

**Discussing and testing efficacy: The never-ending debate about
'traditional/alternative' and 'biomedicines'¹**

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Abstract

Supporters of traditional and alternative medicine reject randomised controlled trials (RCTs) as a suitable instrument to test the efficacy of their products and deny the epistemological neutrality of biomedical research methods. Instead they plead for research designs that are in line with the logics of their own medical tradition. They claim that their approach is based on the active participation of patients as subjects while in RCTs patients are treated as inanimate interchangeable objects. Critics argue, however, that traditional/alternative medicine must prove itself in RCTs. They believe that those involved in traditional/alternative medicine are not willing to subject to RCTs out of fear that their theories and treatment modalities will not withstand scientific scrutiny. The author tries to break the deadlock in this continuing debate about efficacy testing. He argues that the RCT can be applied to any kind of medical tradition, with the advantages and drawbacks of the tool being in fact similar for biomedicine and traditional/alternative medicine. It is a relatively neutral instrument; far from perfect but the best we have so far. It produces vague data but that is more than nothing. It raises more questions than it solves, but that is also useful. What RCTs can do is produce practical knowledge regarding what medicine is most likely to work. There is therefore no reason for advocates of 'traditional' or 'alternative' medicine to refuse RCTs.

Key words : Efficacy, Biomedicine, Traditional Medicine, Alternative Medicine, Randomised Controlled Trial (RCT)

Discuter et tester l'efficacité : l'interminable débat sur les médicaments 'traditionnels / alternatifs' et 'biomédicaux'

Résumé

Les tenants de la médecine traditionnelle ou alternative rejettent le fait que les essais cliniques randomisés (ECRs) soient un outil adéquat pour tester l'efficacité de leurs produits et dénie la neutralité épistémologique des méthodes de recherche biomédicales. Leurs opposants rétorquent toutefois que les médicaments traditionnels / alternatifs doivent prouver leur efficacité à travers des ECR. L'auteur de cet article tente de dépasser ce 'dialogue de sourds' concernant les tests d'efficacité. Il argumente que les ECRs peuvent être appliqués à toute sorte de tradition médicale, sachant que les avantages et les inconvénients de cet outil sont en fait les mêmes, qu'il s'agisse de biomédecine ou de médecine "traditionnelle / alternative".

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C'est finalement un instrument relativement neutre; loin d'être parfait il est néanmoins le meilleur dont nous disposons à ce jour.

Mots clés : efficacité, biomédecine, médicaments traditionnels, médicaments alternatifs, Essais Cliniques Randomisés (ERCs).

Discutir y comprobar la eficacia: El Infinito Debate sobre 'Tradicional/Alternativa' y 'Biomedicina'

Resumen

Los defensores de la medicina tradicional y alternativa no reconocen los protocolos de ensayos clínicos (randomized controlled trials, RCTs) como instrumentos adecuados para verificar la eficacia de sus productos. Niegan la neutralidad de las metodologías de investigación biomédicas. Los críticos piensan que las medicinas tradicionales y alternativas deben evaluarse mediante ensayos clínicos (RCT's) El autor intenta abrir una puerta de entendimiento en ese callejón sin salida en relación con la verificación de la eficacia. El autor argumenta que el RCT debe aplicarse a cualquier tipo de paradigma médico, por las ventajas que supone emplear una herramienta similar para la biomedicina y las medicinas alternativas: se trata de un instrumento relativamente neutro, lejos de ser la perfección, pero el mejor que tenemos hoy.

Términos clave: eficacia, biomedicina, medicina tradicional, medicina alternativa, protocolos de ensayos clínicos (RCTs)

Introduction

Supporters of traditional medicine reject randomised controlled trials (RCTs) as an unsuitable instrument to test the efficacy of their products and deny the epistemological neutrality of biomedical research methods. Instead they plead for research designs that are in line with the medical logics of traditional medicine. They claim that their approach is based on the active participation of patients as subjects while in RCTs patients are treated as inanimate interchangeable objects. Critics argue, however, that traditional medicine must prove itself in RCTs. They believe that those involved in traditional medicine are not willing to subject to RCTs out of fear that their theories and treatment modalities will not withstand scientific scrutiny. They are of the opinion that RCTs, though far from perfect, are relatively neutral in the epistemological sense. I will critically examine this unending *dialogue des sourds* and explore how the deadlock could perhaps be ended.

Aha Erlebnis

There are such moments that – by a stroke of luck – you suddenly see or understand something that never occurred to you before. Like a vision. A sudden light that allows you – to use a popular expression of today – to look ‘outside the box.’ There is a story that tells how this happened to Luther while he was sitting on the toilet suffering from constipation: in a flash he saw what was wrong with the Roman Catholic Church and its theology and wrote his Ninety-Five Theses that launched the creation of Europe’s Protestant churches. I also had my small ‘stroke of lightness;’ not on the toilet (though I believe that a lot of great ideas are born there) but during the previous Conference on ‘The Pharmaceutical Life Cycle’ in Milano². It occurred during a presentation by Maurizio Italiano doctor-patient communication in a homeopathic setting. My thoughts wandered off, as often happens to me during lectures, and I suddenly thought: why do proponents and opponents of traditional, alternative, herbal (etc.) medicine never agree on how to test the efficacy of the medicinal products that are being used?

² This refers to the 3rd International Conference on ‘The Pharmaceutical Life Cycle.’ Milan, 21-24 September 2009.

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For generations these proponents and opponents have been involved in a – by my estimation – unproductive and boring debate. It frequently happens that students in medical anthropology at my university in Amsterdam want to write a thesis about ‘traditional medicine.’ I always try to discourage them, because of the predictable outcome of their research. The conclusion usually contains a plea for more recognition of ‘traditional medicine,’ thus joining the fruitless dialogue between believers and non-believers; fruitless because no side will ever convince (convert) the other. A frustrating result for a whole year of hard work: preaching for your own parish and yet talking ‘nonsense’ to those outside the parish. If a student insists on her topic, I suggest a shift of focus or for her to look for another supervisor. I have had enough of it.

These and other thoughts were spooking through my head while listening to Maurizio Italiano, when I suddenly saw ‘the light.’ I will try to share with you what I saw, but while preparing this presentation I started to doubt my discovery: is it really a new insight, or is it a wide open door? Is what I saw perhaps commonplace, old hat, for others who are experts in the field of efficacy testing? In that case my speech may be more like the observation of that little innocent child who called out loudly: ‘The emperor has no clothes on.’ Anthropologists want to be like such children who in their innocence see and say things that adults have learned not to see and say.

Dialogue des sourds

Basically there are two incorrect attitudes towards traditional or alternative medicine: romanticisation and dogmatic opposition. The former implies gullibility, a priori belief in its efficacy; the latter is a priori rejection because its practice is not based on natural science premises. Both attitudes are premature and uncritical, and therefore unscientific. In the meantime, the crucial question remains: is traditional medicine effective? Most ironically, the answer is: we do not know. The amazing thing about traditional medicine is that in the enormous amount of literature written on the subject one hardly finds an efficacy study that meets the strict requirements of scientific testing.

In an editorial to a special issue of JAMA (Journal of the American Medical Association) on alternative medicine, two editors wrote:

There is no alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking. Whether a therapeutic practice is “Eastern” or “Western,” is unconventional or mainstream, or involves mind-body techniques or molecular genetics is largely irrelevant except for historical purposes and cultural interest. [A]s believers in science and evidence, we must focus on fundamental issues—namely, the patient, the target disease or condition, the proposed or practiced treatment, and the need for convincing data on safety and therapeutic efficacy (Fontanarosa & Lundberg 1998: 1618).

Such statements have been made in abundance by representatives of biomedicine and have been rejected in the same abundance by representatives of alternative medicine. The latter group’s argument was and is that one cannot evaluate one tradition by the criteria of another, certainly if that other tradition is a hostile one. Such imposition of ‘alien’ measurement would be a clear case of colonisation and misguided ethnocentrism. I have always supported that viewpoint. The following text that I wrote about fifteen years ago confirms my scepticism toward biomedicine defining the yardstick for alternative medicine:

The numerous studies on the efficacy of homoeopathy have not been able to end the discussions on this topic. I have the impression that few people changed their opinion about homoeopathy after reading the results of these studies. Opinions differ about what to do with factors such as ‘spontaneous healing’, and how should we treat the therapeutic effects of psychological, social and symbolic factors? Should the placebo effect be excluded from the trial? ‘Scientific’ rules require the exclusion. A double blind trial should teach us what a particular drug or treatment does in the body, independent of a person’s psychology and his social and cultural situation. The problem, of course, is that such a body does not exist. Advocates of biomedicine may brush away that remark as irrelevant, whereas others may emphasise that such a clinical trial does not measure a thing since a purely physical body does not exist in the real world. Accepting or not accepting the outcome of scientific tests of medical efficacy, therefore, depends very much on people’s definitions of ‘health’ and ‘medical effect’. And these are very much part and parcel of their daily philosophy and political stand. For an unbeliever it is hard to accept the positive results of studies on homoeopathic efficacy... (Van der Geest 1995: 361).

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Measuring the efficacy of homeopathy by RCT felt like determining the taste of French wine by molecular research, or rejecting human free will on the basis of brain research: embarrassing scientism, naïveté in an academic cloak. It reminds me of the first Russian cosmonaut Gagarin's conclusion that God does not exist because he did not see him during his space flight.

Lip service

Rejecting biomedical calls for rigorous testing of non-biomedical medicinal products by RCT is, however, not the only reaction by the proponents of alternative medicine. There is now a growing body of literature that presents the results of RCTs of alternative medicines. My colleague Maarten Bode, who did fieldwork with Ayurvedic and Unani companies in India, describes how these companies try to modernise their traditional products by subjecting them to biomedical testing tools and publishing their (positive) results in medical journals that are financed and run by themselves.³ Thus they hope to win a respected position in the global market of pharmaceuticals. Very few of these tests, however, meet the rigorous conditions of RCTs and their reports are not taken seriously by biomedical scientists.

The special issue of JAMA to which I referred above contained a couple of articles that attempted to examine the efficacy of alternative medicines and treatment using RCTs. Their publication in a top journal of American medical science was clearly a welcoming gesture by biomedicine to alternative medicine, but I doubt that JAMA's readers were impressed. The number of participating patients in the trials was very low, rendering the statistical significance of the trials probably worthless in the eyes of most readers (Bensoussan et al. 1998; Heymsfield et al. 1998).

Reports on the efficacy of medicinal herbs in NAPRALERT (Natural Products Alert), the largest database of alternative medicines, show the same picture: hardly any research that will satisfy a biomedical scientist.

³ ... which is not so different from 'Western' medical journals.

Irony

Ironically, a growing number of critics have pointed out that RCT testing in bio-pharmacy also does not meet the scientific standards and requirements that biomedicine has set for itself. Some of these critics have presented their objections very eloquently during the previous three conferences on ‘The Pharmaceutical Life Cycle.’

One objection is very similar to what alternative practitioners argue in their rejection of biomedical testing: RCTs measure dehumanised bodies and overlook the crucial effect of medicines through the human capacity of meaning production. By doing so they miss the point of what health and recovery is for each different individual. Moreover, RCTs focus on medical substances and ignore the totality of treatment where medicines are usually not as crucial as they are within biomedical logic. The aim of Ayurveda therapy, for example, is not to bring down blood pressure or glucose value. Ayurveda practitioners are more concerned with helping their patients cope with health problems through diet and advice for living. Medicines are only supportive and differ little from food.

Interestingly, that awareness of ‘missing the point’ is also growing within clinical pharmacology, as I have been told. Some years ago I gave a presentation on ‘pharmaceutical anthropology,’ in which I discussed the Filipino concept of *hiang*. *Hiang* refers to the widespread belief that a medicine (but also other things like food, clothes, and music) should fit the person that takes it. The same medicine may work for one person and not for another, in the same way that the same music may be liked and not liked by two different people. After the lecture a pharmacologist came to me and explained that this personal fitting/not fitting was exactly what clinical pharmacologists were struggling with and trying to apply in new ways of testing; without success of course.

Another objection to RCTs is that while they may be able to record statistically significant correlations, they are unable to explain them most of the time. In nearly half of the cases the exact working of treatments (including medicines) is unknown (Smulders et al. 2010).

A third objection to RCTs is directed against their claim of objectivity. Double blind RCTs may indeed be relatively objective, but it would be extremely naïve to claim that they are one hundred percent objective. As long as human beings, with their preferences and

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interests, are involved in research, subtle subjective elements such as human fallibility, a patient's refusal to enter a trial, or the researcher's reluctance to randomise practitioners are bound to become entangled with the trials (Kaptchuk 2000: 546).

A fourth problem is a specific type of subjective interference with objectivity. The pharmaceutical industry has a strong – but little known – influence on the results that are published on the efficacy and safety of medicines in even the most renowned international journals. The industry pays for most of the research, decides how the trial will be set up, who the participants are, what will be published and what will be shelved. Delpine and Delpine (2011) write: 'Statisticians analysing the trial know they must not seek scientific truth, but demonstrate the effectiveness of the product, in order to retain their customers.' It has also been reported how the industry subtly manipulates the content of the articles, for example by offering to write the text which will then be published under the name of the pharmacology professor. Healy (2006: 73) estimates that up to seventy-five percent of CMD⁴ articles 'on randomized controlled trials on therapeutic agents appearing in major journals may now be ghostwritten.'

Back to the Aha Erlebnis

My Aha Erlebnis during Maurizio Italiano's presentation had to do with this sudden insight that RCT testing is equally defective for alternative medicine and biomedicine, or equally good for both. The RCT is not a bio-scientific instrument that is imposed on traditional/alternative medicine. Rather, it is a commonsense though imperfect test, a somewhat limited attempt to detect likely effects. There is little science theory in RCTs; they are not carried out on the basis of theoretical reasoning but at a venture, on spec. It is a hit-and-miss method steered by practical thinking. The only theory in it is statistics, another word for probability calculation. Of course, biomedical scientists interpret the outcomes of RCTs differently than alternative practitioners, *but in the test itself is no biomedical theory that could exclude or overrule alternative medical logic*. So, why can we only apply statistics to the effects of biomedicines and not to the effects of alternative medicines? The problems, just sketched, of overlooking the individual uniqueness of people, the wider context, psychological, emotional and symbolic aspects, etc., count for both biomedicine and for

⁴ The Current Medical Direction (CMD) is a medical information company that 'delivers scientifically accurate information strategically developed for specific target audiences' (Healy 2006: 73).

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alternative medicine. Should we stop doing something because it is not perfect? Should we stop playing football because some players break a leg and some referees are corrupt?

RCT testing of medicinal herbs is not an imposition of one worldview on another. The RCT is a relatively neutral instrument with limited capacities for any kind of medical tradition. It is far from perfect but it is the best we have so far; it produces vague data but that is more than nothing; it raises more questions than it solves, but that is also useful. It is simply statistics or epidemiology – calculation of what is likely to happen – and only produces practical knowledge: what medicine is most likely to work. By ignoring the individuality of participants, it produces statistical data on a total of many individuals and does give a rough estimate of the likely effects on the ‘average’ patient, in biomedicine as well as in alternative medicine. There is therefore no reason for advocates of alternative medicine to refuse RCTs. The RCT is indeed just a commonsense thing to do. So, why are RCTs hardly applied in alternative and traditional medicine and even anathema for many of its proponents?

Why?

In a recent appraisal of review articles published in the *Journal of Alternative and Complementary Medicine (JCAM)* – a magazine established in the 1990s with the objective of providing traditional medicine with a research base – Xue et al. (2010, p.310) conclude that there is ‘... an overall lack of evidence of efficacy and research support’ of the therapeutic potential of traditional/complementary medicine (TCM) interventions. This conclusion is revealing because it was published in the *JCAM* and says something about the research base of TCM. This conclusion is supported by other review articles such as a contribution by Liu et al. (2005), who found no compelling evidence to support the use of herbal medicines in the treatment of HIV/AIDS, and a review article by Fritts et al. (2008), who conclude that there is a huge gap between the widespread use of Indian medical traditions by people with HIV/AIDS and evidence on their effectiveness. I repeat my question: why are proper RCTs hardly applied in alternative and traditional medicine?

One reason for this reluctance is that research on various forms of traditional/alternative medicine by scientists belonging to academic disciplines such as biochemistry, pharmacology, phytocognosy, ethnopharmacology, and immunology has in some instances led to the cooptation of some of alternative/traditional medicine’s knowledge

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as leads for designing modern pharmaceuticals. Traditional/alternative medicines have been integrated into the logic of positivist immunology and biomedical nosology and aetiology, while their own nosologies, aetiologies, and epistemologies are totally ignored. Understandably, practitioners of traditional/alternative medicine try to prevent this from happening. This state of affairs has been acknowledged by medical anthropologists and academic researchers (Leslie 1992; Bode 2008; Shankar et al. 2009; Singh 2010; Patwardhan 2010).

Let us look once again at the statement by the editors of JAMA that I quoted earlier, but with the three references to ‘science’ removed, and a few italics added:

There is no alternative medicine. There is only ... *proven*, evidence-based *medicine* supported by solid data or *unproven medicine*, for which ... evidence is lacking. Whether a therapeutic practice is “Eastern” or “Western,” is unconventional or mainstream, or involves mind-body techniques or molecular genetics is largely irrelevant except for historical purposes and cultural interest... [A]s believers in ... evidence, we must focus on fundamental issues—namely, the patient, the target disease or condition, the proposed or practiced treatment, and the need for convincing data on safety and therapeutic efficacy.

When this somewhat arrogant term ‘science’ is left out of the statement, the JAMA editors’ remark about proven and unproven medicine sounds reasonable and respectful. The effect would be stronger still if we did not know who the quote was from. Resistance to this type of statement probably has more to do with the identity of the speaker than with the message itself. McLuhan’s catchphrase from the 1960s, ‘The medium is the message,’ has not lost its topicality. Whatever the ‘enemy’ says is suspect. When someone from their own ranks says it, it will not sound like a hostile takeover, an act of colonisation. But who will say such a thing? Or could a relative outsider propose this, for example an ‘innocent’ anthropologist?

But there may be more reasons for resisting RCT testing. The most popular, of course, commonly launched by the biomedical lobby, is that alternative practitioners fear being ‘found out’ as less effective. However denigrating or offensive this explanation may sound, we cannot exclude it.

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The final explanation for why RCT testing of alternative medicines has hardly been conducted is a stubborn one: *money*. ‘You cannot ask a poor man to build a house.’ Proper RCTs are extremely costly and can only be financed by rich industries, which – by definition – are not interested in funding products that they will not sell. Even if we were to succeed in convincing alternative practitioners to have their products tested by RCTs and thus take their place in health care (and health insurance), they will be unlikely to do so due to lack of funding. I wonder if governments and academic research institutes could play a role, once the present economic crisis is over.

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