

## Progress in the Placebo Debate for Homeopathy?

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**S**INCE ITS INCEPTION 200 years ago, homeopathy has become one of the most popular and widely used forms of medicine in the world. Many reasons have been postulated for this, such as that it is a gentle form of medicine, that it is patient-centered, and that it is inexpensive; but surely such sustained acceptance over 2 centuries must also require that it be effective.

Observational studies in the field of homeopathy demonstrate consistently that 70%–80% of patients benefit clinically from treatment by a homeopath,<sup>1,2</sup> and hence its clinical effectiveness cannot be disputed. However, in spite of high levels of patient satisfaction and an excellent safety record,<sup>3</sup> homeopathy receives more vocal resistance than any other form of alternative and complementary medicine.

Homeopathy is not controversial because it doesn't work. Homeopathy is controversial because homeopaths prescribe medicines that are highly diluted. The challenge is not about whether or not homeopathic treatment can improve health as we know that it can from the results of clinical outcome studies. The question is rather: Are homeopathic medicines different from placebo?

The biggest challenge for homeopaths in the United Kingdom today is in demonstrating that their treatments are more than placebo medicine. This is an important question for homeopaths to address because, until it is answered satisfactorily, the development of homeopathy as a discipline will be stifled. Healthy development of homeopathy will only occur in a culture where homeopathy is accepted as an effective intervention. Until then, research that is aimed at improving practice will continue to be relinquished in favor of research that is aimed at proving efficacy.

Some would have us believe that the placebo question has already been answered. In 2010, the House of Commons Science and Technology Committee published the results of their evidence check into homeopathy,<sup>4</sup> which concluded that homeopathy is a placebo treatment that should not be funded through the National Health Service. In reaching this conclusion, the authors of this report have overlooked the body of evidence from placebo-controlled trials that support the hypothesis that homeopathic remedies have an effect over and above that of placebo.<sup>5</sup> In fact, positive results from clinical trials of homeopathy are regularly dismissed as flukes, flawed by bias, or drawn from poorly designed studies. Moreover, the authors of the report accuse advocates of homeopathy of choosing "to rely on, and promulgate, selective approaches to the treatment of the evidence base"<sup>4</sup>

(page 20), which calls into question the usefulness of undertaking placebo-controlled clinical trials at all.

In addition to the declaration that homeopathy is placebo medicine comes the relatively recent accusation that homeopaths are behaving unethically through the intentional prescription of placebos.<sup>6–8</sup> This argument might carry some weight if it were clearly demonstrated that ultrahigh dilutions have no effect, but this is a field of active and ongoing investigation. The question of whether or not ultrahigh dilutions can have a physical effect is not resolved scientifically and still remains. It is currently being studied in a number of different ways,<sup>9–14</sup> which shows that many scientists and medical researchers believe the phenomena worthy of investigation, and there is extensive ongoing debate and disagreement about the possibility of ultra high dilutions having an effect. The question has clearly not yet been resolved.

With their use of the medical analyzer to test responses of the autonomic nervous system, Mishra et al. (in this issue) may have found a way to move research in this area forward. It appears that the medical analyzer offers a means of measuring a direct physiologic response to homeopathic medicines in an objective, rather than subjective, manner. If the results of this study are to be believed, then this may prove to be a landmark paper in the history of homeopathy.

However, at this time I believe we should proceed with cautious optimism. The medical analyzer is a sensitive instrument that may detect physiologic changes in response to a wide range of stimuli. Initial results suggest that changes in heart rate and peripheral blood flow occurred in response to certain remedies and certain potencies, but this study is exploratory and includes only a small number of participants. The study protocol can be critiqued on a number of factors: for example, the sample size was small, there was no appropriate placebo control group and we don't know how other potential variables were controlled. Nonetheless, the most significant aspect to emerge from this study is the possibility of a new technique and approach for testing and measuring the effects of highly diluted remedies directly on the human body. Furthermore, this method of testing would fit perfectly well into the "gold standard" of double-blind and placebo-controlled trial design that is currently demanded as objective proof of efficacy.

In order to find out if the medical analyzer can be used to find a solution to the placebo debate, refinement and wider replication of the study is needed, preferably by an

independent group(s). If the sample size is large enough to detect statistical differences in response between placebo and homeopathic medicine, then this type of study may help homeopaths to respond to the placebo accusation with evidence that even the most ardent of skeptics would struggle to deny.

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