



Countering misleading information

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Summary Orthodox medicine generally demands evidence in the form of randomised controlled trials (RCTs) before accepting the value of a particular therapy/intervention from the CAM field. Yet many RCTs are badly executed as they are carried out by doctors or scientists rather than holistic practitioners, and peer reviewers for conventional medical journals may not have sufficient knowledge to be able to assess a CAM paper properly. This article discusses inadequacies found in RCTs and other papers related to CAM, and pinpoints how research should be critically evaluated and reviewed. Examples are taken from the fields of aromatherapy, herbalism, acupuncture/TCM and homeopathy. The aim of this paper is to highlight common misunderstandings and misguided assumptions that may arise when undertaking research in the field of complementary medicine that may result in erroneous conclusions being drawn from data and which may have far reaching implications for clinical practice. The STRICTA recommendations for acupuncture are discussed.

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Introduction

Have you ever been in a situation in which you want to offer a complementary therapy of some kind/for a specific reason but are told by medical staff "That herb is dangerous" or "There is no evidence to show that that treatment works" when you know that it does? Sometimes the reason may be that the staff concerned are prejudiced against offering a specific treatment (for instance, the obstetricians on the maternity wards at the Reykjavik hospital are convinced that water births are dangerous so do not offer them, even though they are offered in nearby hospitals) or because they have insufficient or misleading information. This article focuses on the latter.

One of the main problems is the nature of trials that are done. As Carter¹ and others have pointed out, sceptics today want to see the results of clinical trials in the form of double blind, single parameter randomised controlled trials. But these are difficult to do, not to mention expensive, and thus largely beyond the reach of practising com-

plementary therapists who know what they are doing. Instead, trials are carried out by scientists and/or doctors who, it seems, often do not have enough background knowledge of the therapy in question to be able to design a trial that is appropriate to how the therapy is used. Also, even though a paper appears in a peer-reviewed journal, it is quite likely that one of the peer reviewers may not have enough training in complementary therapies to comment in-depth on the quality of a paper. This is particularly likely to be the case with orthodox medical journals, which are also the ones most likely to be read by medics and decision-makers. As a result, papers are published in which not only is the trial irrelevant to the therapist, who knows better, but the information is also misleading to staff of medicine regulatory agencies, who may not possess enough knowledge to realise that a trial is irrelevant to how a therapy is practised and who might dismiss the practise/medicinal agent as a result. This could even mean that a medicinal agent is banned, as are the herbs Golden Seal and Devil's Claw in Iceland. If you are faced with a "no" from your superior over use of a particular therapy/remedy, it is important to be able to show how the

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background research is flawed or has no relevance to your proposed use of the remedy/therapy.

It has been said that 60% of orthodox treatments have not been scientifically proven, and yet such medical interventions are not viewed in the same light as complementary therapies. There are numerous instances of case studies, wrongly performed, that show that a particular remedy/treatment is to be used with caution or is not to be recommended, but this is not the case with orthodox treatments, especially medications, which may have many undesirable side-effects that are dismissed as an unavoidable part of the treatment.

Aromatherapy

The aromatherapy field is rife with papers of spurious validity. Critics will often point to the lack of controls in aromatherapy trials, but that is really a minor problem (although one that aromatherapists are well aware of). More importantly, often the Latin names of the oils are not specified, which can lead to confusion if, for instance, the oil is just called "Orange" oil, when this could be from either Bitter Orange or Sweet Orange. The same applies to place of origin, which can also make a difference—aromatherapists know, for instance, that Bulgarian lavender differs from French lavender. Good papers will always include full botanical information plus full analytical data relating to constituents of the oil(s) used.

A paper that is a good example of the above concerns a trial of aromatherapy on anxiety before an operation. The author is to be commended for carrying out a double blind, randomised control trial but unfortunately the rest of the paper leaves much to be desired. First, the oils used were vetiver, geranium and bergamot, but no botanical information was given such as the place of origin or scientific name. Vetiver varies considerably in odour profile and chemical constituents depending on country of origin, while geranium does so to a lesser extent. Secondly, there is no mention of the amount of carrier oil in which the oils were diluted, so we have no idea whether the concentration represented 1%, 2%, 5%, 10% or more. The choice of carrier oil—soya oil—was also surprising, as it is not commonly used in aromatherapy. And finally, it is debatable whether the method of application, which involved sniffing the diluted oil for 10 min, could be counted as aromatherapy. All in all, this is a paper of zero value to aromatherapists—but the editorial in the journal heralded the paper as a new dawn to controlled research in complementary therapies.

Another paper involving methodology atypical of the way aromatherapy is practised concerns essential oils and epileptic seizures. This compared three cases of essential oil use in which neither the type of use, duration of use, frequency of use or oils used were the same. One case involved bathing a baby using essential oils that no aromatherapist would ever recommend for use with a child, another involved giving 12 drops of oil to someone, and the third case involved a woman taking a mouthful of oil weekly for several years. These are extreme cases, yet the paper does not acknowledge this and instead concludes that a worsening of seizures or onset of seizures could be linked to recent use of essential oils. And again, a sample of three is hardly likely to be considered a viable number from which conclusions can be drawn.

Herbalism

Sometimes recommendations are made over isolated instances. For instance, in one paper a group of medics advised against the use of the herb *Vitex agnus castus* as an ovarian stimulant as it could lead to increased risks of multiple pregnancy and ovarian hyperstimulation syndrome. This deduction was made on the basis of one woman who took the herb—it does not say how often or for how long, though from the description in the paper it would have been for less than a month. However, *Vitex* is generally classified as safe in herbal form, and the German Commission E has approved it for irregularities of the menstrual cycle, premenstrual complaints and mastodynia.² There are many similar instances. A fatal case of liver damage to a newborn infant was attributed to coltsfoot in a herbal tea drunk by the mother and attributed to unsaturated pyrrolizidine components, which are known to be hepatotoxic, and so coltsfoot has been treated with caution. But it was later pointed out that the toxicity was more likely due to the presence of another herb in the tea which contains a much higher level of unsaturated pyrrolizidines than does coltsfoot.²

Some of the research on effects of St John's Wort on depression could also be criticised, as some studies used extracts of the herb that were standardised for hypericin content while it is now thought that hyperforin is an important constituent responsible for the anti-depressant effects of the herb. Different preparations of the herb may well give different results. Some researchers have also suggested that St John's Wort potentiates the

action of MAOI drugs, but this does not happen in vivo so is no longer thought to be a problem.²

Another example concerns the anxiolytic herb Kava, which has been withdrawn in some countries due to cases of severe liver toxicity. One recent publication questions this decision, on the basis that causality is difficult to establish.³ Ernst quite rightly points out that we need to understand whether liver damage by Kava is accidental or not, if it is predictable and how often it occurs. The known benefits of Kava should be assessed and the risks–benefits compared to those of other anxiolytic drugs. It could well be that Kava comes out more favourably in terms of risks–benefits than do conventional anxiolytics.

Acupuncture and traditional Chinese medicine (TCM)

More research has probably been carried out in acupuncture than in any other field of complementary medicine. There are ongoing debates about the value of doing standardised rather than individually based treatments, pitfalls of control treatments that are used, what should be standard practice in a trial, etc. A standard for reporting interventions in clinical trials, known as the STRICTA recommendations, has also been developed by acupuncture practitioners and journal editors, and has become part of the instructions for authors in *Complementary Therapies in Medicine*, *Journal for Alternative and Complementary Medicine*, *Acupuncture in Medicine*, *Clinical Acupuncture and Oriental Medicine*, and *Medical Acupuncture*.⁴ All to the good, and something that should be read and put into practice by editors of conventional medical journals that sometimes publish CAM papers.

Sometimes there are differences between the attitudes of researchers, even when they are sympathetic to the therapy, and practitioners. One researcher investigated a proposed clinical trial on immune responses, using Qi Gong and former cancer patients.⁵ This study is an example of how the beliefs of researchers and practitioners are at odds, as, for instance, the practitioner thought that benefits would only appear after a year of the practice while the treatment was only designed for 14 weeks. The practitioner was also interested in using an outcome measurement relating to movement, known as goniometry, which is well-known to physiotherapists and rehabilitation therapists but unknown to immunologists, but it was only after producing documented results in goniometry to the researchers that they believed him and took the

issue into account. Finally, there were philosophical differences between how the practitioner and researchers viewed Qi Gong as an intervention. The practitioner viewed Qi Gong as “mind-in-body” whereas the principal researcher viewed it as “mind and body”. The trial was modified to allow for some of the concerns of the practitioner, but it is likely that TCM practitioners would still find the results of such a trial unsatisfactory.

The above example highlights differences between Eastern and Western viewpoints. There is also likely to be a clash in interpretation of trial results between those trained in classical, oriental acupuncture and TCM and those who have learned the Western style of acupuncture. Proper research should account for multiple diagnoses and symptom patterns when testing if the research is to be useful to practitioners.

Homeopathy

Concerns have been levied at homeopathy that trials are flawed as they do not have proper protocols or the remedies given are not all identical. Others have said that it is easy to produce controls in homeopathy trials⁶ and a growing number of clinical trials are now being done in homeopathy. There is a catch 22 situation here, though, as, like acupuncture, homeopathy is a very individual therapy—or at least it should be. A remedy that works for one person may not work for another, as the prescription of a remedy depends on a whole range of factors. However, in what can be seen as a parallel to Western acupuncture, a field known as “clinical homeopathy” uses the same remedy or combination of remedies for patients who have the same group of symptoms, and constitutional factors play no part in the diagnosis. In reality, RCTs in homeopathy are undertaken using clinical homeopathy, although this is not always stated and one is led to believe from the conclusions that the results apply to homeopathy as a whole, when this may well not be the case.

One recent double blind, randomised clinical trial in a prominent medical journal looked at the use of Arnica to reduce swelling, bruising and pain in patients undergoing hand surgery. Patients were given three tablets of Arnica daily for three weeks, one week before the operation and 2 weeks afterwards. The study concluded that Arnica had no effect in either of the strengths used. But the study had serious methodological flaws. The Research Council on Complementary Medicine (RCCM) published a press release⁷ that criticised this trial, in which they stated that the authors did not use

(classical) homeopathic principles for all subjects not receiving the placebo, i.e. a different remedy would have suited some patients better, and that pain medications were prescribed at the same time without their effect on the results being taken into account.

Another case concerns a review article on the use of *Caulophyllum* to induce labour or to aid cervical ripening.⁸ Only one RCT was found, and so it was the only trial reviewed. The review paper notes that there were serious methodological issues with the survey, meaningful outcome measures such as cervical changes were not recorded, and the use of classical homeopathic prescribing rather than the simplified clinical homeopathic prescribing may well have indicated that a different remedy would have been more appropriate to use than *Caulophyllum*. For instance, the picture for *Caulophyllum* includes a history of period pains and a general lack of muscular tone as well as a rigid cervix that will not dilate,⁹ but these factors were not taken into account in the study.

Possible solutions

So what can be done? There are a number of possible solutions.

- (1) Read and research as much as possible around your chosen therapy/treatment so you can be prepared for the reaction of sceptical medics, guess what they have read/heard and prepare yourself for possible questions/statements from them.
- (2) White and Ernst¹⁰ put forward arguments for carrying out well-designed uncontrolled clinical trials as a step to double blind RCTs. Amongst other things, they say it is easier to obtain funding for a clinical trial if promising results already exist, and the trials assemble an evidence base for the modality/treatment. If a flawed RCT and a number of well-designed but uncontrolled trials exist for a particular treatment, it may be possible to explain to sceptics the shortcomings of the RCT in light of more valuable evidence from uncontrolled trials. Of course, if RCTs exist that are properly designed and adequately written up, and which support the view that you want to put forward, it is obviously better to refer to these. But if
- good RCTs exist, you are less likely to be in the situation that this article deals with, as the evidence is more likely to be believed.
- (3) Check to see whether the paper describing a treatment/modality focuses only on one or two instances. It is not possible to draw conclusions based on isolated cases, though this happens all too often with CAM therapies. If this was done on a routine basis with allopathic drugs, very few would be allowed.
- (4) Especially in the case of acupuncture, refer sceptics to the STRICTA recommendations and ask them whether they feel the study was carried out according to these. If they ask, tell them that STRICTA is a modified form of the CONSORT recommendations for RCT trials in conventional medicine.¹¹ For therapists practising other modalities, consider devising a parallel set of recommendations to STRICTA.

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