

Complementary medicine: clinical trials

In the 16th article of a series on complementary medicine, **Edzard Ernst** looks at the arguments for and against performing clinical trials

Complementary medicine (CM) has little by way of research tradition and probably even less of critical thinking. When discussing the question of efficacy or effectiveness with CM practitioners or patients, the question “are clinical trials for CM needed?” arises. In this article, I will try to give an answer by dissecting the question’s various meanings.

There are those who say that CM cannot be tested in clinical trials because trials are blunt instruments that do not allow for the subtleties of CM. Homoeopaths or proponents of Bach Flower Remedies might argue, for instance, that their method is highly individualised and not aimed at improving the simplistic outcome variables used in clinical trials. Such arguments are usually based on a lack of understanding of the clinical trial methodology — with some innovative thinking it is possible to incorporate individualised prescribing into clinical trials.¹ And, regarding outcome measures, not all are as reductionist as critics think; consider, for instance, quality of life, patient preference or cost, all of which can be used in clinical trials.

Perhaps the best counter-argument against the notion that clinical trials of CM are not feasible is the fact that hundreds of such studies are already available.² Interestingly, those generating positive findings are usually much appreciated by the “anti-trial brigade”, who typically use the results when trying to convince sceptics that their treatments are effective.

Test of time

Others may claim that conducting clinical trials would be a mistake; the fact that so many people use CM already demonstrates its effectiveness, they insist. In their opinion, CM has been field-tested on millions of patients for thousands of years. What can relatively small clinical trials add to this huge body of evidence? The counter-argument is that, historically, blood-letting, purging and many other treatments (most recently even hormone replacement therapy) have all been field tested in this way. For many years we thought they worked or were safe, but we were wrong. The test of time can be a valuable indicator; it can prompt us to formulate a hypothesis, but if we want to test this, we need clinical trials.

Clinical practice

There are also those who say they do not need clinical trials because, in clinical practice, they see on a daily basis that patients who use CM experience improvements of their symptoms. Whenever a patient gets better, it is tempting to assume that this is causally related to the treatment prescribed. For example, decreasing pain is one of many



Pain reduction could be caused by undeclared therapies

possible outcome measures used in association with the administration of a treatment. However, pain reduction can be caused or contributed to by several factors, including:

- Time (the natural history of the disease is often such that patients improve over time regardless of treatment)
- The expectations of the patient or the practitioner, or both
- Empathy (understanding between the patient and practitioner)
- Placebo effect
- Regression towards the mean (extreme situations always tend to normalise)
- Other therapies the patient is using, but has not declared
- Being kind to the therapist (some patients say they have improved, simply to please their practitioner)

The only way to establish causality in such situations is through controlled clinical trials.

Some sceptics insist that CM is far too implausible and that conducting clinical trials in this area is, therefore, a waste of time. If there are no scientific reasons to assume that

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a treatment could possibly have any specific effects, it is wiser to invest our research funds in areas which do fulfil this condition. The most obvious counter-argument here is that there are several forms of CM for which efficacy has already been established beyond reasonable doubt, using the tools of evidence-based medicine (see Panel).² It is thus simply not true to generalise that all of CM is totally implausible.

Gullible public

Finally, there are those who say that conducting clinical trials of CM will have no effects on human behaviour — the gullible public will use CM regardless of what the trial data demonstrate. People are not interested in evidence but will almost blindly follow what their favourite film stars or other celebrities are using. To some degree this is worryingly true, but happily it does seem to apply less in the long term. For instance, there is a correlation between the robustness of the evidence for specific herbal medicines and the sales figures achieved by these remedies.³

My conclusion from all of this is that CM needs clinical trials just as any other area of therapeutics. There is no better way of determining the efficacy or effectiveness of therapeutic interventions. We may love or hate CM, but considering its high level of usage by the general public, we need to know what works and what does not.

References

1. Ernst E. Randomised clinical trials for CAM. *FACT* 2005;(in press).
2. Ernst E, Pittler MH, Stevinson C, White AR. *The desktop guide to complementary and alternative medicine*. Edinburgh: Mosby; 2001.
3. Schulz V, Hänsel R. *Rational Phytotherapie. A physician's guide to herbal medicine*. 5th ed. Berlin: Springer-Verlag; 2003.

Panel: Examples of treatments with evidence of efficacy

Treatment	Conditions
Acupuncture	Nausea and vomiting
Autogenic training*	Stress reduction
Devil's claw	Musculoskeletal pain
<i>Ginkgo biloba</i>	Dementia
Hawthorn	Mild to moderate congestive heart failure
Saw palmetto	Benign prostatic hyperplasia
St John's wort	Mild to moderate depression

*Autogenic training is a technique of body relaxation achieved through self hypnosis