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## Position Paper

# Role of complementary and alternative medicine in the care of patients with breast cancer: Report of the European Society of Mastology (EUSOMA) Workshop, Florence, Italy, December 2004

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## ABSTRACT

The aim of the European Society of Mastology (EUSOMA) Workshop, Florence, Italy, December 2004, was to produce guidelines on the use of complementary and alternative medicine (CAM) for breast cancer. The widespread use of CAM has to be acknowledged and the reasons for this understood. Deficiencies in the practice of conventional medicine that lead to the adoption of CAM need to be addressed. At the same time, CAM use for breast cancer should be quality controlled, avoiding double standards in evaluation, whilst recognising the problems of CAM research. These guidelines, which appear in an accompanying paper, aim to help oncologists and cancer patients alike.

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## 1. Introduction

Patients diagnosed with breast cancer have many needs. The diagnosis comes as a shock and, maybe for the first time, the individual is facing up to her mortality. So before health service providers even think about the role of medicine, they must consider patients' needs for moral and spiritual support. At times like this, a close supportive family and membership of a faith community are invaluable. Sadly, there are many cancer sufferers who lack family support and have no spiritual mentor.<sup>1</sup> Perhaps one explanation of the growth in

the interest in complementary and alternative medicine (CAM) is the unmet need of the patient when conventional medical practice fails to fill this aching void. It would therefore be an interesting area of research to explore the link between spiritual support and the uptake of CAM.<sup>2</sup>

The next need for cancer subjects is to be free of whatever symptoms they have as a result of the disease. Of course, in the early stages the patients may be symptom-free, but, in the later stages, pain, nausea and weakness are common. The science of pain control is well established and palliative care for those close to death is a well-developed specialty,

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thanks to the European hospice movement. In addition, there may be a role for interventions such as therapeutic massage, acupuncture and counselling to help the patient feel better. Relatively new is the discipline of 'psycho-social oncology', which aims to identify and manage the more subtle subjective symptoms of cancer, such as anxiety and depression.<sup>3</sup> This field of activity emerged about 20 years ago with the development of psychometric instruments, addresses the psychological, social, spiritual and behavioural dimensions of being afflicted with the diagnosis of cancer from both perspectives: the one of the patient and the ones of the members of his or her social network. Furthermore, there exists a mind body nexus that, in theory, could be modulated to influence the natural course of the disease so that if the patient 'feels better' it might indirectly help them to 'get better'.

The third need of cancer victims is to be cured, or at least have their lives prolonged. At this point a short digression is in order to consider a brief history of the treatment of breast cancer.

## 2. History of breast cancer treatment

From the years 200 to 1800 AD, following the teachings of Aristotle and Galen, cancer was believed to be a consequence of the coagulation of 'black bile' (melancholia) in the target organ. Black bile was one of the four metaphysical humours (black bile, yellow bile, phlegm and blood) that needed to be in balance for perfect health. The therapeutic responses to this belief were purgation (enemas), leaching, cupping, blood-letting and extreme diets. There was never any evidence that the treatments worked, but undoubtedly the patient's suffering was increased. In the last 200 years much has been learnt about the exquisite mechanisms of the body at molecular, cellular, whole organ and whole person levels. The realities are more fascinating than ever dreamt of in Galen's philosophy.

In the late 19th century, with the development of anaesthesia and antisepsis, radical surgery began to replace irrational nostrums. Not long after this, radiotherapy was introduced that increased the chances of local control of the cancer. These early successes in functional and symptomatic relief lead to a period of complacency in the medical profession, which began to be shaken with the development of effective (albeit toxic) chemotherapy regimens and less toxic hormonal agents for hormone receptor positive cancers about 30 years ago. At the same time, the randomised controlled trial (RCT) was introduced to evaluate critically combinations of these three modalities measuring both efficacy (improvement in survival) and tolerability (side-effects and quality of life (QoL)). Using this approach, we have made slow incremental improvements and can now negotiate with our patients 'trade-offs' between increasing length of life and the toxicity/side-effects of the treatments, with a degree of precision and individualisation that increases with each trial completed.

Having inherited the radical mastectomy as therapeutic dogma in the 1970s, we can now safely offer breast preservation without compromising cure, whilst the addition of drugs tailored to the biology of the disease has contributed to a 25% reduction in mortality.<sup>4</sup> There is still a long way to go and,

once again, there is no room for complacency. The challenge for oncologists of today is to achieve the correct balance between curiosity (scientific interest in helping patients of the future) and compassion (helping patients of the present) in order to reach the optimal efficiency level of care, both in routine clinical practice and for the patient treated in the context of clinical research.

## 3. Semantics and the definitions of CAM

The working group at the European Society of Mastology (EUSOMA) Workshop, Florence, Italy, December 2004, spent a long time attempting to agree on the correct terminology to describe CAM, and even the shorthand used so far by way of introduction was subject to question.

The English language has a rich vocabulary, words have precise meanings and we tamper with them at our peril. George Orwell's book 1984 illustrates the ultimate triumph of the evil of a totalitarian state. By the simple device of distorting language so as to make it impossible even to harbour subversive thoughts, 'Big Brother' ruled absolutely. It saddens us to witness how language is being debased by a pseudo-culture that encourages transient values and transient meanings to our vocabulary.<sup>5</sup> The same worry concerns the use of the three words: 'alternative', 'complementary' and 'holistic', when applied to the practice of medicine.

The first question one must ask about 'alternative' is: alternative to what? Proponents of alternative medicine will describe the practice of doctors in the European health services, both in primary and tertiary care, as 'orthodox', 'mainstream', 'Western', 'reductionist', and so on. In return, practitioners of conventional medicine view 'alternative/unconventional' medicine as a series of comprehensive health belief systems, superficially with little in common, yet sharing beliefs in metaphysical concepts of balance and similarities which date back to Galenic doctrine from the second century AD, or oriental mysticism 2000 years older. Thus, in this parallel universe of alternative medicine, treatments are based on metaphysical concepts, rather than orthodox physiology and biochemistry, nevertheless, many 'alternative' practices use traditional or autonomous medical concepts, packaged in the garb of modern science. Yet it has to be accepted that each view of the other is to some extent pejorative, and if we are to establish a dialogue between the champions on either side of this conceptual divide, we must show mutual trust and mutual respect. Perhaps for the time being we might blur these distinctions by using the word 'unproven', which can apply equally well to therapeutic interventions on each side. Of course, the issue of the definition of 'proof' then raises problems, but this will be dealt with later in this paper.

Next we must consider the definition of 'complementary'. The *Oxford English Dictionary* defines the word as, 'that which completes or makes perfect, or that which when added completes a whole.' In other words, whilst modern medical science struggles to cure patients, complementary medicine helps patients to feel better, and who knows, by feeling better the act of healing itself may be complemented. Some complementary approaches may be placebos, and the touch of the 'healer' or the hand of the massage

therapist could be guided by strange belief systems that are alien to modern science. Providing the intention is to support the clinician in his or her endeavours rather than compete in the relativistic marketplace of ideas, one might set aside these concerns.

Finally ‘holism’, a slippery word whose ownership is competed for by both sides of the therapeutic divide. The term was coined by Jan Smuts in 1926.<sup>6</sup> He used it to describe the tendency in nature to produce wholes from the ordered grouping of units. The philosopher and author Arthur Koestler developed the idea more fully in his seminal book *Janus: A Summing-Up*,<sup>7</sup> in which he talks about self-regulating open hierarchical orders. ‘Biological holons are self-regulating open systems which display both the autonomous properties of wholes and the dependent properties of parts. This dichotomy is present on every level of every type of hierarchical organisation and is referred to as the Janus Phenomenon’. (Janus being the Roman God who looked in both directions at the same time.) *Chambers Twentieth Century Dictionary* describes holism in a precise and economical way as follows ‘complete and self-contained systems from the atom and the cell by evolution to the most complex forms of life and mind’. It can be perceived then that the concept of holism is complex and exquisite, and as an open system lends itself to study and experimentation. As such it should be a concept that unites us rather than a continuing source of dispute.

To do justice to General Jan Smuts’ definition of the word holism, we have to start with a ‘reductionist’ approach to the molecular level, and then from these basic building blocks attempt to reconstruct the complex organism, which is the human subject living in harmony within the complex structure of a modern democratic nation state. Since Watson and Crick described the structure and function of DNA in 1953, the development of biological holism has grown way beyond anything Jan Smuts might have envisaged. The basic building block of life has to be a sequence of DNA that codes for a specific protein. These DNA sequences, or genes, are organised within chromosomes forming the human genome. The chromosomes are packed within the nucleus with a degree of miniaturisation, which is awe-inspiring. The nucleus is a holon looking inwards at the genome and outwards at the cytoplasm of the cell. The cell is a holon that looks inwards at the proteins, which guarantee its structure and function contained within its plasma membrane, and at the energy transduction pathways contained within the mitochondria, which produce the fuel for life. As a holon, the cell looks outwards at neighbouring cells of a self-similar type, which may group together as glandular elements, but the cellular holon also enjoys cross-talk with cells of a different developmental origin, communicating by touch through tight junctions, or by the exchange of chemical messages via short-lived paracrine polypeptides. These glandular and stromal elements group together as a functioning organ, which is holistic in looking inwards at the exquisite functional integrity of itself, and outwards to act in concert with the other organs of the body. This concert is orchestrated at the next level in the holistic hierarchy through the neuro-endocrine/immunological control mediated via the hypothalamic pituitary axis, the thyroid gland, the adrenal gland, the endocrine glands of sexual iden-

tity, and the lympho-reticular system that can distinguish self from non-self.<sup>8</sup> Even this notion of selfness is primitive compared with the next level up the hierarchy, where the person exists in a conscious state somewhere within the cerebral cortex, with the mind, the great-unexplored frontier, which will be the scientific challenge of doctors in this millennium.

It could even be argued that complementary medicine is practised at the highest level in the hierarchy that governs the human organism. Providing the ‘complementary’ practitioner concentrates on making the patient feel better and spiritually at ease, then his or her position is secure in the modern world. We would also urge proponents of alternative and complementary medicine to appreciate that the holistic system is an open system that lends itself to the experimental method. There is much research that is urgently required to investigate the psychosomatic aspects of disease and the spiritual dimension to healing.

There is yet one more word that was debated, i.e. ‘integrative’. This word has become popular on both sides of the Atlantic with the recent international conference of ‘integrative medicine’ in New York (December 2004) and the Prince of Wales ‘Foundation of Integrated Health’ in the UK. But, again, this poses problems as to what is being integrated. Ideally the best of both worlds; yet if this includes ‘alternative’ medicine we are back to square one and some of the more dubious practices under this rubric might slip in under this cloak of respectability. On the other hand, if the concept is confined to integrating only treatments which are backed-up by evidence, we are really talking about evidence-based medicine and the term ‘integrative’ would be redundant. Attempts have been made to come up with a global definition that suits all, e.g. by the American Cancer Society<sup>9</sup> and the Cochrane Collaboration,<sup>10</sup> but these definitions overlap and in part contradict each other.

Furthermore, the economic environment may influence utilisation of these terms. For example, there has been an evolution in terminology reported in the United States of America (USA) because of the extensive marketing activities around CAM. Over the passage of time, ‘alternative medicine’ has become ‘complementary’ and may finally become ‘integrative medicine’. In other words, whatever terminology we might choose, the language can be subverted and words can be hijacked. Finally cultural and national differences have to be recognised and, so far, we have only been discussing the use of English for a set of guidelines that are meant to be applied across a polyglot group of European nations. [Table 1](#) illustrates some of the popular understandings for the words discussed above, without being exhaustive. A consensus about the most appropriate term could not be reached between the workshop members. This reflects the experience that professionals as well as laities typically decide on the definition for purposes of their particular backgrounds and activities, and definitions vary with the perspectives and affiliations of them (see [Table 2](#)).

In the end, we decided to adopt CAM as a working compromise and alert the readers to be vigilant as the meaning of words can be context-dependent and evolve over time by common usage. Furthermore, whatever words are used to communicate amongst ourselves, one must never forget that,

**Table 1 – Popular understandings of terms in common usage**

Alternative cancer medicine	<ul style="list-style-type: none"> <li>• Treatment not offered within conventional cancer care.</li> <li>• Treatments with a theoretical basis which, in part or in total, is incongruent with the common scientific model.</li> <li>• Treatment aimed as an alternative to conventional medical cancer treatment, without accepted evidence for its efficacy.</li> </ul>
Complementary cancer medicine	<ul style="list-style-type: none"> <li>• Supportive treatment that complements conventional cancer medicine.</li> </ul>
Holistic medicine	<ul style="list-style-type: none"> <li>• Medicine aimed at treating the whole patient in body, mind, and spirit.</li> <li>• Medicine that recognises the hierarchical structure of the human body organised in units of increasing complexity (holons) from the cell to the person.</li> </ul>
Integrated medicine	<p>Medicine that:</p> <ul style="list-style-type: none"> <li>• Integrates the care of body, mind, spirit and environment of the patient.</li> <li>• Integrates all modalities of medicine: orthodox, complementary, self-help and psycho-spiritual.</li> <li>• Integrates the efforts of the patient to help herself.</li> <li>• Transcends the orthodox/alternative divide, reflecting the patients wish for a non-polarised form of medicine (probably better under 'holistic medicine')</li> </ul>
Healing	<p>Healing includes;</p> <ul style="list-style-type: none"> <li>• Physical healing of the body and remission of physical illness.</li> <li>• Emotional healing with recovery from shock, grief and past hurts with the achieving of emotional balance and a positive mental attitude.</li> <li>• Spiritual healing – providing energisation and up-lift as well as the development of inner strength, peace of mind, acceptance of death and help with conscious dignified dying. This can happen within or outside a religious framework.</li> </ul>

**Table 2 – Examples of popular complementary/alternative therapies**

Name	Description
Acupuncture	Insertion of a needle into the skin and underlying tissues in special sites, known as points, for therapeutic or preventive purposes.
Aromatherapy	The controlled use of plant essences for therapeutic purposes.
Bach flower remedies	A therapeutic system that uses specially prepared plant infusions to balance physical and emotional disturbances.
Biofeedback	The use of apparatus to monitor, amplify and feedback information on physiological responses so that a patient can learn to regulate these responses. It is a form of psychophysiological self-regulation.
Chelation therapy	A method for removing toxins, minerals and metabolic wastes from the bloodstream and vessel walls using intravenous ethylene diamine tetra-acetic acid (EDTA) infusions.
Chiropractic	A system of healthcare which is based on the belief that the nervous system is the most important determinant of health and that most diseases are caused by spinal subluxations that respond to spinal manipulation.
Craniosacral therapy	A proprietary form of therapeutic manipulation which is 'tissue-, fluid-, membrane-, and energy-orientated and more subtle than any other type of cranial work.
Herbalism	The medical use of preparations that contain exclusively plant material.
Homoeopathy	A therapeutic method using preparations of substances whose effects when administered to healthy subjects correspond to the manifestations of the disorder (symptoms, clinical signs and pathological states) in the unwell patient.
Hypnotherapy	The induction of a trance-like state to facilitate the relaxation of the conscious mind and make use of enhanced suggestibility to treat psychological and medical conditions and effect behavioural changes.
Massage	A method of manipulating the soft tissue of whole body areas using pressure and traction.
Naturopathy	An eclectic system of healthcare, which integrates elements of complementary and conventional medicine to support and enhance self-healing processes.
Nutritional supplements	Vitamins/trace elements.
Osteopathy	Form of manual therapy involving massage, mobilisation and spinal manipulation.
Reflexology	A therapeutic method that uses manual pressure applied to specific areas, or zones, of the feet (and sometimes the hands or ears) that are believed to correspond to areas of the body, in order to relieve stress and prevent and treat physical disorders.
Relaxation therapy	Techniques for eliciting the 'relaxation response' of the autonomic nervous system.
Special diets	Dietary changes with the intention to directly influence cancer mortality and/or morbidity.
Spiritual healing	The direct interaction between one individual (the healer) and a second (sick) individual with the intention of bringing about an improvement or cure of the illness.
Tissue extracts	The medical use of preparations that contain organ tissue from animals.
Yoga	A practice of gentle stretching, exercises for breath control and meditation as a mind-body intervention.

for some patients, the language used may reflect in a positive or negative manner on their needs, hopes and wishes.

#### 4. Prevalence of CAM

The prevalence of CAM usage worldwide can no longer be ignored by the practitioners of evidence-based medicine. This is relevant to medical practice in a number of ways. First of all, it must reflect the unmet needs of cancer patients. Secondly, we have a duty of care to protect our patients from the dangers of remedies that might be toxic, interact unfavourably with our own medications, or be promoted as alternatives to evidence-based treatment.

Horneber and colleagues have performed a systematic review on surveys providing CAM in cancer prevalence data.<sup>11</sup> They included 99 surveys published between 1979 and 2003, comprising more than 44,000 cancer patients in Australia, Europe, New Zealand and North America. Seventeen surveys included only patients with breast cancer. Among this population a wide range of prevalence of use estimates was reported: 17–91% of breast cancer patients had used CAM. Due to clinical and methodological diversities of the studies, no single variable that explained the heterogeneity of the prevalence estimates could be found.

These difficulties, in defining the actual percentage of breast cancer using CAM notwithstanding, the results of this work showed that many patients apparently are able to sustain psychological distress associated with serious disease and do not share a black and white perception of the relation between CAM and conventional medicine. The important implications of the use of CAM described above make it necessary to add a module on patient history of CAM use to the case report form for future clinical research on breast cancer. It also has to be discussed, on a per protocol basis, whether the use of certain CAM during the study could be accepted. In fact, CAM can be an exclusion factor, i.e. in case of use of biological response modifiers or in cases of possible interactions with conventional drugs or procedures such as radiotherapy.<sup>12–18</sup> The use of CAM may introduce confounding factors, although these would be distributed equally in both arms by the randomisation. In any case the use of CAM could be taken into account as a stratification factor, and is relevant for ensuring the quality of future trials.

#### 5. To what extent does the widespread adoption of CAM reflect the unmet needs of the cancer patient?

The massive emotional impact after the disclosure of diagnosis of cancer can result in fear, confusion and isolation.<sup>19</sup> Fear can be countered by reassurance and the offer of hope by the responsible clinician. Hope is not a promise, but a state of mind. Confusion can be countered by improvement in the communication skills of the practitioner.<sup>20</sup> Recommendations on how to communicate with patients on CAM are published<sup>21–23</sup> and put into practice.<sup>24</sup> We welcome the developments in the undergraduate and postgraduate curricula designed to teach professional development and communication skills.<sup>25,26</sup> At the same time the negative judgement on the medical profession made by some CAM practitioners

and representatives of the media regarding the concern about the subjective outcomes of medical care must be challenged. It should be remembered that surgical and medical oncologists were the first to invent, critically evaluate and implement QoL measurement tools.<sup>27,28</sup> In addition, counselling is well accepted by EUSOMA and the medical profession. Proponents of CAM, many of whom are medical practitioners working within the healthcare services,<sup>28</sup> must recognise these efforts and achievements of the medical profession. Here, for a start, is a non-controversial way of building bridges among all professionals involved. However, the greatest difference in views may not be between practitioners of different ‘persuasions’, but between practitioners and patients.<sup>29</sup>

The sense of isolation, felt by the patient at the time of diagnosis, is more difficult as this is determined more by family and spiritual support than medical intervention (although doctors can considerably add to this sense of isolation by poor communication skills). For this reason we include a separate section on spiritual support below.

Beyond that, the popularity of CAM might reflect the time constraints of medical practitioners in understaffed and underfunded government health services, unrealistic expectations of the patient of the best that modern medicine can offer, a desperation of the patient or her family in facing up to the terminal stages of the disease, or even a cultural/philosophical objection to modern medicine, which is one component of the post-modern relativistic philosophy popular in parts of Europe today.<sup>30–35</sup> In other words, this is yet another rich source for research and an area of common ground upon which to build.

#### 6. Religious and spiritual support

All ‘believers’ and ‘non-believers’ accept that there is a transcendental component to life that can offer comfort, support and an explanation for the ‘human condition’. Atheists might gain this through fine art, music, literature, poetry and theatre. ‘Believers’, in addition to their access to the arts, may achieve the transcendental via membership of a faith community or by seeking their spiritual salvation through any number of ‘new-age’ belief systems. However spiritual comfort is achieved, focusing on the transcendental enhances a sense of personal control, builds self-esteem, offers a meaning to both life and death, provides comfort and hope and if ‘believers’ are members of an organised faith community, they will have access to community support. Of course belief in God and belief in modern medicine are not mutually exclusive.<sup>36,37</sup> However, there can be a down side to all this, if religiosity is confused with magic or subverted to be in conflict with a doctor’s duty of care.

Even the word ‘healing’ is open to semantic abuse, using the term in a loose way to imply ‘healing of the spirit’, rather than the common usage where ‘to heal’ is meant ‘to cure’. (Table 1). Some charlatans appear content to allow this misconception to stand uncorrected, yet deny ever claiming that their interventions contributed to a cure. Others, who truly believe in their healing powers as a cure, often invoke a view of a lost ‘Golden age’ when nature offered a cure for all human ailments. In this respect, medical practitioners must



take a robust position. There never was such a 'Golden age', nature is neutral and 'left to nature' would mean observing the natural history of breast cancer.<sup>38</sup> At the same time 'golden age' beliefs imply a denial of progress despite the fall in breast cancer mortality over the last 20 years. Most sinister of all are the faith systems that look upon disease as 'God's will' and cancer as some kind of punishment, in which case 'healing' can only follow prayer. This is an evil doctrine equivalent to those who claimed that the victims of the tsunami disaster reflected God's anger at mankind's corruption. As practitioners of any camp, we have a duty of care to protect cancer sufferers from possibly harmful implications deriving from such belief systems. 'Miracles' (spontaneous cures) are, by their very nature, extremely rare and significantly seldom reported in the last 30 years.<sup>39,40</sup>

Having stated all that, we now have to make recommendations.

Firstly patient's needs have to be defined and 'instruments' designed to measure such needs and patients' satisfaction.<sup>41</sup> A way of identifying patient's needs in spirituality might be to ask the patient from where the cancer came. The answer would indicate patients' needs in spiritual support (divine punishment versus biological explanation).

Health services should offer access to appropriate support through appropriate staff such as members of the clergy, counsellors, etc.<sup>42</sup> We need to set out guidelines for oncologists on how to deal with these aspects, how to refer patients and to whom. Oncologists could operate in this area, but they are not trained to do so.<sup>43</sup> The way in which practitioners broach patients' religious commitments, might enhance healthcare outcomes.<sup>44</sup>

In this regard it is worth noting Gerd Nagel's aphorism:

- Everybody can have their own beliefs.
- Doctors should respect patients' beliefs.
- Doctors cannot oblige patient to accept treatment, but they have duty of care to do their best to keep the patients safe.

## 7. The rules of evidence and the nature of 'proof'

In order to promote a dialogue and for the sake of our patients, it would be helpful to lay to rest the myth that doctors working in the conventional healthcare systems are knowingly denying patients the proven benefits of therapeutic strategies developed by proponents of CAM. If there is evidence for the claims linked to an intervention, then it doesn't matter what their point of origin or provenance might be. In return, if approached by professionals engaged in CAM for help in testing whether their favoured intervention is of value, then it should be the responsibility of the medical establishment to assist the best they can. What we all agreed, however, is there cannot be a double standard whilst accepting that more than one study design might have to be considered, i.e. 'horses for courses'.

In the broadest terms there are three categories of research design involving cancer patients.

Firstly there is 'qualitative research', which usually has the intention of capturing the individual patient's experience and

defining their needs. This, in itself, does not provide evidence of efficacy of an individual treatment, but should be used to set the agenda for other research models. Next there is 'observational research', e.g. case control and cohort studies, that are the tools of the epidemiologists. They might provide clues to suggest therapies, e.g. dietary intervention, or more importantly on the prevention of disease, that in breast cancer might include exercise, weight control and alcohol avoidance, but in themselves can rarely 'prove' that an intervention works.

Finally there is the 'clinical trial'. Clinical trials are conventionally divided into three phases. Phase I tests for dosimetry and toxicity, but cannot be used as evidence of efficacy. Phase II trials look for evidence of 'activity' against a measurable tumour parameter. For example in advanced breast cancer we would wish to measure the size of the primary or its metastatic foci. As spontaneous remissions can be discounted, then assuming there is histological proof of disease and, assuming no other intervention is being used covertly, reduction in size of the measurable focus will be acceptable as evidence of activity, but cannot in itself be sufficient to displace best standard of care. The only exception to this would be in the unlikely event of a series of complete and durable responses in an unselected sequential series of patients that might indeed represent a 'miracle' cure.

It is at this point we have to consider the randomised controlled trial (RCT). This study design is sufficiently robust to cope with the extraordinary variability and to some extent unpredictability of breast cancer. The properly designed and conducted RCT therefore can control for case mix, selection bias, observer bias and placebo effect and is sufficiently malleable to accommodate the needs of CAM. For example if the CAM intervention is aimed at improving QoL or patients satisfaction, then these can be defined as primary endpoints and measured by one or more of the many psychometric instruments that have already been validated.<sup>45</sup> If the primary endpoint is not already covered by one of the instruments, for example in the spiritual domain, then the onus should be on its proponent to develop a new instrument, remembering the aphorism 'if it exists then you can measure it'. Another problem that has to be accommodated concerns the individualisation of treatment often used as an excuse to avoid RCTs. Here again a robust design would allow randomisation of the 'individualised' intervention against a non-individualised 'one size fits all' treatment, and let the best treatment win.

## 8. Systematic reviews

Clinical trials often generate results that are not entirely in agreement with each other. Thus it is misleading to rely on the finding one prefers and to omit the ones one does not like. In other words, we have to consider the totality of the available data. Systematic reviews (SR) are attempts to summarise and evaluate the totality of the available evidence of a pre-defined nature on a certain subject. All the components of the approach and assessment are made explicit so that the result is entirely reproducible. If statistical pooling is used, this is called a meta-analysis. The strength of systematic reviews is that they minimise selection (i.e. the emphasis on the trials that reinforce a prejudice) and random biases (i.e. the play of chance). Thus they can provide the most objective evidence on a given subject

and are a sound basis for clinical decisions. That is not to say that they are foolproof. In particular, they are prone to publication bias (negative trials may remain unpublished and this could distort the conclusions of systematic reviews) and to poor quality of primary data (if most studies of a systematic review are flawed, its results will be unreliable). SRs are also powerful tools for identifying gaps in our current knowledge that, in turn, can stimulate researchers to fill these gaps.

The same standards of quality must be used for CAM and for mainstream medicine. A double standard situation is not acceptable. Systematic reviews are a useful exercise because they demand the application of the same standard of quality and for evidence on all the reviewed studies.

### 8.1. Systematic review of CAM in breast cancer

A recent paper reviewing RCTs studying the cost-effectiveness of CAM across all medical conditions revealed only 5 studies with rigorous design, and came up with rather equivocal answers.<sup>46</sup> A more focused study by Ernst and colleagues has looked specifically at RCTs of treatment aimed at curing or prolonging the life of patients with breast cancer.<sup>47</sup>

They identified 13 RCTs that met their inclusion criteria.<sup>42-59</sup> The trials were published between 1978 and 2004. In most cases the reviewers judged the methodological quality of the trials to be low, with only 2 RCTs scoring 4<sup>55,60</sup> and 4 RCTs scoring 3<sup>50,54,58,59</sup> out of 5 possible points on the Jadad score.<sup>61</sup> One RCT was published in abstract form only,<sup>52</sup> and therefore no validity and methodological quality assessments were possible. Frequent weaknesses were lack of power or sample size calculations, small sample size, lack of adequate randomisation or (patient and/or assessor) blinding, and insufficient length of follow-up. Only 1 RCT applied an intention-to-treat analysis.<sup>59</sup> The authors concluded that the totality of the data failed to identify a single effective CAM intervention in the treatment of breast cancer.

We feel that, should a promising treatment one day emerge, it should be investigated without delay by oncologists and adopted into routine care as soon as the data supporting its use are sufficiently strong. For example, plant-based cancer medications, such as vincristine and vinblastine (both extract from the plant *Vinca rosea*) or taxol (*Taxus baccata*) are already in routine use.

CAM for treatment of cancer (for which there is, to the best of our knowledge, no evidence of efficacy) and CAM for supportive care of cancer patients, must be clearly separated in our thinking. In the latter area encouraging evidence emerges, for instance acupuncture and progressive muscle relaxation for chemotherapy-related nausea and vomiting,<sup>62,63</sup> acupuncture for xerostomia,<sup>64</sup> aromatherapy for decreasing anxiety and increasing QoL,<sup>65,66</sup> guided imagery for increasing comfort and psychosocial support,<sup>67-69</sup> exercise for the management of chronic fatigue,<sup>70</sup> *Calendula officinalis* for the prevention of dermatitis during radiotherapy<sup>71</sup> and mistletoe extract for the improvement of QoL during chemotherapy.<sup>72</sup>

## 9. Conclusion

This paper was written as a review and by way of setting the scene for the formal guidelines presented in the short accom-

panying paper. The views expressed in this paper are those of the authors themselves, as it proved extremely difficult for all members of the workshop to reach a consensus on the current state of affairs, yet paradoxically it was easy to reach a consensus on the directions we need to travel together in the future. But one thing we all accept is that practitioners of conventional medicine and of CAM are working in good faith to improve the length and QoL for women with breast cancer. The way forward is to build bridges between the cultures based on the guidelines published in the annex. We choose to describe this as a consensual rather than an integrative approach.

## Conflict of interest statement

None declared.

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