

Should we dismiss complementary medicine if evidence tells us to?

In the fourth article on complementary medicine, **Edzard Ernst** looks at the significance of negative evidence to consumers and pharmacists

In complementary medicine (CM), we are often faced with the following conundrum. A particular therapy is submitted to scientific testing and the results subsequently show that it does not work. Yet many patients know better — they have experienced improvement of symptoms. As a consequence, consumers might begin to distrust this specific result and then, if this happens repeatedly, science itself. “How can they tell me it does not work, when I know it does,” they might ask.

This conflict between scientific evidence and individual experience is at the heart of many of the fundamental problems that CM currently faces. It is, therefore, worth exploring what might lie behind it. To do so, let us focus on a concrete example of a CM therapy: flower remedies. Two independent studies have demonstrated that flower remedies (Rescue Remedy or Five Flower Remedies) do not alleviate examination stress.^{1,2} Yet many consumers swear by these products. Is there a plausible explanation for this apparent contradiction?

The evidence could be wrong

Promoters of flower remedies will be certain that the results of the two negative trials must be wrong. In fact, this is always a possibility. Clinical trials can produce false results for a range of reasons. For example, not enough subjects might have been included so that a true effect was overlooked by the statistical analysis (a “type II error”). Another possibility is that investigators failed to use the right outcome measures — if you look in the wrong place you will not find what you are searching for.

Even sufficiently large trials with optimal outcome measures can produce false-negative results. For instance, if the investigators recruited inappropriate subjects or studied the wrong condition, the results of clinical trials are likely to show no effect even if the tested therapies are effective.

Not everyone is a responder

In clinical trials, we typically evaluate groups of patients. Therefore, such investigations tell us little about individuals and their responses. The patient population as a whole might yield no significant effect but, hidden within

this group, there could be individuals (responders) who significantly benefit from the therapy.

We have recently conducted a series of “single subject trials” (often also termed “n of one trials”) and found evidence to suggest that some people reproducibly respond to a particular therapy, in our case *Ginkgo biloba*, while others reproducibly fail to show any effect.³ It is conceivable, therefore, that for a given therapy, two distinct groups of people, — responders and non-responders — exist. However, I must emphasise the importance of reproducibility. Responders need to respond reproducibly and we should have a method of identifying responders and non-responders. We need to be able to predict accurately who will benefit and who will not. If these conditions are not met, individual responses could simply be due to coincidence. In this case they have little or no relevance to health care decisions.

Non-specific effects

It is also possible that both the negative trial evidence and the positive individual experience are correct. In most cases where such contradictions emerge in the area of CM, this is probably the case.

The majority of clinical trials are designed to test whether or not the experimental treatment generates specific therapeutic effects; that is to say, effects beyond a placebo response or other non-specific effects. In the two above-mentioned flower remedy trials, this was certainly so. Essentially, their research question was whether or not flower remedies are different from placebo. Their results showed that, under the specific conditions of the trial, flower remedies are indistinguishable from placebos.

But this finding does not necessarily contradict the fact that some people still benefit from flower remedies. The obvious interpretation is that flower remedies fail to generate specific effects (thus not showing efficacy in a placebo-controlled trial) but, like many medical interventions, they generate more or less powerful non-specific effects (thus providing benefit to some individuals). In other words, a given individual would experience benefit (stress reduction) as a result of a placebo effect. Both clinical trials, in fact, suggested strong placebo responses. Typically, such a trial then shows marked improvements in the experimental group and the placebo group but no differences between these groups.

The causes or mechanisms of placebo effects are largely unknown and probably highly complex. Expectations are certainly



Many consumers swear by Bach's Rescue Remedy

important. If someone has heard positive things about the stress-reducing properties of flower remedies, has made the effort to alleviate his or her stress, has made the effort to purchase such a therapy and has paid his or her own money for it, the chances are that all these circumstances contribute to experiencing the desired effect.⁴

Conclusion

There are several reasons why the evidence from clinical trials can overtly contradict individual experience. In the realm of CM, the most plausible explanation is that both are correct. The trial evidence can demonstrate the absence of a specific effect, while the individual experience is likely to reflect the presence of non-specific effects. The contradiction between evidence and experience thus dissolves into thin air. Progress in determining the therapeutic value (or otherwise) of CM will be determined not least by a clear differentiation between personal experience and scientific evidence.

References

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