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Position Paper

The role of complementary and alternative medicine in the management of early breast cancer: Recommendations of the European Society of Mastology (EUSOMA)

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ABSTRACT

Patients diagnosed with breast cancer have many needs that for a start include the expectation of cure. Where cure is unlikely there is always a place for hope and spiritual support. Furthermore whether dealing with the early stages or with the advanced disease patients require symptomatic control that encompasses pain relief, control of nausea and vomiting and psychological distress.To achieve all of these goals there is a need that goes beyond the role of scientific medicine. This position papers describes the guidelines for the use of complimentary and alternative medicine (CAM) developed by a workshop on behalf of the European Society of Mastology (EUSOMA).

1. Needs of breast cancer patients

Patients diagnosed with breast cancer have many needs, which may include the expectation of cure. Where cure is unlikely there is always a place for hope and spiritual support. Furthermore, whether dealing with the early stages of cancer or with the advanced disease, patients require symptomatic control that encompasses pain relief,

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and control of nausea, vomiting and psychological distress.

Collaboration with a team that may include doctors, nurses and practitioners in professions complementary to medicine may help the patient feel better and improve their quality of life.

1.1. *Recommendation 1*

All patients with breast cancer should be treated by multidisciplinary teams that provide the best chances of cure, palliation, psycho-social and spiritual support.

2. Semantics and definitions of CAM

The working group tried to reach agreement about the correct terminology to describe complementary and alternative medicine (CAM). Table 1 illustrates the complexity of the subject. It was decided to adopt CAM as useful shorthand and alert readers to be vigilant, since the meaning of words can be context-dependent and evolve over time by common usage. Furthermore, whatever words are used, one must not forget that, for some patients, the language employed may reflect in a positive or negative manner on their hopes and wishes.

2.1. *Recommendation 2*

Care must be used in the use of words that may have double meanings or that evolve over time, in order to encourage a dialogue between the 'two cultures' and to make clear to the patient the objectives of any intervention. Although far from perfect, the use of 'CAM' is useful shorthand.

3. How can we address the unmet needs of cancer patients?

The enormous emotional impact of the disclosure of a diagnosis of cancer can result in fear, confusion and isolation. 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. We welcome the developments in the undergraduate and postgraduate curricula designed to teach professional development and communication skills.

At the same time, CAM practitioners, many of whom are members of the medical profession [1], need to recognise the efforts and achievements of conventional medicine. These extend not merely to more humane, empathetic and holistic clinical practice, but also include the development of user-friendly instruments capable of measuring all the domains of quality of life, both in the corporeal and spiritual spheres that are judged important by the patient herself. It is also a plausible hypothesis that if the patient feels better and spiritually at ease then this might help her physical recovery via psycho-neuro-endocrine or immunological pathways. This is another area worthy of research.

3.1. *Recommendation 3*

- Undergraduate and postgraduate students should be taught communication skills as a central component of professional development.
- Health professionals should work together with the use and development of 'psycho-metric' instruments in order to capture, evaluate and ultimately enhance quality of life in both the physical and spiritual domains.

Table 1 – Popular understandings of complementary and alternative medicine terms in common usage

Alternative cancer medicine	• Treatment not offered within conventional cancer care. • Treatments with a theoretical basis, which, in part or totally, is incongruent with the common scientific model. • Treatment intended as an alternative to conventional medical cancer treatment, without accepted evidence for its efficacy.
Complementary cancer medicine	• Supportive treatment that complements conventional cancer medicine.
Holistic medicine	• Medicine aimed at treating the whole patient in body, mind, and spirit. • Medicine that recognises the hierarchical structure of the human body organised in units of increasing complexity (holons) from the cell to the person.
Integrated medicine	Medicine that: • Integrates the care of body, mind, spirit and environment of the patient. • Integrates all modalities of medicine orthodox, complementary, alternative, self-help and psycho-spiritual. • Integrates the efforts of the patient to help herself. • Transcends the orthodox/alternative divide, reflecting the patients wish for a non-polarised form of medicine (probably better under 'holistic medicine').
Healing	Healing includes; • Physical healing of the body and remission of physical illness. • Emotional healing with recovery from shock, grief and past hurts with the achieving of emotional balance and a positive mental attitude. • 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.

4. 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'. 'Believers', in addition to their access to the arts, gain this through 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. Health services should offer access to appropriate support through appropriate staff, such as psychologists, members of the clergy, counsellors and spiritual 'healers'. We need to provide generic guidelines for oncologists on how to deal with these aspects, how to refer patients and to whom? Safeguards should also be available in order to guarantee patient safety towards the exploitation of patient distress by any sectarian movement or 'guru'. Oncologists cannot operate in this area alone and there are many aspects of a patient's life that should not be part of an institutionalised health service.

4.1. *Recommendation 4*

All health professionals should be taught about the needs of patients for spiritual support, and access to these services should be facilitated within the health services.

5. Current and future status of research into the efficacy of CAM

The popularity of CAM is illustrated by the fact that large numbers of patients subscribe to it. In part, this might be a result of the unmet needs described above, or simply by the 'feel-good' factor the therapies might induce, which is another expression of the same. However, of greater concern is the suspicion that some proponents of CAM are offering interventions that claim to influence the natural history of the disease. The medical profession is entitled to remain sceptical about some of the claims, but needs to remain circumspect about claims that do not depend on conceptual models that are incompatible with the modern understanding of life sciences. For example many active anti-cancer agents, such as the vinca alkaloids and the taxanes, were developed from botanicals. Whether the outcome measure is for the patient to feel better or to develop better research, methodology exists that is sufficient to evaluate all types of interventions in an even-handed way, irrespective of the provenance of the therapy being tested.

In the broadest terms there are three categories of research design involving cancer patients. 'Qualitative research', which attempts to capture the individual patient's experience, to understand their needs and to develop hypothetical solutions to their problems. Phase I/II trials look for methods and dose of delivery and evidence of 'activity' of an investigational drug against a measurable tumour parameter. Finally, the randomised controlled trial (RCT) is set up to establish effectiveness, efficiency, harm/benefit trade-off and health economics related to the clinical use of an investigational drug. The RCT is sufficiently robust to cope with the extraordinary variability and unpredictability of breast cancer and to measure the outcomes of simple or complex interventions. The properly designed and conducted RCT can control for case mix, selection bias, observer bias and placebo effect, and is sufficiently malleable largely to accommodate the needs of CAM. For example, if the CAM intervention is aimed at improving quality of life 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. If the primary endpoint is not already covered by one of the instruments, for example in the spiritual domain, then it should be the responsibility of its proponents to develop a new instrument. Another problem that has to be accommodated concerns the individualisation of treatment, which is often judged an important component of CAM. Here again, an elegant design would allow randomisation of the 'individualised' intervention against a non-individualised 'one size fits all' treatment.

So far there is no persuasive evidence from RCTs that CAM interventions favourably influence the natural history of breast cancer. In contrast, a number of CAM interventions aimed at improving symptoms or quality of life are backed up by reasonably good evidence, e.g. acupuncture for nausea, aromatherapy for anxiety, exercise for fatigue, music therapy for quality of life, relaxation therapies for stress.[2]

Finally, as much as it is the responsibility of proponents of CAM critically to evaluate their favoured treatments, the medical profession has a responsibility to mentor, encourage and provide the infrastructure for this type of research.

The National Cancer Research Institute (NCRI) in the UK has now established such a process that works via two study groups: the Psycho-Social Study Group (NCRI PSOSG) and the CAM study group (NCRI CAMSG).

5.1. *Recommendation 5*

- There can be only one standard for the evaluation of interventions to improve the length and quality of survival of patients with breast cancer irrespective of the type and origin of the treatments. Modern scientific methodology can accommodate both simple and complex interventions with outcome measures that are meaningful to the patient herself.
- Modules/lectures about evidence-based CAM should be added to the curricula

6. Duty of care

Finally, all doctors have a duty of care to protect their patients from claims that encourage patients to abandon established beneficial therapies. This duty of care extends to recognising adverse interactions between different medicines that might be taken concurrently. To facilitate

this, all clinical history-taking should include a module on the current or past use of CAM, and this should lead to the inclusion/exclusion criteria or stratification of clinical trials of conventional medicine. Patient's belief systems have to be respected, yet at the same time it is the doctor's duty to alert patients if their belief systems might be a hazard to their length or quality of survival.

6.1. *Recommendation 6*

Clinical case histories and RCTs should contain a module that identifies patient's belief systems and concurrent use of CAM and there should be open and factual discussions between patients and healthcare professionals about CAM.

Conflict of interest statement

None declared.

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