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This is an electronic version of an article published in *Clinical Research Focus: the Journal of the Institute of Clinical Research*, 15 (3). pp. 7-12, April 2004.

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# Research Issues in Complementary Therapy

Janet Richardson

**A** question frequently asked by healthcare professionals and journalists is, "Do complementary therapies work?" Such a question needs to acknowledge that therapies that come under the umbrella of 'complementary and alternative therapies' are many and diverse. The extent to which therapeutic interventions are defined as complementary or alternative is influenced by the leading paradigm of the day, and the power of professional bodies.<sup>1</sup>

The House of Lords Select Committee report divides complementary therapies into three discrete groups (Table 1).<sup>2</sup> This classification was essential to the Select Committee's conclusions regarding regulation, research and availability on the National Health Service (NHS) of the approaches.

Group	Therapeutic discipline
Group 1. Professionally Organised Alternative Therapies	Acupuncture, Chiropractic, Herbal Medicine, Homoeopathy, Osteopathy
Group 2. Complementary Therapies	Alexander Technique, Aromatherapy, Bach flower remedies, Body work therapies, Counselling stress therapy, Hypnotherapy, Meditation, Reflexology, Shiatsu healing, Maharishi Ayurvedic medicine, Nutritional medicine, Yoga
Group 3. Alternative Disciplines	
Group 3a. Long established traditional systems of healing,	Anthroposophical medicine, Ayurvedic medicine, Chinese herbal medicine, Eastern medicine, Naturopathy, Traditional Chinese medicine
Group 3b. Other alternative disciplines	Crystal therapy, Dowsing, Iridology, Kinesiology, Radionics

Table 1. Complementary therapies as grouped by the House of Lords Select Committee on Science and Technology: Complementary and Alternative Medicine.

The Select Committee groupings are interesting, but raise an important issue regarding paradigms. For example, placing acupuncture in Group 1 and traditional Chinese medicine in Group 3a removes a specific intervention from its philosophical tradition and associated therapeutic techniques. The placing of

homoeopathy in the first group, along with therapies such as osteopathy, is also interesting. The use of highly diluted substances has raised a number of conceptual challenges for the scientific establishment and yet here it is alongside a practice that is completely consistent with Western anatomy and physiology, and is now regulated. Traditional Chinese medicine and homoeopathy are both conceptually different from Western medicine. These differences lead to questions about the most appropriate research methods for assessing complementary therapies,<sup>3</sup> but also present a major challenge to their integration with conventional health care. Indeed, such philosophical differences may present more of a challenge than the current lack of evidence for their effectiveness.<sup>4</sup>

## Methodological issues

One of the major objections to the use of randomised, controlled trials (RCTs) in the evaluation of complementary therapies is the blinding procedure.<sup>5</sup> The purpose of blinding is to exclude non-specific factors (placebo effects) which may produce a desirable outcome, but which are not due directly to the active intervention.

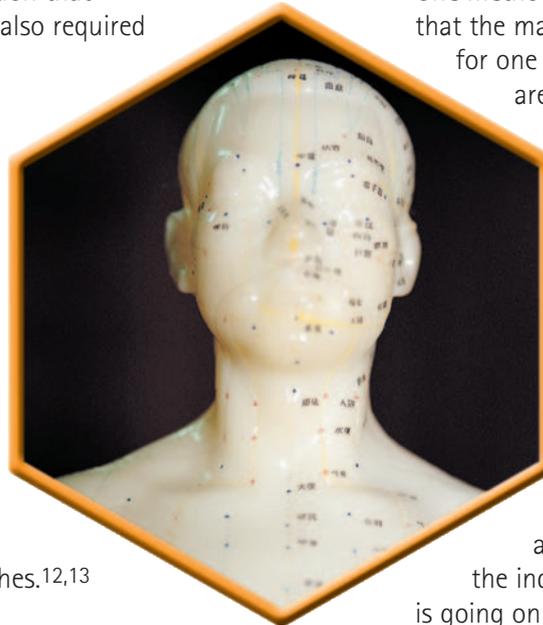
Double-blind trials are the 'gold standard' of clinical trial research, yet double-blind studies for interventions other than pharmaceutical ones are very rare, and for some treatments it is may be impossible to arrange a double-blind trial.

Anthony<sup>5</sup> suggests that blind designs are impossible in complementary therapy as the therapist is an integral part of the intervention. Black<sup>6</sup> argues that the artificiality of the RCT may reduce the placebo element of any intervention, failing to capitalise on the non-specific treatment effects, and therefore the trial will inevitably reflect the minimum level of benefit that can be expected. However, such critiques fail to consider the possibility of conducting RCTS in which the patients and practitioners are not blind to the procedure. For example, it is possible to apply RCTS without adopting a reductionist/materialist approach, such as those evaluating the effects

of psychotherapeutic techniques, healing and prayer.<sup>7</sup> Pocock<sup>8</sup> suggests that there is some confusion within the field of complementary therapy over the applicability of RCTs to therapies such as acupuncture, believing that this is due to the mistaken assumption that trials including a control group are also required to be 'double-blind'.

A number of authors have provided very comprehensive overviews of complementary therapies, together with the philosophical and practical issues associated with their evaluation.<sup>9,10,11</sup> However, in attempting to disentangle the issues relating to the use of RCTs in the context of complementary (and to some extent orthodox) therapies, the research question becomes paramount, as different questions require different approaches.<sup>12,13</sup>

A report prepared by the National Institutes for Health (NIH) in the USA emphasises the type of evidence required is related to the question, and suggests the question should be answerable and important. The report concludes that the RCT is



the gold standard and most reliable method yet developed, and should always be used where it is practical and ethical to do so; however, care should be taken in interpretation of the results.

One methodological assumption of the RCT is that the majority of patients have no preference for one treatment or another.<sup>14</sup> There are, however, a number of ways of dealing with these problems<sup>15</sup>, such as the use of patient selection criteria.<sup>16,17</sup> There are also a number of alternative methodologies for evaluating effectiveness, such as single case designs, qualitative approaches, outcome assessment and clinical audit, and observational studies.<sup>6,18,19,20,21,22</sup> Heron and Reason,<sup>23</sup> however, have gone so far as to categorise the RCT as a source of alienation because the individual is separated from what is going on in their body and from decisions about treatment. Consequently, they suggest a paradigm of research that celebrates a humanistic and holistic approach.

As the RCT remains the 'gold standard' within conventional medical research and has in some cases been applied to the evaluation of complementary therapies, it is important that this form of evidence is used, where possible, to demonstrate effectiveness. The reluctance of some researchers/practitioners to apply an RCT design to assessing the effectiveness of their treatments may have more to do with lack of knowledge regarding experimental design than any inherent faults within the RCT. However, one essential problem remains for any study attempting to assess effectiveness, and that is the problem of generalisability and external validity.<sup>13</sup> Hence the importance of evaluating the therapies under 'normal' service conditions, leaving practitioners free to give individualised patient treatments.<sup>14</sup>

Kelner and Wellman<sup>24</sup> discuss at length the question of what constitutes evidence in complementary therapies, and in particular the thorny issue of the 'levels' of evidence. They suggest that the individualised nature of complementary therapy treatments mitigate against the use of RCTs. However, Richardson<sup>3,25</sup> suggests pragmatic approaches that capitalise on individualised approaches and the subtle (placebo) effects of treatments. Yet even very sophisticated RCTs may fail to

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detect the complexity of factors within the consultation, that contribute to the therapeutic outcome.<sup>3,26,27</sup>

The challenge of research methodology on complimentary therapy is real, but it is also exciting and provides an opportunity for diverse research disciplines to engage. The research questions are not simply about 'evidence' in a narrowly defined biosciences definition. Kelner and Wellman<sup>24</sup> highlight the role of the 'consumer' in the development of complimentary therapy. This points to a different level of evidence from that proposed by our evidence-base professional colleagues. This is 'first person evidence' constructed by the consumer and based on their personal experience. It is only by examining the first person experience as well as using complex RCTs to assess evidence for effectiveness that we will reach a fuller understanding of the effects of complimentary therapy. Inevitably, this requires a multi-disciplinary approach and a combination of quantitative and qualitative methods.



## Finding the evidence

Finding appropriate research in complementary therapy is challenging for practitioners and researchers. The Internet is a major source of information, and numerous complementary and alternative therapy websites exist.<sup>28</sup>

Different databases will produce different search results. This is because they cover different journals and the index terms or keywords that are used vary. Reflexology, for example, is not a recognised index term on Medline and articles on reflexology are indexed using the more general term 'massage'. It is therefore important to be familiar with what the electronic databases cover and how to

search for textwords as well as index terms. Index terms, known as MeSH terms on Medline, are the terms assigned by an indexer to reflect the overall concepts covered in the article while textwords are simply words that appear somewhere in the text. Practitioners will need to be familiar with the best available sources of information in complementary therapy<sup>25</sup>,



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and understand the different approaches to indexing in order to access the most relevant information.

Recent developments, such as the construction of a specialist complementary therapy thesaurus for the Research Council for Complementary Medicine CISCOM database, and plans to develop web technology for cross-database searching<sup>29</sup> will go a long way to addressing these problems.

A number of quality websites are available, many of which provide access to other research-based resources. There are also a number of specialist databases that contain citations of complimentary therapy/CT research. Some of these are available through the internet; others can only be accessed through institutions (such as universities) that hold a licence for access.

The Research Council for Complementary Medicine (RCCM) is currently undertaking a project funded by the department of health to review research evidence for a number of complementary therapies and their use in cancer, mental health, heart disease, and chronic illness. The results of this project will be available through the RCCM website and will make a significant contribution to the research data in this area. The project will also identify gaps in the evidence-base and contribute to the identification of priorities for future research.

## Support for complimentary therapy researchers

Research in complementary therapy is compromised, to some extent, by the fact that many of the disciplines are located outside both the university system and the National Health Service (NHS) and that many of the therapeutic interventions are unlikely to lead to licensed products that have the ability to generate large-scale profits. This presents a challenge for the funding of complementary therapy research and for the development of a professional research-base in the disciplines.

Research capacity in this area is developing slowly, and has recently been supported by a department of health scheme to support postdoctoral research fellows in complementary therapy. However there is a long way to go. As the majority of complementary therapy practitioners work independently in private practice and do not interface either way is the NHS or the local university. This means that

their ability to apply for funding for and engage in complementary therapy research is limited.

One initiative aimed at supporting the development of a complementary therapy research community is that of the Research Council for Complementary Medicine's Complementary and Alternative Medicine Researcher Network (CAMRN). CAMRN is a network of over 250 researchers and practitioners interested in research linked through the RCCM web site. Facilities include details of research funding organisations, conference details, and discussion board. The network also provides specific research expertise that could be accessed by funding bodies requiring the skills of experienced researchers to review grant applications.

The methodological challenges for researching complementary therapy are mainly due to the diversity of the interventions and their associated philosophical underpinnings. Pragmatic research designs and qualitative approaches can contribute to research in this area. As universities become more interested in this type of research and the number of senior researchers working in this area increases, the quality of research will improve. Funding for complementary therapy research continues to be limited, but hopefully this will be more forthcoming in the future.

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