

# A measure of success

G T LEWITH

## SUMMARY

*Complementary medicine is increasing in popularity and is also beginning to develop its own research culture. We are developing strategies that will enable us to measure the success of our interventions, but require more information and more research investment if we are to respond rationally to public demand.*

*Keywords: complementary medicine; acupuncture; homoeopathy; chiropractic; clinical research.*

## Introduction

A VAST amount of literature has been published within the field of complementary medicine, but much of it is of limited value. Many of the published papers are uncontrolled descriptive studies with poor outcome measures, limited and often inadequate statistics, and few hard data; happily, this situation is now beginning to change, with more controlled clinical trials appearing in the literature.<sup>1</sup> In spite of these weaknesses, two-thirds of general practitioners feel that complementary medicine has a place in mainstream medical practice and one-third feel that it should be provided through the National Health Service. Three-quarters of GPs feel that doctors should learn about complementary medicine, and almost all recognize the fact that more research is needed if the NHS is to provide comprehensive complementary medical services.<sup>2</sup> Thomas *et al*'s<sup>3</sup> recent national survey serves to confirm the increasing use of complementary medicine within NHS general practice and suggests that approximately 750 000 consultations are occurring each year within general practice; a similar situation appears to exist both in the United States and in Australia.<sup>4,5</sup>

A small body of work is now emerging within complementary medicine that is at last beginning to sort out the wheat from the chaff. The academic naivety of many of those working in complementary medicine has been based both on the desire to 'prove' the value of a particular alternative belief system and on individual ignorance associated with a misguided view of good-quality clinical research. It would be both impossible and absurdly expensive to construct randomized, controlled clinical trials to validate the whole of this field. We will undoubtedly need information from a broad evidence base that will include descriptive studies (such as case reports),  $n = 1$  clinical trials, and clinical audits if we are to make swift and appropriate purchasing decisions in relation to complementary medicine — particularly if we are going to answer the public's demand for increasing services within this area. Clinical research within complementary medicine has frequently been bedevilled by many complex methodological problems as well as by gross underinvestment in the academic resources required for research within this area.

## Specific research problems

### *Acupuncture and smoking*

Ter Reit *et al*<sup>6</sup> have suggested that acupuncture is an ineffective

method of promoting smoking withdrawal. This is largely based on the assumption that comparing sham (inappropriate acupuncture) with real (appropriate acupuncture) needling results in virtually no difference in cessation rates between these two groups.<sup>7</sup> Such assumptions presume that acupuncture has a point-specific effect in smoking, and therefore that using an inappropriate point for the condition being treated (sham acupuncture) represents a true placebo. If cessation rates for acupuncture as a whole, including real and sham acupuncture, are compared with cessation rates using other techniques, such as nicotine sprays or gum,<sup>8</sup> we find that acupuncture is indeed an effective method of smoking cessation, but that it is probably not point-specific and possibly endorphin-mediated in its effect.

Many of the early acupuncture studies in painful conditions made similar assumptions<sup>9</sup> and, by doing so, confounded the issue of acupuncture's effectiveness with issues surrounding point selection and the differences that exist in clinical effectiveness between good and bad acupuncture. In order to design appropriate clinical trials, it is therefore essential to understand the nature and basic mechanisms of acupuncture, or indeed any other complementary therapeutic intervention, so that important methodological issues do not confound outcome measurements.

### *The treatment of nausea*

Over 30 studies exist analysing the effect of a single acupuncture point, P6, in the treatment of nausea. These clinical trials have looked at the treatment of post-anaesthetic nausea, early morning sickness and nausea created by cytotoxic therapy. The techniques studied have involved acupuncture and other closely related techniques, such as TENS and acupressure.<sup>7,10</sup> The evidence is unequivocal; acupuncture and closely related techniques relieve nausea in all these clinical situations. The studies are carefully controlled, well constructed and uniformly statistically significant.

Many of the studies involve comparing real with sham acupuncture and indicate that the treatment of nausea has a point-specific effect. Therefore, in the acupuncture treatment of an internal illness, such as nausea, a specific acupuncture point produces a defined clinical effect. The confounding issue of point selection and the effectiveness of acupuncture is therefore not relevant in this situation.

This suggests that there may be different types of acupuncture and possibly different mechanisms of acupuncture in differing clinical situations. Acupuncture is therefore a complex therapy that requires detailed and very specific methodology if we are to unravel questions about its effectiveness. Furthermore, it is interesting to note that, in spite of the overwhelming body of evidence attesting to the positive clinical effects of acupuncture in nausea, this technique is not in general use in oncology and obstetric departments, nor in general practice and anaesthetic departments. Such observations are important when considering the implementation of complementary therapies on a broad base within the National Health Service (NHS).

### *Manipulative intervention*

Meade *et al*<sup>11</sup> looked at the pragmatic intervention of chiropractic in private practice versus an uncontrolled group of equivalent patients attending for physiotherapy in NHS physiotherapy departments. The evidence suggested that chiropractic intervention produced better short- and long-term results than conventional physiotherapy, the implication being that this study

G T Lewith, MA, DM, MRCP, MRCP, honorary clinical senior lecturer, Department of Medicine, University of Southampton, Southampton. Submitted: 30 November 1995; accepted: 15 July 1996.

© British Journal of General Practice, 1997, 47, 47-49.

'proved' the effectiveness of chiropractic. The two groups entered into this clinical trial were not necessarily comparable. In one instance, patients were seen in a private chiropractic environment and offered manipulative intervention; similar manipulative intervention may have been on offer in a number of physiotherapy departments. However, the physiotherapy with which chiropractic was compared was far from a uniform treatment and was certainly carried out in a different clinical environment. While this study suggests that chiropractic intervention is a useful way to manage back pain, it illustrates how careful one must be in drawing definitive conclusions from one pragmatic study in which like was not necessarily compared with like. More recent follow up by Meade *et al*<sup>12</sup> further demonstrates that chiropractic appears to have long-term effects when compared with hospital-based treatment, even allowing for the methodological criticisms that such pragmatic studies generate. A further study by Koes *et al*<sup>13</sup> was far more thorough and looked at manipulative intervention in both low back and neck pain within an NHS environment; again, manipulation was shown to be an effective treatment. The study by Koes *et al*<sup>13</sup> would appear to have much more generalizable conclusions; it supports the chiropractic study but suffers from fewer methodological errors.

The relevance of clinical trials to general practice can be well illustrated by comparing these excellent studies with that of Peters *et al*.<sup>14</sup> A manipulative service was established within a north London general practice and, instead of seeing clearly defined back pain, such as that studied by Koes and Meade, the musculoskeletal clinic rapidly became a collecting point for heartsink patients who presented with back pain as part of their symptom complex. The development of a rapid audit cycle allowed both the general practitioners and the complementary practitioners to begin to understand how best to use the services available to them, and indeed to implement in a constructive manner the conclusions derived from detailed clinical trials.

### *Homoeopathic immunotherapy*

David Reilly's work<sup>15</sup> on the placebo effect of homoeopathy has been well documented. His studies on asthma and hay fever are methodologically rigorous and use pure homoeopathic doses of pollen, house dust and house dust mite. They suggest that there is a significant difference in patient perception between placebo and real homoeopathic treatment. Clearly, further studies are needed within this area in order to underpin Reilly's work, but his overall conclusions challenge the myth that homoeopathy is purely a placebo effect and offer an interesting stepping stone in attempting to understand its mechanism. Reilly's work does not attempt to prove the validity of homoeopathy in asthma or hay fever, but demonstrates through a technique that is in fact far removed from classical homoeopathy that homoeopathic intervention has an effect greater than that expected from a pure placebo medication.

### *Descriptive evidence*

We have already noted that patients tend to visit complementary practitioners with long-term chronic problems that have failed to benefit from conventional intervention.<sup>16</sup> A number of NHS providers have begun to establish simple descriptive research projects to evaluate outcome for a well-defined group of patients receiving complementary medicine. Within the Centre for the Study of Complementary Medicine, we have clear entry and outcome criteria for patients entered into pilot projects within both Dorset and Wiltshire. Liverpool has established a referral clinic for complementary medicines and has not been slow to evaluate

this area in terms of cost and effectiveness.<sup>17</sup> Lewisham has established a complementary medical service within its main Trust hospital, and this too is limited to specific therapies and has, as part of the contract with both the referring general practitioner and the patient, very clear outcome measurements that are applied to each patient who enters the service.<sup>18</sup> West Yorkshire has recently published a report in which it demonstrates how a pilot clinic can operate successfully in developing both the general practitioners' understanding of complementary medicine, and the complementary practitioners' understanding of general practice. The Royal London Homoeopathic Hospital and Glasgow Homoeopathic Hospital also have their own internal data collecting systems to evaluate therapeutic outcome. It would appear that this dialogue is of clear benefit to the patient, and a whole variety of outcome measurements would seem to indicate that many 'untreatable or non-specific illnesses' can respond to complementary medical intervention.<sup>19</sup>

### **Conclusion**

Areas such as acupuncture, homoeopathy and spinal manipulation are complex to investigate. Many of them are not readily amenable to the standard randomized, controlled clinical trial, but, with care and thought, useful and scientifically relevant studies can be constructed. It is impossible to validate all complementary medicine solely using the tool of the randomized, controlled clinical trial. However, we will need to look at a whole pattern of evidence, some of which will include randomized controlled trials and studies on patient preference, adverse reactions and simple outcome data; these will involve both clinical outcome and measures of cost-effectiveness and risk benefit in the management of chronic illness.

Patient preference will form an increasingly important part of clinical decision-making, and, if the recent evidence we have from our medical colleagues is anything to go by,<sup>2,3</sup> enthusiasm for complementary medicine is apparent in both the patient and the general practice population. Our unit has adopted an approach that involves both the development of relevant clinical trial methodology and the use of crude outcome measures in busy clinical environments.

If this area is to progress, it requires more support in order to develop the relevant academic skills and to answer the questions being posed by both patients and clinicians with respect to the clinical effectiveness of complementary medicine. This requires research investment and dedicated academic units. As we sort the wheat from the chaff in both conventional and complementary medicine, we will also need to develop better mechanisms for implementing our conclusions. At present, it would appear that there are few, if any, formal pathways through which to implement and integrate the relevant aspects of complementary medicine into conventional medicine.

In the current climate, it is clear that complementary medicine will continue to be provided in both primary and secondary care. We must continue to develop our ability to measure its effectiveness, cost and safety using a wide range of investigative tools that vary from the rigorous randomized, controlled trial to surveys on patient preference. We must also use the information currently being generated from the many models of complementary medical care available to us so that we may begin to develop a coherent pattern of service provision based on sound evidence and competent management. It is fair to say that we are beginning to be able to measure success within complementary medicine, and have been successful at measuring positive outcomes in a small number of illnesses and therapies.

## References

1. Barnes J, Ernst E. Is the interest in complementary medicine increasing? (Letter.) *Compl Therapies Med* (in press).
2. Doctors Decide. *BMA News Review*, July 1995.
3. Thomas K, Fall M, Parry G, Nicholl J. *National Survey of Access to Complementary Health Care via General Practice*. University of Sheffield, 1995.
4. Eisenberg DM, Kessler RC, Foster C, *et al*. Unconventional medicine in the United States. Prevalence, costs, and patterns of use. *N Engl J Med* 1993; **328**: 246-252.
5. MacLennan AH, Wilson DH, Taylor AW. Prevalence and cost of alternative medicine in Australia. *Lancet* 1996; **347**: 569-573.
6. Ter Reit G, Kleijnen J, Knipschild P. A meta-analysis of studies into the effect of acupuncture on addiction. *Br J Gen Pract* 1990; **40**: 379-382.
7. Lewith G, Vincent C. Evaluation of the clinical effects of acupuncture: a problem re-assessed and a framework for future research. *Pain Forum* 1995; **4**: 29-39.
8. Silagy C, Mant D, Fowler G, Lodge M. Meta-analysis on efficacy of nicotine replacement therapies in smoking cessation. *Lancet* 1994; **343**: 139-42.
9. Lewith GT, Machin D. On the evaluation of the clinical effects of acupuncture. *Pain* 1983; **16**: 111-127.
10. Vickers A. *P6 acupuncture point stimulation as an anti-emetic therapy*. A report commissioned by North East Thames Regional Health Authority, 1994.
11. Meade T, Dyer S, Browne W, *et al*. Low back pain of mechanical origin; randomised comparison of chiropractic and hospital outpatient treatment. *BMJ* 1990; **300**: 1431-1437.
12. Meade TW, Dyer S, Browne W, Frank AO. Randomised comparison of chiropractic and hospital outpatient management for low back pain: results from extended follow up. *BMJ* 1995; **311**: 349-51.
13. Koes B, Assendelft W, Van der Heijden G, *et al*. Spinal manipulation and mobilisation for back and neck pain; a blinded review. *BMJ* 1991; **303**: 1298-1303.
14. Peters D, Davies P, Pietroni P. Musculoskeletal clinic in general practice – a study of one year's referrals. *Br J Gen Pract* 1994; **44**: 25-29.
15. Reilly D, Taylor M, Beattie G, *et al*. Is evidence for homoeopathy reproducible? *Lancet* 1994; **334**: 1610-1606.
16. Moore J, Phipps K, Marcer D, Lewith G. Why do people seek treatment by alternative medicine? *BMJ* 1985; **190**: 28-29.
17. Whelan J. Complementary therapies and the changing NHS: a development officer's view. *Compl Therapies Med* 1995; **3**: 79-83.
18. Richardson J. Complementary therapies on the NHS: the experience of a new service. *Compl Therapies Med* 1995; **3**: 153-157.
19. Hooper J, Ruddlesden J, Heyes A. *Introducing independent complementary therapists into GP practices in Huddersfield and Dewsbury – evaluation report*. West Yorkshire Health Authority, 1995.

## Address for correspondence

Dr G T Lewith, University Medicine, Level D, Centre Block, Southampton General Hospital, Tremona Road, Southampton SO16 6YD.