



COMPLEMENTARY AND ALTERNATIVE MEDICINE INNOVATION AND ADDED VALUE FOR EUROPEAN HEALTHCARE

This was the title of a one-day conference held in Brussels at the European Parliament on 9 October 2012. This was the first conference on Complementary and Alternative Medicine (CAM) held at the European institutions. It was accompanied by a three-day exhibition in the Parliament buildings that included posters illustrating several CAM therapies, stands providing publications and information on access and use of the modalities together with live demonstrations of reflexology and shiatsu.

The conference and exhibition were organised by EUROCAM, the European stakeholder group of European umbrella organisations of patients, physicians and practitioners working in CAM. The conference was co-funded by the European Commission, the Robert Bosch Stiftung and the CAM associations of EUROCAM, supported by sponsorship from industry.

Members of the European Parliament, health professionals, health NGO representatives, patients and policy makers attended to hear and debate presentations on the innovative added value of CAM for European Healthcare. The Conference highlighted the capacity of CAM to maintain health, prevent ill-health, offer therapeutic options in common chronic conditions not particularly well treated with conventional medicine, promote healthier lifestyles and contribute to the sustainability of health systems. For these reasons, the Conference concluded that the benefits of CAM should not be disregarded by the European Union at a time when health funding is under so much pressure from economic and demographic pressures.

Executive summary of the presentations¹

Complementary and Alternative Medicine (CAM) is an innovative practice because

- It goes well beyond symptom resolution, enabling patients to understand how they may take control of their health and make active choices to improve and support their well-being.
- It combines individualised, holistic care with the active participation of the patient.
- It promotes healthy lifestyles, illness prevention and an understanding of the principles of maintaining good health e.g. a balanced diet, regular exercise and a good work/life balance.
- It can be used in conjunction with conventional care to the mutual benefit of both forms of treatment, adding to the range of treatment options for a person with an acute or chronic condition.

Research that investigates users' subjective experience of CAM demonstrates that citizens find CAM to be a safe, 'non-invasive' and 'non-polluting' treatment for chronic diseases, to be more whole-person oriented than conventional treatment, to support 'things you can do yourself' to improve your health, to alleviate symptoms and to enhance well-being and quality of life.

Whereas the evidence base of major mainstream medical treatments is less firm than generally thought, there is a growing body of scientific evidence for the effectiveness of CAM therapies in alleviating illnesses that are responsible for a majority of medical costs in Europe, e.g. cancer, heart disease and chronic pain conditions. CAM provision appears relevant for these important health areas.

Chronic, moderate-to-severe, pain affects almost one in five adults across Europe. A multidisciplinary outpatient programme in complementary and alternative medicine employed traditional Chinese medicine and naturopathy to treat patients suffering chronic pain simultaneously reinforcing patients' confidence, self-understanding and self-responsibility. This programme demonstrated that CAM can be effective as part of an interprofessional approach for the management of chronic pain that also reduces hospitalisations and the cost of medicines and medical procedures.

A recent systematic review of economic evaluations of complementary and integrative medicine demonstrated that these cost-utility analyses were of similar or better quality to those published about other aspects of medicine pointed to the potential cost-effectiveness and cost savings of a number of CAM therapies.

Integrated patient-centred healthcare sets the patient at the heart of the process, so that the patient is an integral part of the care team. The emphasis is on self-care and shared care, on prevention and early intervention, and on maximising the possibilities of treatment using a wide range of safe and effective approaches including CAM. A primary

¹ References can be found in the main text of the presentations

healthcare professional who knows the patient well is ideally positioned to coordinate care with a team of CAM practitioners to address the mind, body, and spiritual needs of the patient. Such a system may provide higher quality health care, improve patients' experiences and increase the effectiveness of treatment whilst reducing treatment time.

CAM offers an innovative, whole system approach to chronic disease management, because it focuses on health promotion and salutogenesis that combines well with biomedicine's approach to fighting disease and emphasis on pathogenesis.

Two resolutions of the WHO World Health Assembly have urged Member States, to formulate national policies, regulations and standards, to promote appropriate, safe and effective use of traditional medicine/CAM, to consider including traditional medicine/CAM into their national health systems, to further develop traditional medicine/CAM based on research and innovation and to consider establishing systems for the qualification, accreditation or licensing of traditional medicine/CAM practitioners.

Call for Action

The conference made a Call for Action asking the European Commission, inter alia:

- *to promote equitable access by citizens to Complementary and Alternative Medicine (CAM) in all Member States.*
- *to include CAM in all possible Community Actions dealing with health education and promotion, prevention and treatment of chronic disease, health inequalities, and active and healthy ageing.*
- *to encourage Member States to explore the ways in which CAM can contribute to sustainable healthcare systems in Europe including its role in health maintenance, health education, self-responsibility for health, motivation for healthy lifestyle change and less invasive and more cost-effective treatment of illness.*
- *to propose the requisite draft directives, or amendments to existing directives, to ensure freedom of establishment and freedom to provide services for providers of CAM.*
- *to ensure that the management of the programmes of the Commission – such as the Health for Growth, Horizon 2020, European Innovation Partnership on Healthy and Active Aging and other relevant programmes – gives an equitable opportunity to CAM projects to participate.*

[Please refer to the separate 'Call for action' document for the full version]

CONTENT OF THE VARIOUS PRESENTATIONS

1. Introduction to CAM: An Innovative Healthcare Practice

by *Andrew Long*, Professor of Health Systems Research, University of Leeds, United Kingdom.

The central concepts of Complementary and Alternative Medicine are self-healing, holism [a 'whole health' approach to health] and individualised diagnosis and treatment. Its core goal is to assist the individual in uncovering and mobilising their own healing potential and in opening her/him up to the possibility of change.

Illness is considered as a general imbalance within the body (e.g. energy, toxins). CAM assists in the recognition of such imbalances, promotes change to address these and helps the individual to become more aware of their own health and ways to sustain health and well-being.

CAM focuses on the individual within and also as part of the socio-economic and cultural context of their life (holism). Treatment centres on the whole person, body, mind, and spirit, within their own their environment. The practitioner-client interaction is a participatory relationship in which the individual plays an active role in sustaining her/his own health and wellbeing. The desired outcomes are to resolve initial symptoms, to raise the individual's awareness and understanding of their own body, factors affecting this, in the context of their own life situation (advice giving), and to support and empower the individual in maintaining good health and good health practices.

There is an emerging evidence base of the benefits of particular CAM modalities, their effectiveness and safety. There is increasing recognition of the importance of patient-reported benefits, embracing the 'whole effect' of the CAM modality and aspects beyond symptom change. By contrast, there is a varying picture of recognition of CAM and its benefits by medical practitioners, as well as hesitancy or avoidance by their patients to 'tell' about their CAM use or ask about its possible benefits in treating the illness. In addition legal status of CAM in Europe varies for one EU member state to the other.

CAM is provided by either a CAM practitioner, formally trained in a particular modality or a conventional medical practitioner additionally trained in a particular modality. Citizens may also use 'over the counter' CAM products (herbal or homoeopathic remedies or nutritional supplements, vitamins, etc) and self care (diet, lifestyle changes following CAM provider's advice). Predominantly, the individual pays her/himself for CAM although there is some cover via sickness funds or private health insurance. Commonly, individuals seek out and access a particular CAM modality and CAM practitioner (rather than from CM recommendation). CAM may be provided to an individual and/or pro-actively used by an individual as a part of her/his own self-care, self-pay and self-access.

CAM practitioners actively promote their particular modality and associated treatments as addressing/helping with the symptoms of particular conditions, by trying to get to the root of the problem, by enabling the individual to gain greater control over their health, and thus by maintaining and promoting health and well-being.

CAM is an innovative practice because

- it enhances critical health literacy²
- it goes far beyond symptom resolution, onto increasing self-awareness about how the individual lives her/his life and (re-) gaining greater control *and* making active choices to support her/his own health and well-being
- it combines individualised, holistic care and engagement with client
- it enables health maintenance and health promotion, illness prevention and enhances critical health literacy
- it can be used in conjunction with conventional care, thus, adding to the range of treatment options for a person with an acute or chronic condition.

2. Use of CAM and patients' motivations for it

by *Helle Johannessen*, Professor of Social Studies in Health and Medicine, Institute of Public Health, Faculty of Health Sciences, University of Southern Denmark, Denmark.

There is no definitive or accepted estimate of use of CAM across Europe. Survey data show prevalence rates ranging from 3-85% with wide variability in specific countries and for CAM modalities. This wide variability is also due to the lack of a consistent definition of CAM. Is 'a cup of herbal tea' CAM or is acupuncture CAM when provided by someone's GP? Do people use CAM if they take 'natural' vitamins or if they give themselves the treat of a monthly massage?

The examples of Denmark and Tuscany (Italy) demonstrate the variability. In Denmark CAM treatments can be legally provided by non-authorized persons outside the public health care system and these treatments are called 'Alternative treatment'. In Italy (Tuscany) only doctors have the legal right to give curative treatments to the sick; yet their CAM treatment does not have official recognition, it is called 'non-conventional medicine'; CAM treatments which are recognized officially, are called 'complementary medicine'.

In Tuscany, 17% of cancer patients use some form of CAM. They expect and experience CAM improves physical wellbeing and helps them get relief from the adverse effects of chemotherapy. In Denmark approx. 50 % use some form of CAM. They expect and experience CAM improves physical and emotional wellbeing, relieves the adverse effects of chemotherapy, and prevents future relapses of cancer.

Citizens' motivations for CAM use in Europe may vary according to the local situation of CAM, but some general patterns can be found

- to treat chronic diseases – not always in the expectation to be cured, but in any case to keep its symptoms more comfortable and slow development
- to treat – recurrent – minor diseases (colds, infections, etc)
- to enhance quality of life and general wellbeing.

² Health literacy is the individual's capacity to contextualise health knowledge for his or her own good health, to decide on a certain action after a full appraisal of what that specific action means for them in their own world (Rubinelli et al 2009).

Research that investigates users' subjective experience and evaluation of 'CAM' demonstrates that citizens find CAM to be a safe, 'non-invasive' and 'non-polluting' treatment for chronic diseases, to be more whole-person oriented than conventional treatment, to support 'things you can do yourself' to improve your health, to reduce symptoms, to improve well-being and support quality of life.

3. Evidence base and effectiveness of Complementary and Alternative Medicine

by *Gustav Dobos*, Professor of Internal Medicine, Chair of Complementary and Integrative Medicine, University of Duisburg-Essen, Germany.

The basic principle of CAM is the stimulation of the self-healing ability of the body within the bio-psycho-social context of the person. CAM methods include Naturopathic Medicine (e.g. Kneipp), and other whole system approaches. These have long clinical experience, are mostly safe and often beneficial.

The current prevailing paradigm within the medical community is evidence-based medicine (EBM). According to David Sackett (1996), the founding father of EBM, it is based on 3 pillars, namely

- external evidence (scientific research including randomized-controlled trials, RCTs)
- internal evidence (experience of the physician)
- patients' preferences.

Although the second and third pillars are as important as the first one, EBM is often narrowly restricted to external evidence only, and more specifically RCTs. However, RCTs are typically designed to provide evidence of 'efficacy' of a new agent, where 'efficacy' refers to the extent to which a specific intervention is beneficial under 'ideal' trial conditions. Efficacy is defined as ultimate proof that the agent has a therapeutic effect. The highest level of evidence (1A) is the positive meta-analysis of a number of RCTs. On the other hand, 'effectiveness' is a 'measure of the extent to which a specific intervention when deployed in the field of routine care does what it is intended to do for a specific population.

This presentation focuses on CAM-based Mind-Body Medicine and Lifestyle Change, including health maintenance, health promotion, health literacy and prevention in illnesses that are responsible for a majority of medical costs in Europe, i.e. cancer, heart disease, and chronic pain conditions³.

Cancer

The state of evidence in oncology is described in a recent study by Poonacha & Go as "the level of scientific evidence underlying recommendations arising from the National Comprehensive Cancer Network clinical practice guidelines⁴. Its conclusion is "Of the 1,023 recommendations found in the 10 guidelines, the proportions of category I, IIA,

³ World Economic Forum and the Harvard School of Public Health (2011) The Global Economic Burden of Non-communicable Diseases. See www.weforum.org/EconomicsOfNCD

⁴ Poonacha TK, Go RS (2011). Level of scientific evidence underlying recommendations arising from the National Comprehensive Cancer Network clinical practice guidelines. *Journal of Clinical Oncology*, 29(2):186-191.

IIB, and III EC were 6%, 83%, 10%, and 1%, respectively. Recommendations issued in the NCCN guidelines are largely developed from lower levels of evidence but with uniform expert opinion. This underscores the urgent need and available opportunities to expand the evidence base in oncology". So, only **6% of evidence** fell into category I, i.e. a high level of evidence such as RCTs with uniform consensus.

When focusing on prostate cancer, the most common cancer in men, Wilt et al (2012)⁵ demonstrated that "radical prostatectomy did not significantly reduce all-cause or prostate-cancer mortality, as compared with observation, through at least 12 years of follow-up". Urinary incontinence (17.1 vs 6.3%) and erectile dysfunction (81.1 vs 44.1%) were significantly more common among men who underwent radical prostatectomy.

Intensive lifestyle changes – i.e. combining fat-free diet, regular exercise and stress reducing procedures –, however, demonstrated by a study by Ornish et al (2005)⁶ reduces significantly the number of necessary operations and radiotherapy in men with prostate cancer. Furthermore, Ornish et al (2008) demonstrated that mind-body medicine⁷ and lifestyle change can modulate gene expression in the prostate of men with prostate cancer⁸ and significantly reduce PSA levels. 48 up-regulated and 453 down-regulated transcripts after the intervention were detected.

Heart disease

The level of evidence in cardiology is described in a recent study by Tricoci et al (2009)⁹, "Scientific evidence underlying the ACC/AHA¹⁰ clinical practice guidelines". Its conclusion is "Considering the 16 current guidelines reporting levels of evidence, only 314 recommendations of 2711 total are classified as level of evidence A (median, 11%), whereas 1246 (median, 48%) are level of evidence C". And "Recommendations issued in current ACC/AHA clinical practice guidelines are largely developed from lower levels of evidence or expert opinion. The proportion of recommendations for which there is no conclusive evidence is also growing. These findings highlight the need to improve the process of writing guidelines and to expand the evidence base from which clinical practice guidelines are derived." So, only **11%** fell in category A, i.e. a high level of evidence such as RCTs with uniform consensus.

⁵ Wilt TJ et al (2012). Radical prostatectomy versus observation for localized prostate cancer. Prostate Cancer Intervention versus Observation Trial (PIVOT) Study Group. New England Journal of Medicine, 367(3):203-213.

⁶ Ornish D, et al. (2005) Intensive lifestyle changes may affect the progression of prostate cancer. The Journal of urology, 174:1065–1069;

⁷ Mind-body medicine includes interventions, using a variety of techniques designed to facilitate the mind's capacity to affect bodily function and symptoms. These techniques include: nutrition, exercise, relaxation and mindfulness, stress management, cognitive restructuring and social support.

⁸ Ornish D et al (2008). Changes in prostate gene expression in men undergoing an intensive nutrition and lifestyle intervention. Proceedings of the National Academy of Science of the USA, 105(24):8369-8374.

⁹ Tricoci P et al (2009) Scientific evidence underlying the ACC/AHA clinical practice guidelines. Journal of the American Medical Association (JAMA), 301(8):831-41.

¹⁰ ACC/AHA are the American College of Cardiology and the American Heart Association resp.

When focusing on stable coronary artery disease, a meta-analysis of randomized controlled trials by Stergiopoulos and Brown (2012)¹¹ demonstrated that initial stent implantation for stable coronary artery disease has no evidence of benefit compared with initial medical therapy for prevention of death, nonfatal myocardial infarction, unplanned revascularization, or angina. According to Tricoci et al. only 6.4% of the current ACC/AHA guidelines for stable angina (coronary artery disease) are classified as level of evidence A.

Yusuf et al. (2004)¹² found that stress and factors of lifestyle – abnormal lipids, smoking, hypertension, diabetes, abdominal obesity, psychosocial factors, low consumption of fruits, vegetables, high levels of alcohol, and low levels of regular physical activity – account for 90% (men) and 94% (women) of risk factors for myocardial infarction. A treatment programme that focuses on these factors does not only play an important role in prevention, it can also improve existing coronary heart disease. Compared with percutaneous coronary intervention (PCI) with stenting, Hambrecht et al (2004)¹³ demonstrated that a 12-month program of regular physical exercise in selected patients with stable coronary artery disease resulted in superior event-free survival and exercise capacity at lower costs, notably owing to reduced rehospitalizations and repeat revascularizations. The Lyon Diet Heart Study¹⁴ demonstrated that the protective effect of the Mediterranean dietary pattern was maintained up to 4 years after the first infarction. Horne et al (2008)¹⁵ found that routine periodic fasting is associated with lower risk of coronary artery disease. The Safe-Life study reported by Michalsen et al (2005 and 2006)¹⁶ demonstrated that comprehensive lifestyle modification “improves autonomic function, angina, and quality of life with concomitant reduced need of medication.”

Ornish et al demonstrated that intensive lifestyle changes (10% fat, whole foods, vegetarian diet, aerobic exercise, stress management training, smoking cessation, group

¹¹ Stergiopoulos K, Brown DL (2012). Initial coronary stent implantation with medical therapy vs medical therapy alone for stable coronary artery disease: meta-analysis of randomized controlled trials. *Archives of Internal Medicine*, 172(4):312-319.

¹² Yusuf S et al (2004). Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. *Lancet*, 364(9438):937-952.

¹³ Hambrecht R et al (2004) Percutaneous coronary angioplasty compared with exercise training in patients with stable coronary artery disease: a randomized trial. *Circulation*, 109(11):1371-1378.

¹⁴ de Lorgeril M et al. (1999) Mediterranean diet, traditional risk factors, and the rate of cardiovascular complications after myocardial infarction: final report of the Lyon Diet Heart Study. *Circulation*, 99(6):779-785.

¹⁵ Horne BD et al (2008). Usefulness of routine periodic fasting to lower risk of coronary artery disease in patients undergoing coronary angiography. *American Journal of Cardiology*, 102(7):814-819.

¹⁶ Michalsen A et al (2005) Psychological and quality-of-life outcomes from a comprehensive stress reduction and lifestyle program in patients with coronary artery disease: results of a randomized trial. *Psychotherapy and psychosomatics*, 74(6):344-352.

Michalsen A et al (2006). Effects of lifestyle modification on the progression of coronary atherosclerosis, autonomic function, and angina--the role of GNB3 C825T polymorphism. *American Heart Journal*, 151(4):870-7.

psycho-social support) can stop and even reverse the progression of coronary heart disease without drugs or invasive surgical procedures such as arterial bypasses or angioplasty¹⁷, and lead to a considerable reduction in low-density lipoprotein (LDL) cholesterol levels and an over 90% reduction in the frequency of anginal episodes. The experimental group showed even more regression of coronary atherosclerosis after 5 years than after 1 year as measured by percent diameter stenosis. In contrast, patients following more conventional lifestyle recommendations showed even more progression of coronary atherosclerosis after 5 years than after 1 year, and had more than twice as many cardiac events as patients making comprehensive lifestyle changes. This approach costs about \$7,000 (€ 5,500) per patient, which is only a fraction of the costs for cholesterol-lowering, anti-hypertensive and anti-anginal medications, which may amount to thousands of Euros per year or tens of thousands Euros for life, assuming that the patient lives thirty or forty more years, let alone the costs for coronary bypass surgery and angioplasty (also tens of thousands of Euros).

Chronic Pain conditions

Osteoarthritis of the knee is a major cause of disability among adults worldwide. Many patients report symptomatic relief after undergoing arthroscopy of the knee for osteoarthritis, but a randomised clinical trial had never been conducted until 2002. Moseley et al (2002)¹⁸ demonstrated that the outcomes after arthroscopic lavage or arthroscopic débridement were no better than those after a placebo procedure. A Cochrane database of systematic reviews on this intervention¹⁹, included the Mosely study and two other RCTs and concluded that “there is 'gold' level evidence that arthroscopic débridement has no benefit for undiscriminated osteoarthritis (mechanical or inflammatory causes). Another Cochrane Database of Systematic Reviews²⁰ which included also studies on non-arthroscopic lavage concluded that “joint lavage does not result in a relevant benefit for patients with knee osteoarthritis in terms of pain relief or improvement of function”.

When looking at evidence for CAM modalities in osteoarthritis of the knee, randomized

¹⁷ Ornish D et al.(1990) Can lifestyle changes reverse coronary heart disease? The Lifestyle Heart Trial. *Lancet*, 336(8708):129-133.

Ornish D et al (1998). Intensive lifestyle changes for reversal of coronary heart disease. *Journal of the American Medical Association*, 280:2001–2007.

Pischke CR et al (2008). Long-term effects of lifestyle changes on well-being and cardiac variables among coronary heart disease patients. *Health Psychology*, 27:584-59

Govil SR et al (2009). Socioeconomic status and improvements in lifestyle, coronary risk factors, and quality of life: the Multisite Cardiac Lifestyle Intervention Program. *American Journal of Public Health*, 99:1263-1270.

¹⁸ Moseley JB et al (2002). A controlled trial of arthroscopic surgery for osteoarthritis of the knee. *New England Journal of Medicine*, 347(2):81-88.

¹⁹ Laupattarakasem W et al (2008) Arthroscopic debridement for knee osteoarthritis. *Cochrane Database of Systematic Reviews*, 23:CD005118.

²⁰ Reichenbach S et al (2010). Joint lavage for osteoarthritis of the knee. *Cochrane Database Systematic Reviews*, (5):CD007320.

controlled clinical trials can be found with positive evidence for acupuncture²¹, exercise²², leech therapy²³ and tai chi²⁴.

It can be concluded that the evidence base of major mainstream medical treatments is weaker than generally thought, whereas there is some scientific evidence for the effectiveness of CAM therapies in illnesses that are responsible for a majority of medical costs in Europa, i.e. cancer, heart disease, and chronic pain conditions. This means that CAM might be relevant for these important health areas.

4. Costs and cost-effectiveness of Complementary and Alternative Medicine

by *Claudia Witt*, Professor of Medicine, Institute of Social Medicine, Epidemiology, and Health Economics, Charité University, Berlin, Germany.

Economic evaluation of CAM therapies are important because there are limited financial resources in health care, CAM is often used in addition to conventional medicine, and the question is whether integration into the health care system is justified.

Possible cost savings on provider level

- China: TCM hospital outpatient and inpatient costs are around 30% lower than in conventional hospital²⁵
- UK: (3 case studies of integrative care): 30% less GP visits, 50% reduced drug bill²⁶
- Netherlands: patients whose GP has additional CAM training have up to 30% lower healthcare costs²⁷

Careful interpretation of economic analyses shows that outcomes and costs vary widely depending on treatment and context. There are various types of economic analyses, some of them dealing with the cost of diseases, others are full economic analyses in which different treatments are compared or costs and benefits are described. Interventions with better outcomes and lower costs are easily accepted, those with better outcomes and higher costs need a thorough cost-effectiveness analysis.

²¹ Witt C et al (2005). Acupuncture in patients with osteoarthritis of the knee: a randomised trial. *Lancet*, 366(9480):136-143.

²² Beckwée D et al (2012). Osteoarthritis of the knee: Why does exercise work? A qualitative study of the literature. *Ageing Research Reviews*, 12(1):226-236.

²³ Michalsen A et al (2003). Effectiveness of leech therapy in osteoarthritis of the knee: a randomized, controlled trial. *Annals of Internal Medicine*, 139(9):724-730.

²⁴ Brismée JM et al (2007). Group and home-based tai chi in elderly subjects with knee osteoarthritis: a randomized controlled trial. *Clinical Rehabilitation*, 21(2):99-111.

²⁵ Report of the WHO interregional workshop on the use of traditional medicine in primary health care, Ulaanbaatar, Mongolia, 23-26 August 2007

²⁶ Smallwood C (2005). The role of Complementary and Alternative Medicine in the NHS – an investigation into the potential contribution of mainstream complementary therapies to healthcare in the UK.

²⁷ Kooreman P, Baars EW (2011) Patients whose GP knows complementary medicine tend to have lower costs and live longer. *European Journal of Health Economics*, DOI 10.1007/s10198-011-0330-2

A recent comprehensive systematic review of economic evaluations of complementary and integrative medicine (CIM) to establish the value of these therapies, by Herman et al²⁸ identified 338 economic evaluations, 204 of which were published recently (2001–2010) covering a wide range of CIM therapies for a variety of populations. Therapies included were manipulative/body practices, acupuncture, natural products, mind-body medicine and homeopathy. The authors conclude that cost-utility analyses were of similar or better quality to those published across all medicine and that the higher-quality studies indicate potential cost-effectiveness, and even cost savings across a number of CIM therapies and populations. Of the 56 comparisons made in these studies, 16 (29%) are cost saving—that is, the added CIM therapy had better health outcomes and lower costs than usual care alone. The long-term economic impact is not known, but aspects such as life style change could have a positive economic impact over the long-term.

5. Complementary and Alternative Medicine in health promotion and disease prevention by *Simona Dragan*, Professor of Preventive Cardiology and Rehabilitation, Victor Babes University of Medicine and Pharmacy, Timisoara, Romania.

According to the European Guidelines on cardiovascular disease prevention in clinical practice (version 2012)²⁹ there is strong evidence of a direct relationship between three major psychosocial risk factors and cardiovascular disease. Depression, social isolation and anger/hostility all boast a significant database. The guidelines conclude that “multimodal behavioural interventions, integrating health education, physical exercise and psychological therapy for psychosocial risk factors and coping with illness, should be prescribed”. Despite the evidence linking psychosocial risk factors and heart disease, most patients choose the combination of statins, and stents over psychotherapy to change their lifestyle³⁰.

A recent systematic review and meta-analysis of randomized controlled trials on lifestyle modification programmes for patients with coronary heart disease³¹ confirmed the benefits of these programmes - over and above benefits achieved by routine clinical care alone. Lifestyle modification programmes were associated with reduced all-cause mortality, cardiac mortality, and cardiac readmissions and non-fatal re-infarctions. Furthermore, lifestyle modification programmes positively affect risk factors and related lifestyle behaviours post-treatment, and some of these benefits were maintained at long-term follow up. Improvements in dietary and exercise behaviour were greater

²⁸ Herman PM et al (2012). Are complementary therapies and integrative care cost-effective? A systematic review of economic evaluations. *BMJ Open*, 2:e001046.

²⁹ European Heart Journal, 2012, 33(13):1635-701
European Journal of Preventive Cardiology, 2012, 19(4):585-667

³⁰ Taylor J (2012). Psychosocial risk factors and heart disease. *European Heart Journal*, 33(10):1178-1179.

³¹ Janssen V et al (2012). Lifestyle modification programmes for patients with coronary heart disease : a systematic review and meta-analysis of randomized controlled trials. *European Journal of Preventive Cardiology*, Sep 28.[Epub ahead of print]

for programmes incorporating all four self-regulation techniques (i.e. goal setting, self-monitoring, planning, and feedback techniques) compared to interventions that included none of these techniques.

The chronic care model, a guide to higher-quality chronic illness management within primary care, predicts that improvement in its 6 interrelated components-self-management support, clinical information systems, delivery system redesign, decision support, health care organization, and community resources-can produce system reform in which informed, activated patients interact with prepared, proactive practice teams. Regarding whether chronic care model interventions can reduce costs, 18 of 27 studies concerned with 3 examples of chronic conditions (congestive heart failure, asthma, and diabetes) demonstrated reduced health care costs or lower use of health care services³².

Lifestyle changes (very low-fat vegetarian diet, stress-management training, exercise, group support, and smoking cessation) reduce the need for cardiac medications and improve CHD risk factors and quality of life³³. Tai Chi has been shown to be a suitable exercise for older persons to improve both cardiovascular function and muscle strength³⁴. Tai Chi added to endurance training is more effective than endurance training alone in improving exercise tolerance and quality of life (QOL) of elderly patients with chronic heart failure³⁵.

Diet is a major lifestyle factor in the primary and secondary prevention of numerous chronic diseases, including myocardial infarction, stroke, and diabetes. Epidemiological studies suggest that the beneficial cardiovascular health effects of diets rich in fruits and vegetables are in part mediated by their flavonoid content, with particular benefits provided by one member of this family, the flavanols³⁶.

Health literacy means that citizens should have access to reliable sources of information. On the other hand, physicians have both ethical and legal obligations to their patients,

³² Bodenheimer T, Wagner EH, Grumbach K (2002). Improving primary care for patients with chronic illness. *JAMA*, 288(14):1775-1779. Part 2 in *JAMA*, 288(15):1909-1914.

³³ Toobert DJ et al (2000). Physiologic and related behavioral outcomes from the Women's Lifestyle Heart Trial. *Annals of Behavioral Medicine*, 22(1):1-9.

³⁴ Lu X, Hui-Chan CW, Tsang WW (2012). Tai Chi, arterial compliance, and muscle strength in older adults. *European Journal of Preventive Cardiology* Apr 4. [Epub ahead of print]

³⁵ Caminiti G et al (2011) Tai chi enhances the effects of endurance training in the rehabilitation of elderly patients with chronic heart failure. *Rehabilitation research and practice* 2011:761958. Epub 2010 Sep 13.

³⁶ Heiss C et al (2010). Flavanols and cardiovascular disease prevention. *European Heart Journal*, 31(21):2583-2592.

Cherniack EP (2010). The potential influence of plant polyphenols on the aging process. *Forschende Komplementärmedizin*, 17(4):181-187.

Swaminathan JK et al (2010) Cardioprotective properties of *Crataegus oxycantha* extract against ischemia-reperfusion injury. *Phytomedicine*, 17(10):744-752.

Genser B et al (2012). Plant sterols and cardiovascular disease: a systematic review and meta-analysis. *European Heart Journal*, 33(4):444-451.

including the obligation to respect patient autonomy. This latter obligation extends to the use of CAM by patients and needs to be addressed beginning early in the patient-provider relationship. Discussing CAM with patients is the physician's responsibility, and such discussion will facilitate evidence-based, patient-centred cancer care³⁷.

The internet has a high impact on decisions and actions of the 60% of patients³⁸: who use online health information (e-patients)

- 60% say the information affected a decision about how to treat an illness or condition
- 53% say it led them to ask their physician new questions or to get a second opinion
- 49% say it changed the way they think about diet, exercise, or stress management
- 60% say they or someone they know has been helped.

Integrated patient-centred healthcare includes consideration of patients' cultural traditions, their personal preferences and values, their family situations, and their lifestyles. It makes the patient an integral part of the care team who collaborates with health care professionals in making clinical decisions. The emphasis is on self-care and shared care, on prevention and early intervention, and on maximising the possibilities of treatment using a wider range of safe and effective approaches including Complementary and Alternative Medicine. A primary healthcare professional who acts as a partner, knows the patient well, is able to address mind, body, and spiritual needs, and coordinates care with the help of a team of practitioners is at the centre. Collectively, the team can meet all the health needs of the particular patient and forms the patient-centered healthcare support network. Such a system may provide higher quality health care, improve patients' experiences and increase efficiency.

The Model for Aging Well (NRC data from 9000 surveys on QOL of older adults).

12 strengths grouped into three thematic categories: physical health, outlook on life and connection to others and the community.

Possible CAM therapies' contribution to increase strengths:

- Acupuncture, Osteopathy, Shiatsu, Massage, Naturopathy, Anthroposophy.
- Nutrition, physical activity, Relaxation techniques, Meditation, Spirituality.

Key factors such as promoting healthy diets, physical activities, social relations and meaningful activities are necessary for ageing healthily throughout a person's life. CAM can contribute to healthy ageing by:

- Improving health maintenance, health literacy and supporting self-care
- Prevention of illness
- Offering more personally and financially sustainable treatment methods for chronic diseases

³⁷ Verhoef MJ et al (2008). Talking to cancer patients about complementary therapies: is it the physician's responsibility? *Current Oncology*, Suppl 2:s88-93.

³⁸ Source: Pew Internet & American Life Project, accessible at <http://www.pewinternet.org/reports/2009/8-The-Social-Life-of-Health-Infoma/on.aspx>

6. Complementary and Alternative Medicine and chronic disease management

by Erik Baars, Professor of Anthroposophic Healthcare, University of Applied Sciences, Leiden, the Netherlands.

Europe has an ageing population with growing life expectancy, a growing prevalence of (multiple) chronic diseases, rising health care costs and a declining work force. Chronic diseases are the leading cause of mortality and morbidity in Europe: 77% of the disease burden (115 out of 150 DALYs³⁹) and 86% of all deaths in the WHO European Region is attributed to non-communicable (or chronic) diseases⁴⁰. Older people are not the only ones affected by chronic diseases. Rising numbers of young and middle-aged people have some form of chronic health problem 72% of all deaths before the age of 60 years in 2002 were due to chronic or non-communicable conditions in high-income countries. In the same year, 68% of DALYs lost to chronic diseases in high-income countries occurred among those of working age.

Given this background, the management of chronic disease is increasingly considered an important issue by policy-makers and researchers. Policy-makers across Europe are searching for interventions and strategies to tackle chronic disease.

In chronic disease management CAM fulfills the needs of a large group of EU citizens/patients. CAM can provide positive health outcomes and improvement of Quality of Life, and provide positive benefit/risk balances. In addition, CAM can result in lower healthcare costs, and is increasingly evidence-based. This is confirmed by the following research outcomes:

- *CAM use*

In several developed countries there is a relatively stable group of patients that use CAM⁴¹.

- *Sense of coherence*

The concept of sense of coherence (SOC) arose from the salutogenic approach, that is, the search for the origins of health rather than the causes of disease. The SOC gained widespread attention and has since been linked to health outcomes in many studies. The SOC is defined as: The extent to which one has a pervasive, enduring though dynamic, feeling of confidence that one's environment is predictable and that things will work out as well as can reasonably be expected. A strong sense of coherence is associated with a 30% reduction in mortality from all causes (rate ratio = 0.69, $p < 0.0001$), cardiovascular disease (rate ratio = 0.70, $p = 0.001$), and cancer (rate ratio = 0.74, $p = 0.003$), independent of age, sex, and prevalent chronic disease⁴².

³⁹ DALY, or Disability-Adjusted Life Year, quantifies the impact on a population of premature death and disability by combining them into a single measure. One DALY equals one year of healthy life lost.

⁴⁰ Busse et al (2010) Tackling chronic disease in Europe - Strategies, interventions and challenges. WHO on behalf of the European Observatory on Health Systems and Policies

⁴¹ Harris PE et al (2012). Prevalence of complementary and alternative medicine (CAM) use by the general population: a systematic review and update. *International Journal of Clinical Practice*, 66:924-939

⁴² Surtees et al (2003). Sense of coherence and mortality in men and women in the EPIC-Norfolk United Kingdom prospective cohort study. *Am J Epidemiol*; 158(12):1202-1209.

- *Acupuncture for chronic pain*

Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo⁴³.

- *Mistletoe treatment for cancer*

Mistletoe treatment is associated with better survival rates and quality of life, good safety and is therefore a reasonable referral option⁴⁴.

- *Mind-body interventions for essential hypertension*

Transcendental meditation and mindfulness-based stress reduction may produce clinically significant reductions in systolic and diastolic blood pressure and are therefore a reasonable referral option⁴⁵.

- *St. John's Wort for depression*

St. John's Wort for depression is associated with equal effects and fewer side effects than standard antidepressants and is therefore a reasonable referral option⁴⁶.

- *CAM and cost-effectiveness*

To explore the cost-effectiveness of CAM compared with conventional medicine, data from conventional GPs were compared with data from GPs with additional CAM training in acupuncture, homeopathy, or anthroposophic medicine. Patients whose GP has additional CAM training have 0–30% lower healthcare costs and mortality rates, depending on age groups and type of CAM. The lower costs result from fewer hospital stays and fewer prescription drugs⁴⁷.

As a conclusion, CAM offers an innovative approach to chronic disease management, because it is focused on

- health promotion, salutogenesis and sense of coherence approach in addition to the current fighting disease and pathogenesis approach.
- whole system approach, in addition to biomedical approach.

⁴³ Vickers AJ et al (2012). Acupuncture for Chronic Pain: Individual Patient Data Meta-analysis. Archives of Internal Medicine, Sep 10:1-10. doi: 10.1001/archinternmed.2012.3654.

⁴⁴ Kienle & Kiene (2010). Influence of Viscum album L (European Mistletoe) Extracts on Quality of Life in Cancer Patients: A Systematic Review of Controlled Clinical Studies. Integrative Cancer Therapies 9(2) 142–157. DOI:10.1177/1534735410369673

Ostermann et al (2009). Survival of cancer patients treated with mistletoe extract (Iscador): a Systematic literature review. BMC Cancer,9(1):451. DOI:10.1186/1471-2407-9-451

⁴⁵ Goldstein et al (2012). Current Perspectives on the Use of Meditation to Reduce Blood Pressure. International Journal of Hypertension, vol. 2012, Article ID 578397, 11 pages, 2012. doi:10.1155/2012/578397

⁴⁶ Linde et al (2008). St John's wort for major depression. Cochrane Database of Systematic Reviews 2008, Issue 4. Art. No.: CD000448. DOI: 10.1002/14651858.CD000448.pub3

⁴⁷ Kooreman P & Baars EW (2011). Patients whose GP knows complementary medicine tend to have lower costs and live longer. European Journal of Health Economics, DOI 10.1007/s10198-011-0330-2

EU research framework should invest in:

- Improvement of the quality of CAM for chronic disease & Integrative Medicine in clinical practice
- Improvement of the quality of research on CAM for chronic disease by conducting Comparative Effectiveness Research – leading to more evidence on added value of CAM for chronic disease management –, single-case methodology for further development of individualized diagnostics and treatment, and monitoring of safety
- Further development of whole system approach by clinical programmes,
- a European regulatory framework for medicinal products with a whole system background
- an adequate and appropriate research methodology.

7. Complementary and Alternative Medicine for innovative partnerships

by *Dominik Irrnich*, Head of Multidisciplinary Pain Centre, Department of Anaesthesiology, University of Munich, Germany.

Despite the availability of advanced treatments, nearly one in five adults surveyed experience long-term moderate-to-severe pain, according to the Pain in Europe survey, in which 46,000 people across Europe were screened to determine the prevalence of chronic pain⁴⁸. The initial screening was used to identify 4,839 people with chronic non-cancer pain who were willing to participate in an in-depth attitudinal survey.

Chronic, moderate-to-severe, non-cancer pain affected almost one in five (19%) adults surveyed across Europe (n=46,394). Prevalence was highest in Norway (30%, n=2,018), Poland (27%, n=3,812) and Italy (26%, n=3,849), where just over one in four adults reported suffering from chronic pain. The most common source of pain reported by chronic pain sufferers is the back (24%), and the most common cause is arthritis/osteoarthritis (35%). The median time during which people had been experiencing chronic pain was seven years, with one-fifth of respondents experiencing pain for 20 years or more (21%, n=4,839). Nearly one in five chronic pain sufferers had lost a job as a result of their pain. Over 40% of people with chronic pain reported feelings of helplessness or inability to think or function normally. In a German survey (N=11.000) 38% of patients had experienced an operation without long-term pain relief.

Since clinical trials of acupuncture for chronic low back pain have shown higher rates of symptom improvement than with usual care, guidelines by the American College of Physicians and the American Pain Society recommend that clinicians consider acupuncture as one possible treatment for patients with chronic low back pain⁴⁹.

A multidisciplinary outpatient programme in complementary and alternative medicine (MOCAM) for chronic pain patients based on Traditional Chinese Medicine (TCM) and Classical Natural Medicine/Naturopathy (CNM) at the University of Munich consists of a

⁴⁸ Pain in Europe – a report, available at <http://www.paineurope.com>

⁴⁹ Berman BM et al (2010). Acupuncture for chronic low back pain. *New England Journal of Medicine*, 363(5):454-61.

4-week outpatient program (phase 1) and a follow-up program (phase 2 and 3). It includes methods of TCM (acupuncture, Qi Gong, Tuina, dietetics), CNM (herbal medicine, breath therapy, nutrition, imagination, and body awareness) and educational seminars (chronic pain, pain treatment, life style according to TCM and CMN). Emphasis is placed upon reinforcing patient confidence, self-understanding and self-responsibility. Outcome measures included pain intensity, health related quality of life (SF 36), disability (PDI), return to work and number of doctor visits. Credibility of treatment and motivation (pain stages of change) were evaluated, too.

The programme included 297 patients suffering from chronic pain, mean duration of pain was 110 months. All outcome measures were significantly improved (t-test, $P < 0.001$) immediately and 2 years after completion of the 4-week program compared to baseline. The credibility scale showed high values, motivation was a weak predictor. Its conclusion was that Complementary and alternative Medicine can be an effective part of a multimodal treatment approach for chronic pain including reducing unnecessary hospitalizations and costs of medicines and medical procedures.

8. Innovative use of Complementary and Alternative Medicine in healthcare and public health systems

by *Torkel Falkenberg*, Associate Professor of Health Care Research, Research Constellation Leader - Integrative Health Care, Karolinska Institute, and Director, I C – The Integrative Care Science Center, Sweden.

In May 2003, the 56th WHO World Health Assembly adopted resolution 56.31 which takes note of WHO's strategy for traditional medicine⁵⁰, and its four main objectives of framing policy, enhancing safety, efficacy and quality, ensuring access, and promoting rational use and urged Member States, in accordance with established national legislation and mechanisms, inter alia to adapt, adopt and implement WHO's traditional medicine strategy as a basis for national traditional medicine programmes or work plans, and to formulate and implement national policies and regulations on traditional and complementary and alternative medicine in support of the proper use of traditional medicine, and its integration into national health-care systems.

At the 62nd World Health Assembly in 2009 the World Health Assembly adopted resolution 62.13, which recalls the Declaration of Alma-Ata which states, inter alia, that "The people have the right and duty to participate individually and collectively in the planning and implementation of their health care" and "Primary health care relies, at local and referral levels, on health workers, including physicians, nurses, midwives, auxiliaries and community workers as applicable, as well as traditional practitioners as needed, suitably trained socially and technically to work as a health team and to respond to the expressed health needs of the community". The resolution further notes that the term "traditional medicine" covers a wide variety of therapies and practices, which may vary greatly from country to country and from region to region; it recognizes traditional medicine as one of the resources of primary health care services that could contribute to

⁵⁰ As laid down in: WHO Traditional Medicine Strategy 2002–2005, WHO, Geneva, 2002. The WHO term "Traditional Medicine" includes Complementary and Alternative Medicine.

improved health outcomes, including those in the Millennium Development Goals, it recognizes that Member States have different domestic legislation, approaches, regulatory responsibilities and delivery models related to primary health care, and notes the progress that many governments have made to include traditional medicine into their national health systems.

The 62nd World Health Assembly urged Member States, in accordance with national capacities, priorities, relevant legislation and circumstances:

- (1) to consider adopting and implementing the Beijing Declaration on Traditional Medicine in accordance with national capacities, priorities, relevant legislation and circumstances;
- (2) to respect, preserve and widely communicate, as appropriate, the knowledge of traditional medicine, treatments and practices, appropriately based on the circumstances in each country, and on evidence of safety, efficacy and quality;
- (3) to formulate national policies, regulations and standards, as part of comprehensive national health systems, to promote appropriate, safe and effective use of traditional medicine;
- (4) to consider, where appropriate, including traditional medicine into their national health systems based on national capacities, priorities, relevant legislation and circumstances, and on evidence of safety, efficacy and quality;
- (5) to further develop traditional medicine based on research and innovation, giving due consideration to the specific actions related to traditional medicine in the implementation of the Global strategy and plan of action on public health, innovation and intellectual property;
- (6) to consider, where appropriate, establishing systems for the qualification, accreditation or licensing of traditional medicine practitioners and to assist traditional medicine practitioners to upgrade their knowledge and skill in collaboration with relevant health providers, on the basis of traditions and customs of indigenous peoples and communities;
- (7) to consider strengthening communication between conventional and traditional medicine providers and, where appropriate, establishing appropriate training programmes with content related to traditional medicine for health professionals, medical students and relevant researchers;
- (8) to cooperate with each other in sharing knowledge and practices of traditional medicine and exchanging training programmes on traditional medicine, consistent with national legislation and relevant international obligations.

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