



Deconstructing EBM as applied to homeopathy and CAM

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THE ¥ INDEPENDENT

What flavour crisps do you fancy? Snail, leather or tea- what will Heston cook up?

Complementary therapies: The big con?

We spend billions on complementary therapies. But after 15 years of research, this man has found that most of them don't work. Jeremy Laurance reports

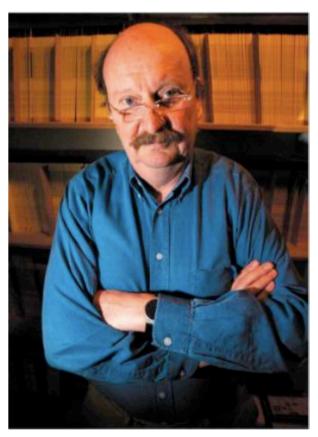
Tuesday, 22 April 2008

Mischief is what Professor Edzard Ernst most enjoys. You can see it in his face, twinkling eyes peering over rimless glasses. You can see it, too, on the first page of his new book, Trick or Treatment, published today, which promises readers the truth about alternative medicine – what works, what doesn't and what is dangerous.

The book is dedicated to the Prince of Wales. Casual readers may take this as the admiration of the foreigner – Ernst was born and brought up in Germany – for British royalty. In fact, it is a jibe at the foremost celebrity supporter of alternative medicine, whom Ernst accuses of promoting therapies and misleading the public.

Their dispute, which has been simmering for years, erupted again last week when Ernst and his co-author, the science writer Simon Singh, wrote to The Times attacking two guides published by the Prince's Foundation for Integrated Health, for being "misleading". The letter elicited a pained response from the foundation, which accused the authors of whipping up controversy to promote their book. Ernst must have been rubbing his hands with glee.

It is 15 years since he was appointed as the world's first professor of complementary medicine, at the University of Exeter, supported with a £1m grant from Maurice Laing, the builder – and he has been causing trouble ever since. Laing, who died earlier this year, had become an enthusiast after his wife had been helped by alternative medicine during a serious illness, and decided it needed a university chair and proper scientific investigation.



MARK SUTHERLAND

Quackbuster? Ernst brought the discipline of the randomised clinical trial to complementary medicine

Review of 'Trick or Treatment' in Nature

Nature. 2008 Jun 12;453(7197):856-857.

Complementary cures tested

Trick or Treatment? Alternative Medicine on Trial

by Simon Singh and Edzard Ernst Random House/Norton: 2008. 352 pp. £16.99/\$25.95

The international market for alternative therapies is estimated at US\$40 billion. Because so many people use alternative medicine, it provides an excellent vehicle for discussing the nature of scientific research. Yet explaining the evaluation of evidence, balance of probabilities and risk is not easy.

Combining their communication skills and knowledge, writer Simon Singh and professor of complementary medicine Edzard Ernst set out for the lay person the scientific approach to testing alternative medical treatments. Trick or Treatment? starts by detailing the development and evolution of the double-blind, placebo-controlled, randomized controlled trial and its role in evidence-based medicine. The authors evaluate the evidence for four common alternative therapies acupuncture, homeopathy, herbal medicine and chiropractic. They discuss the pitfalls of placebo-based medicine and ask who is to be blamed for spreading misinformation about unproven treatments. The book concludes with a manifesto for better regulation of

alternative medicine and reliance on properly tested therapies.

Trick or Treatment? is thoroughly researched and clearly written. Historical descriptions sit beside detailed and lucid evaluations of the research evidence. Some stories are well known, such as how naval surgeon James Lind developed the first clinical trial to test the effectiveness of lemons for treating scurvy. Others are less familiar, such as

Florence Nightingale's aptitude for statistics and her development of a variant of the pie chart, the polar area chart, to support the case that good sanitation dramatically reduced deaths in military hospitals. The description of the Nazis' adoption of homeopathy is particularly compelling and sobering. These tales make the book entertaining as well as informative.

In the discussions of the four therapies, the authors' combined strengths shine through. The examination of the evidence is comprehensive, forensic and, for champions of these therapies, damning. For each treatment, Singh and Ernst present the available randomized controlled trials. They describe and dissect good-quality evidence and dismiss the poorquality stuff, giving their reasons why it should



Acupuncture: pain relief or placebo?

be discounted. The authors conclude that acupuncture works as a short-term analgesic and can relieve nausea but not much else; that some herbs such as Devil's Claw for musculoskeletal pain or garlic for high cholesterol are effective; chiropractic can improve back pain but less well than conventional treatments; and that homeopathy is no better than placebo. They summarize evidence for a further 30 therapies, most of which they find wanting.

Singh and Ernst base their evaluations solely on results from randomized controlled trials. Many advocates of alternative treatments argue

natural health



Review of 'Trick or Treatment' in Nature

Nature. 2008 Jun 12;453(7197):856-857.

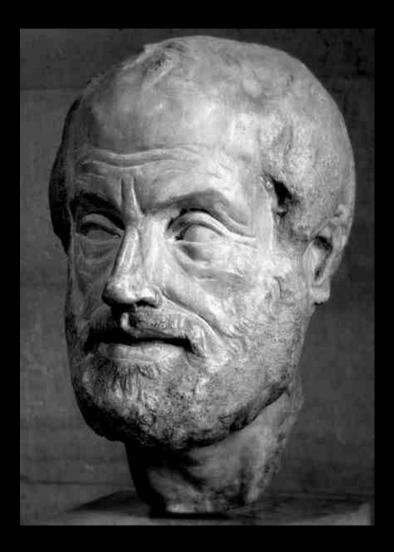
Singh and Ernst base their evaluations solely on results from randomized controlled trials. Many advocates of alternative treatments argue that these trials are unsuitable. Some of these practitioners' arguments are easily dismissed, for example, the idea that alternative treatments are beyond science. Other criticisms come from respectable commentators and are harder to ignore; for instance, the difficulties of designing trials to investigate complex treatments with multiple variables, or whether these trials use test conditions that differ from a treatment as practised. Randomized controlled trials are powerful tools, but they are imperfect and it would have strengthened the argument of *Trick or Treatment? had* the book discussed these downsides. Scientific research is intrinsically provisional; it may asymptotically approach a truth, but it is never unequivocal. Singh and Ernst, however, make repeated claims that they provide the truth, and have even included this word in the title of every chapter. The balance of evidence from randomized controlled trials supports their arguments, but the authors are not tendering a disprovable hypothesis.

SCIENCE

Unknown Known **Evolution of science** Thought Belief Knowledge Truth?

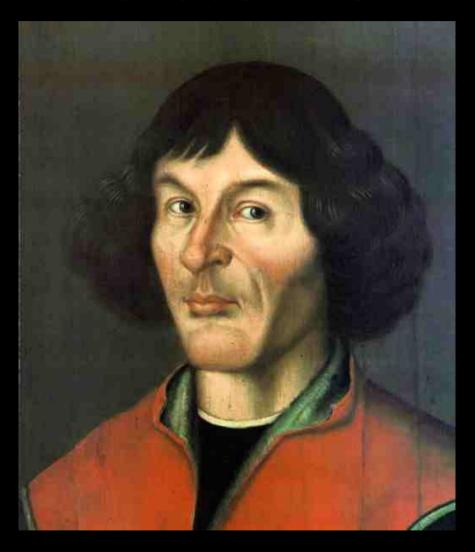
Degree of certainty

Geocentrism



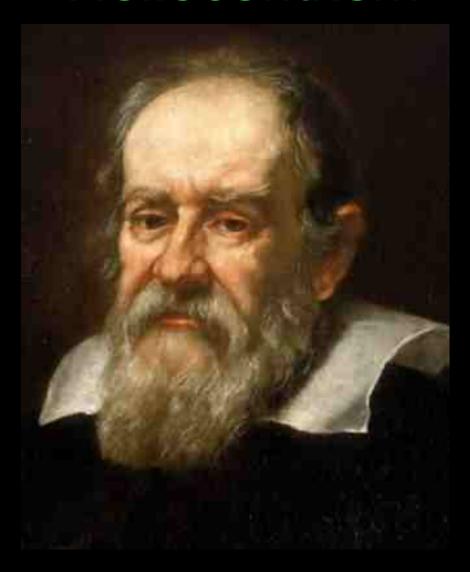
Aristotle (384 BC – 322 BC)

Heliocentrism



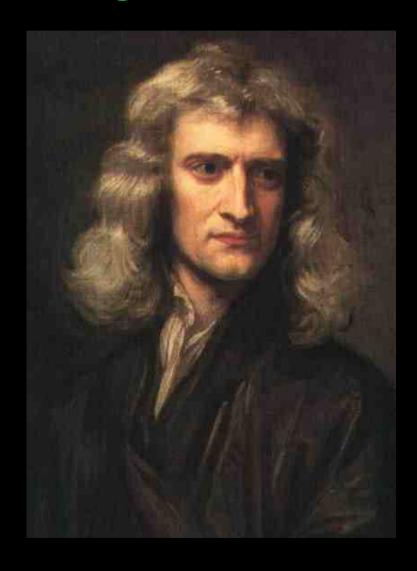
Copernicus (1473 – 1543)

Heliocentrism



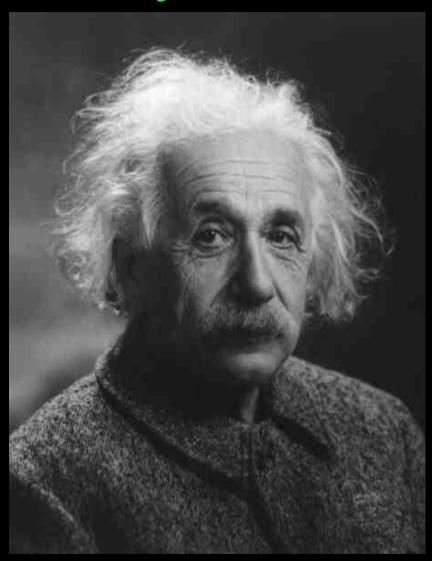
Galileo (1564 – 1642)

Heliocentrism/gravitation/mechanics



Newton (1643 – 1727)

Relativity / Universe



Einstein (1879 – 1955)

Unified theory / Multiverse



Hawking (1942 –)

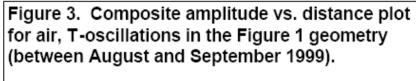
Quantum
"Nothing exists until it is measured."

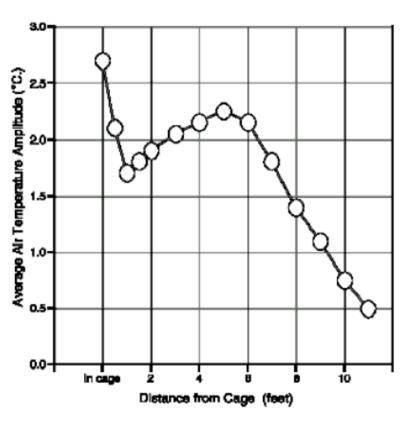


Bohr (1885 – 1962)

Subtle energy / consciousness

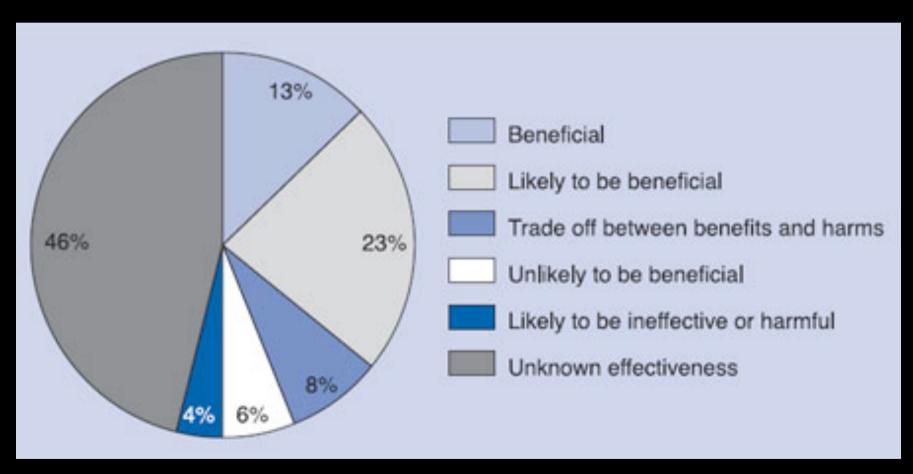








Evidence in orthodox medicine



http://clinicalevidence.bmj.com/ceweb/about/knowledge.jsp



Orthodox medicine (USA data)

Source of deaths	Mortality	Reference
latrogenic errors in hospitals	98,000	Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. JAMA. 2003 Oct 8;290(14):1868-74.
Preventable infections in hospitals	90,000	Jarvis WR. The Lowbury Lecture. The United States approach to strategies in the battle against healthcare-associated infections, 2006. J Hosp Infect. 2007 Jun;65 Suppl 2:3-9.
Medications/ ADRs, non-error	106,000	Lazarou J, Pomeranz B, Corey P. Incidence of adverse drug reactions in hospitalized patients. JAMA. 1998; 279:1200-1205.
Total	294,000	



Pathways to better health

- Mobility and exercise
- Diet and nutrition
- Hydration
- Environmental toxins
- Psychosocial stress
- Electromagnetic pollution and geopathic stress





EBM or EBM?

ebm-first.com

WHAT ALTERNATIVE HEALTH PRACTITIONERS MIGHT NOT TELL YOU

"Either it is true that a medicine works or it isn't. It cannot be false in the ordinary sense but true in some 'alternative' sense."

> Prof. Richard Dawkins, Oxford, April 2001 from the foreword to 'SNAKE OIL' by John Diamond

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www.ebm-first.com



The EBM Working Group, JAMA, 1992

The Rational Clinical Examination

Evidence-Based Medicine

A New Approach to Teaching the Practice of Medicine

Evidence-Based Medicine Working Group

A NEW paradigm for medical practice is emerging. Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. Evidence-based medicine re-

dose of phenytoin intravenously and the drug is continued orally. A computed tomographic head scan is completely normal, and an electroencephalogram shows only nonspecific findings. The patient is very concerned about his risk of seizure recurrence. How might the resident proceed?

year is between 43% and 51%, and at 3 years the risk is between 51% and 60%. After a seizure-free period of 18 months his risk of recurrence would likely be less than 20%. She conveys this information to the patient, along with a recommendation that he take his medication, see his family doctor regularly, and

Evidence-Based Medicine Working Group. Evidence-based medicine. A new approach to teaching the practice of medicine. JAMA. 1992 Nov 4;268(17):2420-5.



David Sackett MD, BMJ Editorial, 1996

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BMJ 1996;312:71-72 (13 January)

Editorials

Evidence based medicine: what it is and what it isn't

It's about integrating individual clinical expertise and the best external evidence

Evidence based medicine, whose philosophical origins extend back to mid-19th century Paris and earlier, remains a hot topic for clinicians, public health practitioners, purchasers, planners, and the public. There are now frequent workshops in how to practice and teach it (one sponsored by the BMJ will be held in London on 24 April); undergraduate¹ and postgraduate² training programmes are incorporating it³ (or pondering how to do so); British centres for evidence based practice have been established or planned in adult medicine, child health, surgery, pathology, pharmacotherapy, nursing, general practice, and dentistry; the Cochrane Collaboration and Britain's Centre for Review and Dissemination in York are providing systematic reviews of the effects of health care; new evidence based practice journals are being launched; and it has become a common topic in the lay media. But enthusiasm has been mixed with some negative reaction.^{4 5 6} Criticism has ranged from evidence based medicine being old hat to it being a dangerous innovation, perpetrated by the arrogant to serve cost cutters and suppress clinical freedom. As evidence based medicine continues to evolve and adapt, now is a useful time to refine the discussion of what it is and what it is not.

Sackett DL et al. Evidence-based medicine: what it is and what it isn't. BMJ. 1996 312: 71-72.



David Sackett MD, BMJ Editorial, 1996

Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

Evidence based medicine is not restricted to randomised trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions.

Sackett DL et al. Evidence-based medicine: what it is and what it isn't. BMJ. 1996 312: 71-72.



Boseley on Ernst [1]: Guardian, 25 Sept 2003

It is hard to imagine a member of the UK's medical elite devoting their life to complementary medicine. Ernst, however, comes from a culture where alternative therapies have long blended with the mainstream. He is from four generations of conventional doctors but, he says, "Even as a young boy I was treated with complementary therapies - mostly homeopathy."

His first post was in a homeopathic hospital in Munich, where he was greatly impressed. "If you study medicine and pharmacology, you know [homeopathy] can't work," he says. The active substances in homeopathic medicines are so diluted that pharmacology says they cannot have an effect. "Then you start working in a homeopathic hospital and people get better. Is that a miracle? It certainly is very impressive for a young doctor.

http://www.guardian.co.uk/science/2003/sep/25/scienceinterviews.health



Boseley on Ernst [2]

"Looking back, I wonder if a lot was a placebo effect." Placebo to him, however, is not a negative. He would never assume people who get better on placebos were not ill in the first place. "I would like to have an institute of placebo research, but the funding would be even worse. You would get placebo money! But it's absolutely fascinating what's happening there. It is what gels mainstream and complementary medicine together. As doctors, we don't want to realise it. We pride ourselves that therapy does the trick."

...Scientific logic says homeopathy cannot work, but Ernst continues to study its therapies not to shoot it down, but in the hope of discovering what it is that does work. He treats his French wife with homeopathy, he says. "We were both brought up with it."

But he adds: "People mistakenly think I must be a promoter of complementary medicine - that I should have an allegiance to the camp. I don't. My allegiance is firstly to the patient - I feel that very strongly as an exclinician - and secondly to science. If in the course of that I have to hurt the feelings of homeopaths I regret that, but I can't help it."



Ernst on the "evidence hierarchy"

Systematic reviews of RCTs

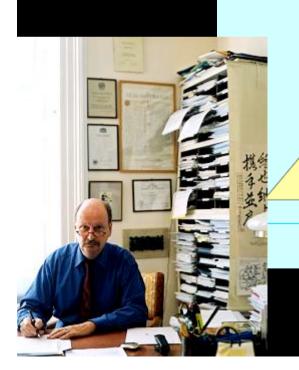
Randomised clinical trials

Controlled clinical trails

Uncontrolled data (e.g. case reports, case series, observational studies)

Ernst E. Complementary Medicine, Peninsula Medical School

PPS-02-04 Stockholm-13





Other science

Biochemistry

Pharmacology

Cell studies

An alternative view

All

Combinations

Multiple RCTs, systematic review/ pooled/meta-analysis

RCTs (where appropriate)

Uncontrolled trials

Observational / epidemiological studies

Case reports/series

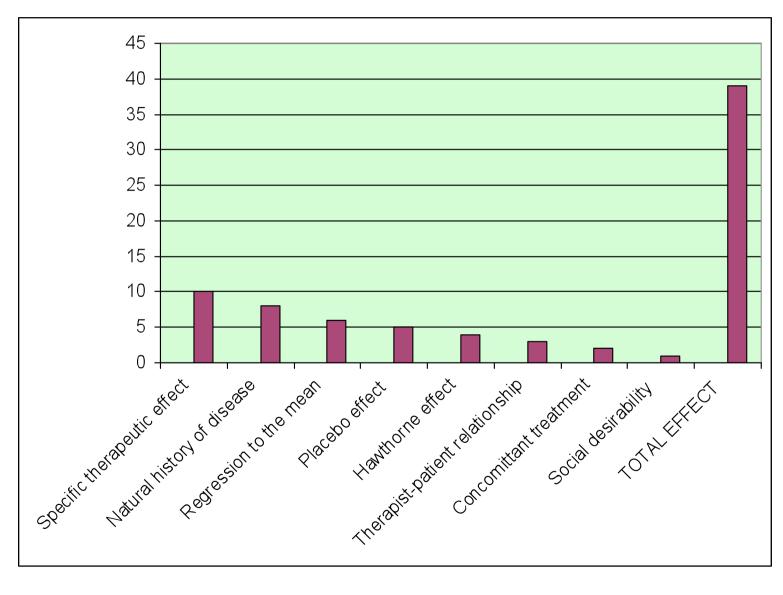
Best clinical practice by CAM practitioners

Historical evolution through traditional medicinal/healing cultures

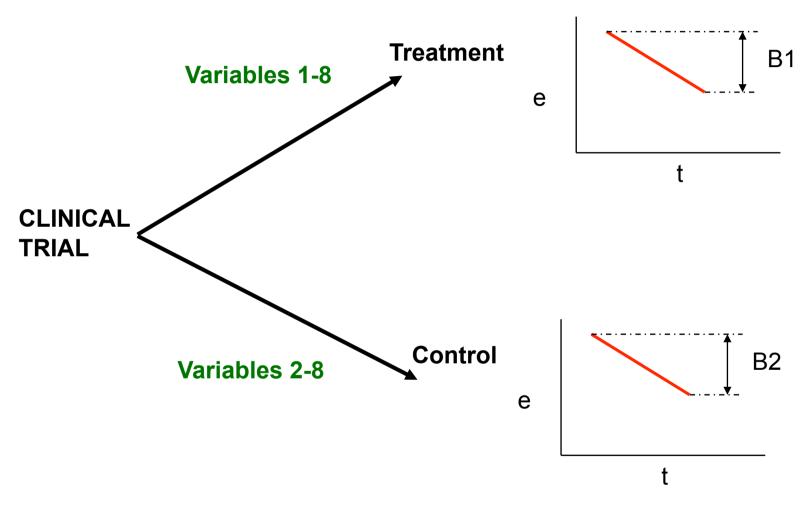
Safety

AERs Medical/gvt records

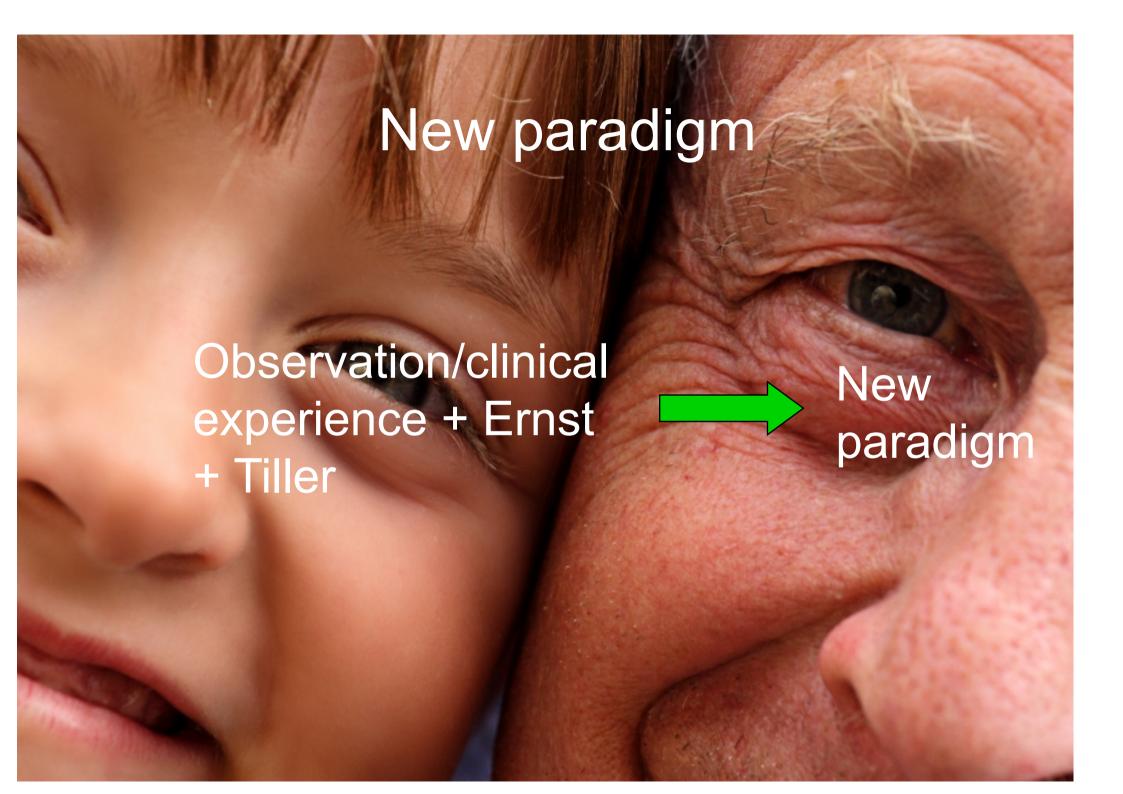
Edzard Ernst: 06/10/07



Edzard Ernst: 06/10/07



B1 - B2 = variable 1 = "specific therapeutic effect"





Bad science. media misrepresentations



They warn healthy people who take antioxidant supplements, including vitamins A and E, to try to keep diseases such as cancer at bay that they are interfering with their natural body defences and may be increasing their risk of an early death by up to 16 per cent.

Researchers at Copenhagen University carried out a review of 67 studies on 230,000 healthy people and found "no convincing evidence" that any of the antioxidants helped to prolong life expectancy. But some "increased mortality".

About 12 million Britons supplement their diets with vitamins and the industry is worth £330 million. But little research has been done on the long-term health implications.

The Department of Health said yesterday that people should try to get the vitamins they need by eating a balanced diet and advised care in taking large doses of supplements.



ng vitamins A, E, and C are said to mop up free

A spokesman said: "There is a need to exercise caution in the use of high doses of purified supplements of vitamins, including antioxidant vitamins, and minerals. Their impact on long-term health may not have been fully established and they cannot be assumed to be without risk.

advertisement

"Anyone concerned about their diet should speak to their doctor or dietitian."

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Fantasy Games



Summarising the problems with contemporary EBM model [1]

- Avoidance of experiential, clinical and observational evidence
- The individual vs the 'mean population'
- Comparing the role of the practitioner in conventional and CAM therapies
- Patient response in non-trial vs RCT situations
- Randomization and other assumptions relating to trials



Summarising the problems with contemporary EBM model [2]

- Assumptions relating to 'treatment' and 'placebo/ control' groups
- Statistical noise in RCTs
- The nature of evidence
- Inappropriate interpretation of results
- Multiple factors and the 'curse of dimensionality'





Do we need a new paradigm?

ALTERNATIVE ORTHODOX MEDICINE MEDICINE sustainability



Sustainable healthcare







Sustainable healthcare







FIND OUT MORE

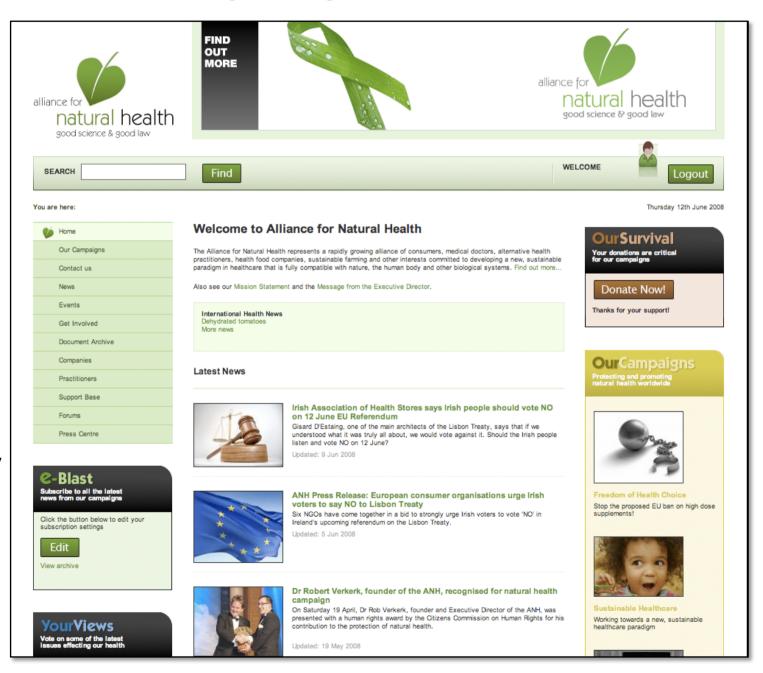


Sustainable healthcare

"A complex system of interacting approaches to the restoration, management and optimisation of human health that has an ecological base, that is environmentally, economically and socially viable indefinitely, that works harmoniously both with the human body and the non-human environment, and which does not cause any significant unfair or disproportionate effects that may hinder the functioning, development or viability of the healthcare system itself."

- Alliance for Natural Health (2007)

www.anhcampaign.org — new website



- Be informed
- Get involved
- Have your say