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Complementary Therapies – Considerations Before Recommend, Tolerate or Proscribe Them

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<http://dx.doi.org/10.5772/50446>

1. Introduction

According to the World Health Organization, "health is a state of complete physical, mental and social wellbeing, not merely the absence of disease or infirmity." This definition was adopted at the founding of this organization in 1948 and has not been modified since then [1]. By this definition, clinical and conventional surgical treatment, in their strict sense, would not encompass everything the patient needs to balance your health. When applied alone, conventional health treatment may bring limited results, adverse effects from the interventions, and the high inherent cost. Many symptoms are multi-factorial and the role of the psyche is crucial. In such cases, many complementary interventions have great potential to alleviate these symptoms.

In recent years, many patients have shown dissatisfaction with conventional medicine due to its more technical approach, the morbidity by side effects of the treatment, and absence of cure for some diseases. In this scenario, complementary therapies have become an attractive option for many patients. The growing interest of patients by complementary therapies is due to [2]: evidences linking many diseases to some lifestyle; patients focusing more their welfare; and their desire to consume fewer drugs. At the same time, physicians and health services are progressively having more positive attitudes about to complementary therapies. The CT aim to optimize physical symptoms, quality of life and emotional aspects, and to prevent or delay the onset of some diseases. There are many advantages resulting from the use of CT: it emphasizes the well-being and global healing (not just symptoms or diseases), encourages the patient to actively participate in their healing process, and supports the concept that treatment is possible even when the cure is not.

An estimated 30 to 62 percent of adults in the United States use CT [3]. A lack of consensus on the definition of CT has led to inconsistencies among the reports of various surveys on CT prevalence and patterns of use. Educated individuals tend to use CT more than poorly

educated individuals [3]. This goes against the idea that using CT is a non informed choice resulted from ignorance. This chapter will discuss controversies related to complementary therapies and the ways to increase their integration to the present biomedical model. The following topics will be addressed:

- Concepts
- Elements that may limitate the use of ct
- A special word on the placebo effect
- A special word on herbal treatment
- Roles of the involved personages
- Integrating conventional and complementary healthcare
- A framework for rational decision
- Conclusions

2. Concepts

In this field, the most used term is Complementary and Alternative Medicine (CAM). We instead prefer the term Complementary Therapies (CT), not only because it is simpler, but also because the adjectives “complementary” and “alternative” should not be used together in one expression. “Complementary” therapies are used together with conventional medicine, unlike “alternative” therapies, which are used in place of conventional medicine. In addition, the “medicine” from CAM is compromising, suggesting a parallel model. However, in practice, CT and CAM are used almost as synonyms, without harm for the overall comprehension.

These terms refer to a broad range of healing philosophies (schools of thought), approaches and therapies that mainstream Western (conventional) medicine does not commonly use, accept, study, understand, or make available [3]. CT are therapeutic products or practices which are not currently part of the conventional curative approach, but whose safety and efficacy have been scientifically studied. CT compose a group of diverse health care systems, practices, and products [4]. Many CT are also called holistic, because generally they consider the whole person, including physical, mental, emotional and spiritual aspects.

There are many definitions of CT, none of them perfect. The National Center for Complementary and Alternative Medicine (NCCAM, a department from National Institutes of Health, from USA) defines them simply as a group of diverse medical and health care interventions, practices, products, or disciplines that are not generally considered part of conventional medicine [5]. Broadly, CT are practices and ideas that are outside the domain of conventional medicine in several countries and defined by its users as preventing or treating illness, or promoting health and well-being. These practices complement mainstream medicine by satisfying a demand not met by conventional practices and diversifying the conceptual framework of medicine [6].

Defining CT is difficult, because the field is very broad and constantly changing. There is much debate over accurately defining CT and as more therapies and practices appear (or re-

emerge) in popular culture, and as more gain scientific merit and become conventional treatments, definitions continue to evolve [7]. The list of what's considered CT changes continually and therapies whose safety and effectiveness are demonstrated will become part of conventional medicine. For instance, several orthodox pharmaceuticals including anti-inflammatories and diuretics have been found from traditional herbal medicines.

3. Elements that may limitate the use of CT

Efficacy: Three concepts related to testing healthcare interventions must be differentiated [8]:

- Efficacy is the extent to which an intervention does good in ideal circumstances. The question is: "Can it work?" The answer is given by explanatory trials
- Effectiveness refers to whether an intervention does good under usual healthcare practice. The question is: "Does it work in practice?" The answer is given by management trials
- Efficiency refers to the effect of an intervention in relation to the resources it consumes. The question is: "Is it worth it?" The answer is given by cost benefit trials

Studies in complementary therapies follow a different dynamic from that of studies with drugs. Figure 1 (adapted from Kienle [9]) illustrates this reality. Some characteristics of CT treatments and modalities make it difficult to apply the traditional RCTs or treatment effectiveness studies used in conventional medicine. Some study designs that might be used to address some of these characteristics including [3]: N-of-1 trials, preference RCTs, observational and cohort studies, case control studies, studies of bundles or combinations of therapies, attribute-treatment interaction analyses, and qualitative research. It is difficult or impossible to conduct double-blind trials with some modalities. The concept of blinding in which the patients and the treating clinicians participating in clinical trials do not know what treatment the patient is receiving is an important way to minimize expectation effects and biases on the part of both the patient and the clinician. For most CT modalities, however, blinding is very difficult or impossible.

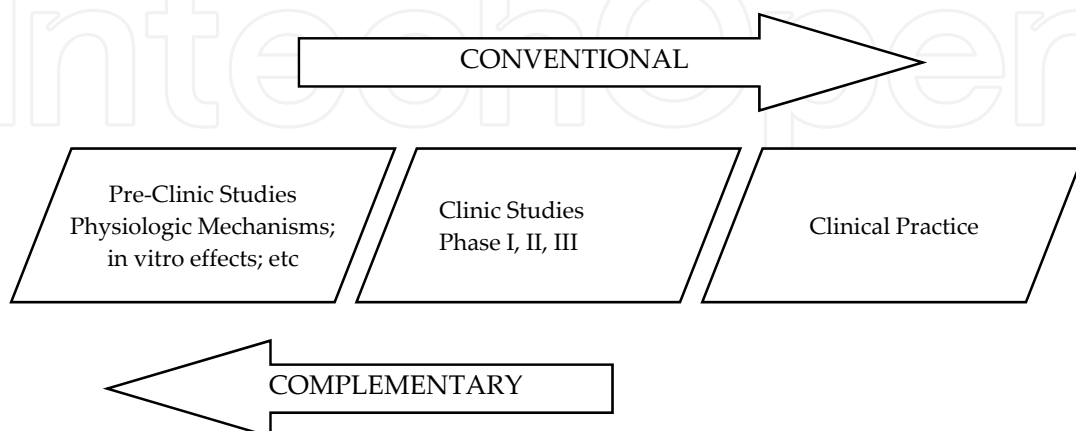


Figure 1. In the model proposed by Kienle [9], the investigation of complementary therapies follow the opposite flux of that one followed by the investigation of conventional pharmacotherapy.

Finally, when considering scientific evidence about the efficacy of any treatment, one must remember that "absence of evidence" (meaning that currently there are no adequate studies) is different from "absence of effect" (meaning that studies have failed to show adequate improvement). This classification is dynamic, as new studies being published periodically and bringing new information.

Safety: It is always important to remember that natural therapy is not synonymous of safe therapy. The general opinion that CT are harmless, healthy, pure, biological and without adverse events is a myth. There are varying degrees of potential patient harm that can result from either conventional medical practices or CT [3]:

- Economic harm, which results in monetary loss but presents no health hazard;
- Indirect harm, which results in a delay of appropriate treatment, or in unreasonable expectations that discourage patients and their families from accepting and dealing effectively with their medical conditions;
- Direct harm, which results in adverse patient outcome.

Legislation: CT are unregulated in most countries, and there is an urgent need to develop policies in order to minimize the risks and maximize the benefits of CT use [10]. CT must ideally be provided by a qualified practitioner, preferably registered and certified, with adequate training background, good skills and knowledge. The provider must be competent to provide CT services of quality. A surveillance system for malpractice must be established. In different countries, the same product can be labeled as a dietary supplement (available in stores) or medication (available at drugstores).

Cost-Benefit: CT have a potential for reducing costs in health because they are relatively non-expensive and avoid high technology, among other motives. Obviously, immediately after their introduction, there is a small increase in cost, which is added to the sum of treatments. The cost-benefit may appear later, by saving money with further healthcare. A number of systematic reviews of economic evaluations of CT have been published. These reviews almost universally conclude that the economic outcomes of some CT therapies are encouraging, but that more and better quality studies are needed. A recent study [11] showed that patients whose general practitioner has additional CT training have 0–30% lower healthcare costs and mortality rates, depending on age groups and type of CT. The lower costs result from fewer hospital stays and fewer prescription drugs.

Risk-Benefit Analysis: There is also little research on how the public understands the information in terms of risks and benefits and how such perceptions support decision making process. Considerable misinformation is dispersed by vendors and on the Internet. A significant percentage of CT use is unsupervised and engaged in as self-care [3]. A majority of patients who use CT do not disclose such use to their physicians.

Adams et al [12] tracing some guidelines for risk-benefit analysis, invites us to consider:

- Severity and acuteness of illness
- Curability with conventional treatment
- Degree of invasiveness, associated toxicities, and side effects of the CT

- Quality of evidence of safety and efficacy of the desired CT treatment
- Degree of understanding of the risks and benefits of CT treatment
- Knowledge and voluntary acceptance of those risks by the patient
- Persistence of the patient's intention to use CT treatment

So, the efficacy is just one of the factors that must be considerate. CT would be used even without solid evidence of efficacy if:

- The condition is highly prevalent (e.g., diabetes mellitus).
- The condition causes a heavy burden of suffering.
- The potential benefit is great.
- Some evidence that the intervention is effective already exists.
- Some evidence that there are safety concerns exists.

Physician must also consider a balance between efficacy and safety, classifying treatments as:

- effective and safe (having adequate scientific evidence of efficacy and/or safety or greater safety than other established treatment models for the same condition). CT belonging to this group surely must always be used.
- effective, but with some real or potential danger (having evidence of efficacy, but also of adverse side effects). CT belonging to this group may sometimes be used, under close supervision.
- unknown effectiveness, but safe (having insufficient evidence of clinical efficacy, but reasonable evidence to suggest relative safety). CT belonging to this group may sometimes be used, under close supervision.
- ineffective and dangerous (proven to be ineffective or unsafe through controlled trials or documented evidence or as measured by a risk/benefit assessment). CT belonging to this group may never be used.

4. A special word on placebo effect

The placebo effect is the therapeutic effect produced by something that objectively has no activity on the treated condition [13]. It corresponds to a physical or psychological beneficial change that occurs in response to factors that can be considered a placebo, such as an inactive substance made to resemble a drug (as a flour tablet), a false equipment or procedure (as acupuncture needle which does not penetrate effectively into the skin) or a therapeutic experience or a symbol (such as doctor-patient relationship in the "white-coat effect").

In any health treatment, the following factors are at stake: (a) specific elements (such as acupuncture needling); (b) undetectable and incidental elements (such as patient's beliefs, contextual factors and meaning, the listening and speech process); and (c) items not related to treatment (such as the natural course of disease or spontaneous regression). The placebo effect is in the second group, comprising the non-specific effects present in any doctor-patient relationship, including: attention, empathic concern, examinations, qualifications of health status and monitoring.

The dynamic set of all these treatment elements impacts over the patient's anxiety and the relationship he makes with the disease. As each therapy has these elements, even surgery is a field in which the placebo effect may be present in some degree [13]. So, to say that a CT "is no better than placebo" does not mean that this therapy is ineffective.

All facets of the placebo effect can not be explained by a single theory. Several explanations take into account the inter-relations between mental processes (expectations) and brain (neurophysiology). Currently, two theories have been more involved: the classical theories of conditioning and expectation [14]. Studies on the placebo effect have assisted in understanding the influence of mind over body. Placebo analgesia (caused by the injection of saline solution) elicits the production of endogenous opioids. It can be reversed by opioid antagonists such as naloxone. [13].

The randomized controlled trial was designed to test new drugs and it is based on physiological biomedical assumptions. In an essay on drugs, some elements such as speaking and listening are taken as incidental factors separate of the objective effect of pharmacological treatment. On CT, both incidental and biological phenomena are intertwined and can be equally important (Figure 2). A factor that is also at stake is the performative efficacy. This is based on the power of belief, mentalizing, the expectation of the symbols and their meanings. Complementary therapies, therapeutic rituals tend to have an especially powerful performative efficacy. This could amplify the extension of the non-biological effects.

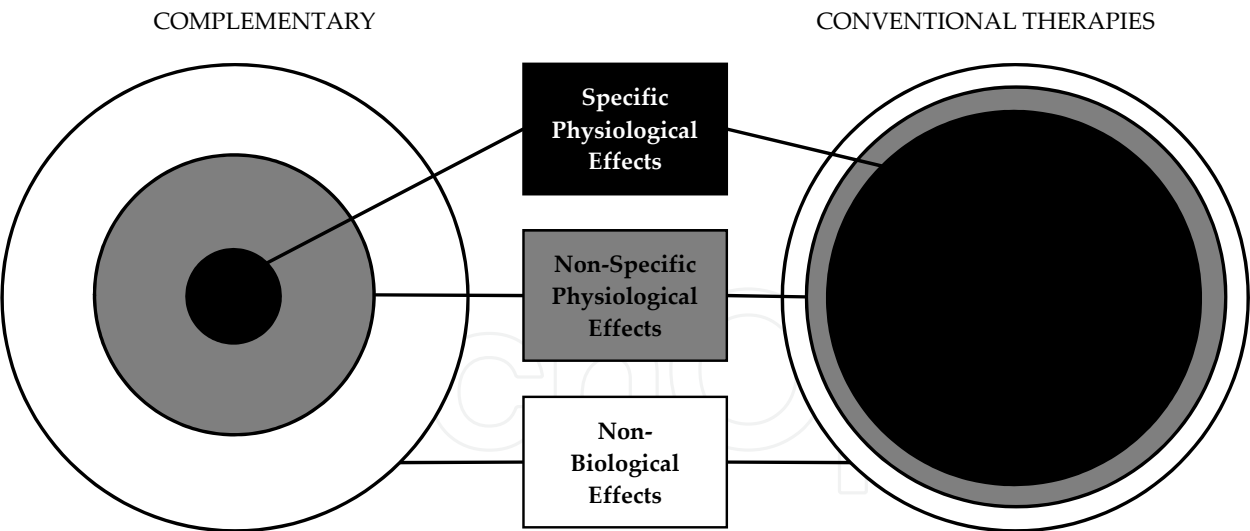


Figure 2. Representation of the importance of specific physiological effects, non-specific effects and non-biological effects on conventional and on complementary therapies.

The use of placebo-controlled trial to study unconventional interventions can lead to false-negative results. A recurrent paradox related to clinical trials with acupuncture is the fact that both the false and real acupuncture have good therapeutic effects [15]. This could lead to the belief that acupuncture acts exclusively via the placebo effect. However, this belief would be inappropriate. The classic design of a trial controlled by false acupuncture is based

on the assumption that only the needling is effective treatment in acupuncture. Thus, patients in the control group receive almost everything except the real needling. As other elements of treatment (such the diagnostic process of Chinese medicine that involves listening and speaking) also have practical effect, this design is inappropriate because the two groups are getting these other elements. Consequently, the difference between the groups may underestimate the total therapeutic effect of acupuncture [15].

By studying the placebo effect in complementary therapies, Kaptchuk [16] divided the factors that may modulate this effect in groups: (a) patient characteristics (expectations, preference for participatory interventions); (b) the therapist characteristics (the image of "savior" that he can pass to the patient by an enthusiastic attitude); (c) therapist-patient interaction (when both share beliefs, generating empathy in clinical consultation); and (d) the nature of the disease (good results in situations with subjective symptoms, chronic conditions with variable course influenced by selective attention and affective disorders. Examples include chronic pain, fatigue, headache, arthritis, allergies, hypertension, insomnia, asthma, digestive disorders, depression and anxiety).

5. A special word on herbal treatment

CT are perceived by general population as more "natural" and less aggressive. Although the side effects of CT are generally smaller, they are not negligible. For example, many botanical products contain active ingredients potentially harmful [17]. Herbal medicines may have adverse events, which are attributable to irregular quality of the products, as well as unwanted interactions (with drugs or other supplements). As many supplements are not categorized as drugs, their manufacturers are not required to prove they are safe and effective (although supplements must have a safety record). The lack of reliable and consistent products is a challenge to the research and clinical practice.

- The main problems regarding use of herbal treatment is listed below [18]:
- Contamination with heavy metals: mercury, arsenic and lead are the most commonly detected
- Contamination with agriculture inputs: insecticides, fungicides and herbicides.
- Contamination with pathogenic microbes and poisonous mycotoxins
- Absence of laws to regulate and commercialize with proof of efficacy and safety.
- Variation in the amount of active ingredients (related to purity and standardization).
- Variation on the origin (local harvest, harvest, plant species, etc.).
- Unlike vitamins and minerals, herbal supplements are composed of many active compounds

Health professionals and providers of CT involving herbal medication should follow the national pharmacovigilance legislation [10]. At other side, manufacturers and importers/distributors of CT medication products could be a source of information on adverse events involving their products. Some countries have included this source of information as part of their regulatory framework. Manufacturers should report directly to the national pharmacovigilance centre or to the regulatory authority.

Herbal medications must bring wrote information equivalent to conventional remedies, such as precise therapeutic claims and corresponding level of evidence, quality control on production, precautions and adverse events, interactions and contraindications, posology and methods of administration, and considerations for children, pregnant or lactating women and the elderly [10].

6. Roles of the involved personages

There is a challenge to provide ethical, medically responsible counseling and provision of CT that respects and acknowledges the patient's values. For the proper use of a CT is necessary for the physician, the patient, the therapist and the health services to play their expected roles. Table 1 provides a description of these expected obligations.

Role of the Health Care Service	<ul style="list-style-type: none"> - Focus on the patient's interest, according to a humanized care giving. - Allow and encourage the use of CT in an open and evidence-based way. - Disseminate guidance on the nature of these treatments and their features. - Inform the patient about potential risks and benefits, on realistic expectations.
Role of the physician	<ul style="list-style-type: none"> - Actively ask the patient about past and current use of CT. - Educate and encourage patients to use CT when indicated. - Help the patient to interpret texts found on CT elsewhere. - Respect and support the wishes and values of the patient.
Role of the CT therapist	<ul style="list-style-type: none"> - Have written policy and procedures in place to avoid any misunderstandings. - Contact local council to check out health and safety requirements. - Ensure adequate data storage and protection when retaining client information. - Check about professional indemnity insurance with your professional body.
Role of the patient	<ul style="list-style-type: none"> - Do not stop conventional treatments on your own. - Inform your assistent physician which CT is being used. - Request information from reliable sources. - Find the indication of a therapist of confidence. - Supplements should be from a reliable source. - Be aware that different patients respond in different ways .

Table 1. Description of the expected roles for the proper use of CT in health services.

Patients as informed clients: Clients may identify reliable information by their purpose, relevance/accuracy, sources, updated information, and objectivity [10]. For example, is the information intended to educate the consumer or sell a product? Also, good information meets the needs of the consumer and is relevant to his/her lifestyle and situation. It should

not give unrealistic recommendations and should be written in a language that is easy to understand and does not contain obvious errors such as misspellings and grammatical mistakes. Credible information states clearly who is responsible for the information, who is financially supporting the information and where the information comes from (i.e. the original source). It should be clear whether the information is opinion-based or factual. A good source of information provides unbiased and balanced information. Such information should be honest about areas of uncertainty and enable consumers to make therapy choices that are in his/her best interest. In case of commercial information, relationships to product manufacturers, for example, should be clearly stated.

Motivations to use CT: The motivations for using CT are numerous, but a major contributor appears to be the pursuit of wellness. Many patients appear to use CT for this goal and not just the treatment of disease. Besides well-being, patient may be seeking cure for a disease, symptom control. It is important that patient expectations be realistic about the results under the current knowledge. Certainly it will be always a wrong motivation to search a CT only based on “fashion”. There is a natural selection that leads people to use CT. People with a low taste for medical interventions might be more likely to choose CT. Also patient may seek better practices (less overtreatment, more focus on preventive and curative health promotion).

7. Integrating conventional and complementary healthcare

An unconventional therapy may be used alone, as an alternative to conventional therapies, or in addition to conventional therapies. This third trend is referred to as an integrative approach. Health care that integrates CT therapies with conventional medicine has been termed “integrative medicine” by many. Whatever term is used, the goal should be the provision of comprehensive care that is safe and effective, care that is collaborative and interdisciplinary, and care that respects and joins effective interventions from all sources. This comprehensive approach should be based on customization based on patient needs and values, being the patient as the source of control.

The boundaries between CT and conventional medicine are constantly evolving, since interventions such as hospice care or relaxation and breathing techniques in childbirth that were once considered unconventional are now widely accepted. CT interventions are being incorporated into integrative medicine practices located in conventional medical care settings.

As the quantity and quality of research in CT is growing, there is a more open attitude to CT among conventional health professionals. Guidelines and consensus statements issued by conventional medical organizations have recommended some CT, which are increasingly practiced in conventional medical settings, particularly acupuncture for pain, and massage, music therapy, and relaxation techniques for mild anxiety and depression. Some forms of CT are being incorporated into services provided by hospitals; covered by health maintenance organizations; delivered in conventional medical practitioners’ offices; and taught in medical, nursing, and other health professions schools. Insurance coverage of CT therapies is increasing and integrative medicine centers and clinics are being established.

Comprehensive health care must go beyond the conventional clinical and surgical treatment. Ideally, it should also involve changes in the patient's lifestyle (nutrition, exercise, stress management, etc.), associated with multidisciplinary treatments (physiotherapy, psychotherapy, etc.) and complementary therapies (CT) (Figure 3). This ideal model should include both conventional medical and CT approaches to health promotion, disease prevention, and the treatment of illness that have been shown to be safe and effective.

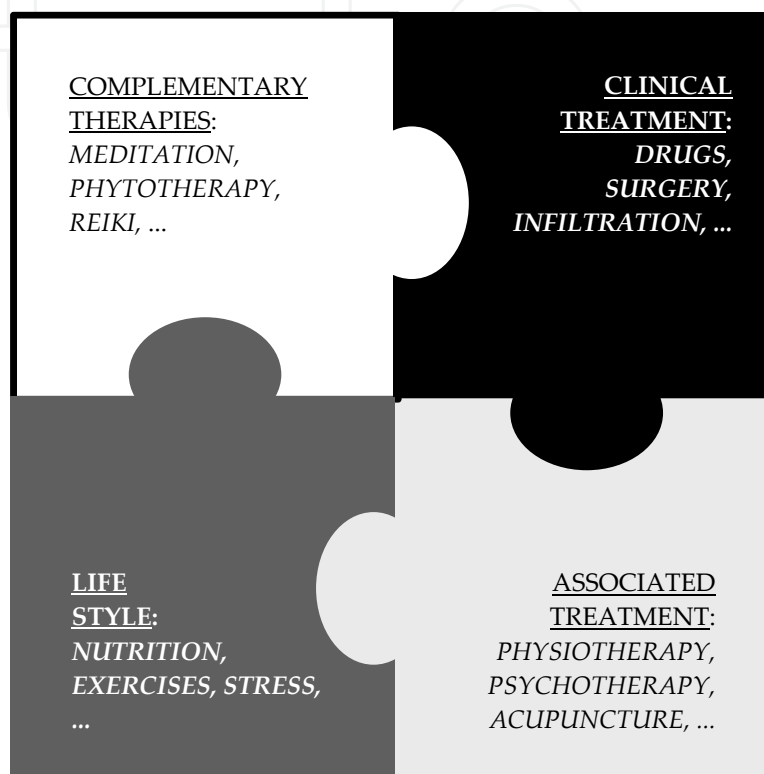


Figure 3. Illustration of an ideal model of integrative health approach

An example of successful use of CT in a general hospital was published by Dusek [19]. The adoption of CT had a significant impact in promoting analgesia with a reduction in pain score by an average of 50%. The techniques used were relaxation, acupuncture, acupressure, massage, therapeutic touch, music therapy, aromatherapy and reflexology.

Education in CT is an important field for all health professionals. Although many non-conventional therapeutic modalities have already passed through scientific analysis, there is still much ignorance and prejudice from health professionals. For those in conventional practice, it is important to learn about CT to appropriately interact with and advise patients in a manner that contributes to high-quality, comprehensive care. Health profession schools (e.g., schools of medicine, nursing, pharmacy, and allied health) incorporate sufficient information about CT into the standard curriculum at the undergraduate, graduate, and postgraduate levels to enable licensed professionals to competently advise their patients about CT.

Education is also important because patient prone to use CT may search it independently of approval of the physician. Patient must feel safe and comfortable to bring this discussion to the clinical visit. Otherwise, there is the risk of seeking a non-orthodox treatment without

the knowledge of the assistant physician. The lack of guidance by the physician may lead to harming results. Physician and patient, in joint decision, may choose CT that are safe and have some potential benefit.

8. Future steps

The NCCAM (already cited) proposed these 3 goals for the period 2011–2015: advance the science and practice of symptom management; develop effective, practical, personalized strategies for promoting health and well-being; and enable better evidence-based decision making regarding CT use and its integration into health care and health promotion. To achieve it, the institution stated these strategic objectives [5]:

- Advance research on mind and body interventions, practices, and disciplines.
- Advance research on CT natural products.
- Increase understanding of “real world” patterns and outcomes of CT use and its integration into health care and health promotion.
- Improve the capacity of the field to carry out rigorous research.
- Develop and disseminate objective, evidence-based information on CT interventions.

It will be important to understand how CT and conventional treatments interact with each other and to study models of how CT and conventional medical treatments can be provided in integrated and coordinated ways. Unfortunately, little information is available about the outcomes and the effectiveness of various models of integration.

Many critics of CT argue that some of them are explained by theories that do not follow the current biomedical model. The fact is these CT were born in the past and reflect the worldview of that time. But a model is just a way to explain a phenomenon and make it teachable. This model might make sense in that epoch, and we must understand the theory of CT under the light of this sense. If it does not fit the current model, there should not be immediately discarded. In the past, conclusions were drawn from the intensive observation of nature, and they have insights we could not draw today.

Thus, old theories have considerable value, although they may have gross errors (for example, on anatomy and physiology). One way to reconcile this dilemma could be the realization that current conventional model best explains mechanical (materials) problems, while CT best explain functional disorders (which are actually related to most of the medical appointments). An allegory for this would imagine that if human beings were a computer, the current biomedical model would better take care of the hardware, whereas CT better fix the software.

9. A framework for rational decision

The increasing use of CT by patients, health care providers, and institutions makes it imperative that physicians consider their ethical obligations when recommending, tolerating, or proscribing these therapies. Table 2 proposes a framework for rational decisions about CT based on different scenarios. Note that no isolated factor (such as efficacy) is the only one to be scaled. The decision about a CT will be based ultimately on the

judgment of the components of this matrix. For example: when a technique has not proven efficacy, but it can improve the quality of life of patient, it should not be discarded immediately. It could not be used for therapeutic purposes, but to enhance well-being. For such, it is necessary the technique be not harmful and be aligned to the values of the patient. This is the case of techniques such Reiki and Bach Flower Remedies.

	Use broadly this CT without major concerns	Use this CT in some cases with close supervision	Avoid use this CT and counter-indicate it
<i>Efficacy (mechanisms of action)</i>	Totally known	Partially known	Totally unknown
<i>Effectiveness (effect in practice)</i>	Well documented for the condition treated	Some evidences for the condition treated	Unknown results for the condition treated
<i>Efficiency (cost-benefit ratio)</i>	Certainly worthy	Potentially worthy	Not worthy at all
<i>Safety</i>	No possible direct harm	Potential harm	Documented major harm
<i>Risk-benefit ratio</i>	Patient has incurable burdened disease	Patient has chronic burdened disease	Patient has mild self-limited disease
<i>Legislation</i>	Board or council regulations	Acknowledged by some agencies	Marginal situation before health agencies
<i>Patient characteristics</i>	Adequately informed, motivated and/or expectant	Moderately informed, motivated and/or expectant	Badly informed, motivated and/or expectant
<i>Physician characteristics</i>	Partnership on a real patient-centered care	Respect to the will of patient, but suspicious about CT	Very uncomfortable with these patients values
<i>Healthcare service (HS) characteristics</i>	CT offered inside HS	CT referred from HS	CT not linked at all with a HS
<i>Practitioner characteristics</i>	Well trained, board certified, good experience	Some training , informal certification, some experience	Self trained, no certification, unknown experience
<i>Objective (Purpose)</i>	Realistic (e.g. searching for wellbeing)	Unrealistic (e.g. stop all conventional remedies)	Impossible (e.g. to cure advanced cancer)
<i>Combination with conventional treatment</i>	Full compatibility, no conflict if used simultaneously	Some paradigm conflict between conventional and complementary	Use of CT demands abandonment of conventional treatment

Table 2. A framework for rational decisions when recommending, tolerating or proscribing a CT

10. Conclusions

There is a growing interest of patients by complementary therapies (CT), the therapeutic products or practices which are not currently part of the conventional curative approach, but whose safety and efficacy have been scientifically studied. Defining CT is difficult, because the field is very broad and constantly changing. Health care that integrates CT therapies with conventional medicine has been termed “integrative medicine”. There is a challenge to provide ethical, medically responsible counseling and provision of CT that respects and acknowledges the patient’s values. For the proper use of a CT is necessary for the physician, the patient, the therapist and the health services to play their expected roles.

This chapter proposes a framework for rational decisions when recommending, tolerating or proscribing a CT, based on different scenarios. A matrix of factors that must be considered includes efficacy (mechanisms of action); effectiveness (effect in practice); efficiency (cost-benefit ratio); safety; risk-benefit ratio; legislation; patient characteristics; physician characteristics; healthcare service characteristics; practitioner characteristics; objective (purpose); and potential of combination with conventional treatment. Based on these elements, the decision may be: (a) Use broadly this CT without major concerns; (b) Use this CT in some cases with close supervision; or (c) Avoid use this CT and counter-indicate it.

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