



## REVIEW PAPER

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# Clinical trials in complementary and alternative medicine – the myth of limitations

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### ABSTRACT

The paper aims to dispute common arguments put forward by practitioners of complementary and alternative medicine (CAM) in discussions against conducting clinical trials in CAM treatment protocols. It is argued that CAM therapies cannot be evaluated by the same criteria as those applied in conventional medicine due to specificity of CAM. This paper suggests that this line of thought undermines not only the validity of CAM therapies, but, importantly, is delaying understanding their therapeutical value. We also argue that despite apparent differences in approach both conventional medicine and CAM aim to improve human well being therefore CAM should be validated with well established and widely accepted process of balancing of risks and benefits of individual therapies as in conventional medicine clinical trials.

**Keywords:** clinical trial, CAM, prognosis, decision making.

## Introduction

Introducing the evidence-based medicine (EBM) into medical practice has changed significantly our understanding of benefits of medical therapies. The EBM principles define rules how to design good clinical study in order to evaluate efficacy and adverse effects of treatment so that the conclusions can be trusted and applied in clinical practice. Despite of long history of modern medical sciences, since Renaissance, it is only recently that the principle of rigorous evaluation of clinical practices has been established in conventional medicine via clinical trial. It seemed natural that the same process, possibly delayed would occur in CAM therapies. Nevertheless, introducing the EBM principles into CAM is not entirely a smooth transition. One of obstacles is that numerous CAM providers believe that evidence-based concepts are not valid for of CAM [1]. Conducting clinical trials, and randomized control trials in particular, is certainly the major issue under dispute between the proponents and opponents of the evidence-based complementary and alternative

medicine (EBCAM). In this dispute, it is the individual practitioners of CAM who very often turn out to be the strongest opponents of EBCAM. When putting forward their argument, they point to certain limitations, according to which, it is impossible to plan and carry out clinical trials in CAM. There are two major arguments presented. One is that CAM therapies concern ailments that are not treated by conventional medicine and that, therefore, we do not have any precise criteria for including patients in clinical trials. Establishing such a criterion is, on the other hand, a prerequisite for carrying out an appropriate trial. The other argument is that the majority of CAM therapies cannot be standardized, because they seek to meet the individual needs of patients. Both of these arguments will be referred to as *the arguments from the specificity of CAM*. The present paper argues that these arguments not only question the validity of CAM therapy, but, first and foremost, delay the process of establishing scientific knowledge within the scope of this discipline.

## Discussion

Let us discuss the first argument that in CAM we do not have precise admission criteria. It is true that CAM has some limitation of scope as compared to conventional medicine. Conventional medicine relies heavily on understanding causative relationship and therefore employs many tests. Therefore admission criteria are formulated in such a way as to be useful for the study. Good illustration would be evaluation of the prognostic value of certain size of lung nodule as detected by chest CT. Thus, it seems obvious that conventional medicine manifests its efficacy not only via the therapies employed, but also includes the possibility of predicting the future conditions of the body on the basis of previously gathered data. The argument that points to the difficulties in including patients in clinical trials in CAM, has two negative implications that are of crucial importance for the development of CAM. Firstly, it leads to the conclusion that we are completely incapable of diagnosing the patients that CAM therapies should be employed to. Secondly and most importantly, it rules out the possibility of making any prognoses.

The tenet guiding modern medicine is first to understand the causal mechanisms that are responsible for the occurrence of various bodily processes (physiology), then to understand what goes wrong (pathophysiology) so that we can make prognoses, intelligently design and validate treatments [2]. Until the development of EBM, the knowledge of the causal mechanisms was assumed to be a prerequisite for any prognosis [3]. Now, we know that data obtained from clinical trials are of greater value than results predicted from preclinical tests. As it is paramount that for given therapeutical approach the evaluation of benefits over risks is much more important than understanding of mechanisms then there are no limitation of CAM to be tested the same way as conventional medicine.

The other argument, so often advocated by individual CAM practitioners, is even more dubious. It says that no standardization of therapeutic techniques in CAM is possible due to the necessity to adjust these techniques to the individual needs of patients. First and foremost, it has to be noted that, contrary to the widespread opinion, the problem is encountered not only in CAM but also in conventional medicine. When treating a single patient we need to appreciate if he/she 'falls within' the group for which the clinical trial has been conducted. Generally, it can be said that the problem of standardization of therapeutic techniques is related to modeling therapeutic interventions. Mod-

els of therapeutic interventions are group of algorithms which specify what actions need to be taken with regard to people who fall within the group that has been chosen on the basis of the diagnosis. The same process occurs both in conventional medicine and in CAM. In conventional medicine, models of therapeutic interventions can be made using theories of a basic science (biochemistry, pharmacology etc.). In this case, the model of therapeutic intervention, which is based on scientific argument, specifies how the therapy works and what result can be expected. The very same theories specify the contraindications for its use with regard to both the patient's general condition and other pharmaceutical agents that the patient is taking. Thus, the therapist's knowledge allows them to determine how a given group of patients should be treated. The problem is that we cannot use one universal model to all patients within a given group. Various factors of social, economic, and medical nature need to be taken into account when choosing a particular therapeutic model. The effects of the therapy are as important as the patient's expectations and preferences: the quality of life and medical costs in particular [4].

Models of therapeutic interventions can also be established using clinical trials. In this case, they are far more reliable, since previous experience shows that scientific theories do not fail to predict all the effects of the therapy employed. Suffice it to remind the results of the CAST trial, which revealed the harmfulness of certain antiarrhythmic agents (encainide and flecainide) administered to MI (myocardial ischemia) patients. Moreover clinical trials make it possible to correlate the information about short- and long-term effects of treatment with knowledge about the patient's preferences. That is precisely why the information obtained from clinical trials makes it possible to adjust clinical treatment to the patient's expectations in the most desirable way [5].

In CAM, models of therapeutic interventions are based on various sources, ranging from oral folk traditions and common religious beliefs to the 'theories' of alternative medical systems (e.g. Chinese medical system). It is desired in both conventional medicine as well as in CAM that models of therapeutic interventions should be characterized by the greatest accuracy possible, i.e. they should, in the most precise way, assign particular therapeutic actions to given groups of people, taking into consideration the individual preferences of the patients. Thus, maintaining that 'CAM techniques are not subject to standardizations' is tantamount to not specifying what actions need to be

taken with respect to a group of people diagnosed in a particular way, or, more specifically, those who have been classified to particular groups in accordance with their ailments, age, sex, life style and patients expectations. It is therefore surprising, that such a statement raises serious objections by CAM practitioners. It can be explained by the fact, that majority of CAM therapists make models of therapeutic interventions quite arbitrarily. However, one should expect that the choice of the therapeutic model would be entirely rational. The rationality of the choice presupposes that the therapists who have particular knowledge about the patient's expectations and the available methods of treatment make the same conclusions that result in the choice of similar models of therapeutic interventions [6].

A confounding issue in CAM is that there is a large number of equally justified therapeutic actions. The problem also is that without conducting any clinical trials in CAM, we have no instrument for eliminating false therapeutic models that forestall the implementation of therapeutic goals. Yet, the possibility of falsification is an essential criterion for distinguishing a science from non-scientific beliefs [7].

A therapy evaluation requires – as Lundberg and Fontanarosa have observed – answering a few important questions [8]. The question whether or not a given therapy is effective seems to be of secondary importance. First of all, it has to be established: (i) *what does the therapy consist in?* and (ii) *when should it be employed?* The inability to answer these questions means that the actions undertaken cannot at all be regarded as therapeutic. The problem is that *the arguments from the specificity of CAM*, which individual practitioners put forward so often, challenge the validity of raising these questions. Consequently, the arguments delay the process of establishing standards of treatment, which would make unification of therapeutic procedures in CAM possible. Establishing standards of treatment, that would answer the questions (i) and (ii) appears, at the moment, to be the most important factor determining the future development of CAM, as it is the starting point for the process of establishing scientific knowledge in complementary and alternative medicine.

## Conclusions

It appears that the appeal to *the arguments from the specificity of CAM*, which is so common among individual practitioners, poses, in fact, a threat to the status of this discipline. These arguments create a myth

of limitations for clinical trials in CAM. In fact these limitations are not a consequence of the specificity of CAM, but they are rather temporal in nature, as they are due to the problem that this discipline is evolving rapidly and its relations to conventional medicine are in flux. Whether it becomes 'magic' or a reliable scientific discipline is being determined now in the process of establishing the standards of scientific accuracy. As it is now, putting forward the *arguments from the specificity of CAM* is dangerous, since it disqualifies complementary and alternative medicine to be taken seriously and jeopardizes a chance to take potentially important place in broadly understood medicine.

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