

Re-analysis of clinical trial of homoeopathic treatment in fibrositis

SIR,—A double-blind, crossover, placebo-controlled trial by Fisher and colleagues claimed that a homoeopathic treatment produced improvement in 30 patients with fibrositis.¹ Pain and sleep were assessed on visual analogue scales, tender spots were counted, and there was a global assessment on a scale from "useless" to "excellent". These responses were measured initially and at the end of the first and second 4-week treatment periods. A statistically significant improvement was claimed for sleep and pain scores combined and for tender spots but not for the global assessment. My re-analysis of the data (kindly provided by Dr Peter Fisher) suggests that the trial provides no firm support for the efficacy of the homocopathic treatment.

The results were analysed by standard methods for crossover trials^{3,4} except that the final tests were done, not by rank methods² or *t*-tests, but by randomisation tests.⁵ The original data set was randomised 20 000–50 000 times, and the proportion of cases in which the difference between means exceeded the observed value was taken as *P*. This test is both powerful and distribution-free. The responses for the first treatment period were taken as the difference between the score at the end of the first period and the initial score. The responses for the second treatment period were taken as the difference between the scores at the end of the second period and the scores at the end of the first period. The results were tested for treatment period interaction.⁴ These tests were applied separately to the numerical scores for pain, sleep, and tender points. Combining pain and sleep scores, in the way Fisher et al did, is invalid (simple addition of the number of improvers on each criterion makes it appear as though there were twice as many patients as there were).

The two-tailed *P* values for the tests are as follows:

Effect	Two-tail P values		
	Pain	Sleep	Tender points
Treatment effect	0.40	0.64	0.0021
Treatment period interaction	0.027	0.13	0.070
First period only	0.85	0.72	0.13

If there is a treatment period interaction the only safe procedure is to restrict attention to the first treatment period only.^{3,4} There is good evidence for a treatment period interaction for pain scores and a strong suspicion of one for the tender points. Re-analysis of the data for the first treatment period only indicates no effect of treatment in

the first period alone. If the response for the second period was taken to be the difference between the response at the end of the second period and the initial value then no evidence for a treatment period interaction was found, but there is no reason to prefer this approach to the one used here. In the absence of a "washout" period between the first and second treatment periods, the best method of analysis is bound to be uncertain but that used here is at least as plausible as any other.²

This re-analysis shows that the trial of Fisher et al provides no firm evidence for the efficacy of homoeopathic treatment of fibrositis.

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