

## Homoeopathy in the management of headache and migraine – a narrative review

### Homeopatía en el tratamiento de la cefalea y la migraña - una reseña narrativa

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#### ABSTRACT

##### Background

Homeopathy appears scientifically implausible and is one of the most contentious CAM therapies. The purpose of this review is to summarise the treatment effects of homeopathy in migraine. There will be no disease if there is no definite cause. The disease's nature will follow the cause, and the effect will make the person sick. The effects and the sick person will be treated in a straightforward and understandable manner. Migraine is the result of the cause, and the well-known Homoeopathic medicine can produce better results on this ailment when used in conjunction with the presence of the symptoms. This study is to search the well-known, rare medicine and its efficacy in such condition which is described in different literature as well as different research study. There are wide ranges of Homoeopathic medicines considered rare remedies based on the paucity of symptoms and a large number of medicines with rare symptoms representing uniqueness when selected on the basis of totality. Practising a Homoeopathic physician requires well-known medicine as well as rare medicine that helps in the management of migraine.

## Methods

Relevant studies were identified by a comprehensive literature search in electronic databases, a reference list of relevant papers, and contacts with experts. Randomized controlled trials comparing individualized homeopathic treatment strategy with a placebo were eligible. Information on patients, methods, interventions, outcomes, and results was extracted in a standardized manner and quality was assessed using a checklist and scoring system.

## Results

Six papers met criteria for inclusion. Three out of the six papers studied migraine headache, two studied cervicogenic and tension type headache, and one included all types of headaches. Four studies were randomized clinical trials, and two were prospective observational studies. Validity scores ranged from 25.0% to 63.4%. Homeopathy was superior to placebo in one randomized clinical trial and equal to placebo in three randomized trials. In no study was homeopathy less effective than placebo in treating headache, or harmful. Two prospective observational studies demonstrated improvement in patients receiving homeopathic care.

## Conclusion

There is insufficient evidence to support or refute the use of homeopathy for managing tension-type, cervicogenic, or migraine headaches. The studies reviewed possessed several flaws in the design. Given these findings, further research is warranted to better investigate the effectiveness of homeopathic treatment of headaches. (J Chiropr Med 2004; 3:45–52)

*Keywords:* Homoeopathy, Migraine, Headache

## RESUMEN

### Antecedentes

La homeopatía parece científicamente inverosímil y es una de las terapias de CAM más polémicas. El propósito de esta revisión es resumir los efectos terapéuticos de la homeopatía en la migraña. No habrá enfermedad si no hay una causa definida. La naturaleza de la enfermedad seguirá a la causa, y el efecto hará que la persona enferme. Los efectos y la persona enferma se tratarán de forma sencilla y comprensible. La migraña es el resultado de la causa y el conocido medicamento homeopático puede producir mejores resultados en esta dolencia cuando se utiliza junto con la presencia de los síntomas. El objetivo de este estudio es buscar el medicamento conocido y poco común y su eficacia en esta afección, descrita en diferentes publicaciones y estudios de investigación. Hay una amplia gama de medicamentos homeopáticos que se consideran remedios raros en función de la escasez de síntomas y un gran número de medicamentos con síntomas raros que representan la singularidad cuando se seleccionan en función de la totalidad. El ejercicio de la medicina homeopática requiere tanto medicamentos conocidos como medicamentos raros que ayuden en el tratamiento de la migraña.

## Métodos

Los estudios pertinentes se identificaron mediante una búsqueda bibliográfica exhaustiva en bases de datos electrónicas, una lista de referencias de artículos pertinentes y contactos con expertos. Fueron elegibles los ensayos controlados aleatorios que comparaban la estrategia de tratamiento homeopático individualizado con un placebo. La información sobre pacientes, métodos, intervenciones, medidas de resultado y resultados se extrajo de manera estandarizada y la calidad se evaluó mediante una lista de verificación y un sistema de puntuación.

## Conclusión

No hay pruebas suficientes para apoyar o refutar el uso de la homeopatía para el tratamiento de las cefaleas de tipo tensional, cervicogénicas o migrañosas. Los estudios revisados presentaban varios defectos en el diseño. Dados estos hallazgos, se justifica una investigación adicional para investigar mejor la efectividad del tratamiento homeopático de las cefaleas. (J Chiropr Med 2004; 3:45-52)

*Palabras clave:* homeopatía, migraña, cefalea

## INTRODUCTION

Migraine is a brain dysfunction of multisensory modulatory networks involving light, sound and smell, with the disturbance affecting processing of normal neural signals (Goadsby PJ et al., 2009, Elrington G et al., 2002). Migraine is the sixth most disabling and the third most prevalent illness in the world (Estemalik E et al., 2013). It reduces the quality of the patient's life, reducing his productivity to a great extent, along with increasing the medical expenditure of the family. It is one of the most incapacitating and widespread neurological conditions, affecting 1 billion people worldwide. Migraine is typically a hereditary disorder. Approximately 90% of migraine sufferers have a family history of the condition. If one parent has migraine, the children have a 50% chance of inheriting migraine. If both parents have migraines, the chances are 75% (Estemalik E et al., 2013). The aetiology and pathogenesis is complex and might involve genetic, neurovascular, neuro-hormonal and environmental factors (Anttila V et al., 2010, Friedman DI et al., 2009).

Because of hormonal influences, approximately three times more women suffer from migraine than men. In women, migraine most often begins at puberty. Before puberty boys are affected more than girls, but during adolescence, the risk and intensity of migraine rise in girls. Every 10 seconds one person visits the emergency room (ER) due to migraine, making an annual 1.2 million total patients visit ER. More than 90% of sufferers are unable to work or function normally during their migraine episode. Common problems associated with chronic migraine patients are depression, anxiety, sleep disturbances and medication habituation/overdose. Treating migraine symptomatically with pain relievers rather than treating the cause of the disease could be one of the reasons migraine becomes a chronic condition (Estemalik E et al., 2013).

Homoeopathy is a medical system developed by German physician Dr. Christian Friedrich Samuel Hahnemann (10 April, 1755 – 2nd July, 1843). The main principle of homoeopathy is 'Similia Similibus Curantur,' which means 'let likes be treated by likes'. Another principle, individualisation, refers to a holistic approach to health, disease, and treatment that takes into account the sick individual on physical, mental, social, and spiritual levels (Pingel S et al., 1992) Complementary and alternative medicine is an 'umbrella' term reflecting a wide variety of modalities that can be operationally defined as the 'diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, satisfying a demand not met by orthodoxy, or diversifying the conceptual framework of medicine'(Ernst E et al., 2006).

Homeopathic medicines are effective? Still a topic of debate due to lack of sufficient evidence. To answer this question, more scientific and evidence-based research is the need of time. Homoeopathy not only gained enormous popularity worldwide for its use in a variety of clinical conditions, but it also drew criticism for its highly diluted, minimum doses and therapeutic efficacy in some conditions. We conducted a thorough search for available evidence in homoeopathy for treating migraine and headaches.

The purpose of this paper is to systematically review peer-reviewed, published prospective trials relating to the use of homeopathic treatment for symptomatic headaches and focuses on the three most common types of headaches, as determined by the International Headache Society: tension type headache, cervicogenic headache and migraine headache (HIS Cephalgia, 1988). Thus, our narrative review was aimed to evaluate the efficacy of homeopathic medicines in migraine and headache.

## MATERIALS AND METHODS

A comprehensive computerized literature search was carried out to find clinical research Articles. Pub med, Cochrane controlled register of trials (CENTRAL) and two specialty databases called Core-Hom and Cam-Quest, Medline, Google scholars, science direct and Thieme – E - journal of homeopathy was searched extensively. Only human based clinical trials were included in this review. Animal trials, abstracts of articles and pilot studies were not included. Full length research articles were included. Controlled clinical trials (randomised or non-randomised), observational studies were eligible for the inclusion. All randomized double-blind placebo-controlled prospective observational clinical research articles were included. We also excluded the articles which were not relevant to our study. Opinion papers and articles without any solid conclusion were also excluded from review.

## RESULT

Four studies were found which met the inclusion/exclusion criteria. (9–12) No trials for the treatment of acute headache or migraine were located. Data extraction could be performed from all randomized controlled trials (RCTs). The key data of all included studies are summarized in Table 1.

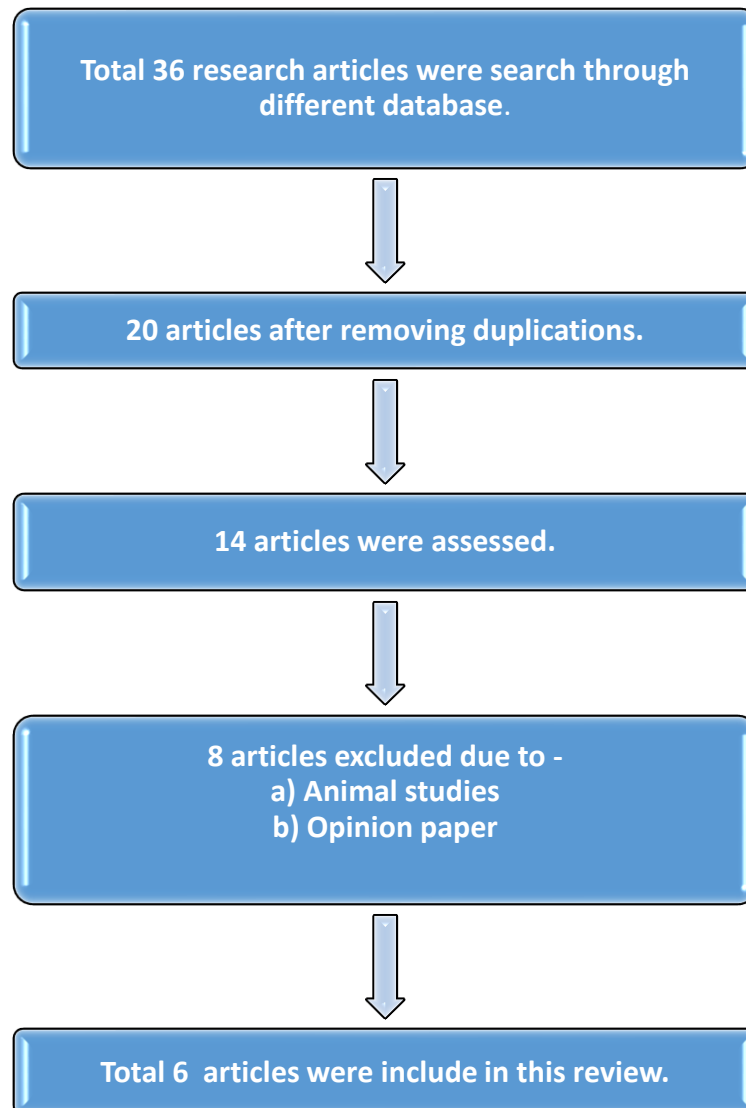


Fig 1: overview of study

Classical homeopathic treatment of chronic headaches (Walach H et al., 1997), the objective of this trial was to determine the efficacy of traditional homeopathy treatment in chronic headache patients. Randomised, placebo-controlled, double-blind clinical trial. Patients enrolled: 98, duration of trial: 12 weeks A total of 98 patients enrolled in the trial, of which 65 were females, 33 males: the median age was 48.5 years. These patients were suffering from chronic headache (since 2–54 years, median: 23 years) with at least one headache per week. According to the International Headache Society criteria 75 patients had migraine, 48 patients had tension-type headache and 15 had other types of headaches. Overall, 94% patients were previously treated for headache, 79% reported poor benefit from treatment and hence they were participating in this trial. The study includes 6weeks of baseline observation period followed by 12 weeks of randomised treatment period/ either homeopathic treatment or placebo treatment group. It was seen that out of 98 patients, 37 patients received

placebo and 61 received individualised homeopathic remedies. The findings were as follows: Patients showed a reduction of one headache day per month and reduction in medication usage for an acute headache in both groups. The headache frequency of 21 patients was reduced by more than 40%, whereas in 39 patients there was neither improvement nor aggravations. There was no significant difference in any parameter between homeopathy and placebo. The study concluded that there was no difference in the effect of individualised homeopathy remedies and placebo.

Table 1: Table of Included Studies

| Author                       | Headache            | Study design                      | Sample size | Duration                                  | Intervention                                  | Outcomes  |
|------------------------------|---------------------|-----------------------------------|-------------|---|---|---|
| Walach<br>1997 (19)          | CHRONIC<br>HEADACHE | Randomized<br>Controlled<br>Trial | 98          | 6 weeks baseline<br>3 months<br>treatment | Individualized<br>homeopathic<br>prescription | Both homeopathic and<br>placebo reduction<br>in all categories    |
| Straumsheim<br>1997          | MIGRAINE            | Randomized<br>Controlled<br>Trial | 73          | 1 month<br>Baseline 4 months<br>treatment | Individualized<br>homeopathic<br>prescription | Both homeopathic and<br>placebo reduction<br>in all categories    |
| Brigo 1991                   | MIGRAINE            | RCT                               | 60          | 4 MONTH                                   | Single dose<br>30c/4x in 2 wks                | Superior to placebo<br>all categories                             |
| Whitmarsh<br>1997            | MIGRAINE            | RCT                               | 60          | 4 MONTH                                   | Individualized<br>homeopathic<br>prescription | Chance difference in<br>all categories<br>Both groups<br>improved |
| Muscari-<br>Tomaioli<br>2001 | ALL TYPES           | Prospective<br>Observational      | 53          | 4 – 6 MONTH                               | Individualized<br>homeopathic<br>prescription | >60% improvement  |
| Walach<br>2001               | CHRONIC<br>HEADACHE | Prospective<br>Observational      | 18          | 1 YEAR                                    | Individualized<br>homeopathic<br>prescription | >30% improvement<br>homeopathic<br>group, most<br>within 12 wks   |

Homeopathic treatment of migraine: a double blind, placebo-controlled trial of 68 patients. British Homeopathic Journal (Straumsheim P et al., 2000). Patients enrolled: 68, duration of trial for 4 months. The objective of this trial was to evaluate the efficacy of homeopathy in preventing migraine attacks and accompanying symptoms. A total of 73 patients having common or classical migraine were randomised into individualised homeopathic treatment groups or identical placebo group. Baseline values were similar in two

groups. Out of 73 patients, 68 patients completed the trial. Results showed that both homeopathy and placebo groups had a reduction in attack frequency, pain intensity and drug consumption. As there was no statistically significant difference in effectiveness in both groups and migraine diaries also showed no difference, homeopathy cannot be recommended. However, neurologists' trial evaluation showed that there was a significant statistical reduction in migraine attack frequency in the homeopathy group ( $p \leq 0.04$ ), pain intensity, the overall assessment showed significant non-statistical trends which favour homeopathy. The study concluded that more research is warranted with improved trial design to support a possible role of homeopathy in migraine prophylaxis.

Bruno Brigo et al., 1991, the objective of this trial was to evaluate the effectiveness of classical homeopathic treatment for migraine. A total of 60 migraine patients were randomised into two groups: constitutional homeopathy treatment group/or placebo group over the period of 4 months. After evaluating the patients as per classical homeopathy, one or two of the following remedies were prescribed in 30c potency, Belladonna, Ignatia amara, Lachesis, Silica, Gelsemium, Cyclamen, Natrum muriaticum, Sulfur or placebo. Study results showed that patients in the control group experienced a reduction in migraine frequency from 9.9 attacks per month to 7.9 attacks per month. Those in the treatment group reduced their monthly attack frequency from 10 to 1.8–3 per month. Study results showed that homeopathic treatment brought a marked reduction in the frequency of migraine attacks and has an effect on both severity and duration of this disease. The study concluded that individualised homeopathy proved to be superior to placebo for the treatment of migraine.

The objective of this trial was to see if individualised homeopathic treatment will be more efficient for migraine prophylaxis as compared with placebo (Whitmarsh TE et al., 1997), Patients enrolled: 63, duration of trial: 4 months. A total of 63 outpatients meeting International Headache criteria for migraine were enrolled in this 4- month trial. The first month was baseline and all patients were on placebo. As 3 patients dropped out, the remaining 60 patients were randomised into two treatment groups. There was a chance of a difference in migraine attack frequency and severity in two groups. The frequency was more, and severity was less in the placebo group. The primary outcome measure was migraine attack frequency. The study results showed improvement in both groups but not much improvement in primary outcome measure. For example, the number of attacks reduced in the treatment group was 19% as compared to 16% in the placebo group. The reduction was mostly in mild attacks in the placebo group and moderate/severe attacks in the treatment group. There were few adverse events. The study concluded that there was no statistically significant benefit of homeopathic medicines over the placebo treatment. This led to the conclusion that we cannot recommend homeopathy for migraine prophylaxis but cannot conclude that it is without effect.

This study describes the findings of a prospective observational study of homoeopathic treatment for headache patients (migraine with- and without aura and tension-type headache). The SF-36 questionnaire was administered to 53 patients at the start of treatment and again after 4-6 months. The homoeopathic medicine and potency were not pre-determined but were tailored to each individual patient based on a personalised homoeopathic prescription. Most patients (73.6%) completed the study. There was some variation in the responses (patients in very poor health as well as those with only slight disorders). Data analysis using the

'intention-to-treat' concept revealed that after therapy, the mean and median scores of all life quality dimensions increased. More than 60% of the cases experienced an improvement in pain and the limitations caused by pain, as well as in limitations in social activities and health in general. All the differences between pre/post treatment were statistically highly significant, with the strongest results in the 'bodily pain' and 'vitality' parameters ( $P < 0.0001$ ) (Muscari-Tomaioli G et al., 2001).

All patients enrolled in the double-blind study were sent a 6-week headache diary, a follow-up questionnaire, a personality inventory, and a complaint list. Eighty-seven of the original 98 patients enrolled returned questionnaires, 81 returned diaries. There was no additional change from the end of the trial to the one-year follow-up. The improvement seen at the end of the 12-week trial was stable after 1 y. No differential effects according to treatment after the trial could be seen. Patients with no treatment following the trial had the most improvement after 1 y. Five of 18 patients can be counted responders according to ARIMA analysis of single-case time-series. Patients with double diagnoses and longer treatment duration tended to have clearer improvements than the rest of the patients. Approximately 30% of patients in homeopathic treatment will benefit after 1 y of treatment. There is no indication of a specific, or of a delayed effect of homeopathy (Walach H et al., 2001).

Three of the six papers studied migraine headache (Muscari-Tomaioli G et al., 1997, Whitmarsh et al., 2001) while two studied cervicogenic and tension type headache (Walach H et al., 1997, 2001). The remaining study included all types of headaches. Four of the six studies were randomized controlled trials and two were prospective observational studies. Sample size ranged from 18 to 98 subjects. Five of the six studies had a four-to-six-month study duration while one study had a one-year duration. Interventions in five of the six studies were individualized homeopathic prescriptions. The remaining study had a single dose of a 30c potency given four times over a two-week period (Brigo B et al., 1991); this study limited remedies to eight commonly used headache remedies and excluded subjects that did not present with headaches requiring one of these remedies. Of the five studies mentioned above, one of these studies individualized a homeopathic prescription that had been agreed upon by a practitioner group to minimize remedy selection error.

## DISCUSSION

Randomised, placebo-controlled, double-blind trials may be the best way to prove the effectiveness of various therapies. However, if the results of the clinical trials are not reproducible in subsequent clinical trials, then it will not have any clinical significance. Reproducibility is still challenging; there are reasons behind it. Also, the conduct of clinical trials will remain an unending process. Large patient sample size and longer duration of clinical trials can predict the effectiveness of study drug treatment in best possible way, especially when the disease is chronic. Homeopathic ultra-dilutions are still not understood in current pharmacological concepts. This may lead to disbelief about this therapy among some patients. However, until now, 200 homeopathic clinical trial research articles have been published which have provided positive conclusion about the effectiveness of homeopathy. Many clinical trials which have provided positive results earlier failed to produce similar positive



results in subsequent trials. Homeopathic prescriptions differ as per the knowledge and judgement of the prescriber. This will affect the study result. Also, this is the biggest challenge or limitation in homeopathic clinical trials. Another challenge is the patient's willingness to participate in the trial, as there is always the possibility of receiving placebo treatment. Every patient would like to get the best possible treatment—is it correct and fair? Yes, it is! And this affects in the following way. Many times, patients come to a homeopath after exhausting all their treatment resources, or after they have tried many practices of medicine for the treatment of their migraine. It is challenging to get such population for clinical trials even though that population could be the best sample size to see homeopathic treatment effectiveness. IHS classification guidelines for migraine diagnosis should be used while selecting sample size for migraine trials. Not every headache is migraine. Case studies, observational studies would be the best approach to see the effectiveness of homeopathic remedies. Researchers should focus more on practice-based research studies. Migraine cases treated with homeopathy need to be published worldwide with evidence. Open-label clinical trials should also be conducted. These methods will give new input into homeopathic research/ treatment approach and will improve the quality of the homeopathic practice of medicine.

Sufficiently large sample sizes are a precondition for conclusive results. Guidelines and expert recommendations on the conduct of clinical trials with limited resource and infrastructure as in individualized homeopathy are available [41-46]. We should stay close to real homeopathic practice and should try to produce robust results with methodological rigor and thereby show the true effects of this therapy.

#### LIMITATIONS

Migraine has a notoriously high rate of placebo response. Any individual taking interest in migraine sufferings is likely to demonstrate some therapeutic improvement by virtue of apparent interest. However, CAM approaches including homeopathy can demonstrate clinical results clearly [Lewith GT et al.,1996]. The mechanism by which homeopathy worked could be described as 'systemic'. However, the evidence base contains too few trials as well as trials resulting in contradictory findings which preclude any definitive summary (Vernon H et al.,1997).

#### CONCLUSION

The studies reviewed, overall, showed many flaws in design and there were few studies to review. The present review found that homeopathy was superior to placebo in one randomized clinical trial and equal to placebo in three. There is insufficient evidence to support or refute the use of homeopathy for tension type headache, cervicogenic headache and migraine headache. In no study was homeopathy found to be less effective than placebo in treating headache, or harmful. Two prospective observational studies demonstrated improvement in patients receiving homeopathic care. Given the insufficient quality and quantity of the literature,

further research is warranted to better investigate the effectiveness of homeopathic treatment of chronic headaches.

#### CONFLICT OF INTEREST STATEMENT

None declared.

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