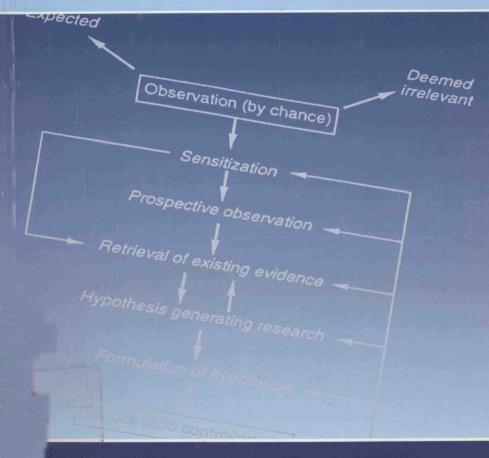
Complementary Medicine

an objective appraisal



Edited by **Edzard Ernst**

Complementary Medicine

An objective appraisal

Edited by

Professor Edzard Ernst MD PhD
Director
Department of Complementary Medicine
Postgraduate Medical School
University of Exeter
UK



Butterworth-Heinemann Linacre House, Jordan Hill, Oxford OX2 8DP A division of Reed Educational and Professional Publishing Ltd

A member of the Reed Elsevier plc group

OXFORD BOSTON JOHANNESBURG MELBOURNE NEW DELHI SINGAPORE

First published 1996 Reprinted 1997

© Reed Education and Professional Publishing Ltd 1996

All rights reserved. No part of this publication may be reproduced in any material form (including photocopying or storing in any medium by electronic means and whether or not transiently or incidentally to some other use of this publication) without the written permission of the copyright holder except in accordance with the provisions of the Copyright, Designs and Patents Act 1988 or under the terms of a licence issued by the Copyright Licensing Agency Ltd, 90 Tottenham Court Road, London, England W1P 9HE. Applications for the copyright holder's written permission to reproduce any part of this publication should be addressed to the publishers

British Library Cataloguing in Publication Data
A catalogue record for this book is available from the British Library

Library of Congress Cataloguing in Publication Data
A catalogue record for this book is available from the Library of Congress

ISBN 0 7506 3141 4

Typeset by Keytec Typesetting Ltd, Bridport, Dorset Printed and bound in Great Britain by Biddles Ltd, Guildford and King's Lynn

Complementary Medicine

List of contributors

Anton J. M. de Craen MSc

Department of Clinical Epidemiology and Biostatistics, Academic Medical Center, Amsterdam, The Netherlands

David P. S. Dickinson MA

Editor, Health Which?, Consumers' Association, London, UK

David M. Eisenberg MD

Assistant Professor of Medicine, Harvard Medical School, Boston, Massachusetts, USA

Edzard Ernst MD PhD

Director, Department of Complementary Medicine, Postgraduate Medical School, University of Exeter, Exeter, UK

Roger A. Edwards ScD

Instructor in Medicine, Harvard Medical School, Boston, Massachusetts, USA

Adrian Furnham DPhil DSc DLitt

Professor of Psychology, Department of Psychology, University College London, London, UK

Wayne B. Jonas MD

Director, Office of Alternative Medicine, United States National Institutes of Health, Rockville, Maryland, USA

Ted J. Kaptchuk OMD

Instructor in Medicine, Harvard Medical School, Boston, Massachusetts, USA

Jos Kleijnen MD PhD

Department of Clinical Epidemiology and Biostatistics, Academic Medical Center, Amsterdam, The Netherlands

George T. Lewith MA DM MRCP MRCGP

Hon. Clinical Senior Lecturer, University Medicine, Southampton General Hospital, Southampton, UK

Karl-Ludwig Resch MD PhD

Senior Lecturer, Department of Complementary Medicine, Postgraduate Medical School, University of Exeter, Exeter, UK

Andrew Vickers

Director, Information Service, The Research Council for Complementary Medicine, London, UK

Adrian R. White MA BM BCh

Research Fellow, Department of Complementary Medicine, Postgraduate Medical School, University of Exeter, Exeter, UK

Preface

Complementary medicine (CM) has undoubtedly become 'big business'. One third to one half of the general population is using one or more forms of complementary therapy. Sales of herbal and homoeopathic remedies are associated with annual growth rates of around 20%. In addition, more and more institutions are training would-be practitioners. Users of CM are prepared to pay considerable sums out of their own pocket. Also, an increasing number of health insurance companies are willing to take over some of the costs for CM. This growing interest in CM is also reflected in the literature – since 1966 there has been a six-fold increase in the number of CM-related publications in mainstream medical journals.

It is hardly surprising then, that a veritable plethora of books on various aspects of CM is available in our bookshops. One disappointing but outstanding hallmark of this literature is its uncritical nature. Some of these publications are hardly more than promotional texts written by, at best, the well-meaning and read by the gullible. Even some volumes written for professionals and aspiring to an academic standard suffer from being overtly promotional. There are certainly few books available where the author(s) has made a serious attempt to objectively assess CM in general terms and to explore the numerous open questions related to it.

The flurry of interest in CM seems sharply contrasted by an astonishing and embarrassing lack of knowledge in and information on the subject. The void even relates to the most fundamental questions. Does CM work? Is it safe? Can it reduce healthcare costs? How can it be researched?

This volume aims at filling this most obvious gap. It consists of ten contributions by experts from various countries, each of whom looks critically and constructively at a fundamental aspect of CM. The book is neither confined to the agenda of a particular nation, nor does it express the views of either proponents or opponents of CM, nor is it confined to specific therapies, nor is it a book solely written by doctors or by lay-practitioners. It provides balanced and informed views on fundamental, general issues within CM and is aimed at *all* professionals who are seriously interested in the topic.

x Complementary Medicine

If the present popularity of CM is to be more than yet another passing fashion, it is essential to cultivate constructive criticism, informed debate and balanced views. Paradoxical as it may seem, those who are inspired by an attitude of constructive criticism will surely turn out to be the true champions of CM, while the naive smugness that is still regrettably prevalent will prove to be counterproductive and, more importantly, against the interests of the patient.

I thank all contributors, the Ciba-Foundation and the publishers for their help in creating this book. I sincerely hope that it will form an important landmark on the way to an understanding of CM that is based more and more on reliable evidence and less and less on personal belief.

Edzard Ernst, Exeter

Contents

List	of contributors	vii
Pref	face	ix
1	Research paradigms in mainstream and complementary medicine Andrew Vickers	1
2	Research methodologies in complementary medicine: making sure it works Karl-Ludwig Resch and Edzard Ernst	18
3	The importance of the placebo effect: a proposal for further research Jos Kleijnen and Anton J. M. de Craen	31
4	Complementary medicine: efficacy beyond the placebo effect Ted J. Kaptchuk, Roger A. Edwards and David M. Eisenber	42 g
5	Why do people choose and use complementary therapies? Adrian Furnham	71
6	Do complementary therapies offer value for money? <i>Adrian R. White</i>	89
7	The use and abuse of evidence-based medicine: an example from general practice George T. Lewith	106
8	Direct risks associated with complementary therapies Edzard Ernst	112
9	Safety in complementary medicine Wayne B. Jonas	126
10	The growth of complementary therapies: a consumer-led boom David P. S. Dickinson	150
	Index	163

Research paradigms in mainstream and complementary medicine

Andrew Vickers

Summary

Our worlds are built up from profound and often hidden assumptions about the nature of reality. These assumptions tend to vary between individuals and groups in systematic ways. Some writers on complementary medicine research have used the term 'paradigm' to capture this idea of conceptual differences between different systems of medicine. I will argue that the notion of a paradigm is not a useful generalization in the methodological debate. Effort seems better spent on the practical matter of how particular research questions can be matched to particular research designs than on esoteric debates about the vague and slippery notion of the paradigm.

Introduction

The concept of the paradigm has become an institutionalized feature of complementary medicine research. Perhaps the best example of this is *The Journal of Alternative and Complementary Medicine*, which describes its aim as 'research on paradigm, practice and policy'. When the Office of Alternative Medicine was established as part of the National Institutes for Health, paradigms even made it to government. The Chantilly report – which outlines the goals of the newly formed office – explicitly states that a major barrier to alternative medicine is that it has a different paradigm to mainstream medicine (National Institutes for Health, 1994).

'Paradigm' is a term borrowed from the history and philosophy of science. It was introduced in 1962 in a text written by Thomas Kuhn, a historian at Princeton University. A year earlier, Nagel had published *The Structure of Science*, a conventional textbook of the philosophy of science: inductive and deductive logic were compared, the problem of the theory laden nature of observations analysed, the difficulty of choosing between two theories $-T_1$ and T_2 — discussed at length. Kuhn's book had an almost identical title, but the addition of a single

word could not have been more significant. In The Structure of Scientific Revolutions, Kuhn brought a historian's eye to the philosophy of science. The interesting thing about science, according to Kuhn, was change. Moreover, change did not necessarily happen gradually. Science was not just a steady accumulation of facts, it sometimes involved revolutions in which knowledge was radically reconstituted. Scientific revolutions allowed the incorporation of new facts which failed to fit previous theories ('anomalies') and cast existing knowledge in a new light. Kuhn's most notable example of a scientific revolution was that initiated by Copernicus. The suggestion that the earth orbits the sun goes beyond a mere change in theory: Copernican astronomy involves the replacement of key cosmological concepts such as the immutability of the heavens and the Aristotelian notion that the earth and heavens are subject to different physical laws. Kuhn described such revolutions as a shift from one paradigm - a pattern of seeing the world - to another.

Kuhn's thesis was subjected to bitter attack as soon as it was published. Conservative critics claimed that Kuhn had reduced science to fashion. If all that changed in science were general views about how the world was constituted, and if these views were themselves not testable, how could science be said to progress towards the truth? How could science be said to be rational if important changes – scientific revolutions – did not take place by rational processes? Sympathetic critics pointed out that, though of interest, Kuhn's ideas were often too ambiguous to be of significant explanatory value. The concept of the paradigm was a prime example: Masterman (1965), for example, claimed that Kuhn used the term in 21 different ways.

The argument presented in The Structure of Scientific Revolutions is no longer current in the philosophy of science. It is typically taught as a historical introduction, as a background to contemporary debates. What was valuable about Kuhn's theory was the demonstration that change in science can be discontinuous and that scientific theories make relatively global assumptions about both the nature of reality and how to find out about it. Perhaps of greatest importance was Kuhn's insistence that philosophical analysis of science should be rooted in what has happened in the real world: rather than 'T₁' and 'T₂', Kuhn discussed Copernicus, Newton, Preistley and Lavoisier. What was less salutary was the attempt to use large, simple concepts to explain local, complex events. In retrospect it seems naive to suppose that the historical development of a human activity as rich and complex as science can be described in terms of one paradigm replacing another during a scientific revolution. It is also interesting that, despite Kuhn's empirical orientation, the debates about the nature of science following the publication of The Structure of Scientific Revolutions (e.g. see Lakatos and Musgrave, 1965) were almost completely devoid of examinations of what scientists actually did: reference to sociological studies of science and scientists were few and far between.

Given that the concept of paradigms has just about left contemporary discourse in the philosophy of science, it is strange to see it playing such a central role in the debate about complementary medicine research. It is my contention that the notion of the paradigm has been of little practical value in this methodological debate. If anything, it has hindered the development of clear ideas about how complementary medicine should be researched. This is partly because discussion about paradigms seems almost inevitably to involve the use of esoteric and obscure language. But it is also because those writing about paradigms have often articulated the idea crudely and have made over-simplistic assumptions about what they claim to describe. In short, it is difficult to apply big, simple generalizations to complex, real world situations.

The paradigm argument in complementary medicine research

There is no single line of thought common to all of those who write about paradigms in complementary medicine research. However, it is possible to discern a number of themes which are common among those who use the concept of paradigms. The general argument about paradigms has been presented to me orally on numerous occasions at conferences, seminars, lectures and other meetings and it is possible to find important strands of this argument in the methodological literature.

The argument goes as follows: there is such a thing as paradigms; these govern the way we look at the world. There are two entirely separate paradigms, one associated with orthodox medicine and one with complementary medicine. Research methods are paradigm-specific, in other words, research methods used in one paradigm cannot be used in another. Therefore conventional research methodology is inappropriate for complementary medicine. Those working in a paradigm are unable to look outside of it. Conventional scientists are therefore blind to important healing phenomena. Partly because of this, the current medical paradigm is outdated and is about to be replaced. This is a good thing because the methodologies of the orthodox paradigm have had adverse effects on medicine and society and have been nothing less than tools of oppression.

I do not agree with this argument and I will challenge each step in turn.

The concept of a paradigm in complementary medicine research is a meaningful one

One remarkable feature of the current methodological discourse on paradigms is that the term is so rarely explained. 'Paradigm' tends to be used without an accompanying definition or discussion, as though it has an unambiguous and widely understood meaning. Given that researchers often fail to agree on the meaning of terms such as 'audit', 'primary health care' or 'basic research', and given that Kuhn himself used the term in as many as 21 different ways (Masterman, 1965), this assumption is unhelpful at best.

However, when a definition of paradigm is presented, we are often none the better for it. In an explanatory footnote to the Chantilly report (National Institutes for Health, 1994), the Office of Alternative Medicine defines paradigm as an 'overarching cosmological conceptual scheme' which 'tells whole societies in whole historical periods how to think about ... big issues. This is contrasted with an explanatory model, which is 'the way one discipline, denomination or health care system explains itself - the details of its assumptions, logic and rationale'. It is also claimed that whereas a paradigm is largely out of awareness, an explanatory model is not, and is therefore open to argument, criticism and change. Yet in the accompanying text, the first mention of paradigm is followed by the words, 'i.e. broad views of how ... facts should be organized. Differences in views among groups of people are a reflection of the different scientific paradigms they adhere to'. If the groups of people are part of the same society in the same historical period, and if, as it appears, those who hold broad views of how facts should be organized are aware that they are doing so, the definition of 'paradigm' in the text now sounds somewhat like the definition of 'explanatory model' given in the footnote. Consequently, two inconsistent interpretations of 'paradigm' appear on the same page.

The root of this inconsistency is that it is unclear at what metaphysical level paradigms operate. Are paradigms global and all encompassing (whole societies in whole historical periods) or do they refer to 'particular groups of people'? Rubik (1994) talked in the former terms when she spoke of 'the dominant paradigm of mechanical reductionism that shaped science for the past few centuries ... [and] still governs modern biology and medicine'. Coulter (1990) suggested a more localized meaning for the concept of the paradigm when claiming that homoeopathy, osteopathy, naturopathy and chiropractic constituted four separate paradigms in the latter half of the 19th century in North America. Similarly, when Korr (1991) talked of paradigms as 'investigative strategies' and Coulter (1993) discussed the

'alternative social science paradigms', the concept seems to refer to the specific rather than the general.

In sum, the meaning of 'paradigm' remains impenetrable, a feature that could be said to characterize much of the language used in discussions of the concept. Watson (1995) talked of moving from 'a separatist-interactionist ontology to a relational-transformative ontology of connectedness and unity of life itself'. Later she claimed that 'the paradigm I, particular-deterministic model parallels era I medicine described by Dossey as body-machine, mechanical-material physical medicine, and "doing" therapies'. It is hard to see how the use of such obscure language advances either the methodological debate, or our understanding of the differences between medical philosophies.

There is a more fundamental point to be made with respect to paradigms, language and communication. At first sight, the concept of the paradigm seems to be about acknowledging that there are different ways of looking at the world and that we should try to understand each other's points of view. Some methodological writers, however, seem to use the concept to demonstrate the impossibility of discourse. Launsø (1994), for example, stated that complementary medicine 'must produce a knowledge system other than the mechanistic-objectifying paradigm'. Perhaps more worrying, is the statement from the Chantilly report that 'differences in views among groups of people are a reflection of the different scientific paradigms they adhere to'. Given the earlier suggestion that, unlike an explanatory model, a paradigm is not open to argument, the implication of this statement is that people holding different views cannot talk to one another. I hold one view, you hold a different one and there's nothing we can do about it because we have different paradigms. A paradigm can become an 'inference ticket': claiming that you are in a different paradigm gives you a ticket to make whatever inference you please.

A further argument against the concept of paradigm in complementary medicine research is that of *parsimony*. In short, why use a concept if it is not necessary to do so? Many of the arguments around the issue of paradigms would continue to make perfect sense even if the authors did not make reference to the term. For example, Rubik (1994) analysed the obstacles facing scientists working in unusual areas of science ('frontier science') and claimed that these stem from resistance of the dominant paradigm to 'anomalies' (a Kuhnian expression). However, the problems encountered by frontier scientists can be explained on a case-by-case basis without reference to paradigms. The resistance to say, Semmelweiss, is better understood by close historical analysis than by a quick reference to paradigms. It seems more valuable to say that Semmelweiss was scorned by his peers because of his implicit criticism of physicians — and the lack of a

theory to account for his observations – than merely to say that he discovered an anomaly which challenged the dominant paradigm. Looking more specifically at research methodology, both Korr (1991) and Masarsky and Weber (1991) provided excellent analyses of research questions pertinent to osteopathy and chiropractic (e.g. is 'upper cervical dysfunction ... more common in (adductor-type spasmodic dysphonia) patients than in the population at large?'). They claimed that these questions stemmed from a paradigm, but it is entirely unclear whether this statement provides any useful additional information. The authors may have been better off stating simply that the questions were suggested by the theory and practice of osteopathy and chiropractic.

There can be little doubt that our worlds are built up from profound and hidden assumptions about the nature of reality. Moreover, these assumptions tend to vary between individuals and groups in systematic ways. As Coulter (1990) put it: 'chiropractors begin with a different set of assumptions, use different theoretical explanations, embrace a different philosophy, pose different questions and use a different language ... than medicine'. But this does not imply that the concept of a paradigm is a useful generalization, or that differences in beliefs and attitudes of individuals and groups cannot be identified and explored on a case-by-case basis. Explicit and implicit assumptions of medical systems need to be teased out and examined individually or in groups. Their implications need to be analysed and discussed and solutions to possible misunderstandings developed. It may be that some aspects of some medical systems cannot be understood as completely in terms used outside of that system, in the same way that esprit de corps has an immediate meaning in French which is not easy to describe in English. However, merely asserting that there are profound differences between 'paradigms' seems to take us no further in this project of analysis and understanding. Paradigms might well have a useful conceptual role in some fields of discourse; it has yet to be argued that this is the case in complementary medicine research.

There are two entirely separate paradigms, one associated with orthodox and one with complementary medicine

In a discussion of Chinese medicine, Beinfield and Korngold (1995) included a drawing of two hollow human forms, one labelled West and the other East. Whereas West consisted of mechanical levels and joints and test tubes, the body of East was filled with mountains, clouds, rivers and gardens. This diagram was presented to demonstrate the difference between entirely separate and non-overlapping medical

philosophies. In the western biomechanical model, the body is 'like a machine which can be dismantled and reduced into ... constituent parts'; medicine is a 'war on disease with doctor as general, disease as enemy, patient as occupied territory'. In the eastern holographic model, however, the view of anatomy and physiology is that of the 'body as garden' so that the aim of health care is to 'cultivate health with doctor and patient in partnership to improve ecological conditions'.

Beinfield and Korngold presented perhaps the most explicit articulation of the idea that the differences between complementary and conventional medicine are profound - that beyond the superficial distinctions of legal status and treatment techniques lies something more: a clash of world-views, a mismatch of paradigms. Though superficially attractive, and though it does contain a kernel of truth, the notion that complementary and conventional medicine have different paradigms is deeply flawed. This is because it assumes the heterogeneity of medical systems, that complementary medicine is all one thing and conventional medicine is all something different. Such an assumption does scant justice to the range and variety of medical practices. It is not difficult to argue that there can often be greater differences within complementary or conventional medicine (psychotherapy and physical therapy; chiropractic and radionics) as between the two (chiropractic and physical therapy). Both mainstream and unconventional medical practices are diverse and based on numerous different overlapping (and sometimes conflicting) understandings of health and treatment. It is of interest that, in discussing the 'chiropractic paradigm', Coulter (1990) left it open as to whether chiropractic is its own unique paradigm, or consists of two or more paradigms or whether it is in fact a 'sub-paradigm' of naturopathy. Once more, the concept of a paradigm seems too flexible to be of explanatory value.

By requiring that complementary and conventional medicine are in themselves homogeneous, those who argue for the notion of separate paradigms tend to caricature what they claim to describe. Beinfield and Korngold (1995), for example, quoted Descartes to explain western medical thinking. St George (1994a) stated that, in conventional medicine, 'subjective influences on the body are excluded as irrelevant, reducing the body to an impersonal biomolecular machine'. In addition, treatment is based on the 'external engineering of (physicochemical) derangements by a doctor-scientist'. It is not at all clear how, say, general practice, hospice care, clinical psychology or nursing are based on Descartes, or reduce the body to a machine, utilize Beinfield and Korngold's conception of health care as a 'war on disease' or involve the external engineering of 'physicochemical derangements'. Crucially, no evidence is ever presented to justify these

models of conventional and complementary medicine. This allows authors to become increasingly divorced from reality: Launsø (1994), for example, stated that, in conventional medicine, 'the placebo is defined as an evil to be fought against. How placebo effects are activated ... and with what consequence for the healing process have been of very little interest. In medical circles, the placebo has been considered uncontrollable, something the researcher had no power over: a Monster'. Placebo is no doubt an underexplored concept in medicine, but it is simply false to claim that conventional scientists consider it an evil to be fought against (e.g. see White, Tursky and Schwartz, 1985).

One of the most interesting features of these caricatures, and certainly the most important from the perspective of research, is the assertion that conventional medicine is only interested in objective changes and processes. Watson (1995), for example, stated that 'paradigm I science is structured to remove any human factors from the context of the study, setting up a model that is detached from feelings, meaning and subjective experiences'. Similarly, Mills (1986) asserted that 'current medical research generally concerns itself only with measuring events and data divorced from the human being', while St George (1994a) claimed, 'the subjectivity of doctor and the patient, as well as doctor/patient interactions, are understood to be irrelevant to therapy'. It is hard to see what evidence there is for such statements. Patient-assessed pain and anxiety are typical outcome measures in clinical trials. Both have at least something to do with feelings and subjective experiences. Similarly, it has been possible not only to conduct but to publish conventional clinical trials on techniques such as psychotherapy (e.g. Winston et al. 1994) and meditation (e.g. Dillbeck, 1977) in which the subjectivity of the patient is crucial to therapy. Moreover, it would surely be difficult to find any health care professional who believes that the interaction between doctor and patient is irrelevant. Again we see that reference to paradigms leads to crude generalizations rather than useful, detailed analysis.

Research methods are paradigm-specific

If the same research methods can be used across different paradigms, there would be no point in raising the issue of paradigms in the methodology debate. So even if it were to be argued that 'paradigm' was a coherent, meaningful and accurate generalization to apply to health care, a case would still need to made that, because a complementary therapy constitutes a different paradigm, it requires different research methods. This is perhaps the key issue in the