OMT on a sample of adult chronic migraineurs by measuring the baseline changes of the headache impact test (HIT-6) questionnaire.

## Materials and methods

The aim of this 3-armed randomized control study was to determine the extent to which OMT was effective in improving the HIT-6 score on a sample of subjects affected by chronic migraine. In addition, the variation of monthly days with migraine, pain intensity, drug assumption and functional disability was measured. The trial was registered on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) (identifier: NCT01851148) and approved by the institutional review board of Ancona's hospital.

## Population

This study was carried out in the Department of Neurology of Ancona's United Hospitals in the period between March 2010 and November 2011. Patients admitted in the unit with the following criteria were included: diagnosis of chronic migraine according to ICHD-II criteria, lasting 15 or more days per month for more than 3 months in the absence of medication overuse and not attributable to any other disease; pain refractory to preventive medications; headache pattern has been present for 12 months or longer; current acute and prophylactic headache medication regimens have been stabilized for four weeks prior to preliminary enrolment visit; headache of any pain intensity (0–10 scale) on days over 15 during each four-week period; aged between 18 and 60 years old of either sex. Exclusion criteria applied were: patients with secondary forms of headache, chronic illness, psychiatric disorders, postmenopausal women, aged under 18 and over 60 years old, with significant psychological signs on examination and/or history, or serious drug habituation or behavioral issues that in physician's judgment makes the subject inappropriate for study, alternative treatment to treatment migraine pain (e.g. acupuncture, massage, biofeedback) and previous experience of osteopathic treatment.

## Interventions

The sample was randomly divided into three groups: OMT + medication therapy (OMT group), sham + medication therapy (sham group) and medication therapy only (control group).

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