

# **The untenable boundaries of biomedical knowledge: epistemologies and rhetoric strategies in the debate over evaluating complementary and alternative medicine**

**Yael Keshet**

*Western Galilee Academic College, Israel*

**ABSTRACT** The article addresses contemporary epistemologies in examining struggles between the proponents of diverse medical approaches – some accepted as scientific and others that have not gained this status. It is based on research that investigated one of the central questions raised as a result of the growing popularity of complementary and alternative medicine (CAM) in western countries during the past three decades, namely: How can we know if CAM treatments are effective and beneficial? Discourse analysis was conducted on publications written by medical knowledge producers – experts participating in different professional groups addressing controversies over questions such as the desirability of researching CAM treatment effects, the appropriate methodology to be employed and the appropriate criteria for evaluating these effects. Some central debates are presented in the article. Examination of these controversies indicates that diverse kinds of knowledge are held by different groups of medical professionals. The ways in which they justify their knowledge and the rhetoric strategies they use for legitimizing it are specified. The great variety found among the different kinds of medical knowledge and rhetoric strategies and their dispersal along a ‘scientific’–‘non-scientific’ continuum, highlight the untenable and ambiguous boundaries of orthodox institutionalized biomedical knowledge.

**KEYWORDS** *boundary work; clinical trial; complementary and alternative medicine; rhetoric; sociology of knowledge*

**ADDRESS** Dr Yael Keshet, Department of Sociology, Department of Information Studies, Western Galilee Academic College – Bar Ilan University, Izrael St. 19, Kiryat Tivon 36032, Israel. [Tel: +972 4 9833840; e-mail: yaelke@research.haifa.ac.il; yaelk@wgalil.ac.il]

## **Introduction**

This article presents a study of the debate over complementary and alternative medicine (CAM) treatment effects, which is part of a broader and more general subject dealt with by both Epistemology and the Sociology of Knowledge in an attempt to determine the nature and scope of medical knowledge. This quest involves notions such as belief and truth, as well as issues regarding the social groups that take part in the construction or reconstruction of medical knowledge; the kind of knowledge they hold; and the manner in which they justify it and maintain or gain legitimacy for it.

CAM is a common term used by researchers to denote practices that lie outside the dominant medical orthodoxy (House of Lords Science and Technology Committee, 2000; NCCAM, 2006). Complementary and alternative medicine is a title used to refer to a diverse group of health-related therapies and disciplines that are not considered to be a part of mainstream medical care. Other terms sometimes used to describe them include 'natural medicine', 'non-conventional medicine' and 'holistic medicine' (House of Lords Science and Technology Committee, 2000).

The various CAM therapies are defined and classified in different ways. The UK House of Lords Science and Technology Committee (2000) defined three groups of therapies: (1) professionally organized alternative therapies, including acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy; (2) complementary therapies, including Alexander technique, aromatherapy, Bach and other flower remedies, body and work therapies, massage, counselling therapy, hypnotherapy, meditation, reflexology, shiatsu, healing, Maharishi Ayurvedic medicine, nutritional medicine and yoga; and (3) alternative disciplines, including long-established and traditional systems of health care, such as anthroposophical medicine, Ayurvedic medicine, Chinese herbal medicine, eastern medicine, naturopathy, traditional Chinese medicine; and other alternative disciplines, such as crystal therapy, dowsing, iridology, kinesiology and radionics. The US National Center for Complementary and Alternative Medicine (NCCAM, 2006) proposed a five-way classification of therapies: (1) holistic medical systems (such as homeopathic medicine, traditional medicine and Ayurveda); (2) mind-body medicine (such as patient support groups and cognitive-behavioural therapy, prayer, mental healing and therapies that use creative outlets such as art, music or dance); (3) biologically based practices (such as herbs, foods, vitamins, dietary supplements, herbal products and the use of shark cartilage to treat cancer); (4) manipulative and body-based practices (including chiropractic medicine, massage and osteopathic manipulation); (5) energy medicine (such as bio-field therapies: qi gong, reiki, therapeutic touch and bio-electromagnetic-based therapies).

CAM has been steadily expanding for the past few decades. Research in western countries indicates an increase in the number of people using CAM

treatments (Eisenberg et al., 1998; Thomas et al., 2001; Goldstein, 2002; Shuval et al., 2002; Hanssen et al., 2005; Molassiotis et al., 2005; Pud et al., 2005; Scott et al., 2005; Tindle et al., 2005; Winnick, 2007). The growth of CAM popularity and its penetration into medical health care organizations (Schneirov and Geczik, 2002; Shuval and Mizrahi, 2004), raises a number of questions, such as: Does it work? Are CAM treatments effective and beneficial? These questions arise when people search for a solution to medical problems, or when they seek general guidance regarding health issues. It is not just the individual, however, who faces these questions; public discussions about health policy, allocation of research budgets and coverage of public and private health insurance raise questions such as: Are CAM treatments effective or is their seeming effectiveness only a delusion? Should the State support CAM development? Should medical insurance cover these treatments? Should we encourage CAM treatments or, on the contrary, try to prohibit them?

Diverse medical systems based on fundamentally different medical theories and methods of validating treatments inhabit the medical landscape. CAM does not rely on evaluations of treatments by experimental control, blind assessment, placebo comparison and statistical inference, even though such methods are considered essential by the adherents of mainstream medicine who seek to evaluate CAM therapies (Kaptchuk and Miller, 2005). The study of the effects of CAM treatment is of sociological interest, since, on the one hand, broad sectors of the public are attracted by these treatments and consider them effective, while on the other hand, a large group of medical scientists and bio-medical researchers displays hostility to CAM and argues that it does not work. One of many examples of CAM controversies, in this instance concerning the attitude towards homeopathy, is provided by three articles published in the August–September 2005 issue of *The Lancet* (Anonymous, 2005; Shang et al., 2005; Vandenbroucke, 2005). Shang and colleagues (2005) reported that the results of their research confirmed the following hypotheses: when analyses were restricted to large trials of higher quality, there was no convincing evidence that homoeopathy was superior to a placebo, whereas a significant effect was found for conventional medicine. They assert that these results support the hypothesis that the clinical effects of homoeopathy, in contrast to those of conventional medicine, are unspecific placebo or contextual effects. Vandenbroucke (2005) responded that Shang and colleagues had arrived at a judgement about homoeopathy that would gladly be accepted by many who consider that homoeopathic evidence is contaminated, whereas others would claim that this analysis amounts to ‘data dredging’.

The debate over the appropriate ways to evaluate CAM treatment effects is not a new one, but the terms in which it is couched have expanded and changed throughout the history of medicine (Gijswijt-Hofstra et al., 1997; Eklöf and Nelson, 2001). Contemporary debate emphasizes the role

of evidence-based medicine (EBM) and in particular that of the randomized controlled clinical trial (RCT), whose methodological foundations were formulated as a coherent theory after the Second World War (Davidovitch, 2004). The emergence of EBM as the gold-standard practice in biomedicine and public health practices represents a significant epistemological turn in modern medicine (Davidovitch and Filc, 2006). EBM became the dominant discourse as a result of certain processes, such as subjection of the clinical encounter to scientific analysis; the sense of crisis within the medical profession, which has generated the need to preserve the profession's monopoly; and the transition of medical practice and welfare services into a neo-liberal organization that puts economic pressure on medical providers to contain costs, and that has introduced the language and practices of the business sector into the medical field (Davidovitch and Filc, 2006).

Sociological research has dealt with the dynamics of the relationship between CAM and the dominant medical institution, focusing on the influence of bio-medical institutionalized medicine on CAM (Cant and Sharma, 1996; Baer et al., 1997; Frank, 2002; Scheid, 2002; Shuval and Mizrachi, 2004; Fadlon, 2005; Mizrachi et al., 2005), and has investigated professionalization processes and power relations between the medical profession and CAM practitioners (Saks, 2001; Mizrachi et al., 2005; Winnick, 2005). Only recently, however, have researchers referred to the debate over medical knowledge from a sociological point of view, in dealing with ways of evaluating CAM treatment effects (Callahan, 2002; Hufford, 2003; Morreim, 2003; Tovey et al., 2004; Kaptchuk and Miller, 2005). Owing perhaps to the dominance of consensual medical knowledge, which strives to create an evidential base according to hegemonic medical themes and perceptions, sociological research has barely dealt with the issue of evaluating CAM treatment effects. As Tovey et al. (2004) have pointed out, the debate over CAM influences, as a social and historical event, is worthy of sociological research that clearly distinguishes between the medical and sociological points of view. This topic still requires critical investigation, free of the influences of accepted medical assumptions and conventions.

To gain a better understanding of the debates over CAM effects, we must examine questions such as those raised in the book edited by Callahan (2002): What is meant by saying that a therapy works or does not work? How should the influences of CAM treatments be evaluated, and what is the research agenda that suits CAM? Is it appropriate to examine CAM effects using the clinical trial, which is accepted as a medical standard for evaluating health intervention effects? To what degree should medicine be tolerant of different methodologies and standards of appreciation? These questions, which provide a basis for understanding the dispute and controversies over CAM, also have implications for research of other types of medical intervention, and for medical knowledge in general.

## **Methodology**

The article is based on research that utilizes the Sociology of Knowledge and Science approach. The Sociology of Science undermines the seemingly obvious dichotomy between the cognitive basis of knowledge and social factors (Latour, 1987; Shapin, 1995), and consequently views scientific knowledge, which is generally presented as 'truth' and taken for granted, as a product of social construction processes (Swidler and Ardit, 1994). My research methodology draws on certain concrete elements from the works of the philosopher Michel Foucault and the sociologist of science, Bruno Latour. Foucault (1972, 1994) linked knowledge to the practice of discourse, and showed how both scientific knowledge and knowledge accepted as unscientific originate and are shaped at the discourse level. For Foucault, looking for knowledge entails the making and shaping of objects of discourse. He emphasized knowledge–power relationships, and proposed a method of discourse analysis and an 'archaeology' of knowledge (Foucault, 1972). Study of discourse is 'not just a method but a whole perspective on social life and research into it' (Potter, 1996: 130). Latour's approach is to study 'science in action', as part of the Actor Network Theory (ANT), developed in the course of science and technology studies (Callon et al., 1986; Latour, 1987, 1988), and which concretizes Foucault's concepts. This approach proposes an explanation of the ways by which certain scientific methods are chosen and how they acquire power. Latour (1987) speaks of a 'hardening' process of scientific facts. This process promotes a theoretical principle, practical method or mechanical part as a scientific tool, which becomes a 'black box' that is routinely used in scientists' work. According to the ANT, scientists are involved in what Latour (1987: 78) calls 'trials of strength', while trying to make their mark through their research. In order to succeed they have to marshal various 'allies' in trying to 'harden' their cases. All these allies – facts, people, money, methodological principles, machines, etc. – constitute a network.

The ANT as a research strategy accepts reflexivity and empirical relativism, which are reflections of the dissolution of the expert/lay boundary (Wynne, 1996). ANT can be distinguished from both 'modern' and 'post-modern' research strategies in its ontological relativism – in that it typically embarks on research without a clear picture of what sort of entities it will discover through interaction; and in its empirical realism – in the sense that it leaves the task of challenging its empirical base to the research and the user communities it addresses (Gergen, 1992; Nick and John, 1999).

One of Latour's (1987) suggestions was to follow controversies among scientists that reopen 'black boxes'. While doing so, Latour wrote, we have to remain undecided as to what science is made of. Every time an inside–outside division is built, we should study the two sides simultaneously and make a list, no matter how long and heterogeneous, of those who construct the divisions. Accordingly, I have followed controversies among diverse

medical professional groups by using discourse analysis methodology. Publications analysis was chosen because of the central position occupied by written publications as sites at which controversies concerning knowledge take place, and as junctions of medical knowledge diffusion. Articles, letters, responses, editorials and other publications from medical journals and Internet sites were collected and analysed. An effort was made to reach all relevant texts published in English over a three-year period. This relatively restricted time frame was dictated by the vast number of publications, the wide scope of the investigation and the task of condensing a wide range of biomedical and CAM debates about efficacy. The years 1999–2001 were chosen since this was a period when the rate of increase of published articles about researching the effects of CAM treatments was accelerating (Keshet, 2008), and during which discourse and debate on this issue was growing. During this period, increased consumer utilization of CAM prompted concern, the condemnation phase was left behind and medical authors pondered whether patient dissatisfaction and shortcomings in conventional care contributed to this trend. Throughout the 1990s, struggles to outlaw CAM were abandoned, physicians began learning how to work around or administer CAM and the subjugation of CAM to scientific scrutiny became the primary means of control (Winnick, 2005).

It should be noted that the discourse and debates are not only ‘factual’ arguments about clinical efficacy, but are framed by country-specific, socio-political circumstances. Although it might be important to highlight some of the differences between the various western countries regarding opinions towards CAM, because of the wide scope of the research I decided not to examine these differences, and to confine the study to international medical discourse conducted in the English language.

In order to follow the dominant medical discourse, publications from three sources were analysed. The first comprises the publications of the US National Center of Complementary and Alternative Medicine (NCCAM) and the publications of the organization’s opponents. The second consists of reports (and abstracts) of systematic reviews regarding the therapeutic efficacy of CAM treatments, carried out by the Cochrane Collaboration. The third source includes a sampling of articles from the medical databases MEDLINE/PubMed and AMED, which reported on research into CAM treatment effects.

I chose publications dealing with CAM in general or with one of the following methods: methods that can be considered material – dietary supplements; physical methods – spinal manipulation and acupuncture; methods whose operating mechanisms raise doubts – homeopathy and the healing touch; and methods dealing in mental processes – mental healing and meditation. These methods were chosen in order to cover a wide variety of attitudes towards CAM practices. An effort was made to retrieve all the articles reporting clinical trials or meta-analysis of these CAM methods that were written in English in the years 1999–2001. I found some

600 article abstracts and chose only articles whose writers deal with and debate the specific issue of the appropriate ways to evaluate the effects of CAM treatments. I was left with 35 articles and 41 responses to the discussions that the articles triggered. Six further articles were found in the Allied and Alternative Medicine (AMED) database, which meet the same criteria and were not found in the MEDLINE/PubMed database.

Since CAM discourse (which cannot be clearly distinguished from the dominant medical discourse) is not always published in major medical journals, I analysed texts published on online CAM professional association sites as well as journal articles that the associations recommend to their members. Another source of publications included books that were written by the most popular writers about CAM. These were drawn in 2002 from three online bookstores that rank popularity: Amazon.com,<sup>1</sup> Barnes & Noble,<sup>2</sup> Alibris<sup>3</sup> and two major online sites that compare prices for books: Best Book Buys<sup>4</sup> and All Bookstores.<sup>5</sup>

I have maintained a clear distinction between the primary references analysed and secondary references, most of them sociological articles. The analysed texts are referenced in end notes, while the sociological articles are referenced in brackets in the body of the article.

## **Overview**

By following some central debates over the evaluation of CAM treatment effects, the article will detail the diverse kinds of knowledge held by different groups of medical professionals, and the rhetoric strategies they use for preserving or gaining legitimacy, while revealing the untenable boundaries of biomedical knowledge. The article comprises five parts. The first, 'rationalists vs experimentalists', explores the debate about whether to research CAM treatment effects or not. It focuses on the discussion between Straus, the director of NCCAM and his opponents, and shows that the essence of the discussion revolves around the priority of rationale or experiments – not a new question in science. The second part, 'rigorous trial vs hierarchy of evidence', explores how policy making is influenced by research on CAM treatment effects. It sheds light on the controversy between scientists who insist on rigorously designed clinical trials, and others who favour considering hierarchical evidence derived from various kinds of research. The third part, 'clinical vs pragmatic trial', examines the practical level of research, and the debate surrounding the work of Ernst and his colleagues. While Ernst's group accepts 'ready made science', their opponents, mostly CAM practitioners, try to create a new 'science in the making', and propose practice-based research to evaluate the effects of CAM treatments. The fourth part, 'anecdotes vs healing cases', focuses on descriptions of healing cases which, although not considered as scientific evidence, are widely disseminated among the public with the aid of charismatic rhetoric.

The last part, the discussion, concludes that the debates between groups of medical scientists themselves, the inability to distinguish sharply between medical scientists and CAM practitioners, the difficulty in categorizing precisely the diverse kinds of knowledge held by different professional groups and the rhetoric strategies these groups use to legitimize knowledge claims, highlight the untenable and ambiguous boundaries of orthodox institutionalized biomedical knowledge.

## **Rationalists vs experimentalists**

Controversies over whether or not to research CAM and, if so, how to do this, have persisted for a long time. They have been waged by a large number of participants at both the research policy and practical levels. A prominent discussion at the research policy level has been held at the NCCAM organization.<sup>6</sup> Its growing budgets and the fact that it is a part of the US National Institute of Health (NIH) have made it a centre of debate.

The controversy is rooted in the establishment of the Office of Alternative Medicine (OAM) by the NIH in 1993, and its development into the NCCAM in 1998. The goal of the OAM was to promote the discovery, development and validation of potent treatments that could be added to the pool of complementary medical alternatives currently available to patients and practitioners. Politicians tried to funnel funding through the office to their pet interest groups, while scientists sought to limit funding to accredited professionals and physicians with ties to conventional institutions (Miles, 1998). The office provided fertile ground not only for exploring alternative medicine, but also for examining the position of science in American culture. Throughout its development, the OAM has raised numerous issues concerning science: Who should be practising it and where? How do we measure good science? And who should control medical science? Groups of scientists, politicians and CAM practitioners have fought for the right to engage in science and medicine, to decide how to practise it and to criticize and supervise its practitioners (Miles, 1998).

Dr Stephen Straus, a physician from Columbia University, became the first director of the NCCAM in 1999. He is an internationally recognized expert in clinical research, and a senior investigator in the Laboratory of Clinical Investigation at the National Institute of Allergy and Infectious Diseases (NIAID). Straus wrote that the growing appeal of CAM at the dawn of the 21st century has created both the opportunity and the obligation to engage in scientific study and evaluation. He maintained that he was committed to evidence-based standards of science, and approached his task with curiosity and open-mindedness.<sup>7</sup>

One of his opponents is Wallace Sampson, clinical professor at Stanford University, and editor of the *Scientific Review of Alternative Medicine*. While Straus promotes a policy that favours CAM research, Sampson

argues against it. First, asserts Sampson,<sup>8</sup> Straus calls for rigorous research on alternative methods, implying that such trials have not yet been performed. However, adequate information already exists, indicating that the 'alternatives' are ineffective. Sampson claims that the best quality trials of the most common CAM methods show them to be ineffective, while the poorest trials show the most effectiveness. He concludes that while politically and ideologically motivated interest groups press to continue the research, CAM has already been proven to be ineffective. Sampson argues that 'New Age' influence, melded with cultural relativism and post-modern movements in universities, encourages the growth of CAM and research into it. He writes:

Straus's basic error was to disregard this philosophical and ideological geography. He stepped into the controversy as though there was little history preceding the NCCAM creation, and as if the problem were merely a contest between unproved practices and proved ones.<sup>9</sup>

Sampson takes issue with Straus's declaration that the NCCAM was established in response to popular demand for greater attention to CAM, and argues that only a few members of Congress have promoted this trend, influenced by special interest advocates such as clinics, the supplement industry and some lay supporters. Sampson fears that the NCCAM will continue for many years to come its attempts to prove something that has already been disproved. He argues that belief in CAM prevents proponents from accepting scientific evidence, and that continuing CAM research just to show that it is not effective will not convince anybody who already believes in CAM.<sup>10</sup>

Sampson considers rationality and reason as fundamental to medical activity, while many alternative methods are based on pseudoscientific claims. 'Although experimental science is recent, rational observation and thought in medicine are millennia old', he declares.<sup>11</sup> Some of Sampson's colleagues, who have published articles on the Quackwatch website<sup>12</sup> and in the *Scientific Review of Alternative Medicine*, also regard CAM as a pseudoscience that avoids rational methods and conflicts with scientific rationale,<sup>13</sup> describing CAM's illogical methods as fraudulent or as quackery.<sup>14</sup> Barrett,<sup>15</sup> for example, argues that most alternative medicine is rooted in a philosophy unrelated to forces subject to the laws of physics and chemistry and detectable by scientific instrumentation. Homeopaths, for example, claim that illness is due to a disturbance of the body's 'vital force', which they can correct with special remedies, while many acupuncturists claim that disease is due to an imbalance in the bodily flow of 'life energy' (chi or Qi). Many chiropractors claim to assist the body's 'innate intelligence', while Ayurvedic physicians refer to '*prana*'.<sup>16</sup>

These arguments highlight the distinction made by opponents to CAM research between scientific rationale – the fundamental way of obtaining facts and knowledge – and CAM rationale and theories, which they regard

as beliefs at best, and quackery at worst. CAM therapists are branded as frauds motivated by personal and financial interests.

The arguments against researching the efficacy of CAM treatments, and especially the argument about rationality, raise an old question: Does accurate knowledge about causes or a generally accepted rationale as to their effects constitute a necessary condition for science, or are we entitled to set up experiments in order to examine arguments whose basic rationale is disputed?

Opposition to researching CAM efficacy stems from the notion that we cannot scientifically check irrational and illogical treatments with scientific tools. From this point of view, the clinical trial, which examines specific physiological effects, cannot serve as an instrument for examining modalities whose proposed mechanism is different. For supporters of CAM research, on the other hand, the therapeutic process is a 'black box', about which we know little and perhaps cannot know more – a box about which we need to know nothing but its input and output. Supporters of CAM research advocate use of the clinical trial as an instrument to examine whether the health intervention 'works', although there is no accepted knowledge about the way in which it operates.

Dilemmas such as this are not new to science. One of the most famous controversies of this kind was waged in England in the 1660s and early 1670s between Boyle and Hobbes (Shapin and Schaffer, 1985). Boyle was a major practitioner of systematic experimentation and one of the foremost advocates of the value of experimental practices in natural philosophy. He is considered a founding father of the experimental world in which scientists now live and operate. Hobbes took on the role of Boyle's most vigorous local opponent, seeking to undermine the particular claims and interpretations produced by Boyle's research and, crucially, mobilizing powerful arguments to explain why the experimental programme could not produce the sort of knowledge that Boyle sought (Shapin and Schaffer, 1985). Hobbes and Boyle proposed radically different solutions to the question of what should count as knowledge, that is, which propositions were to be considered as meaningful and which absurd. Their specific controversy over the air-pump experiments and the existence of a vacuum generated broader questions about scientific knowledge. The air-pump experiments were designed to provide a heuristic model of how authentic scientific knowledge should be secured. While Boyle proposed laboratory experiment, Hobbes maintained that the search for knowledge must be more public; it could not become the preserve of interested professionals. He saw professional group interests as having acted historically to corrupt knowledge. Hobbes' philosophy was directed at the establishment of public peace, which commenced with social acts of agreement. This was not a witnessing public, but an assenting and professing public; not a public of eyes and hands, but a public of minds and tongues. Hobbes and Boyle thus strove to delineate the nature of philosophical life, and to define the permissible or obligatory

ways for philosophers to determine what to question and what to take for granted. Shapin and Schaffer (1985) have shown that the Hobbes–Boyle debate about knowledge is embedded within practical solutions to the problem of social order, and that the various solutions to this problem encapsulate contrasting practical solutions to the problem of knowledge. They have argued that the generation and protection of knowledge is a problem of politics, and conversely, that problems of political order always involve solutions to the problem of knowledge.

A similar logic can be discerned in the controversy between Straus and Sampson over CAM research. It illustrates two different ways by which physicians-scientists perceive medical knowledge. One advocates conducting clinical trials to examine the effects of CAM treatments, while the other opposes CAM research, considering the field itself to be illogical and irrational, and potentially threatening, corrupting or destructive to medical knowledge.

A considerable volume of research on the effects of CAM is currently being conducted. A search of the central medical database PubMed shows 8600 publications on clinical trials of CAM treatments (to 17 March 2007).<sup>17</sup> The number of publications is growing each year. In the 1970s, an average of 46 articles per year was published. This rose to 74 in the 1980s and to 228 in the 1990s, and in the past seven years an average of 687 articles on clinical trials of CAM has been published annually. Research into the medical influences on CAM methods, despite its odd, mystical and sometimes even magical-seeming philosophical base, is an example of Boyle's victory, namely, the experimental world in which scientists now operate. The social victory of the experimental way has led to the construction of what is considered to be true scientific knowledge.

## **The rigorous trial vs a hierarchy of evidence**

This section addresses policy-making controversies within the NCCAM, waged between groups of scientists insisting on rigorously designed clinical trials, and others who are willing to consider hierarchical evidence derived from various kinds of research. The controversies over questions of how to research CAM and what should constitute evidence of its effectiveness raise dilemmas typical not only of 'soft' sciences like medicine.

Straus, the director of the NCCAM, sees himself '... committed to bring to this position the evidence-based standards of science'<sup>18</sup> and declares that the NCCAM will examine a hierarchy of evidence. The centre has planned diverse research designs to assess the spectrum of CAM techniques and products, and to support large (Phase III) clinical trials of CAM substances and modalities that appear to be the most promising on the basis of evidence-based reviews. The centre has also planned to fund initial Phase I or Phase II trials in order to establish the scientific rationale and methodological feasibility required to justify large, randomized clinical trials. To help identify

areas for clinical investigation and the appropriate level of investigation in each area, NCCAM has decided to examine a hierarchy of evidence, ranging from levels considered to provide the weakest evidence, for example, anecdotes and case studies, through observational studies, uncontrolled trials, small randomized controlled trials and large randomized clinical trials, considered the gold-standard in terms of level of evidence. Systematic reviews may be conducted, as Straus sees it, at and across every level.<sup>19</sup> Straus has written that diverse research designs are needed to assess the spectrum of CAM techniques and products, since it is impossible to examine some CAM modalities (e.g. massage) through double-blind trials.<sup>20</sup> He has relied on two studies published in the prestigious *New England Journal of Medicine*,<sup>21</sup> which suggest that observational studies can be sufficiently well designed to yield data comparable to those of randomized, controlled trials. One of the articles<sup>22</sup> shows that, contrary to prevailing beliefs, the 'average results' from well-designed observational studies (with a cohort or case-control design) do not systematically overestimate the magnitude of the associations between exposure and outcome compared with the results of randomized, controlled trials on the same topic. The authors conclude that the popular belief that only randomized, controlled trials produce trustworthy results, and that all observational studies are misleading does a disservice to patient care, clinical investigation and to the education of health care professionals.

Some medical scientists<sup>23</sup> insist that CAM treatments should be valued critically and objectively by using the accepted principles and rigorous standards of scientific research. They argue that randomized, controlled double-blind clinical trials are necessary in order to answer questions pertaining to the therapeutic efficacy of these treatments. Barrett,<sup>24</sup> for example, writing on the Quackwatch Internet site, warns about the confusing term 'alternative'. While use of this term supports the belief that there is a working alternative to conventional medicine, Barrett argues that there is none. He proposes focusing on basic issues such as the illness situation and the treatment or practice, while seeking convincing evidence of therapeutic efficacy and safety, arguing that this can only be obtained from well-designed clinical trials. In an article in the *New England Journal of Medicine* (NEJM), Angell and Kassirer<sup>25</sup> likewise argue that alternative medicine should be scientifically tested. By this they mean marshalling rigorous evidence of safety and efficacy, as required by the Food and Drug Administration (FDA) for the approval of drugs, and publication of research reports by the best peer-reviewed medical journals. The writers argue that the different rationale of CAM, which violates fundamental scientific laws, calls for more, rather than less, evidence.

The position of Straus, head of NCCAM, reveals the dilemma of a scientist who attempts to initiate change and to 'expand horizons'. He declares that he maintains an open mind and, at the same time, is committed to the evidence-based standards of science. He is aware of the difficulties in

researching most CAM treatments by means of rigorously designed clinical trials, but nevertheless seeks to conduct high quality research. This dilemma regarding the kind of research to perform and what can be considered as legitimate evidence is typical of scientists. Collins (1998), in his work on physics laboratories, describes two 'evidential cultures', one 'open' and the other 'closed'. The 'open culture' considers a wider variety of findings as data, while the 'closed culture' restricts this range. In his writings, Collins shows that the very notion of 'data' is an outcome of different scientific traditions and institutional settings. In the same manner, the two approaches to research of CAM effects can be considered as two evidential cultures. Yonay (2000), writing about struggles between groups of economists, employed useful military metaphors. On the one hand, 'tactician scientists' tend to limit research to evidence about which precise and accurate statements can be made. On the other hand, from the point of view of scientific strategy, which refers metaphorically to long-standing disputes, excluding any evidence relevant to the problem at hand is considered to be unscientific (Yonay, 2000).

### **The clinical vs pragmatic trial**

On a practical level, the work of Ernst and his colleagues features prominently in a number of publications, along with the reactions to it. Ernst is the Chair of the Department of Complementary Medicine in the School of Postgraduate Medicine and Health Sciences at the University of Exeter in Britain. Ernst's department aims at conducting rigorous, interdisciplinary and international collaborative research into the efficacy, safety and cost of CAM techniques.<sup>26</sup> Although Ernst and his colleagues are committed to rigorous and objective research, which means obtaining evidence from large, double-blind randomized controlled trials (RCTs), they are aware of the difficulty in accomplishing this, and propose, for example, performance of uncontrolled clinical trials as a starting point for establishing a base of evidence for CAM.<sup>27</sup> They likewise advocate the use of initially uncontrolled observations, such as historical use, case reports, case series and outcome studies as a step towards determining whether there is any clinical effect worth investigating. They cite some of the advantages of the uncontrolled trial, including the ability to relate to every patient individually, as CAM practitioners usually do. This initial stage should be followed by rigorous testing of the efficacy of CAM intervention, culminating in controlled clinical trials in an attempt to determine whether the observed effect is specific or non-specific (i.e. a placebo effect).<sup>28</sup>

The nature of Ernst's research has evoked antagonism among CAM practitioners and teachers.<sup>29</sup> While Ernst and his colleagues consider their own work as neutral and objective, their opponents see them as shackled to conventional rules of research according to the bio-medical paradigm. 'Science is the religion of today ...', writes Morrell.<sup>30</sup> He sees the work of

Ernst as reductionist, providing only one side of the story, that of EBM.<sup>31</sup> Churchill,<sup>32</sup> an acupuncturist and herbalist, also argues that researchers such as Ernst give precedence to the scientific paradigm, while CAM research should be sensitive to the CAM paradigm. Heptonstall<sup>33</sup> regards CAM research that employs the rigorously designed clinical trial as detrimental to the discipline, while Morrell<sup>34</sup> accuses Ernst of seeking to weaken CAM. Churchill<sup>35</sup> resists the idea of integrating CAM with biomedicine, fearing the loss of its unique philosophies. If its practices are researched in biochemical terms, he asserts, CAM will be incorporated into bio-medicine. Along the way, Churchill argues, CAM systems will lose their rationale and philosophy. Heptonstall<sup>36</sup> notes that many medical institutional figures would like to see CAM separated from its practitioners and packaged according to the institutional scientific paradigm, consequently losing its defining principles such as holism, which have contributed to its dramatic success.

Antagonism among CAM practitioners to the acceptance of the rigorous clinical trial as the final determinant of the efficacy of their treatments arises from their holistic and individualistic principles. The clinical trial rests on the assumption that human beings, while generally different, have enough in common so that similar symptoms and diseases can be treated in the same way. A further assumption holds that, although the human body is a whole, it can be separated into levels (such as mind [psyche] and body [soma], systems, organs, tissues, cells and molecules), and that these can be treated separately. CAM practitioners, on their part, take the opposite view: despite the similarity between human beings, individual treatment, which is specifically attuned to the uniqueness of each person as a whole, is preferable. While the clinical trial assumes a basic similarity between the same type of disease in different persons, as well as the benefits of separating the 'body' into levels, CAM invokes the individuality of different people suffering from the same disease and the unification of all levels of the human body and its surroundings.

While Ernst and his colleagues seek effective methods of health care in the fight against illness, and advocate studying the efficacy of CAM treatments in ways that are accepted within mainstream medicine, CAM practitioners reject this approach and take issue with the very notion of evaluating the effectiveness of CAM. The debate between Ernst and his colleagues and their opponents is thus a result of two different points of view. According to Latour (1987), we can regard the attitude of Ernst and colleagues as 'ready made science', and their opponents' attitude as 'science in the making'. While 'ready made science' seeks the most effective 'machines', 'science in the making' still asks questions such as: What kind of effectiveness do we seek? (Latour, 1987). The goal of biomedical scientists like Ernst, who advocate use of the research tools that have been institutionalized in medical research for studying the efficacy of medical treatments, is to find the 'best machines', that is, the best treatment methods. A remarkable example of this approach is the argument of Lewith, Ernst,

Mills and Fisher, that, even if a CAM system has a different paradigm, we can still appreciate it through ‘*appropriate clinical research*’, ‘*in a proper manner*’, ‘*appropriately evaluated*’.<sup>37</sup>

What kind of ‘science in the making’, then, do CAM practitioners propose? This can best be ascertained by examining the publications of professional associations of CAM practitioners. Although CAM practitioners are generally not considered to be scientists, and their knowledge lacks the legitimacy of scientific knowledge, we may employ ‘the symmetry principle’ first formulated by Bloor (1976). This states that, in order to understand scientific knowledge as a social product, we should be free from scientific hegemonic thought and relate equally to scientific knowledge accepted as ‘right’ and to knowledge considered as ‘wrong’; to arguments scientists see as ‘truth’ and to what is treated as ‘false’.

CAM practitioners favour medical research that is closely related to everyday practice. They regard case studies, series of cases and variations of pragmatic trials as suitable ways for evaluating CAM treatment. This is the way, some CAM practitioners<sup>38</sup> argue, to evaluate effects while respecting CAM’s practices and ideas, and to obtain far more valid results than those that emerge from the ‘gold-standard’ clinical trial.

The pragmatic trial proposed by some CAM practitioners<sup>39</sup> is considered an appropriate research tool to evaluate treatments as they are routinely practised. This method respects the individuality of the treatment given to every patient by every practitioner, and includes the placebo effect as part of the treatment. The distinction between pragmatic and explanatory trials was made by Schwartz and Lellouch in 1967. While the pragmatic trial seeks to study the totality of a particular approach to therapy, the explanatory trial separates the therapy into its constituent dimensions, such as time, active intervention and therapeutic setting (Schwartz and Lellouch, 1967). The purpose of the explanatory trial, like that of the randomized controlled trial, is to control for all the variables except for the one in question. It is designed to pinpoint which specific component of an intervention produces the outcome, and to determine whether the treatment has a specific effect. The pragmatic trial, on the other hand, addresses the question of whether the therapy as a whole works in everyday practice. Contextual factors are optimized, and the objective is to discover the effect and outcome of the whole ‘package’ of treatment.<sup>40</sup>

Hugh MacPherson,<sup>41</sup> a researcher and member of the Foundation of Traditional Chinese Medicine, suggests that the practical relevance of the pragmatic trial is one of its strengths. The pragmatic trial, writes MacPherson, takes account of the practitioner’s flexible approach in seeking to maximize both the placebo effect and the treatment effect. The pragmatic trial has an advantage in evaluating the overall effectiveness of acupuncture treatment, for example, since this treatment includes a variety of techniques such as dietary and lifestyle advice, as well as a range of non-specific ingredients of treatment, such as expectations, beliefs and the quality of relationships.

J. Richardson,<sup>42</sup> a CAM researcher, likewise asserts that the pragmatic trial provides a more valid assessment of treatment effectiveness in actual clinical practice.

The pragmatic trial can be designed in various ways. A particular example of such a trial was aimed at answering the question: 'Does complementary therapy (acupuncture, homeopathy and osteopathy) improve the patient's health status?'<sup>43</sup> It was designed as a pragmatic quasi-experiment with a waiting-list control group. It did not evaluate to what extent the homeopathic remedies, the acupuncture points or the specific manipulation techniques were responsible for any change in health status, but rather assessed the overall benefit of the total therapeutic care package. This study demonstrates how the benefits, in terms of health status, of a CAM service given in the regular way, can be compared to the status of an untreated control group.<sup>44</sup>

The pragmatic trial rationale is compatible with Barry's (2003) anthropological research findings, which showed that the effectiveness of homeopathic therapy, from the perspective of both therapists and patients, was embedded in the development, over time, of a whole new set of beliefs about health, illness and the body, and about the nature of the healing process. Committed users of this therapy regarded health as having an ongoing interdependency with the social, physical and spiritual spheres, and regarded illness as an active and positive part of health. The healing process starts with health rather than sickness, and the body does the healing naturally. Ultimately, homeopathy helps while pharmaceuticals hinder, and the user takes primary responsibility for his health care. The development of this new belief system about health was seen in itself as evidence of the power of homeopathy for many users (Barry, 2003). Non-biomedically trained alternative practitioners have a knowledge system that is more grounded in the phenomena of everyday life and experience than that of those trained in science-based medicine. In their view, the relevant approach is that which investigates not whether a therapy is working according to biomedical and scientific criteria, but whether it is making a difference to the bodies, beliefs and social and cultural experiences of its clients, and whether patients keep coming back (Barry, 2005).

The rationale for collecting evidence from everyday practice can be supported by general medical and philosophically relevant discussions. For example, the 'outcome movement' (Epstein, 1990), an idea that has virtually never been applied, proposed the creation of a permanent national medical database that would include information on the evaluation of all treatments in the health care system. Evaluations of health status and quality of life would be matched with information about patients' conditions and the treatments they received, in order to determine what works for whom and how well. The physician and philosopher D.C. Hadorn (2001) has also called for accumulation of medical information from everyday practice, arguing that observational databases can serve as legitimate

sources for causal knowledge in medicine. The epistemologically privileged status of the randomized controlled trial, he maintains, must not deter us from developing more efficient routes to causal knowledge in medicine (Hadorn, 2001).

### **Anecdotes vs healing cases**

In the dominant medical discourse, case studies are considered the lowest level of evidence, as the lack of control and statistical analysis detract from the anecdote's reliability. By contrast, CAM practitioners emphasize the important function of the healing case study as a main resource of knowledge, and call upon peers to publish high-quality case reports in professional journals. The homeopaths Thompson, Owen and Swayne, for example, favour detailed clinical information including patient narratives, details of case analyses, remedy, differential diagnoses, discussions of treatment strategies and rationales and follow-ups of appropriate duration, adequately described and clearly interpreted: 'Don't keep it to yourself! The homeopathic community needs access to your case material – for both education and research purposes'.<sup>45</sup>

Other practitioners argue that series of cases often provide better information than do randomized clinical trials, which are not appropriate to CAM practice.<sup>46</sup> The case study as a research tool, practitioners<sup>47</sup> argue, preserves the individualistic and holistic character of the treatment during research as well, so that every patient is provided with the appropriate individual treatment, as in everyday practice. CAM practitioners further propose undertaking research-like case studies, case series and outcome studies at CAM schools, carried out by the same practitioner or group of practitioners, and using the same treatment modalities, thereby documenting a number of cases treated under the same circumstances.<sup>48</sup> CAM practitioners seek to arrive at consensual processes for developing series of cases, emphasizing the importance of establishing standard criteria suitable for case studies, in order to promote public confidence in CAM's effectiveness.<sup>49</sup>

CAM practitioners do not regard the healing case study merely as a resource of knowledge, but also use descriptions of cases of healing as a rhetoric strategy for gaining legitimacy for their knowledge in the public domain. Examination of the rhetoric of popular writers who are considered 'leaders',<sup>50</sup> shows that they tend to use descriptions of successful healing cases when trying to convince others of the effectiveness of their ways. One of the most prominent among such leaders is Deepak Chopra, a popular writer and lecturer, who established the 'Chopra Center', an association that offers study, lectures, an Internet site, workshops and treatments in several centres in the USA. Use of the charismatic rhetoric of 'soft' arguments, although they are not considered to be scientific evidence, facilitates the wide dissemination of CAM ideas. Popular writers tend to present descriptions

of cases while trying to convince the reader that healing can be achieved, and that those who follow the proposed way can be healed. The charisma of the rhetoric is evident in the way cases are described, by highlighting the supernatural, the superhuman and the exceptional nature of the healing. Elements of spirituality and magic attest to its sacred nature.

Analysis of charismatic rhetoric indicates that it is directed less towards glorifying the writers themselves and bolstering their authority, and more towards inspiring a process of becoming a 'sacred self' (as analysed by Csordas, 1994) among the readers. As Max Weber (1985 [1922]) pointed out, while charisma can be seen as a kind of authority that a leader with charismatic personality uses, it can also undergo dissociation from a particular character, thereby transforming it into an objective, transferable entity. When it develops into the charisma of office, the belief in legitimacy is no longer directed at the individual, but rather at the acquired qualities and effectiveness of the ritual acts. A most important example is the transmission of priestly charisma by anointing, consecration or the laying of hands. Thus, the charismatic qualities and powers of the office are emancipated from the personal qualities of the priest.

Writers describe cases of extraordinary healing, perceived as miracles, in order to convince readers that miracles do indeed occur. The healing is described as an internal transformation and a growth of awareness, which can lead to a spiritual process of creation of the 'sacred self'.

## **Discussion: the untenable boundaries of biomedical knowledge**

The debate over evaluating the effects of CAM treatments can be seen as a dichotomy between two different ways of knowing. From the viewpoint of physicians, researchers, medical journal editors and policy shapers in mainstream medicine, the rigorous clinical trial is regarded as 'the gold standard'. CAM practitioners and teachers, on the other hand, oppose the clinical trial and propose practice-based research. The epistemological foundation underlying the various suggestions, and which distinguishes between the approaches of the two 'camps', is the tension between two philosophical principles in medicine, namely, Holism and Reductionism (Rosenberg, 1998). While followers of the dominant medical approach give precedence to reductionism, CAM practitioners base their treatments on perceptions that give precedence to holism. It is widely accepted that reductionism and holism, both as research strategies and as guidelines for interpretation in science in general and in medicine in particular, are not contradictory but complement each other. These two epistemological points of view serve as ideologies in a struggle for dominance over the same niche. While CAM practitioners use holism and 'healing' as a rhetoric strategy for gaining popularity, biomedical discourse seeks to secure its dominant position by discursive practices of boundary work. Gieryn (1983) coined the term

'boundary work' to characterize discursive practices by which scientists attribute selected qualities to science in order to draw a boundary that distinguishes their field and its practitioners from less authoritative, non-science practitioners, thereby establishing their own epistemic authority. In Gieryn's (1999: 4-5) words, boundary-work is 'the discursive attribution of selected qualities to scientists, scientific methods, and scientific claims for the purpose of drawing a rhetorical boundary between science and some less authoritative residual non-science'. The notion of boundaries has in recent years become an organizing frame for various sociological approaches to social inequality, minorities, collective and national identity, class, gender and ethnic relations, as well as for the sociology of science, knowledge and professions (Lamont and Molnar, 2002).

But, as this article has shown, a closer look at the debate over evaluating the effects of CAM treatments exposes more than two mutually exclusive collectives. Controversies waged at the level of shaping research policy, as well as at the level of research practice, deal with two kinds of question: whether or not to research CAM, and if so, how to do this. Different groups of experts hold diverse kinds of knowledge and use different rhetoric strategies to legitimize it. Opponents of researching CAM treatment effects use 'the priority of rationalism' argument as a rhetoric strategy. Supporters of CAM research, the experimentalists, argue that experiments designed to evaluate CAM treatment effects should indeed be performed, even though the tools usually used for explaining such effects are not accepted scientifically, and continue to debate the appropriate ways and criteria. Some medical scientists are willing to consider only the results of rigorous, randomized, controlled double-blind clinical trials as evidence of the therapeutic efficacy of CAM treatments. They see therapeutic efficacy as the specific effect of the treatments. Their rhetoric strategy for justification of their knowledge involves arguments regarding criticism, objectivity, standards and accepted principles of scientific research. In view of the difficulties and problems in performing rigorous clinical trials to evaluate the effects of CAM therapies, other groups advocate conducting different kinds of research. Some groups of scientists consider the evidence as a hierarchy, ranging from soft to hard. Other groups of experts, most of them CAM practitioners, who can be termed 'the pragmatists', use the strategy of arguing for the need to bring research closer to practice, which is holistic and individualistic in nature, and regard the evidence gained from a pragmatic trial as superior. Some CAM practitioners also view the study of healing cases as an important resource of knowledge. Popular and charismatic CAM leaders regale the public with descriptions of spiritual and even magical cases of healing as a rhetoric strategy for spreading their knowledge and gaining legitimacy for it.

The debates between groups of medical scientists themselves, the inability to distinguish sharply between medical scientists and CAM practitioners (many of them physicians (MDs) themselves), the difficulty in categorizing

the diverse kinds of knowledge held by different professional groups and the rhetoric strategies they use to legitimize knowledge claims, all highlight the untenable boundaries and ambiguity of orthodox institutionalized biomedical knowledge.

### Notes

1. Available at [www.amazon.com](http://www.amazon.com) 1 September 2002.
2. Available at [www.barnesandnoble.com](http://www.barnesandnoble.com) 1 September 2002.
3. Available at [www.alibris.com](http://www.alibris.com) 1 September 2002.
4. Available at [www.bestbookbuys.com](http://www.bestbookbuys.com) 1 September 2002.
5. Available at [www.allbookstores.com](http://www.allbookstores.com) 1 September 2002.
6. Information about the organization can be found online on the Internet site [nccam.nih.gov](http://nccam.nih.gov)
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11. Quoted from Sampson (2001a: 111) (see note 8).
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16. Quoted from Barrett (2001: 4) (see note 13).
17. The retrieval was made for 'complementary therapies' [MeSH] with limits: clinical trial.
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32. Churchill (2000) (see note 29).
33. Heptonstall (2000a) (see note 29).
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35. Churchill (2000) (see note 29).
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42. Richardson (2001) (see note 39).
43. Quoted from Richardson (2001: 317) (see note 39).
44. See note 41.
45. Quoted from Thompson et al. (2002: 2) (see note 38).
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### **Author biography**

Yael Keshet is a lecturer of Sociology at the Western Galilee College of Bar Ilan University (Israel). She has been researching processes of medical knowledge construction taking place with the growth of complementary and alternative medicine, while combining theories from the sociology of science and knowledge with the sociology of medicine, the sociology of body, health and illness and the sociology of professions. She is presently doing research on the professionalization process of complementary and alternative medicine practitioners in Israel. An additional area of expertise is information retrieval.