



Patient-Reported Outcomes of Individualised Homeopathic Care for Chronic Tension-Type Headache: A Review of the Evidence

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Abstract

Chronic tension-type headache is common, burdensome and only partly helped by conventional prophylaxis, and some patients turn to individualised homeopathy. Because the condition has no biomarker, any claim of benefit rests on what patients report. This narrative review examines the published evidence on patient-reported outcomes of individualised homeopathic care for chronic tension-type headache and for chronic headache more broadly. It first considers which patient-reported measures are suited to the condition, then summarises placebo-controlled trials, observational outcome studies and the general meta-analytic literature on homeopathy. The trials that have tested individualised prescribing for chronic headache against placebo did not find a reliable advantage for the remedy on diary-based outcomes. Uncontrolled cohort studies, by contrast, record substantial improvement in symptoms and quality of life during homeopathic care. The review argues that these two bodies of evidence are compatible: improvement reported in routine care reflects natural fluctuation, regression to the mean, concurrent treatment and the effects of a long, attentive consultation, none of which requires a specific action of the medicine. The review sets out what is established, what remains uncertain, and what a credible future study would need to measure and report.

Keywords: Homeopathy, Tension-type headache, Patient-reported outcomes, Placebo, Context effects, Narrative review

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1. Introduction

Tension-type headache is the most prevalent primary headache disorder, and its chronic form, in which headache is present on most days, accounts for a disproportionate share of the disability. The third edition of the International Classification of Headache Disorders defines chronic tension-type headache as headache of the typical bilateral, pressing, mild-to-moderate kind occurring on 15 or more days per month on average for more than three months ([Headache Classification Committee, 2018](#)). Conventional

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prophylaxis helps some patients and not others. European guidance places amitriptyline first among the preventive drugs and gives a role to electromyographic biofeedback, cognitive behavioural therapy, relaxation training and physical therapy, while acknowledging that the evidence for several of these is limited (Bendtsen *et al.*, 2010a).

People whose headaches persist despite such measures often look elsewhere, and homeopathy is among the options they find. In its classical form a practitioner takes a long history covering the headache, the person's general health, temperament and circumstances, and selects a single remedy judged to match the whole picture. The remedies are usually diluted far beyond the point at which any molecule of the starting material could be expected to remain, which is the source of the long-running dispute over whether they can have any pharmacological action at all.

For a condition diagnosed entirely from the history, the patient's own account is the only available measure of benefit. That makes patient-reported outcomes the proper endpoint and also the endpoint most exposed to bias. This article reviews what the published literature shows about patient-reported outcomes of individualised homeopathic care in chronic tension-type headache, and how the apparently conflicting findings of trials and of routine-care studies should be read.

2. Scope and Approach

This is a narrative review of the published literature. It draws on placebo-controlled trials of homeopathy in chronic headache, on prospective outcome studies from homeopathic practice, on the major meta-analyses and official evidence assessments of homeopathy in general, and on the methodological literature concerning headache trials and patient-reported measures. No formal search protocol was applied and no pooled estimate is offered. Trials that enrolled only patients with chronic tension-type headache are scarce, so the review also considers studies of mixed chronic headache and of migraine where these bear on the question, and it says so where the evidence is indirect.

3. Measuring Outcomes in Chronic Tension-Type Headache

The International Headache Society's guidance for drug trials in tension-type headache recommends a prospective daily diary as the basis for the main efficacy measure, with headache days or a related index of headache burden as the primary endpoint and intensity, analgesic use and functional measures as secondary ones (Bendtsen *et al.*, 2010b). A diary completed each evening is less vulnerable to recall bias than a questionnaire asking about the past month, and it allows a baseline period to be compared with a treatment period in the same person.

Several validated questionnaires add information about impact. The six-item Headache Impact Test covers pain, social and role functioning, vitality, cognition and distress (Kosinski *et al.*, 2003). The Migraine Disability Assessment counts days lost or impaired over three months and, despite its name, is often applied to other headaches (Stewart *et al.*, 2001). Generic instruments such as the SF-36 allow comparison with other conditions (Ware and Sherbourne, 1992). Homeopathic outcome studies have also favoured individualised tools, notably the Measure Yourself Medical Outcome Profile, in which the patient names the symptoms and activities that matter most and scores them over time (Paterson, 1996). Table 1 compares these measures.

How these outcomes are reported matters as much as which are chosen. The CONSORT extension for patient-reported outcomes asks authors to state the outcome hypothesis in advance, to give evidence of the instrument's validity, to describe how missing data were handled and to interpret the result in terms of clinical importance (Calvert *et al.*, 2013). Few reports of homeopathic care in headache, controlled or not, meet all of these expectations, and retrospective global ratings in particular are easy to collect and difficult to interpret.

4. Evidence From Placebo-Controlled Trials

The trial closest to the present question was conducted in Germany by Walach *et al.* (1997). Patients with chronic headache, a group that included tension-type headache as well as migraine, received a full

classical consultation and an individually chosen remedy, and were then allocated under double-blind conditions to that remedy or to placebo for twelve weeks. Outcomes were taken from headache diaries. The authors reported no significant difference between the groups in headache frequency, duration or intensity. Because every patient received the consultation, the design isolated the contribution of the medicine itself, and found none that could be distinguished from placebo.

Table 1: Patient-reported measures relevant to chronic tension-type headache and their main limits

Measure	What it captures	Main limit in this setting
Daily headache diary	Headache days, duration, intensity and analgesic use, recorded prospectively	Burdensome over long periods; missing days are common
Pain intensity scale	Severity on a numerical or visual analogue scale	Says little about frequency or function
HIT-6 (Kosinski et al., 2003)	Impact on functioning, vitality and mood over four weeks	Relies on recall; developed across headache types
MIDAS (Stewart et al., 2001)	Days of lost or reduced activity over three months	Designed for migraine; long recall period
SF-36 (Ware and Sherbourne, 1992)	Generic health-related quality of life	Not specific to headache; may miss change
MYMOP (Paterson, 1996)	Patient-chosen symptoms, activity and wellbeing	Not comparable across patients; sensitive to expectation
Global rating of change	A single retrospective judgement of improvement	Highly open to recall and courtesy bias

The best-known trial in migraine points the same way. A British double-blind study of homeopathic prophylaxis found no significant advantage over placebo on attack frequency or severity ([Whitmarsh et al., 1997](#)). A systematic review of the headache and migraine prophylaxis trials concluded that the data did not suggest an effect beyond placebo, and noted that the one strongly positive early trial had not been confirmed by the more rigorous studies that followed ([Ernst, 1999](#)).

The general literature gives the context for these results. An early meta-analysis of placebo-controlled trials across all conditions found a pooled result that was not compatible with the hypothesis that all effects were due to placebo, yet found insufficient evidence that homeopathy was clearly efficacious for any single condition ([Linde et al., 1997](#)). A re-analysis by the same group showed that trials of better methodological quality tended to yield less positive results ([Linde et al., 1999](#)). A later comparative study matched homeopathy trials with trials of conventional medicine and concluded that, once the analysis was restricted to large trials of higher quality, the evidence for a specific effect of homeopathic remedies was weak and compatible with placebo ([Shang et al., 2005](#)). A meta-analysis confined to individualised homeopathy reported a small pooled effect but judged very few of the trials to be reliable evidence and urged caution ([Mathie et al., 2014](#)). The Australian National Health and Medical Research Council, after assessing systematic reviews across many conditions, concluded that there were no health conditions for which there was reliable evidence that homeopathy was effective ([NHMRC, 2015](#)).

5. Evidence From Routine Care

Observational studies tell what looks like a different story. In a large German and Swiss cohort of patients treated by homeopathic physicians, headache was among the most frequent reasons for consulting, and both patients' and physicians' ratings of severity fell markedly over the following two years, with parallel gains in quality of life ([Witt et al., 2005](#)). An outcome study from a British homeopathic hospital, covering six years of outpatient follow-up, recorded that a majority of patients rated themselves as improved, headache among the conditions represented ([Spence et al., 2005](#)).

These studies are informative about what happens to people who choose homeopathic care. They are

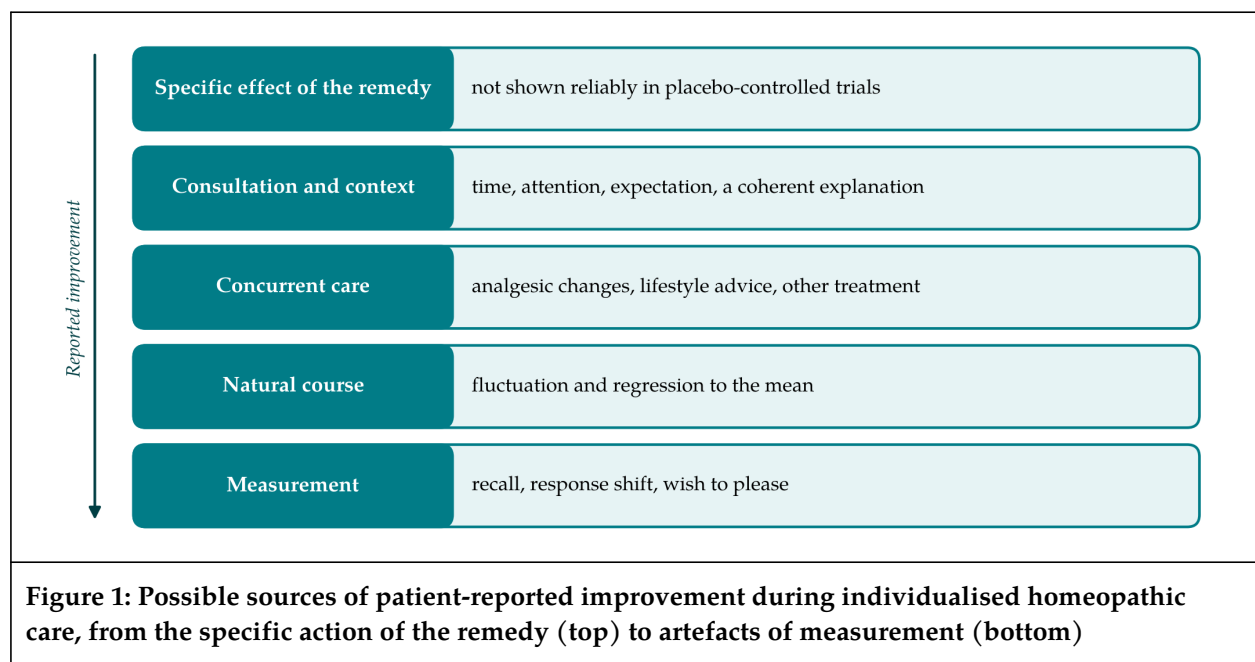
not informative about why. Neither had a comparison group, both enrolled patients who had sought out the treatment and presumably expected it to help, and both relied on ratings given to, or in the knowledge of, the treating service. Their authors were generally careful to say that the design could not attribute the change to the remedies. Read in that light, the cohort data and the trial data do not contradict each other. They answer different questions.

6. Interpreting Patient-Reported Improvement

Improvement recorded during a course of care has several possible sources, and Figure 1 sets them out as layers. The lowest layers are present in any study of a fluctuating condition. People seek help when their headaches are at their worst, and a symptom measured at its peak will on average be lower when measured again, whatever is done in between. This is regression to the mean, and in uncontrolled before-and-after comparisons it can produce an impression of benefit by itself (Barnett *et al.*, 2005). Measurement adds its own distortions: recall of earlier severity is unreliable, and patients who like their practitioner tend to give generous ratings.

The middle layers concern what else changes. Patients entering homeopathic care often adjust their use of analgesics, and since frequent analgesic use can itself sustain daily headache, a reduction may help independently of any remedy. Advice on sleep, posture, caffeine and stress is commonly given in the same consultation.

Above these lies the consultation itself. A first homeopathic appointment is long, covers the whole of the patient's life and ends with a confident, personalised explanation. A systematic review of context effects found that practitioners who combined a warm, reassuring manner with positive expectations obtained better outcomes than those who kept consultations formal (Di Blasi *et al.*, 2001). An experiment in irritable bowel syndrome showed that adding an attentive, empathic interaction to a placebo procedure produced a graded increase in symptom relief (Kaptchuk *et al.*, 2008). A meta-analysis of trials with both placebo and no-treatment arms found little evidence of large placebo effects on objective outcomes, with a possible modest effect on continuous subjective outcomes and pain (Hróbjartsson and Gøtzsche, 2001). Headache burden is exactly such an outcome.



The most direct evidence comes from a factorial trial in rheumatoid arthritis that randomised patients separately to receive or not receive a homeopathic consultation and to receive remedy or placebo. Clinical benefit was associated with the consultation and not with the remedy (Brien *et al.*, 2011). No equivalent trial exists in tension-type headache, so the inference is by analogy, but it fits the headache data: where everyone receives the consultation and only the medicine differs, as in the German trial, the groups do not

diverge.

7. Safety and the Cost of Delay

Highly diluted remedies are unlikely to be toxic, and a meta-analysis of randomised trials found adverse effects reported at similar rates with homeopathy and with placebo (Stub *et al.*, 2016). Harm has nonetheless been documented in case reports, both directly from low-dilution or contaminated products and indirectly when homeopathy was used in place of effective treatment (Posadzki *et al.*, 2012). In chronic tension-type headache the indirect risks are the relevant ones: a secondary headache that goes uninvestigated, medication overuse that is not addressed, or coexisting depression and anxiety left untreated. Any patient-reported outcome study should therefore record the diagnostic work-up and the conventional care received alongside the homeopathic prescription.

8. Gaps and Priorities for Future Work

The evidence base has clear gaps. No adequately sized placebo-controlled trial has enrolled only patients meeting current criteria for chronic tension-type headache. The existing headache trials were small, used differing diagnostic mixes and predate current reporting standards. The observational studies did not separate headache types and offered no comparison with usual care. None of the studies reviewed here was designed to estimate the size of the consultation effect in headache specifically.

A study capable of settling the practical question would use a prospective diary with a baseline period, a validated impact measure such as the HIT-6, and a design that distinguishes the remedy from the consultation, for example by comparing consultation plus remedy, consultation plus placebo and usual care alone. It would record analgesic use throughout, test whether blinding held and follow the CONSORT guidance on patient-reported outcomes. Given the consistent direction of the placebo-controlled evidence to date, the prior expectation for a specific remedy effect must be low, and such a trial would be justified mainly by what it could show about consultation effects that might be reproduced without the remedy.

9. Conclusion

Patients with chronic headache who receive individualised homeopathic care frequently report feeling better, and that observation is not in doubt. What the published trials do not support is the claim that the remedy is responsible. Where the consultation was held constant and only the medicine varied, diary-based outcomes did not differ from placebo, and the broader assessments of homeopathy reach the same verdict. For chronic tension-type headache specifically the direct evidence is thin, and honest reporting should say so. The reported improvements are best understood as the combined result of natural fluctuation, concurrent changes in care and the therapeutic value of time and attention. That last element deserves study in its own right, because it could be offered to patients without any claim that cannot be supported.

Conflict of interest

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