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Integrative Medicine in Cancer Care: an Inside Perspective

G. Deng

Memorial Sloan-Kettering Cancer Center, New York, USA

Integrative oncology has been described as both a science and a philosophy that focuses on the complexity in health of people with cancer, and proposes an array of approaches to accompany the conventional therapies of surgery, chemotherapy, molecular therapeutics, and radiotherapy in order to promote health and well-being. It emphasizes the connection between mind, body, spirit and incorporates the application of therapeutic modalities that historically were not part of conventional Western medicine.

Despite the long history of use of many such therapies, a gap exists between the current level of scientific evidence and what we need to know in order to provide evidence-based advice.

Many major cancer centers in the United States have established integrative medicine programs to address cancer patients’ need of taking advantage of these therapies during cancer treatment. Comprehensive clinical services are made available to cancer patients. Research programs have been developed to conduct rigorous scientific studies of botanical agents, acupuncture, mind-body therapies, etc. Various educational programs have also been in place to educate health care professionals involved in cancer care.

A professional organization, the Society for Integrative Oncology, has been formed to provide a platform for academic exchange and networking. Here Dr. Deng will review clinical, research and educational activities of integrative oncology in the United States, describe the current state of science, discuss progress achieved and obstacles encountered, and explore prospective of further integration with conventional oncology practice.
The bridge between patient and doctor: the shift from CAM to integrative medicine

V. Diehl

First Department of Internal Medicine, University of Cologne, Cologne, Germany

Integrative medicine (IM) has become a major challenge for doctors and nurses, as well as psychologists and many other disciplines involved in the endeavor to help patients to better tolerate the burden of toxic therapies and give patients tools so they can actively participate in their “salutogenesis.” IM encompasses psycho-oncology, acupuncture, and physical and mental exercises to restore vital capacities lost due to toxic therapies; furthermore, it aims to replenish nutritional and metabolic deficits during and after cancer treatment.

IM gains an ever increasing importance in the face of the rapidly growing number of cancer survivors demanding more than just evidence-based diagnostic and therapeutic strategies. IM has to prove its value and justification by filling the gap between unproven methods of alternative medicine, still used by many cancer patients, and academic conventional medicine, which often does not satisfy the emotional and spiritual needs of cancer patients.

The term “CAM” (Complementary and Alternative Medicine) is generally used as a generic name for “unconventional methods,” distinct from “conventional methods” that characterize the classical type of academic medicine as taught at academic institutions and Universities and practiced in most clinics and in private doctors offices. According to Ernst and Resch, (2) the term CAM encompasses “any diagnosis, treatment or prevention that complements mainstream medicine by contributing to a common whole, by satisfying a demand not by orthodoxy or by diversifying the conceptual framework of medicine.” (Singh and Ernst)

If we want to achieve an objective opinion about CAM as it is practiced in the USA and Europe today, we have to try to get as close to the scientific proof of effectiveness and safety as we do for all other so called “mainstream” medicinal procedures. When we do that, we have to realize that there is an astonishing discrepancy between the acceptance and widespread use of alternative and/or complementary methods by cancer patients and the lack of knowledge and/or reluctance of hematologists/oncologists to test or even apply these in cancer care. The reasons are plentiful; the main obstacle seems to be that many alternative ingredients or procedures are based more on opinions than on science and reflect more faith than facts.(1)

There is, however, mounting evidence for a substantial impact of complementary procedures and some phytotherapies as supportive, auxiliary adjuncts to improve the quality of life of cancer patients and sometimes even increase tumor response. (3) Therefore, it is important to separate the objectively helpful complementary entities from the often dangerous and nearly always expensive alternative and unproven remedies and procedures!

More and more the term CAM has become an amalgam of unproven alternative methods and useful supportive measures used by many doctors to strengthen and reconstitute the self-healing capacity of cancer patients who are weakened by chemo-radiotherapy. Therefore, most academic institutions now tend to use the term “Integrative Medicine” (IM) to describe activities complementing modern strategies of academic medicine.

An important aspect of IM in parts of Europe, especially in Germany, is the philosophy of giving incentives and practical help to the patient to detect, realize and mobilize his/her own individual resources of self-defense and resistance to the adverse effects of anticancer therapy (“Patient’s Competence”, Nagel). The physician is interested in the “pathogenesis” of the disease, objectifies the disease process and the host response, and often does not meet the
psychological and spiritual demands of the patient. Paracelsus visualized a better understanding between patient and doctor, when both recognize a complementary reality of experiencing the disease, when the treating doctor speaks to the “doctor in the patient.”
Integrative medicine in paediatrics

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Children, in particular if they are critically ill, need a comprehensive approach to therapy, care, and cure. They have to consider several aspects: 1. underlying or suspected disease, 2. age of the child, 3. developmental stage, 4. general condition, 5. accompanying person(s), 6. familial and social conditions. Already at the first contact mistakes can be made which are crucial for the future relationship between the patient, the parents and the treating doctor(s) and the medical and – if existent – the psychosocial team.

In this sense, paediatrics is a prime example for integrative medicine. The need to involve integrative measures is variable. In general, requirements are less in ambulatory than in inpatient medicine. However, this depends strongly on the underlying disease. Children with severe and/or chronic diseases have higher demands than those with a short-lasting acute illness.

The structures are different in paediatric subspecialties. Among the best organized structures are those in paediatric oncology which were established during the past decades. Uniform treatment protocols including consequent supportive care are being used since the early 70ies. As a consequence of parent initiatives psychosocial care has become an integral part of paediatric cancer treatment institutions. Thus, psychosocial teams – financed by the hospital and in part still additionally by parent initiatives – exist in all larger paediatric oncology units in Germany. They consist of social workers, psychologists, occupational therapists, music therapists, teachers, and frequently also pastoral caregivers.

While integrative networking between the involved disciplines is firmly established in paediatric oncology the role of complementary and alternative therapies (CAM) is still an issue of debate. In a recent survey it turned out that 35% of the responders had used CAM, most frequently homeopathy, dietary supplements and anthroposophic medicine including mistletoe therapy. In order to evaluate whether CAM provides any additional benefit for the children during the course of intensive chemotherapy/radiotherapy we are currently conducting a randomized, multicentric clinical trial in Germany. The children are randomized to receive or not to receive a standardized CAM based on the experience with established anthroposophic medicine.
Neurobiological underpinnings of mindfulness meditation

S. Lazar

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Our lab uses MRI to study the neural underpinnings of mindfulness and meditation. We will present data from two projects that were designed to identify how practice of mindfulness meditation impacts neural function and structure, and how such changes lead to long-term changes in physical and psychological health and well-being. In the first study, functional and structural images were acquired from 18 experienced mindfulness meditation practitioners and 15 matched controls. Multiple brain regions important for autonomic regulation and emotion modulation were active during meditation compared to rest or exhibited increased cortical thickness in the meditators compared to controls. In the second study, anatomical scans were acquired from 16 healthy but stressed individuals before and after participating in an MBSR course. Increases in gray matter density were observed in several regions compared to a wait-list control group. The neurological findings from both studies will be discussed in relation to behavioral measures, and the implications for the use of meditation as a “mind-body” intervention will also be discussed.
Acupuncture for chronic pain: an individual patient data meta-analysis of randomized trials

H. MacPherson


Background: Acupuncture is widely used for chronic pain. Equivocal evidence, lack of biological plausibility and a provenance in theories lying outside of biomedicine makes acupuncture a highly controversial therapy.

Purpose: To determine the effect size of acupuncture for chronic pain, first when comparing acupuncture vs. sham acupuncture and second comparing acupuncture vs. no acupuncture controls.

Data sources: MEDLINE, the Cochrane Collaboration and the citation lists of systematic reviews.

Study selection: Randomized trials where allocation concealment was determined unambiguously to be adequate.

Data extraction: Individual patient data were obtained for 29 of 31 eligible trials, with a total of 17,922 patients analyzed.

Data synthesis: Results will be presented as to whether or not acupuncture was found to be superior to sham and/or no acupuncture controls for the following pain conditions: back and neck pain, osteoarthritis, and chronic headache. Using sensitivity analysis, we excluded an outlying set of trials that showed a very large difference between acupuncture and sham, and explored the resulting effect sizes.

Strengths and limitations: This is the most robust meta-analysis of acupuncture for chronic pain, as it is based on individual patient data. However the comparisons between acupuncture and no acupuncture control cannot be blinded, and so both performance and response bias are possible for this comparison.
Mind-Body-Medicine

A. Michalsen

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There is increasing use of Mind-Body-Medicine (MBM) worldwide, however no common definition exists. The U.S. national Center for Complementary Medicine (NCCAM) has noted that “mind-body practices focus on the interactions among the brain, mind, body, and behavior, with the intent to use the mind to affect physical functioning and promote health”. Among listed methods are relaxation techniques, as meditation, progressive relaxation, deep breathing, guided imagery but also body practices as yoga, tai chi, qi gong, and techniques as biofeedback, hypnosis.

Of note, in ancient healing practices, such as Traditional Chinese Medicine, Traditional European Medicine, and Ayurvedic Medicine, the current understanding of MBM was inherent as no dualism between the mind and the body was perceived. With the integration of MBM into modern medicine a focus was set on understanding physiological mechanism and obvious physical effects of the techniques. Stress research, the description of the relaxation response, the emerging field of Psychoneuroimmunology and the rapidly advanced brain imaging techniques have allowed better understanding of underlying mechanisms that may cause, or, at least accompany the clinical effects of MBM and the subjective cognition. However, while this research supports the integration of MBM into conventional Medicine it also carries forward a reductionist view of MBM techniques. Here, MBM will have to clarify the role of spirituality, of inner experiences, mindfulness, social support and secondary health-related lifestyle modifications within the whole concept.

Recent data point to promising clinical indications of MBM. Examples are the use of yoga in chronic pain, of meditation and mindfulness in cancer, hypertension or insomnia, of biofeedback in headache and of hypnosis in addiction. Yet, recent data also show, that MBM will not be a panacea for all chronic diseases and that adherence might be a problem in the general population. Future research will have to evaluate the differential effects of techniques and programs for specific diseases. MBM is self-effective, generally very safe and works well when combined with usual medical care, thus it might be the most suitable candidate for successful Integrative Medicine. Importantly, MBM should not give up its broader perspective within this process of integration. Then, concepts as mindfulness, loving kindness or awareness through inner experience could have dramatic impact when supported by social and corporate action.
Integrative Oncology – the view of a Comprehensive Cancer Center

P.M. Schlag

Charité Comprehensive Cancer Center, Berlin, Germany

Tumor diseases are multifactorial and complex disorders. Therefore, they require a complex treatment, which is subject to a continuous challenge. It is considered that an optimal tumor treatment cannot be achieved by one discipline alone, but always needs an interdisciplinary approach for an efficient treatment plan. The necessary medical structures are provided and best placed under the umbrella of a Comprehensive Cancer Center. Further, these structures ensure that new findings from basic research reach the patient in advance and will then be translated into an optimized treatment standard for tumor patients.

In this context, novel treatment options can be tested and further developed in the framework of clinical trials. One of our major concerns is - beyond this cancer-centered care – a holistic overview of a tumor disease. This means that aspects of psycho-oncology are considered as well as different approaches in the field of integrative oncology, including rehabilitation and aftercare. Based on the experience of the Charité Comprehensive Cancer Center, the results, but also the hurdles to realize such a concept, will be analyzed and discussed in the talk in terms of further optimization and the outreach.
Mind-Body-Medicine in a clinical outpatient clinic

W. Stör

President German Medical Acupuncture Association DÄGfA

MBM in an outpatient family clinic is a concept of illnesses in a whole system.

This presentation less focusses on stress reduction and meditation but points out some aspects to be integrated in daily practice caring for patients with acute and chronic deseases.

First, to do so time is a crucial, less the quantum of but far more the quality of time spent with and donated to the patient: there is a need to create a space of awareness and privacy, even intimacy to make the patient feel to come to an „eternal presence“. Interrogating helps both establishing a diagnosis in terms of biomedicine and stimulating the patient to act and show all aspects of his personality. The doctor is listening, watching and feeling to understand the patient and his illness: why this person? why here? why now?

In a family clinic patients want to present problems related to their body. So this is to start with. Acupuncture as working with the lively body (german: „Leib“) bridges from merely bodily aspects to more awareness.

The Zang Fu concept of chinese medicine mainly relates to negative emotions like fear, grief etc.. This tends to establish a negative point of view to the patients problems, while easily it can be turned into a positive one: the area of the biggest lack usually reveals the patient’s longest power! Showing this the doctor might lead the patient back through the meander of his labyrinth to more resilience. So the Zang Fu concept may work as an easy access to salutogenesis.

Furthermore the traditional philosophical concept of wu wei offers a simple but effective way to turn the patient’s view.

Sexual desire and its satisfaction are a great biological impetus. Though it also is a maior source of (dis-)comfort for mind and body, current concepts of MBM rarely refer to this fact. The reasons might be cultutral ones and are to be reflected.

As spiritual aspects also have a graet impact an health, trespasses and forgiveness resp. not forgiveness might be one of the deepest. Councelling this is a rather easy thing for the doctor but for the patient changing the attitude is a very difficult way!

Successfull counselling also should find out what could help apart from any medical based advices, meetings, exercises etc. to reduce „medicalisation“ of daily life.
An international Delphi process to develop a pediatric CAM research agenda

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Pediatric CAM use is common, and offers numerous research questions. CAM research for pediatric populations requires special consideration for at least five reasons: (i) the broad age range represented (ii) the vulnerability of children; (iii) proxy reporting and decision-making by parents/caregivers; (iv) the potential for pediatric exposure to have long term effects and (v) unique ethical challenges related to each of the above.

We initiated an international consensus-based Delphi process to develop a pediatric CAM research agenda. We received 376 responses; participants included conventional and CAM providers and researchers as well as educators, administrators, and policy-makers from 12 countries. After 3 rounds of review, participants identified the highest priorities for pediatric CAM research as: (i) safety of CAM therapies; and (ii) conditions for which CAM use is highly prevalent and those for which conventional medicine lacks safe, cost-effective therapies. The following were proposed as a “minimum set” for a pediatric CAM research agenda:

1. Safety. Assess potential adverse events including “direct” harms such as side-effects and interactions, and “indirect” harms, such as delays in diagnosis or treatment, decreased treatment adherence, or excessive cost.

2. Conditions. High priority conditions included: atopy; cancer; digestive health problems; infection and (auto) immunity; neurodevelopmental and behavioural health; obesity; chronic pain; and health promotion and disease prevention.

3. Therapies/therapists. There is a clear need for research regarding (i) the quality and reproducibility of interventions; (ii) comparative effectiveness and cost effectiveness; and (iii) pediatric dosage and interactions, and (iv) pediatric expertise of providers. Therapies of greatest interest include: acupuncture, ayurveda, dietary supplements, energy medicine, homeopathy, manual therapies mind-body, nutrition, whole system approaches and multiple simultaneous interventions.

4. Outcome measurement requires valid and reliable tools that consider and measure: (i) multiple perspective; (ii) multiple dimensions of health; (iii) duration of effect; (iv) health promotion; (v) safety; and (vi) non-invasive age appropriate biomarkers.

To improve pediatric health care, multi/transdisciplinary collaborative approaches are needed between CAM and conventional providers and researchers. We urgently need resources to translate new and existing pediatric research evidence into policy and practice.
Evidence of Tai Chi in Mind-Body-Medicine

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The purpose of this speech is to discuss how evidence-based Tai Chi mind-body exercise therapies can be integrated into clinical practice to better inform clinical decision-making. Dr. Wang will review evidence based multi-component Tai Chi with focus on its physical and psychological benefits on variety of chronic medical conditions. In addition, Dr. Wang will highlight her recent New England Journal Medicine publication “A randomized controlled trial of Tai Chi for fibromyalgia” to illustrate Tai Chi mind-body exercise for pain relief and well-being.

A single-blind, randomized trial of classic Yang-style Tai Chi vs. wellness education and stretching was conducted for the treatment of fibromyalgia. Sessions lasted 60 minutes each and took place twice a week for 12 weeks for each of the study groups. The primary end point was change in the Fibromyalgia Impact Questionnaire (FIQ) score at 12 weeks. Secondary end points included summary scores on the physical and mental components of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). All assessments were repeated at 24 weeks to test durability of response. The Tai Chi and control groups were compared using an intent-to-treat analysis. Participants’ baseline expectation scores were similar between the groups. At 12 weeks, patients assigned to Tai Chi exhibited significantly greater improvement in FIQ total score [between-group difference -18.4 points; P< 0.001]. The corresponding SF-36 physical-component scores were 28.5±8.4 and 37.0±10.5 for the Tai Chi group versus 28.0±7.8 and 29.4±7.4 for the control group (between-group difference, 7.1 points; P = 0.001), and the mental component scores were 42.6±12.2 and 50.3±10.2 for the Tai Chi group versus 37.8±10.5 and 39.4±11.9 for the control group [between-group difference, 6.1 points; P = 0.03]. Improvements were maintained at 24 weeks [between-group difference in the FIQ score, -18.3 points; P<0.001]. No adverse events were observed. Tai chi may be a useful treatment for fibromyalgia and merits long-term study in larger study populations.

Upon completion of this session, participants should be able to: 1) Explain the Tai Chi exercise treatments for chronic medical conditions. 2) Describe how evidence can be integrated into Tai Chi exercise treatments for chronic pain syndrome. 3) Discuss how mind body therapies can be utilized in clinical practice.
Effectiveness studies measure the extent to which an intervention, when deployed in the field in routine circumstances, does what it is intended to do for a specific population. To this end, effectiveness trials use eligibility criteria, treatment protocol and outcomes that are close to usual care.\(^1\) For valid decision making in usual care, there is an urgent need for more evidence from Comparative Effectiveness Research (CER).\(^2\) In addition health economic data have become increasingly relevant for decision makers faced with the challenge of reconciling the growing demand for healthcare services with the funds available. In this context the number of economic evaluations on complementary and integrative medicine has increased over the last few years, and the largest number has been done for acupuncture either in addition or compared to routine care.\(^3\)

The movement towards CER provides a good basis for health economic studies such as cost-effectiveness studies, and strategic advice how to combine both aspects would support more sound research for the future.

One approach is the development of Effectiveness Guidance Documents (EGDs) with the aim to guide the design of studies that meet the criteria of CER. EDGs have to be developed in consensus procedures including the relevant stakeholders.

This presentation will use the example of acupuncture research to provide information about relevant aspects of CER and a strategic approach that combines CER with economic studies.

References

Duckweed and yeast as model organisms for homeopathic basic research investigations – an overview

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In the context of homeopathically potentised remedies there are still many open fundamental questions, e.g. regarding the mode of action and the specificity of remedies, and the possible role of external influences that may hamper the remedies’ effects. The purpose of homeopathic basic research is to find answers to such questions by investigations with simple and easy to handle model organisms.

Over the last years we have performed many randomized and blinded experiments using the small free-floating water plant \textit{Lemna gibba} as well as different yeast species by measuring growth rate parameters in the presence of potentised substances or controls (unsuccussed and succussed water). We also closely monitored the natural variability of the test systems by systematic negative control experiments to avoid false positive results.

The results with healthy organisms clearly showed significant effects of some potentised substances tested though the effects on yeasts were only small and were modulated by additional factors. Compared to yeasts duckweed reacted more pronounced to potentised substances, but only in particular potency levels. Especially, potencies of the plant hormone gibberellic acid reduced the duckweed’s growth rate.

In order to investigate the hypothesis that organisms out of homeostasis may react more strongly to homeopathic preparations, we decided to stress the organisms with arsenic (V) prior to treatment with potentised substances. The growth rate of impaired duckweed was significantly improved after the application of potentised Arsenicum album and nosode in several potency levels. In contrast, the growth of impaired yeast was not affected. This may indicate that for yeast (1) growth is not a suitable parameter to measure the effects of homeopathic potencies, (2) the applied substances were not appropriate, or (3) more complex organisms like duckweed react more pronounced to homeopathic preparations than simple organisms like yeast.

In general, our findings support the notion of homeopathy, that homeopathic potencies may exert specific biological effects. Additionally, evidence accumulates that adjacent potency levels may strongly differ in their biological activity. We recommend use of the duckweed bioassays to investigate scientific and pharmaceutical questions after further optimisation and replication trials in independent laboratories.
A qualitative study on the thoughts, beliefs and concepts towards infectious childhood diseases held by physicians practising homoeopathic, anthroposophic and conventional medicine

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Objectives: Physicians who practise complementary medicine very often have a different understanding of health and disease compared to their colleagues practising conventional medicine. The aim of this study was to identify the thoughts, beliefs and concepts towards infectious childhood disease held by physicians practising homoeopathic, anthroposophic and conventional medicine.

Study-Design and Sample: This qualitative study used a grounded theory approach. Data from semi structured interviews with 18 physicians in Germany, either general practitioners or pediatricians (6 homeopathic, 6 anthroposophic and 6 conventional) were collected.

Results: All physicians agreed that while many classical infectious childhood diseases like measles, mumps and rubella are seen only very rarely today, others such as the chicken pox, mononucleosis and scarlet fever are still commonly diagnosed. A core concern for physicians practising conventional medicine was the risk of complications. Therefore, it was considered very important to strictly follow the vaccination schedule and to adopt standard conventional therapy. However, homeopathic physicians view acute disease as a biological process where it is necessary to train the organism in order to prevent chronic disease. They tend to treat infectious childhood diseases with predominantly homeopathic remedies and administer vaccines in an individualized manner. Informing parents of potential benefits and risks of vaccination is considered very important. For anthroposophic physicians, infectious childhood diseases are an important factor in the psychosocial and spiritual growth of the child. They tend to treat infectious childhood diseases with anthroposophic medicine, and consider the support and use of family resources as very important. In accordance with homeopathic physicians, vaccinations are applied in an individualized manner and providing the critical information about potential benefits and risks is also important. All physicians agreed that the loving care of the sick child benefits the child-parent relationship. However, in modern society with both parents working, they often can not afford to spend time caring for their children. For this reason vaccinations and medication have increasingly been used to allow parents to return to work sooner.

Conclusion: Differing concepts of infectious childhood diseases between physicians practising complementary and conventional medicine results in differing methods of prevention and therapy. This has consequences for public health. A critical dialogue between conventional and complementary practitioners should include conceptual frameworks that shape the clinical decisions and allow for consequent treatment methodologies to be established.
Prescribing homeopathy for cancer patients – a best case series.

L. Thompson

This presentation will describe my approach over the past 11 years to prescribing homeopathy within the Integrative Cancer Care Service at the Bristol Homeopathic Hospital. Improving symptoms and quality of life has been my primary aim rather than suggesting that homeopathy might affect survival. However over the years, a number of patients have lived longer than expected. The National Cancer Institute’s (NCI) Office of Cancer Complementary and Alternative Medicine (OCCAM) was established in October 1998 to coordinate and enhance complementary and alternative medicine activity in cancer care in the USA. OCCAM funds research and provides evidence based information about complementary therapies. OCCAM has encouraged complementary cancer prescribers to submit cases where outcome has been particularly good as a best case series. Here I present a number of patients seen over the past ten years where improvements in symptoms, well being, scan results and apparent survival have been noted. A range of remedies will be discussed.
Effects of acupuncture on sensory perception: evidence from clinical and experimental research

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The assessment of sensory pain and detection thresholds plays a central role in clinical as well as experimental acupuncture research. An evaluation of changes in sensory perception caused by acupuncture in patients or healthy probands allows to draw conclusions regarding the effectiveness of acupuncture in the treatment of painful pathological conditions or the mechanisms underlying acupuncture analgesia. In recent years Quantitative Sensory Testing (QST), a battery combining measurements of mechanical and thermal thresholds, was developed. Since QST is standardized and easily applicable, it might be the method of choice for assessing the acupuncture effect on sensory perception. Thus, we intend to provide an overview of the current scientific knowledge about the effects of acupuncture on the detection and pain thresholds that are included in QST (warm and cold detection threshold, heat and cold pain threshold, mechanical detection and pain threshold, mechanical pain sensitivity, wind up, vibration threshold, pressure pain threshold). Currently we are performing electronic literature searches for clinical and experimental trials in MEDLINE and SCOPUS by combining the search terms “pain threshold”, “sensory perception”, “sensory threshold”, “thermal threshold”, “mechanical threshold”, “vibration” with the search term “acupuncture”. Acupuncture and electroacupuncture trials published in English or German before July 2011 will be included in this overview. Animal studies, and trials investigating the effects of TENS or other acupuncture related techniques will be excluded. So far, we have identified 65 research articles that describe acupuncture effects on sensory detection and pain thresholds in healthy probands and patients suffering from various painful disorders. In 50% of these studies the pressure pain threshold was used to assess the effectiveness of acupuncture in improving sensibility in painful pathologic conditions. In studies conducted with healthy volunteers researchers evaluated mostly the acupuncture effect on thermal pain thresholds. Results of several studies appear to be contradictory. According to this overview of literature concerning the effect of acupuncture on sensory perception implications for the treatment of painful conditions and for research focusing on processes involved in acupuncture analgesia will be discussed.
Complementary therapies in fibromyalgia syndrome – efficacy of hydrotherapy, aerobic exercise, acupuncture, MBSR and meditative movement therapies – systematic reviews with meta-analysis of controlled clinical trials

J. Langhorst, F. Musial, P. Klose, D. Irnich, G. J. Dobos, W. Häuser

Objectives: To systematically review the efficacy of hydrotherapy (HT), aerobic exercise (AE), acupuncture (AP), mindfulness-based-stress-reduction (MBSR) and meditative movement therapies (MMT) in fibromyalgia syndrome (FMS).

Methods: We screened MEDLINE, PsychInfo, EMBASE, CAMBASE, Cochrane Library, CENTRAL and SPORTDISCUS (through December 2008 (HT) and March 2009 (AE), through June 2009 (AP, MBSR) and through December 2010 (MMT)) the reference sections of original studies, reviews and evidence-based guidelines. Randomized controlled trials (RCT’s) comparing the requested therapy modalities in adult FMS-patients to controls (attention placebo, treatment as usual, no or active therapy) were analyzed.

Results: In HT 10 out of 13 RCTs with 446 pts were included. Effects were summarized using standardized mean difference (SMD). There was moderate evidence for a reduction of pain (SMD-0.92, 95% CI -1.56, -0.28; p = 0.005) and improved health-related quality of life (HRQOL) (-1.67, 95% CI -2.91, -0.43; p = 0.008) at the end of treatment. There was moderate evidence that the reduction of pain (-1.27, 95% CI -2.15, -0.38; p = 0.005) and improvement of HRQOL (-1.16, 95% CI -1.96, -0.33; p = 0.005) could be maintained at follow-up (median 14 weeks).

In AE 32 out of 60 RCTs with 1770 pts were included. There was strong evidence that AE reduces pain (SMD -0.42, 95% CI -0.61, -0.22; p < 0.001), fatigue (-0.41, 95% CI -0.71, -0.12; p = 0.006), depressed mood (-0.44, 95% CI -0.68, -0.20; p < 0.001) and improves HRQOL (0.61, 95% CI 0.37, 0.85; p < 0.001) and physical fitness (0.61, 95% CI 0.37, 0.85; p < 0.001) at post-treatment. There was strong evidence that the positive effects on depressed mood (-0.42, 95% CI -0.79, -0.05; p = 0.03), HRQOL (-0.28, 95% CI -0.53, -0.04; p = 0.02) and physical fitness (0.65, 95% CI 0.35, 0.96; p < 0.001) could be maintained at follow-up (median 26 weeks).

In acupuncture 7 RCTs and 337 subjects were included. We found conflicting evidence of the efficacy of AP in reducing pain (SMD = -0.25, 95% CI -0.80, 0.10, p = 0.28) and fatigue (0.08, 95% CI 0.55, 0.71, p = 0.81) and improve sleep (0.04, 95% CI -0.80, 0.89, p = 0.92) at the end of the treatment. In addition, we found strong evidence that the positive effects of acupuncture declined with time.

In MBSR 3 RCTs with 207 subjects were included. MBSR reduced depressed mood (-0.31, 95% CI -0.59, -0.02; p = 0.03) at post-treatment. There was no significant effect on pain, self-efficacy pain and HRQOL at post-treatment and at follow-up. Sensitivity analyses showed that the positive effect on depressed mood could not be distinguished from some risks of bias.

In MMT a total of 7 out of 117 studies with 362 subjects and a median of 12 sessions (range 8 – 24) were included. MMT reduced sleep disturbances (-0.61 [-0.95, -0.27]; 0.0004), fatigue (-0.66 [-0.99, -0.34]; < 0.0001), depression (-0.49 [-0.76, -0.22]; 0.0004) and limitations of HRQOL (-0.59 [-0.93, -0.24]; 0.0009), but not pain (-0.35 [-0.80, 0.11]; 0.14) compared to controls at final treatment. The significant effects on sleep disturbances (-0.52 [-0.80, -0.30]; 0.0003) could be maintained at follow-up (median 26 weeks).
0.97, -0.07], 0.02) and HRQOL (-0.66 [-1.31, -0.01]; 0.05) could be maintained after a median of 4.5 (range 3 – 6) months. In subgroup analyses only Yoga yielded significant effects on pain, fatigue, depression and HRQOL at final treatment.

Conclusions: There is moderate evidence that HT and there is strong evidence that AE has short-term beneficial effects on some key domains of FMS. Due to heterogeneity and methodological shortcomings of existing controlled trials there is inconclusive evidence for the efficacy of acupuncture in FMS. At present MBSR cannot be recommended as single therapy for FMS. A combination of MBSR with treatment options effective for the relief of pain, sleep disturbances and fatigue can be considered. Yoga had short-term beneficial effects on some key domains of FMS. There is a need for high quality studies with larger sample sizes to confirm the results.
Integrative Treatment of chronic headache in children

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Background and aims: Chronic headache is a rising therapeutic problem in all industrialized countries. Because of the unknown reasons for this phenomenon at lot of speculations and only very few studies have been done. Often unidimensional investigations did not show any convincing longstanding effects on headache items. A change of paradigm could be observed during the last few years focusing on the functional aspects of children instead of the headache parameters.

Methods: 1100 children suffering from chronic headaches for 3 years on the average were evaluated during the therapeutic process and one year after the intervention. A solution focused brief multimodal treatment including at least one acupuncture intervention was started.

Results: A sample of 300 children and adolescents with an average age of 11 years gained a therapeutic effect of 73% which did not significantly changed over the following 5 years. Four hours of intervention was sufficient to reach this level. Quality of life improved as well as school attendance. Medication dropped to seldom intake rates.

Conclusions: The results show the effectiveness of an ambulatory intervention in chronic headache children and adolescents far away from spontaneous courses in a chronified pediatric population. A systemic approach including acupuncture and nutritional counselling could be utilized for the first time in pediatric outpatient headache patients.
Acupuncture in pediatrics: is there evidence?

R. Kracht

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Still acupuncture has to prove its significance against natural science. Therefore more and more studies try to fulfil high standards in their methodology as there are randomised controlled double blinded trials. As a matter of fact problems have to rise up for technical reason. Sometimes it seems to be rather impossible to overcome the above mentioned standards with a treatment technique like acupuncture which appears to be not suitable for these new methodological standards.

This speech will name these problems emphasise them and show - while giving examples for paediatric studies with a good design - how to face and overcome these problems. The presented studies will show the efficacy of acupuncture in the field of nocturnal enuresis, chronic headache and colicky crying in infants.
The Development of Complementary Medicine in Paediatrics:
Deployment of naturopathic treatments towards an integrative care concept

M. Ogal

Brunnen, Germany

In the past, medicine dosages were empirically scaled down for children. Children were treated as “small adults”. They were allowed to remain sick for longer periods than today and were raised and cared for in larger family environments. Naturopathic courses of treatment were handed down from family to family and implemented by these. It was not before the year 1890 that Paediatrics evolved from Internal Medicine into an independent, specialized sector.

Today, efforts are underway to define medicine dosages for children by way of studies. The emphasis is on the integrity of the applied treatments. Parents are increasingly requesting that treatments based on complementary medicine be considered for their children. Several paediatricians have responded and are including complementary medicinal practices in their treatment of patients – to some degree prompted by the parents. In today’s social environment, children must convalesce more rapidly than before, due to the pressures of school and employer demands on the parents. The child oscillates between the states of “Fit” and “Misfit”.

The perspectives for the future should encompass the following extensions/innovations for paediatrics:

The medicine dosages are securely defined and tailored to each individual by epigenomics. Children are given the appropriate time to take them and to convalesce. The paediatricians operate according to an integrated care concept, meaning that they are aware of and understand the benefits of many techniques of complementary medicine. They practice these methods themselves or refer to other therapists / colleagues / naturopaths. Training centres or “postgraduate courses” enable clinically employed paediatricians to gain a specialized access to complementary medicine.

Thus, the paediatrician develops into a “Gate Keeper” with a profound understanding of the child as a complete human entity; socially, and in the sense of orthodox as well as complementary medicine. He/She has the unique opportunity to live a strategy of prevention together with the parents – as a fundamental principle, and to establish a true “health system”.

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Hyposenzitation in pediatric sprengtime allergic rhinitis

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Prevalence of allergic diseases has shown a dramatic increase over the last 30 years. Up to 50 % of schoolchildren are suffering from various kinds of allergies or intolerances. Because conventional treatment is often not sufficient, additional complementary medicine especially in case of side effects, therapeutic resistance, as well as in acute stages and lack of therapeutic offers comes into play. Classical acupuncture is typically important presaisonally and applied during acute emergencies.

Profound improvement of allergen tolerance will be possible, if the triggering substance(s) are in skin contact during the acupuncture process. By means of soft stimulation techniques like soft laser or infrared radiation at the terminal points of the channels Lung (Lu), Spleen (Sp), Large Intestine (LI) and Stomach (St) for few seconds per point the allergic hyperreactivity can be lowered.

The treatment of acute allergic reactions to foodstuffs especially fruits like apple, cherries or peach show best results. Allergies to early blossoming and allergies against single animals are most positive even after a short tolerance-raising acupoint stimulation. Allergies against dust and suiltate blossoming flowers must be treated more often. Therapeutic resistance is often due to pronounced psychic stress. The therapeutic efficacy can be supported by an oligoantigenic diet.

Acupuncture together with skin contact of allergic substances is an encouraging option. Controlled investigations should be started in order to integrate this method onto the canon of complementary medicine.
Case Report Treatment of Atopic Eczema with Traditional Chinese medicine and complementary methods

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Atopic eczema is the commonest inflammatory skin disease of childhood, affecting 15-20% of children in Germany at any one time. Moderate-to-severe atopic eczema can have a profound effect on the quality of life for both sufferers and their families. In addition to the effects of intractable itching, skin damage, soreness, sleep loss and the social stigma of a visible skin disease, other factors such as frequent visits to doctors, special clothing and the need to constantly apply topical applications all add to the burden of disease. The cause of atopic eczema is unknown, though a genetic pre-disposition and a combination of allergic and non-allergic factors appear to be important in determining disease expression. Atopic eczema is usually triggered by inhaled or ingested allergens, such as certain foods, pollen, dust or animal dander.

The casuistic describes a 14 month old boy suffering from atopic dermatitis since 9 month. Before we started our complementary therapy he tried a variety of treatments, including use of emollient, topical and systemic antimicrobial agents, corticosteroid and immune modulating agents, all of which provided no noticeable changes in his symptoms. He also seeks alternative treatments such as dietary and homeopathy.

His condition had been fluctuating with periodic flare-ups. Severe and widespread atopic eczema often fails to respond adequately to currently available therapies.

On base of this casuistic we will see the effectiveness of the combination of individual Chinese herbal medicine, acupuncture, diet that reduce the food hypersensitivities and topical skin care for the treatment of atopic dermatitis.

Researchers have also tested the effectiveness of acupuncture and Chinese herbal medicine in treating eczema. Current studies will be shown.
Integrative therapy of inflammatory bowel diseases

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The term integrative Medicine defined by the WHO combines conventional therapies with evidence-based medicine to a “best practice”.

Integrative Medicine of inflammatory bowel diseases (IBD) like Crohn’s disease (CD) or ulcerative colitis (UC) combines a treatment according to the accepted therapies in mainstream medicine with complementary and naturopathic therapies and approaches from mind-body medicine focussing on life-style changes in an individualized way.

More than 50% of IBD patients in Germany have personal experience with CAM. Though only 25% are satisfied with their knowledge about CAM, approximately 80% are interested in using CAM in the future.

While whole medical systems like homeopathy or anthroposophic medicine lack evidenced based data in IBD, acupuncture is a recommended complementary treatment in the German guidelines for CD and UC. In biologically based practices various herbal treatments like myrrh, frankincense or wormwood are promising and plantago ovata and curcuma are included in the current German guidelines for UC as well as mind-body medicine strengthening self-help strategies of IBD patients.

More therapeutic studies in the field of CAM in IBD are needed to expand the available treatment options for an integrative medicine approach in IBD.
Predictors of therapy responsiveness for a multimodal therapy concept and aerobic training in breast cancer patients with chronic Cancer-Related-Fatigue

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Background: Cancer-Related-Fatigue (CRF) and insomniac sleep disturbances are the most frequent and burdensome symptoms in disease-free breast cancer patients (BC). Non-pharmacological treatments such as aerobic training (AT) and sleep education (SE) are the treatments with the best evidence. In this prospective controlled intervention pilot-study we tested beside the implementation of a new multimodal concept of therapy (MM), consisting of sleep- and psycho-education, group therapy, eurhythmy, and painting therapy and it’s comparison to AT, which questionnaire is the best predictor for the treatment’s responsiveness.

Methods: At the Community Hospital Havelhöhe and at the Hannover Medical School 31 patients suffering from BC and CRF could be fully evaluated in a ten-week intervention study; 21 of them chose MM and 10 decided for AT. CRF was the main outcome parameter which was measured with the help of the Cancer Fatigue Scale (CFS-D). Beside the CFS-D we captured by questionnaire the Pittsburgh Sleep-quality-index (PSQI), autonomic regulation (aR), self-regulation (SR), internal coherence (ICS) and quality of life (HRQL) with EORTC-QLQ C30.

Results: The correlations of baseline PSQI and EORTC-QLQ C30 subscales emotional, physical, role functioning and global health with CFS-D at baseline were R² = 0.02 – 0.40 and at the end of the intervention R² = 0.05 – 0.24. Baseline aR, SR and ICS corrrelated with CFS-D with R² = 0.27, 0.17 and 0.44 at baseline and with R² = 0.22, 0.38 and 0.48 at the end. Participants with high SR or ICS and high CFS-D at baseline had the best CRF improvement after the intervention.
Conclusion: This pilot-study supports the hypothesis that questionnaires measuring adaptive capacities such as self-regulation and internal coherence are more appropriate as outcome predictors than classical HRQL or sleep questionnaire for educative intervention studies.
OP-054

Any difference? Use of a CAM provider among cancer patients, coronary heart disease (CHD) patients and individuals with no cancer/no CHD

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Background: Although use of Complementary and alternative medicine (CAM) among cancer patients has been described, prevalence of use has not commonly been compared to other disease groups in a true population sample where CAM use or cancer is not the main focus. The aims of this study were to examine if the use of a CAM provider among cancer patients differs from coronary heart disease (CHD) patients and individuals with no cancer/no CHD.

Methods: A total of 8040 men and women age-d 29 to 87 in the county of Tromsø, Norway filled in a self constructed questionnaire with questions on life style and health issues. Use of a CAM provider within the last 12 months and information on cancer, heart attack and angina pectoris (heart cramp) were among the questions.

Results: Among 8040 adult survey respondents 331 had a prior cancer diagnosis, of whom 7.9 % reported to have seen a CAM provider within the last 12 months. This did not differ significantly from neither the CHD group (p = 0.402) nor the no cancer/no CHD group (p = 0.325).

Conclusion: According to this study, cancer patients in the 2001 Tromsø study did not use a CAM provider to a larger degree than patients with CHD or people with no cancer/no CHD.
Trends in complementary/alternative medicine use by cancer patients: comparing survey data from 2001 and 2007

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Background: It has been suggested that CAM use among cancer patients is increasing, yet few follow up studies are there to confirm this. Different populations, definitions of CAM use and time frame of use makes it difficult to compare studies at different points of time. The aims of the present study are to (1) investigate the use of a CAM provider among people with a previous cancer diagnosis and (2) compare use at two different points of time (2001 vs 2007/2008).

Methods: This paper is based on data from the Tromsø studies conducted in 2002 (Tromsø 5 (T5)) and 2007/2008 (Tromsø 6 (T6)). The Tromsø Study series (I-VI) are prospective studies in the municipality of Tromsø, Northern Norway. The design includes repeated population health surveys to which total birth cohorts and random samples are invited. The T5 study includes 8040 subjects, 4565 women and 3475 men aged between 29 and 88 (response rate 77.6 %). The T6 study includes 12984 participants, 6054 men and 6930 women aged between 30 to 87 (response rate 65.7 %).

Results: Thirteen percent of the cancer patients in T6 reported to have seen a CAM provider within the last 12 months (n = 92) as compared to 7.7 % (n = 32) in T5. The increased use is higher among men (from 4.8 to 9.3 %) than among women (from 10.1 to 16.2 %). Also in the no cancer group we find increased use, mostly among men.

Conclusion: Our findings suggest that there has been a substantially increase of self reported Cam use in cancer patients between 2001 and 2007 in the county of Tromsø, both among women and men.
**Integrative approach with complementary medicine and diet to cancer patients in the Hospital of Lucca (Italy)**

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**Introduction:** The incidence of CAM use after the cancer diagnosis among the Tuscan cancer patients was 17%. The most widely used forms were herbal medicine (52 %), homeopathy (30 %) and acupuncture (13 %). Use was higher in the urban area and among women and persons with a higher education (Johannessen H. 2008). That’s why we decided to establish an Outpatient Clinic for integrative medicine applied to oncology.

**Aim:** The aim is to give citizens qualified and evidence-based information about the use of Complementary Medicine and the principles of the correct nutrition of cancer patients; to address patients to the treatment by acupuncture, homeopathy and herbal medicine in order to decrease the adverse effects of radiation therapy, chemotherapy and hormonal therapies and improve their quality of life.

**Materials and Methods:** the patient sets up a consultation visit calling to the phone number of CUP, or he’s addressed by the Cancer Department of Lucca (CORD) to the info-point. In the clinic he/she will meet a medical doctor, specialised in oncology and expert in nutrition and complementary medicine, who listens to his/her problems and advise him/her about nutrition and complementary medicine. The indications to complementary treatments include the application of simple pre-defined protocols to decrease some of side effects of cancer therapies (i.e. acupuncture and/or homeopathy in chemotherapy/radiation therapy), the indication of therapeutic sessions of acupuncture/homeopathy to decrease side effects during anti-hormonal treatments (weight increase, water retention, problems of amenorrhea or menopause) and improve the quality of life.

**Results:** In the preliminary stage of activities, from the end of October 2010 till April 2011 (6 months), 42 patients have been visited (6 male and 36 female); the average age is 56.5 (40–85) years; 28 patients with breast cancer, 4 ginecologic cancer, 1 colon-rectal cancer, 1 gastric cancer, 1 head and neck cancer, 1 prostate cancer, 1 brain cancer, 3 NSCLC, 1 Multiple Myeloma and 1 Hodgkin’s lymphoma. In 12 patient we had already metastasis. The most used remedies were Nux vomica (symptoms from chemotherapy) Radium bromatum and Belladonna (symptoms from radiation therapy) and Lachesis and Sepia in artificial menopausal syndrome. However, the first results seem positive.

**Conclusions:** Preliminary data about the effects of complementary treatment seem to confirm its usefulness. Statistically evaluated data will be available next months.
Yoga for promoting quality of life and psychological health in patients with breast cancer - a systematic review and meta-analysis

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**Background:** Breast cancer, the most common cancer type in women, is frequently associated with severe impairments of quality of life and psychological health. Deriving from ancient India, yoga has become an important part of modern integrative oncology.

**Objectives:** To systematically review the efficacy of yoga in promoting quality of life and psychological health in patients with breast cancer.

**Methods:** MEDLINE, PsychInfo, Psyndex, EMBASE, CAMBASE, Cochrane Library and CENTRAL were screened through March 2011. The reference sections of original studies, reviews and the International Journal of Yoga Therapy were screened by hand. Randomized controlled trials (RCTs) comparing yoga to controls (other treatments or no treatment) were analyzed, when they assessed health-related quality of life (QoL) and/or psychological health. Data extraction and quality assessment were conducted by two reviewers independently.

**Results:** 11 RCTs and 655 subjects were included. RCTs were heterogeneous regarding yoga tradition, length and intensity of intervention, stage of disease and conventional treatment. 7 RCTs compared yoga with waitlist control groups, 3 RCTs compared yoga with supportive therapy and 1 RCT compared a combination of physiotherapy and yoga with physiotherapy alone. Standardized mean differences (SMD) comparing yoga and waitlist or supportive therapy, respectively were calculated. Yoga compared to waitlist control showed significantly greater improvements in overall QoL (SMD = 0.29 [95% CI 0.01, 0.57], p = 0.04), as well as in several subdimensions of QoL: functional (0.30 [0.03, 0.57], p = 0.03), social (0.32 [0.08, 0.56], p = 0.009) and spiritual well-being (0.41 [0.08, 0.74], p = 0.01). Yoga compared to supportive therapy showed significantly greater improvements in psychological health: anxiety (-2.21 [-3.90, -0.52], p = 0.01), depression (-2.94 [-5.27, -0.60], p = 0.01) and psychological stress (-1.55 [-2.83, -0.28], p = 0.02).

**Conclusions:** There is encouraging evidence that yoga has beneficial effects on overall, as well as on several sub-dimensions of quality of life, and on psychological health in patients with breast cancer. Due to clinical and statistical heterogeneity, there is a need for high quality studies with larger sample sizes to confirm these results.
OP-203

Psychosomatic disorders in patients with breast cancer – RCT with three mind/body interventions

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\textbf{Background:} Quality of life for patients with breast cancer is impaired by fatigue, sleeplessness, depression and various other psychosomatic complaints due to the disease itself as well as to side effects of radio-, chemo-, and anti-estrogen therapy. In recent years, several methods of mind/body interventions for these conditions have been introduced but only marginally evaluated in Natural Medicine.

\textbf{Methods:} In a 4-armed RCT, patients with breast cancer with minimum of 6 weeks after cytoreductive treatment and minimal psychosomatic symptom score were randomized to either one of three commonly practised therapies – autogenous training (AT), breath therapy (BT) and health training (HT) or to a waiting group (WT). Patients were offered weekly group sessions of 5 x 90 minutes. Primary outcome was defined as group differences before and after therapy in Quality of Life (measured with the EORTC QLQ-C30), and Depression (measured with the HADS-A and HADS-D). Differences were evaluated by two-sided T-test statistics where \( p<0.05 \) was judged as significant. Due to the pilot character of the trial, test results were mainly interpreted as to generate hypotheses.

\textbf{Results:} 81 patients (mean age 58.0 \pm 8.6 y) started, 68 completed the trial. Predominating reason for discontinuation was non-compliance for unknown reasons, only in one case explicitly dissatisfaction. No undesired effects were reported. EORTC QLQ-C30 was significantly improved in all three interventions: by +11.1 (20.3 \%) for AT, by +8.5 (15.8 \%) for BT, and by +11.4 (19.9 \%) for HT with almost no change for WT (\(-0.8\) (-1.4 \%, n.s.). Similarly, anxiety (HADS-A) decreased significantly (with the exception of AT – 1.6 units, n.s.; BT -1.5; HT – 2.7; WT + 0.2) as did depression (HADS-D) (AT – 1.0 units; BT -1.2; HT – 2.8; WT -0.9) for interventions but not significantly for waiting.

\textbf{Conclusions:} Short-term group interventions to cope psychosomatic complaints in breast cancer patients seem to be very efficacious for disease-specific quality of life as well as for anxiety and depression. As there were only little differences between the three therapies investigated, they deserve further research particularly into sustaination of effects.

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Change of inner congruence with yoga practices and association with mindfulness and positive mood

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Introduction: Besides physical movements, yoga involves mental techniques which are considered to be essential for its effectiveness. However, an active participation of the practitioners seems to be essential. This attitude can be operationalized and measured with the “Inner Congruence and Peaceful Harmony” (ICPH) questionnaire. We investigated whether ICPH may change during yoga practice, and suggested significant correlations with mindfulness and other variables of mental stability.

Methods: Prospective analysis of data from 160 individuals participating in a two-year yoga teacher training (Yoga Vidya). The following standardized questionnaires were applied at 0, 3 and 6 months (t1-t3): ICPH, mindfulness (FMI), life satisfaction (BMLSS), mood states (ASTS), health related quality of life (QoL: SF-12), light-heartedness / easiness (LHE).

Results: We relied on data of 160 individuals (91% women; mean age of 41 ± 8 years; mean duration of yoga practice 39 ± 53 months); most were healthy (68%), while 32% experienced chronic diseases. During the course of intensified yoga practice, particularly LHE (d = .71), FMI (d = .40), positive mood (PoM: d = .29), mental health (d = .29) and ICPH (d = .22) increased significantly (p < .01; Friedman). Those with chronic disease had stronger t1:t3 effect sizes for FMI than healthy practitioners, while the effect sized for ICPH, LHE, PoM, and mental QoL changed similarly in both groups. Individuals with primarily low/intermediate ICPH scores (28 %) showed significant (p < .01) increases in FMI, FMI’s acceptance component, LHE, symptoms and ICPH within 6 months; even practitioners with very high ICPH scores at t1 (19 %) had significant (p < .05) increases in FMI, LHE and mental QoL. At the start of the course (t1), ICPH was moderately associated with FMI (r = .44), LHE (r = .41), PoM (r = .40), and weakly with BMLSS (r = .25) and mental QoL (r = .22). Six months later (t3), ICPH was steady associated with FMI (r = .43) and LHE (r = .38), and weakly with PoM (r = .24), BMLSS (r = .23) and mental QoL (r = .19).

Conclusion: ICPH was expressed relatively high in the already experienced yoga practitioners; nevertheless, particularly those with lower scores had strong increase in this attitude during time. The moderate association with mindfulness and LHE remained stable. One could suggest that ICPH represents a trait which may be developed. Further investigation enrolling patients with chronic diseases is required.
OP-019

The assessment and management of depression and anxiety in prostate cancer patients undergoing active surveillance

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Introduction: Prostate cancer (PCa) is the most commonly diagnosed malignancy in British men, accounting for almost 25 % of the total number of male cancer diagnoses each year. Active surveillance is becoming one of the most commonly prescribed treatment modalities for men with localised PCa. Research in other cancer populations suggests that up to 45 % of patients have clinically significant levels of depression and anxiety. The dearth of research in PCa patients undergoing active surveillance limits our current understanding of this group and their psychological needs. It is crucial that we first assess the incidence of these conditions before designing and implementing interventions to manage depression and anxiety.

Method: We plan to recruit 300 active surveillance patients from Southampton University Hospitals Trust in England. All participants will be invited to complete the Hospital Anxiety and Depression Scale (HADS); a widely used, valid and reliable questionnaire. We will also record ethnicity, age and educational, marital and economic status. Descriptive statistics will be run on the HADS data to provide estimates of depression and anxiety. We will run correlation analyses between the HADS data and the demographics to establish the incidence of depression and/or anxiety according to these potentially important variables.

Results: Preliminary findings will be available by August 2011. The primary outcome measure for this investigation will be the percentage incidence scores of depression and anxiety as assessed by the HADS. Secondary outcomes will be focused on participant demographics and their correlations with depression and anxiety incidence.

Conclusions: It is hoped that this investigation will provide an initial baseline estimate of the incidence of depression and anxiety within this population of older, chronically ill men. Once established, these data will then assist in the design of a feasibility study investigating the effectiveness of a mindfulness based meditation programme to provide PCa patients with the resources to self-manage depression and anxiety over the course of their disease.
OP-022

Forging a conviction: the effects of active participation in a clinical trial

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This qualitative study explored non-specific influences on participation in, and outcomes of, a randomised controlled trial.

It was nested within a single-blind clinical trial of western acupuncture which compared real acupuncture with two types of placebo control administered to patients awaiting hip and knee replacement surgery. Data collection (2004-8) was based on narrative-style interviews and participant observation.

The results indicate that trial recruitment and retention depend on a set of convictions forged largely as a result of contextual factors peripheral to the intervention, including the friendliness and helpfulness of research centre staff and status of the administering practitioner. These convictions also influence the reporting of the study outcomes, particularly if participants experience uncertainties when choosing an appropriate response.

The findings suggest that participants in clinical trials are actively involved in shaping the research process, rather than passive recipients of treatment. Thus the outcomes of trials, notably those involving contact interventions, should be regarded not as matters of fact, but as products of complex environmental, social, interpretive and biological processes.

In this paper, we develop and present a ‘theory of active research participation’ which offers a framework for understanding the impact of non-specific processes in clinical trials.
OP-028

Why are people meditating? – the Meditation Motivation Scale

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Objectives: Meditation origins from religious traditions in the ancient East. In our modern western society the practice of meditation grew very popular in recent years. This may be due to secular or non-secular reasons. The motivation to practice meditation may range from intentions like well-being and health related issues up to the concept of self-transformation by following a spiritual path. Since it can be assumed that the motivation for a meditation practice is strongly related to the outcome we decided to construct a questionnaire assessing motives for meditation.

Methods: A large range of meditators was asked for their motivations to meditate. Based on their answers we constructed a 58 item scale in German offering a large range of motivations. All items had to be rated on 5 point scale. 549 meditators filled in the scale online. We performed a psychometric assessment. 27 items were discarded because of low variance, low discriminatory power, skewed distributions or loadings on multiple factors. We performed an exploratory factor analysis (Varimax) with orthogonal scale rotation.

Results: The final scale has 31 items and explains a total of 55.3 % of variance with a internal consistency of Cronbach’s $\alpha = .90$. Motivations could be grouped into four distinct factors: 1. Wellbeing and Relaxation (9 Items, $\alpha = .90$, 17.6% variance), 2. Regulation of Emotions (9 Items, $\alpha = .89$, 14.3 % variance), 3. Self-exploration (7 Items, $\alpha = .85$, 12.5 % variance), 4. Self-transformation (6 Items, $\alpha = .81$, 11.0 % variance).

Conclusion: The newly constructed Meditation Motivation Scale is suitable to assess motivations for the practice of meditation with high reliability. A clear-cut four factor structure emerged from the data of our sample demonstrating that secular and various non-secular motivations can be clearly separated.
Effect of Taiji practice on self-compassion in healthy subjects – results from a randomized waiting list controlled trial

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Background: Taiji, a mindful and gentle form of body movement originating from Chinese martial arts, is known for its positive effects on physical and mental well-being. The preventive and therapeutic value of various components of this mind-body practice have been previously discussed, however until now Self-Compassion (SC) has not been considered. The construct SC comprises kindness towards one’s self, feeling of connectedness with others, and mindful awareness of distressing experiences. SC has recently been found not only to increase in response to mindfulness based interventions but also to mediate their health promoting effects. The aim of our study was to investigate the impact of Taiji practice on SC.

Materials and Methods: 70 healthy participants were randomly assigned either to receive Taiji classes (2 x 1h per week for 3 months) or to a waiting list. SC and subscale values were measured pre, post, and two months after the intervention period by using a validated German version of the Self-Compassion-Scale. Data were analysed by using two-way ANOVA’s and ANCOVA’s (group by time) with repeated measurement controlling for significant baseline differences.

Results: Compared to controls (n = 31) participants in the Taiji group (n = 28) reported a significant increase of SC (F(2, 0.35) = 6.77, p = 0.002) and higher subscale values for self-kindness (F(2, 0.46) = 4.80, p = 0.010) and mindfulness (F(2, 0.38) = 3.24, p = 0.043), as well as lower subscale values for isolation (F(2, 0.60) = 3.18, p = 0.045) from baseline to follow up measurement.

Conclusion: Our findings suggest, that SC can be increased through Taiji practice in healthy subjects. Its contribution to health promoting effects of Taiji is subject of further research.
OP-081

A spirituality teaching program for depression: shifts in spiritual involvement and beliefs

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Background: Spirituality may be an important resource for coping with depression and there may be ways to nurture this mental health resource. Here we report on the effects a Spirituality Teaching Program had on the self reported spirituality levels of depressed individuals.

Methods: Study Design: Spirituality levels were assessed in a total of 113 depressed individuals who participated in a randomized trial testing an 8-week Spirituality Teaching Program as a depression intervention. Participants were randomized to two study arms: 1. Spirituality Teaching Program Group (eight week spirituality teaching program) and 2. Waitlist Control Group (no intervention followed by use of the eight week spirituality teaching program starting at week 9). Assessments were taken at baseline, 8, 16 and 24 weeks.

Intervention: The trial intervention was a self-study Spirituality Teaching Program delivered over 8 weeks. The program included the use of weekly 90 minute audio CDs as well as daily relaxation exercises and addressed the following spiritual concepts: self-transcendence, connectedness, forgiveness, self-acceptance, detachment, compassion and gratitude. The presented content was nondenominational to ensure compatibility with any beliefs participants may hold.

Outcome Measure: The Spiritual involvement and Beliefs Scale (SIBS) was used to assess spirituality levels at baseline, 8, 16 and 24 weeks.

Results: At baseline the two trial groups were similar in their spirituality levels (Spirituality Teaching Program Group: SIBS = 95, 95 % CI: 89 to 101; Waitlist Control Group: SIBS 98, 95 % CI: 92 to 103). After 8 weeks, mean spirituality levels were significantly different (p < 0.001) between the two groups (Spirituality Teaching Program Group: SIBS = 113, 95 % CI: 108 to 117; Waitlist Control Group: SIBS 98, 95 % CI: 93 to 103). For the Spirituality Teaching Program group participants the increase in spirituality levels remained throughout the observation period with mean SIBS scores of 114 at 16 weeks and 113 at 24 weeks. After the wait list control group received the intervention, their mean SIBS score also increased significantly (p < 0.001) to 112 (95 % CI: 108 to 117) at 16 weeks and to 114 (95 % CI: 109 to 120) at 24 weeks.

Conclusion: The tested Spirituality Teaching Program appears to increase spirituality levels and may present an adjunct intervention for nurturing spirituality as mental health resource.
The influence of traditional cupping on the body image in patients with chronic non specific neck pain – a qualitative study

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Background: The body image (BI) is the representation of perceived body dimensions. Pain conditions like phantom pain, CRPS and most likely functional pain disorders might severely distort BI and thereby affect everyday life. In this study we investigated whether patients with chronic neck pain had a distorted BI and how it would be influenced by cupping therapy.

Methods: This qualitative study was nested within a larger trial on traditional cupping for chronic non specific neck pain. A subsample of six patients was drawn from this sample. Patients were asked to complete a life-size drawing of their upper body and to fill the perceived outline of the neck and shoulder area. Three of the patients then received a single cupping treatment and four days later the task was repeated. After drawing we used a semi standardised interview to retrieve more information on the drawings and the BI. An interdisciplinary interpretation group analysed the interviews using the content analysis approach according to Mayring.

Results: The drawings revealed possible BI distortions, including missing body parts and distortions in shape and dimension. Analysis of the interviews revealed the very dominance of pain. Pain was further described as heaviness, a burden and alien. Patients seemed disconnected from their body and their emotions to some extent. There were different ways of dealing with the pain like “endurance”, “distraction” or relieving postures. Pain might also be re-interpreted cognitively. When those strategies failed, patients sought medical treatment in order to get “fixed”. All strategies were used not only to ease the pain but also to ensure efficiency. While patients in the control group reported no changes in body perception the treated patients reported less pain, tension and heaviness after cupping. Equivalently the drawings showed shrinking outlines and rounder edges. Pain areas were perceived more punctuate and distinct and they also seemed to be more integrated in BI.

Discussion: The results of this qualitative study reveal possible body image distortions in patients with chronic non specific neck pain. Drawings as well as interviews might be helpful to evaluate the nature and impact of the distortions. Cupping treatment might further alter the body perception, however further research is necessary to validate these findings.

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Results of a randomised controlled pilot study on the effect of traditional cupping in chronic non-specific neck pain

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Background: Traditional cupping, i.e. wet cupping, has been used since antiquity in the treatment of pain conditions. In the last decade studies showed that traditional cupping might be effective in various diseases, e.g. back pain, carpal tunnel syndrome and migraine. However, no randomised controlled trial has yet investigated the effects of traditional cupping on chronic non-specific neck pain. In the present study we investigated whether a single application of traditional cupping influences neck pain and sensory perception.

Methods: 50 patients with chronic non-specific neck pain (mean age 56.0 ± 9.5 years) were randomised into treatment group (TG) or waiting list control group (WL). Measurement before (T1) and 4 days after a single traditional cupping treatment (T2) included pain related to movement (PRTM), neck disability (NDI) and quality of life (SF-36) questionnaires. In addition mechanical detection threshold (MDT), vibration detection threshold (VDT) and pressure pain threshold (PPT) were determined at two pain related and two control sites. To investigate the course of pain patients kept a pain diary (PD) from 7 days prior to T1 until T2.

Results: Analysis of PD revealed significant pain relief in the TG compared to WL already at the second day following cupping treatment. This effect was sustained until T2. Furthermore TG reported significant less PRTM and higher physical quality of life (SF-36) at T2 compared to WL. For PPT significant group differences were found at pain related sites, but not at the control sites. No effect was found for NDI, MDT or VDT.

Discussion: A single application of traditional cupping might be effective in the treatment of chronic non-specific neck pain. Not only did neck pain but also pressure pain sensitivity decrease after cupping indicating possible changes in pain processing.

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Willow bark extract STW 33-I is safe and effective in the long term - treatment of degenerative joint diseases

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Objectives: Degenerative joint diseases are of increasing relevance in an ageing population. The efficacy and safety of willow bark extract in the therapy of painful diseases of the support and locomotor system has been shown in a large number of clinical studies. This 6 months post-marketing surveillance study with STW 33-I (Proaktiv®, extraction solvent water; drug-extract ratio 16-23:1) included 350 patients suffering mainly from arthrotic and back pain diseases for several years. The patients were mainly treated with STW 33-I alone but also in combination with other NSAIDs and opioids.

Method: An extensive case report form with pain questionnaires and patient diary was used to evaluate and compare the long term outcome of the treatment with STW 33-I and combinations.

Results: 62 % of the patients were treated with STW 33-I mono therapy, 28 % with a combination of STW 33-I and NSAIDs and about 5 % received additionally opioids. The mean change from baseline of the pain intensity score was -23.5 in the subgroup of the patients receiving STW 33-I only, - 18.8 in the STW 33-I and NSAIDs subgroup and -21.2 in the STW 33-I, NSAIDs and opioids subgroup. These results were comparable to other scales concerning pain intensity at rest and in motion and pain duration. The tolerability of STW 33-I was distinctly better compared to the other investigated subgroups. No relevant drug interactions were reported.

Conclusions: These data suggest that the phytomedicinal approach, and especially STW 33-I (Proaktiv®), can be used as a basic treatment in the long term therapy of degenerative joint diseases and that it can be combined with NSAIDs and opioids if necessary.
The influence of physicians’ expectations on the treatment outcome of chronic pain patients treated with usual care only or additional acupuncture

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Background: While patients’ expectations in acupuncture treatment have been much investigated, less focus has been on physicians’ expectations. Our aim was to investigate if physicians’ baseline expectations regarding the treatment outcome of chronic pain patients are related with treatment success in acupuncture and usual care treatment.

Methods: Patients with chronic low back pain, headache, neck pain, or pain due to osteoarthritis of the knee/hip from 4 large multi-center, randomized trials were randomized to receive usual care only or 10 additional acupuncture treatments. Data were pooled, and the physicians’ expectation at baseline and its interaction with the treatment group was included in a logistic regression model predicting treatment success (defined as a change of 10 points or more between baseline and 3 months on the SF-36 bodily pain subscale).

Results: A total of 9,900 patients (mean age 49.6 ± 13.7 years; 67.7% women) treated by 2,781 physicians specialized in acupuncture were analyzed. The treatment group did not moderate the relation between expectations and outcome. Patients for whom the physicians had expected strong improvement performed better than patients for whom moderate improvement had been expected (OR = 1.29; CI: 1.15, 1.44; p < .001). No differences were found for patients with moderate expected treatment success versus those where no treatment success was expected (OR = .96; CI: .76, 1.21; p = .71).

Conclusion: High expectations of physicians at baseline predict a better treatment outcome, independent of the treatment. Since we adjusted for several patient variables including duration and severity of disease, this cannot be explained by patients’ prognostic factors only. Context factors might play the relevant role.
STW1 (Phytodolor®) in rheumatic pain: re-analysis and meta-analysis

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\textbf{Background/Aim:} Most common causes for pain are musculoskeletal disorders (MD). Treatment of MD is multi-disciplinary including herbal analgesics. Although reviewed no quantitative evaluation of efficacy and safety of the herbal combination Phytodolor (STW1) is available.

\textbf{Methods:} For systematic review databases (e.g. Embase, Medline) were searched and authors and the manufacturer were contacted to identify randomized controlled trials (RCT) examining pain reduction under STW1 in patients with MD. Due to an evident publication bias we decided to re-analyse raw data of eligible published and unpublished RCTs and pooled the results for meta-analysis according to Cochrane guidelines and an intention-to-treat approach. Primary outcome was patient global assessment, secondary pain at rest and movement. Results were stratified according to treatment groups.

\textbf{Results:} Patient data of 11 RCTs were eligible for pooling to evaluate efficacy and pain assessment. STW1 was significantly superior to placebo in reducing pain in the entire population (group difference 20 %; \( p < 0.001; \) OR 0.43; 95 % CI 0.28, 0.65) and in the subpopulation 'other rheumatic diseases' (\( p < 0.001; \) OR 0.32; 95 % CI 0.2, 0.52) but not in the subpopulation 'gonarthrosis'. STW1 did not differ significantly compared to NSAIDs neither in the entire population nor the subpopulations. Similar results were found for pain at rest and movement. No serious adverse events (AE) but minor AE were reported (8.1 % of placebo, 14.2 % of STW1, 18.9 % of NSAID patients).

\textbf{Conclusion:} According to the data analysed STW1 shows better pain reduction than placebo in patients with pain due to MD, probably equivalent to NSAID and is well tolerated.
OP-137

Iyengar yoga compared to home-based exercise for patients with chronic neck pain: a randomized controlled trial

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**Background:** Deriving from ancient India, yoga is receiving more and more attention as a part of modern mind/body medicine. Iyengar yoga, the most prevalent style of yoga taught in the west, applies therapeutic variations of classical yoga postures to many health problems. As growing evidence supports the value of yoga in treating chronic pain conditions, this randomized controlled trial investigated the effect of Iyengar yoga on chronic neck pain compared to home-based exercise.

**Methods:** Patients with chronic non-specific neck pain were randomized to either a yoga group or a home-based exercise group. The yoga group participated in weekly 90-minute Iyengar yoga-classes over a period of 9 weeks. The exercise group received a manual on exercises for the neck and shoulder region, designed by a statutory German health insurance company. Both groups were instructed to practice at home for 10 minutes each day. Main outcome measure was present neck pain intensity (100 mm visual analog scale, VAS). Secondary outcome measures included functional disability (Neck Disability Index), pain at motion (VAS), health-related quality of life (Short Form 36 questionnaire), cervical range of motion, proprioceptive acuity and pressure pain threshold.

**Results:** 51 patients (mean age 47.8; 82.4% female) were randomized to yoga (n = 25) and exercise (n = 26) intervention. After the study period, patients in the yoga group reported significantly less neck pain intensity compared to the exercise group (mean difference: -13.9 mm [95% CI = -26.4; -1.4], p = 0.03). The yoga group reported less disability and better mental quality of life. Range of motion and proprioceptive acuity were improved and pressure pain threshold was elevated in the yoga group. There were no serious adverse events.

**Conclusions:** A 9-week Iyengar yoga regimen was more effective in relieving chronic non-specific neck pain than a home-based exercise program. Yoga reduced neck pain intensity and disability and improved health-related quality of life. Moreover, yoga seems to influence functional status of neck muscles, as indicated by improvement of biologically-based measures of neck pain.
Initial homeopathic aggravation and adverse effects of homeopathic treatment- a literature review of randomized control trials, observational studies and surveys

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Content: Background In homeopathy symptoms appearing after taking the homeopathic remedy, are recognized as the body's attempt to restore its balance. Ideally, and according to the literature, this process should proceed without complaints. In practice the patients often get “worse before they get better”. Such a reaction is temporary, and is generally considered a favourable response and a part of a healing process. Adverse effects have been reported in randomized controlled trials, but so far no serious effects of homeopathic treatment have been reported. In this review we will explore to which extent observational studies and surveys add important information to what we know so far about initial homeopathic aggravation and adverse effects, as these studies are more likely to have explored these issues.

Objective: Our aim is to classify and identify adverse effects and initial aggravations after homeopathic treatment.

Methods: We performed a systematic search in the literature for homeopathic aggravation and adverse effects. We searched for randomized controlled trials, observational studies and surveys in order to explore how initial aggravations and adverse effects are reported and registered in these studies. The following electronic databases were searched: AMED, Cinahl, Cochrane Central register for Controlled Trials (Central) in the Cochrane library, Embase, MedLine, PsycINFO, PubMed, CAMbas, Datadiwan, GIRQ, HomBRex and Hom-Inform. Filter: Year 2000 -2010.

Results: From searches performed in October and November 2010, a total of 630 articles were identified. Out of these, 568 were clearly not of interest, 33 were randomized controlled trials, 22 were observational studies and 7 were surveys concerning adverse effects. All together, 62 studies were included.

Conclusions: Homeopathic aggravation was seldom reported in observational studies and surveys. Generally, aggravations were reported predominantly in the body as a whole. Adverse effects that were reported in randomized controlled trials were of mild and transient origin. The data analysis is in progress and will be completed before October 2011.
**OP-027**

**Challenging dose-response dogma: the realm of very diluted xenobiotic concentrations**

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Some years ago we suggested that hormesis may provide a central concept for pharmacology development\textsuperscript{[1]}. The basis of this expectation was given from elementary nonequilibrium thermodynamics considerations. Unfortunately, despite its theoretical roots, it was found difficult to be verified according to the instrumental limit of signal detection of the most sensitive physicochemical technologies. We have tried to overcome this difficulty using genome-wide gene expression analysis on cellular systems in collaboration with the Professor P. Dolara group of the Department of Pharmacology of the Firenze University. This contribution concerns the results of these studies and its discussion is believed to provide some important perspectives.

Human prostate epithelial cells were exposed to aqueous solutions of different xenobiotics in the concentration range 10\textsuperscript{-6}-10\textsuperscript{-18} M and their gene expression profiles were compared with those of reference cells exposed to xenobiotic-free water\textsuperscript{[2]}. The analysis was performed with microarray technology using the Whole Human Genome Array from Agilent. Microarray data demonstrated that xenobiotics affect gene expression at all concentrations tested. Many genes belonging to functional gene families were concentration-dependently modulated by xenobiotics, in agreement with the hormetic paradigm. Reverse-transcription-PCR analysis, performed on different genes on biological replicates for selected genes, confirmed the xenobiotic concentration dependent trend observed in microarray results.

The observed hormetic behaviour of gene expression profiles involves two main perspectives. The first is associated with the possibility of exploiting the dose-dependent cell answers in pharmacology. The large amount of operational tenets of the homeopathic therapeutic tradition is believed to provide a significant amount of data. The second is that the properties of the drugs currently used in biomedicine must be reconsidered, since slow pharmacokinetics may involve unexpected undesirable effects at low concentration. Examples of the latter behaviour are still known.

\textsuperscript{[1]} S. Bernardini, A. Dei Toxicol. Appl. Pharm. 2006, 211, 84
A randomised, double-blind comparability study of a placebo for individualised Western herbal medicine in adult outpatients

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Introduction: Remarkably, despite the emphasis on clinical trials being ‘double-blind’, data on adequacy of blinding is rarely reported in clinical trials. When blinding is actually tested, it is often found that participants are not in fact fully blinded, thereby undermining one of the supposed foundations of evidence-based medicine. The current study of individualised phytotherapy attempts to avoid this pitfall by rigorously testing a placebo for its comparability with herbal medicines. There is a contrast between the widespread use of single herbal products indicated for specific conditions, such as St John’s Wort for depression, for which there is often an established evidence base, and the approach of Western herbal practitioners (over one thousand in the UK), who prescribe individualised combinations of liquid herbal extracts to improve general function as well as treat the index condition. A systematic review of individualised phytotherapy in any condition only found only three randomised controlled trials (RCTs), all of which were methodologically flawed. In order to develop an evidence base for individualised phytotherapy, there are formidable methodological challenges including the development of placebos. Our study tested the comparability of placebos manufactured by a professional flavour chemist with herbal medicines in a “taste test”.

Methods: Two different verum tinctures were made up by the study pharmacist from a list of eleven widely used herbs. Their distinctive taste was partially masked by adding 15% by volume of a flavouring mixture. Two different inert placebos were designed to mimic the taste of herbal mixtures, containing alcohol, caramel colouring and food flavouring extracts. Adult outpatients of either sex attending our hospital were randomised to taste either two verum or two placebo tinctures, prepared in individual 10ml vials in a sealed envelope. A sample size calculation based on pilot data indicated that using a one-sided non-inferiority comparison with a 25% threshold, a 5% significance level and 80% power, 102 subjects were required. A one-sided test of proportions was used to examine if the proportion of patients who stated that they tasted herbal medicines in the placebo group was significantly lower than in the verum group.

Results and conclusion: The study is ongoing and will finish in August 2011. Statistical analysis of the results will be available in time for the conference.
OP-070

An autonomic brainstem network mediates antiemetic and cardiovascular effects of acupuncture in man

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Despite acupuncture's effectiveness in the treatment of various diseases, its underlying mechanisms are largely unknown. Most of today's knowledge stems from animal experiments, and the findings can usually not be verified in humans due to the need for invasiveness. Functional magnetic resonance imaging offers a way for non-invasive measurements of the human brain under acupuncture stimulation.

So far, physiological noise has restricted the use of fMRI to the cerebral and cerebellar cortices. However, with the recent advent of brainstem-sensitive fMRI sequences, it has become possible to measure the activity of this neglected but highly important part of the brain. This has opened a new window to assess the role of autonomic and nociceptive brainstem centres in mediating acupuncture’s effects. We used brainstem-sensitive fMRI and heart rate recording during acupuncture stimulation of acupoint Pc6.

Subjects had to rate the intensity of their needling sensation (Deqi) every 10 seconds on a visual analogue scale (VAS).

Comparing needling sensation and heart rate time courses, we observed a pronounced sympatho-inhibitory effect. fMRI analysis revealed, that this effect was mediated by a network of brainstem nuclei comprising rostral ventrolateral medulla, medial vestibular nuclei, ventrolateral periaqueductal gray, and hypothalamic areas.

Our results provide evidence for an autonomic action mechanism of acupuncture, which could explain its effectiveness for the treatment of nausea, vomiting and possibly migraine prophylaxis.
OP-080

Promoting vs. misleading factors influencing an integrative medicine course

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Since 1999 the Emilia Romagna Region (Italy) is facing the issue of the possible Unconventional Medicines integration in the National Health System (SSN) through a strategy based on the direct financial support of studies aimed to evaluate the effectiveness and safety of specific unconventional treatments. This strategy has been realized through two consecutive Regional Experimental Programs, which included surveys, observational and experimental studies.

Research activities have been supported by educational initiatives to improve skills of researchers involved in the Programs, and by joint seminars with the conventional medical community, in order to enhance open scientific discussion and overcome prejudicial oppositions.

The implementation of such a course has been influenced by a number of drivers and barriers. Their historical and social motivations and their (sometimes solid, sometimes weak) ideological basis seems to us worth disclosing and presenting to stimulate an open discussion and distinguish the best contributes that both Conventional and Unconventional Medicine have to put in the basket from what it’s better to give up, along the way to an inclusive, effective and safe Integrative Medicine.

At present, the Unconventional Medicines Observatory of Emilia Romagna Region is planning a possible 3rd Experimental Program, focused on researching Integrative Medicine models of care. A possible set of selection criteria for funding research projects will be presented and offered to discussion.
OP-118

Integrative healthcare: a bibliometric-based analysis of an emerging concept

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Background: In response to the demand for and use of complementary and alternative medicine (CAM) by health consumers, such therapies are increasingly being incorporated into health care provision within contemporary health care settings. Integrative health care (IHC) or integrative medicine (IM) has become a term used by the CAM research and practice communities to identify these innovative practices and health care delivery models.

Purpose: This bibliometric analysis aims to evaluate the IHC literature in order to develop a better understanding of the development of the IHC concept and its application specifically in the CAM field. The purpose of this review is to identify: (1) the degree of scientific production of papers that defined or conceptualized IHC, and (2) overall trends in and developments of the field.

Methods: All articles on IHC published between 1915 and 2010 indexed in MEDLINE, EMBASE, AMED, CINAHL, and PSYCHInfo were retrieved. The article screening process consisted of a title, abstract, and full article review to determine the final sample of papers discussing the integration of CAM and conventional care. Bibliometric indicators such as impact factor, year, country, and field of publication, as well as indexing keywords were used to create a cartography of research areas and related trends, and to trace the production dynamics.

Findings: Of the 4716 references retrieved, 268 met the inclusion criteria and were included in the analysis. There were 129 journals from a range of health related disciplines that published on or about IHC; 29 of these journals were from the CAM field. IHC articles were published in relatively high impact factor journals. Almost half (42 %) of the research productivity, reflected as the percentage of overall volume of academic publications in the sample, occurred between 2005 and 2007. Corresponding authors who have published on IHC represented researchers and practitioners from 19 countries. Keywords most frequently used to index IHC articles were specific to diseases, symptoms, and healthcare concepts (such as healing, clinic, and terms derived from “integrate”).

Conclusion: This bibliometric analysis allows for a broader overview of the IHC literature. It enables the evaluation of the research output and its impact in the healthcare field. It also provides important insights on how the field has developed and to identify potential directions for future research in IHC.
New eLearning technologies in Mind-Body-Medicine to promote healthy lifestyle-changes – introduction of the model

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Studies reveal that 60-90 % of all visits to the doctor in Western countries are due to stress- and lifestyle-related illnesses. It could be shown that structured Lifestyle Change Programs are effective in symptom-reduction in a variety of diseases. The Department of Internal and Integrative Medicine at Kliniken Essen-Mitte gathered more than 10 years of experience in running a Mind/Body Medicine Outpatient Day Clinic (10 weeks, once a week for 6 hours each).

Mind/Body Medicine aims at incorporating stress-alleviation procedures and new forms of lifestyle changing methods into people’s everyday lives and works on the principle that a health-oriented lifestyle mobilizes self-healing capacities. Mind/Body therapy embraces nutrition, exercise, relaxation response, cognitive restructuring and stress management. These contents are taught to mostly chronically sick patients. The most frequently treated diseases are chronic internal and pain diseases respectively. A limiting factor though in the Outpatient Day Clinic Model, especially for professionally mobile patients, is the requirement of the physical presence in the treatment groups.

In recent years eLearning has become a common component in the field of medical education. With the latest growth rates in the eHealth market, eLearning Technologies will also increasingly be leveraged for the patient education. Health oriented social networking sites, mobile Health (mHealth) applications and the use of videos for learning will enable an active patient involvement in their virtual education. Here we introduce an e-learning-based MBM-Program for Breast Cancer patients to reduce chemotherapy side-effects and improve physical fitness.

In the presentation, we will provide an overview and demonstration on how we are enhancing the existing Outpatient Day Clinic with eLearning Technologies eventually offering a complete online version of our program. The audience can learn how face-2-face patient education services can successfully be migrated to virtual deliveries. Moreover, we are exploring opportunities and key success factors of using eLearning Technologies in Mind/Body Medicine to promote healthy and sustainable lifestyle changes.
Effectiveness of Iyengar yoga in patients with chronic neck pain: a randomized controlled trial

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Background: Hatha yoga has been proven effective in reducing pain and improving function in patients with chronic low back pain. We aimed to investigate the effectiveness of Iyengar Hatha yoga in chronic upper back/neck pain by means of a clinical randomized controlled trial comparing the Iyengar yoga approach with home-based standard exercise.

Methods: Patients with chronic neck pain (mean duration <6 years) and pain intensity of > 40mm on a 100 mm VAS were randomized to either a Iyengar yoga group or a home-based exercise group. Patients in the Yoga group was offered participation in 9-week Iyengar yoga course with weekly 90 min classes guided by an experienced Iyengar yoga teacher (HT), patients in the exercise group received a standard manual on exercise for chronic neck pain. Primary outcome measure was change of neck pain intensity (100 mm Visual Analog Scale, VAS) after 9 weeks. Secondary outcomes included function and disability (Neck Disability Index), pain at motion (VAS), mood (POMS), anxiety and depression (ADL) and quality-of-life (SF-36).

Results: 77 patients were initially included in the trial. 24 patients dropped out due to unwillingness to attend classes/follow-up visit or other reasons not related to the study. 53 patients (yoga n = 25, men age 47.5 y); exercise n = 28, mean age 48.3 y) completed the follow-up. Mean pain decreased from 44.3 ± 20.6 to 13.0 ± 11.6 mm in the yoga group and from 41.9 ± 21.9 to 34.4 ± 22.1 mm in the exercise group resulting in a mean group difference of -20.1 mm (95 % CI -30.0; -10.2; p < 0.001). Also, mean pain at motion, neck ± pain disability and function improved highly significant in the yoga group compared to exercise (each p < 0.001). Notably, Iyengar yoga reduced anxiety and depression (p < 0.001), improved various dimensions of mood (p < 0.01) and physical quality-of-life (p = 0.003). There were no serious adverse events.

Conclusions: A 9-week Iyengar yoga approach is highly effective in relieving chronic neck pain and improving function compared to standard exercise recommendations. Moreover, affective states (mood, anxiety, depressive symptoms) as well as quality-of-life were largely improved. Iyengar yoga seems to be a promising option in the management of chronic upper back/neck pain.
OP-143

Arts speech therapy and its influence on the regularity of the heart beat

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Introduction: Previous studies revealed that arts speech therapy (AST) – a therapeutic method used in anthroposophic medicine – affects the cardiorespiratory system as well as cerebral hemodynamics and oxygenation. The aim of the present study was to further investigate effects of AST by assessing changes in heart rate variability (HRV) indices.

Material and methods: Measurements were performed in 24 adult volunteers during AST. Each measurement lasted 43min (8min pre-baseline, 5min recitation, 5min recovery, 5min recit., 20min post-baseline). For each subject, measurements were performed for 3 different AST tasks (recitation of alliterative (RA), hexameter (RH), and prose (RP) verses) and a control task (mental arithmetic (MA) with voicing of the result) according to a randomized crossover design. HRV was determined using a Medilog AR12 holter ECG. The multifractality of HRV was determined using the multifractal detrending moving average (MFDMA) method. Statistical analysis was applied to the difference between pre-baseline, 2 recitation and 5 baseline periods. The 4 tasks were tested separately; p≤0.05 was considered significant.

Results (significant changes): (1) During recitation: Heart rate (HR) increased during RA, RH and MA but not during RP. The coefficient of variation (CV) increased during RH and MA. The normalized high frequency (nHF, 0.15-0.4 Hz) and low frequency (nLF, 0.04-0.15 Hz) power of the HRV decreased (nHF) and increased (nLF) during RA, RH and RP. The multifractal parameter α mode showed a decrease during MA. The degree of multifractality (Δα) increased during PR and MA. Heart rate coherence (HRC) decreased during RP, RH and MA. (2) After recitation: PR caused an increase in Δα; RH caused an increase in the very low frequency (VLF, <0.04 Hz) power, and the HR decreased after RA and RH. HRC decreased after RH.

Conclusion: The study showed that AST affects HRV indices during and after the AST tasks. The changes indicate that AST during the recitation decreases the activity of the parasympathicus (decrease in HFn, increase in LFn). The multifractality of HRV changed during MA and after MA and PR; the physiological meaning of these changes has to be discussed. The decrease in HRC after RH indicates a change in the activity of the hypothalamus-pituitary-adrenal axis. In conclusion, HRV changed differently during and after AST depending on the specific AST task. The changes may have the potential to be used for therapeutic purposes.
Health-related quality of life and practicing qi gong and yoga: the effect of an integrative lifestyle modification program

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Physical inactivity is a common problem in all industrialized countries and one of the main risk factors of several chronic diseases. In the context of Complementary and Alternative Medicine (CAM) various kinds of Asian and western physical education programs have been applied to promote physical and mental health. The aim of this study was to investigate whether a two-week integrative inpatient therapy with focus on lifestyle modification would affect physical activity level and its relation to health-related quality of life.

Methods: In a prospective observational design with three and six month follow-ups, 551 patients (mean age 53.9 ± 14.2 years) with chronic diseases (e.g. specific and non-specific chronic pain syndromes, fibromyalgia, arthropathies, bronchial asthma, inflammatory bowel diseases) were examined. They received a 14-day integrative inpatient treatment, that included methods of conventional and traditional European and Chinese medicine, mind-body medicine, exercise training, physical therapy and nutritional advice. Before and two times after treatment, we assessed health-related quality of life (SF-36) together with frequency of everyday activity, qi gong / yoga practice and western endurance and weight training.

Results: 155 responders, which did not systematically differ from non-responders, reported significant higher frequency of qi gong and yoga practice after three (66.7 % increase from 1.2 to 2 times per week) and also after six months (50 % increase from 1.2 to 1.8 times per week). However there was no relevant gain in everyday activity, western endurance or weight training. At both follow-ups the health-related quality of life at all SF-36 subscales was significant elevated. Additionally we found significant partial correlations (adjusted by age, gender and education) between the change in qi gong / yoga practice and changes in bodily pain (r = 0.19; p = 0.025), mental health (r = 0.29; p = 0.000), vitality (r = 0.17; p = 0.049) and social function (r = 0.25; p = 0.002).

Conclusions: Study results suggest that an integrative inpatient therapy could lead to a specific higher practice in qi gong and yoga practice and enhance health-related quality of life up to six months. Furthermore an increased practice of Asian techniques is associated with lower pain and higher mental quality of life in patients with chronic diseases.
The effects of guided imagery on preoperative anxiety and pain management in patients undergoing laparoscopic cholecystectomy: a multi-centre, randomized controlled study

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**Background:** Laparoscopic Cholecystectomy (LC) is common practice in the treatment of symptomatic gall stones. LC is often associated with preoperative stress which may negatively impact postoperative pain perception, analgesics requirement and recovery from surgery. It is therefore of importance to design and investigate treatment strategies that minimize preoperative stress.

**Objective:** To investigate whether guided imagery can reduce preoperative anxiety and postoperative pain perception and medication, compared to standard care, in patients undergoing LC.

**Methods:** The study was designed as a multi-centre, randomized controlled study with two parallel groups. In total 140 patients (\(\geq 18\) year) that were scheduled for LC were randomly allocated to a guided imagery group (\(n = 70\)) or a control group (\(n = 70\)). The guided imagery group was provided with a CD to practice guided imagery once a day, 7 days prior to surgery. Patients in the control group received standard care instructions only. Primary outcome measurements were preoperative anxiety levels; Amsterdam Preoperative Anxiety and Information Scale (APAIS), postoperative pain perception (VAS-scale) and use of postoperative analgesics. Secondary outcome measurements were patient satisfaction (PSQ) and safety.

**Results and Conclusions:** A first analysis of 134 patients demonstrates that 103 (77\%) patients completed the study, 50 in the guided imagery and 53 in the control group. In total, 31 patients (23\%) dropped out, 18 in the intervention and 13 in the control group. The major reason for drop-out was that surgery dates became known to the patient at a very late stage (1-3 days before surgery), so that so that guided imagery and standard care could not be followed according to protocol. Both groups were highly comparable with respect to demographic data. The majority of patients were female (76\% in guided imagery; 78\% in control group). The average age was not significantly different (51.68 \(\pm\) 13.73 years with guided imagery; 49.7 \(\pm\) 14.51 in control group) and both groups had comparable co-morbidity (45.6\% of patients with guided imagery; 42.2\% in the control group). Complete data on (outcome) measurements are currently being analysed and will be presented. With this study we anticipate to gain more insight whether guided imagery can be used as an effective self-management tool in pain management for patients undergoing laparoscopic surgery.
Is Taichi community programme effective in reducing fall-related hospital utilization? An observational study

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Background: Overseas studies and reviews showed that about 30% of elderly may suffer from falls every year and approximately one fall in ten resulted in fractures. Fall is also a major cause of hospitalization in Hong Kong, ranking the fifth in terms of total bed days of all public acute hospitals. Tai Chi (TC) is a Chinese martial art form for centuries and seems to be an effective intervention to prevent falls through improving functional balance and physical response.

Study Design: We carried out a prospective observational study of 3,222 community-dwelling elderly aged 60 or above to assess the effect of TC in reducing the incidence of injurious falls.

Intervention: A one-hour simplified TC session led by recognized TC coaches was performed twice a week in a period of four weeks. Participants were encouraged to continue TC sessions after the course of training.

Outcome Measures: Injurious fall incidents were retrieved from medical records database 12 months before and after TC training. Injurious fall incident rates were compared before and after TC training, as well as between 2 strata: continue (n = 1,269) vs cease (n = 1,360) TC in 12 months post training.

Results: The injurious fall rate dropped from 2.21% (pre) to 1.34% (post) in continuing TC group while the fall rate increased from 2.06% (pre) to 3.46% (post) in non-continuing TC group. The percentage of hospitalization due to fall-related injuries was 0.39% and 1.03% respectively in continuing TC and non-continuing TC group.

Conclusion: Study results demonstrated that TC has potential preventive effect in injurious falls and hospital utilization.

Relevance: TC is attributed to variations, coordination and socialization effect. Promoting TC in elderly community could be beneficial for better health, preventing falls or injurious falls and reducing hospital admissions. It is obviously a cost effective approach to reduce the public health burden.
Integrated medical treatment in children suffering from attention deficit disorder with and without hyperactivity – long-term follow-up


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Background: Attention deficit disorder with and without hyperactivity (ADD/ADHD) is one of the most important neuropsychological and psychiatric diagnoses in childhood and adolescence, affecting 3–5% of school-age children in Europe. Conventional therapy consists of administration of stimulants; classical homeopathy seems to be a reliable alternative or complementary treatment.

Objective: To assess long-term follow-up of children treated by a combination of stimulants and potentized homeopathic remedies.

Method: Due to dissatisfaction with stimulant treatment, children and adolescents with ADD/ADHD diagnosis according to the Diagnostic and Statistical Manual of Psychiatric Diseases (DSM-IV) participated in an observational study for classical homeopathic therapy. During the screening phase to determine the optimal individually prescribed remedies, stimulants were reduced according to the beneficial effects of homeopathic therapy. In the following double-blind cross-over randomized clinical trial (RCT), no stimulants were administered at all. During ongoing open label extension study, treatments were according to children’s and adolescents’ needs including both, stimulants, and homeopathic remedies.

Results: Eleven (18%) out of 83 children had appropriate methylphenidate (MPH) therapy prior to, and stepwise reduced during screening phase. All of them had no stimulant therapy during RCT. After five years of open label extension study, two of these children had again stimulant therapy continuing up to actually more than 8 years. Another four to seven children and adolescents were given stimulants during the last seven years, both in addition to homeopathic remedies, or as sole therapy. Single case studies as well as quantitative studies according to a Kaplan-Meier design will be presented.

Discussion: Due to the numeric limits of this prospective observational study, 11/83 children were followed for actually (mean) 8.5 years.

Conclusion: Approximately 10 to 20% of children and adolescents with ADD/ADHD diagnosis according to DSM-IV are in need of stimulant treatment, for another 80 to 90% are successfully treated by individually administered potentized homeopathic remedies.
OP-049

Homeopathic therapy in paediatric respiratory complains from 1998 to 2009: long-term outcomes in asthma and allergic rhinitis

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Aim: To study the socio-demographic features of the paediatric population homeopathically treated for respiratory diseases, the follow-up and the long-term results in asthma and allergic rhinitis.

Materials and Methods: An observational longitudinal study was conducted 651 paediatric patients (25.1 %) mean age < 14 years, consecutively visited at the Homeopathic Clinic of Lucca from 1998 until 2010, on. 410 (63 %) were aged 0-6 years, and 241 (37 %) were aged 7-14 years. A total of 48 % of children performed at least one follow-up visit. The GHHOS (Glasgow Homeopathic Hospital Outcome Score) was used to assess outcome; whereas the degree of symptom intensity and the regression after treatment were assessed by means of a numerical rate scale (NRS). The reference values of the GHHOS scale were distributed according to a Likert scale from -1 to + 4. Moreover, parents of all paediatric patients’ suffering from allergic respiratory complains with at least 5 years of follow up, were telephonically called and invited for a re-evaluation.

Results: Children with respiratory diseases were 388 (59.6 %), mainly with asthma: 104, allergic rhinitis: 52 and recurrent upper respiratory tract infections: 232. At least one follow-up visit was performed in 52.6 % of children. The probability of important improvement or resolution of the problem is significantly higher among patients with upper respiratory tract infections, who present success rates of 77 %, followed by patients with allergic rhinoconjunctivitis (63 %), and finally those with disease of the lower respiratory tract (54 %). Patients who reported significant improvement or resolution of their symptoms ranged from 38 % at 2nd month to 94 % at 24-month or more of follow-up. The likelihood of success is considerably higher in patients with follow-up of at least one year. The long-term results of homeopathic therapy in asthma and allergic rhinitis are in course of evaluation. Till now we have the possibility to contact parents of 51 children with asthma after a period of at least 5 years (range 5 – 10 years) and we found 36 (70.6 %) with a complete remission of asthma and 15 (29.4 %) with asthma, 12 of episodic and 3 with light and moderate persistent asthma; 12 (76.5 %) have also/or allergic rhinitis, 9 slight and 3 moderate.

Conclusion: The results seem to confirm that homeopathic medicine produces a positive therapeutic response in children presenting respiratory complains, mainly in with allergic rhinitis and asthma.
OP-050

The variations of brain activities of acupuncture to TE5 of left hand in normal subjects

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This paper presents the evident effects of acupoint stimulation, using EEG measurements. With acupuncture stimulation and the EEG measurement on the same meridian, EEG is able to accurately detect the effects of acupunctural point stimulation on brain waves.

In our study, 24 subjects without heart or nervous diseases were randomly separated into two groups of 12. In the first group, the subjects laid on a bed with eyes closed for 10 minutes. They then received acupuncture at their waiguan points (TE5) on their left hands for 20 minutes. After plucked the fine point, they were observed after a five-minute pause. The other 12 subjects belonged to the control group. They followed the same procedures as the acupuncture group, but the needle was instead inserted at non-vital points in their left hands. The acupoints located on EEG waves were presented as: T3, T4, 01, 02. The study did not adopt needle twirling to develop our experiments.

According to our adopted continuous wavelet transform analysis, the brain waves are identified as: $\delta$ (0.5~4 HZ), $\theta$ (4~8 HZ), $\alpha$ (8~13 HZ) and $\beta$ (13~30 HZ). During acupuncture stimulation, the $\theta$ wave’s energy increased more at all statistical points than before. Upon removing the needle, T3 and T4 points slowly declined and revealed the obvious differences in energy levels between rest and exposure to acupuncture. During acupuncture, only T3 on the $\alpha$ wave showed small statistical energy variations, but levels began decreasing after the first five minutes. Using EEG readouts gathered during our research, we prove that acupuncture affects brain waves and that the stimulation changes based on the potential of the cranium and scalp tissue.
A holistic scale for the assessment of physical and psychological functioning in children with developmental disorders

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Objective: The bio-psycho-social health problems of children with developmental disorders show considerable variability. In this study the objective is to construct a measuring instrument (scale) that enables to individualize diagnostics and treatment, in addition to the classification of the psychiatric disorder on the group level. Classification is a means to design generalized treatment of a disorder. The use of the newly developed instrument is a powerful help in making, in addition or as an alternative, choices for individualized support.

Methods: The instrument is based on a holistic view of health (balance and wholeness) and disease/illness as a disturbance of balance and wholeness. The instrument contains two parts, each with three domains. These domains contain physical and psychological symptoms of the cognitive, emotional and conative functioning of the child. The first part of the instrument is a questionnaire with 12 items for each domain. Each item contains a polarity of symptoms and has to be scored on a 7-points scale. This part of the scale is completed by caregivers or parents. The second part is a Visual Analogue Scale (VAS) for each domain and is completed by professionals. These scales result in a personal profile for the child on all three domains of development. The study of construction and validation of the scale is finished in the summer of 2011.

Results: In care facilities for children and adolescents with developmental disorders, assessment is completed for more than 1000 children, with autism, attachment disorders, ADHD, McD, Down-syndrome, with and without an intellectual disability. Results of validation (validity, reliability and responsivity to change) and outcome will be presented and discussed.

Discussion: In healthcare in general there is a current professional development aiming at individualization in diagnostics and therapy. This validated measuring instrument can serve as a valid individualization tool for diagnostic, care and therapy for children and adolescents with developmental disorders.
Melodic events in early parent-child interaction and its relation to music therapy in developmentally delayed children without speech – a comparative single case study

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Background: Findings of developmental psychology within the last decades reveal that newborns from the moment of birth have the ability to interact. Several investigations suggest that parental competence to react adequately and intuitively on prespeech signals of the newborn are major factors for a positive development of the child. In addition studies suggest that music therapy with improvised elements of developmentally and speech delayed children often is the starting point of the child’s speech development. In this respect vocal and tonal-melodic response and interaction to the offers of the child is a common technique in professional music therapy. Aim: We aimed at investigating the tonal dialogue between newborns and parent and its improvisatory and creative elements with the emphasis on tonal-melodic adaptation.

Methods: Two video sequences of mother-child and music therapist-child interaction were analysed by means of melodic micro analysis using a musical transcription program with four times reduced speed. This analysis led to a precise notation of sung and sounding elements between a) music therapist and developmentally delayed child and b) mother and newborn.

Results: Moments of melodic coordination were found in both sequences. Additionally it was found that coordination was initiated or replied within the melodic framework both from the newborn/developmentally delayed child and the mother/music therapist. Musical answers ranged from imitation of melodic fragments to continuation of a tonal sequence. Based on these findings categories of tonal-melodic coordination and scores are currently developed. More detailed results are shown in the presentation.

Discussion: Based on the findings of this pilot investigation a systematic evaluation is conducted to further investigate parallels but also differences in melodic interaction of parents/newborns in a home based environment compared to sequences of music therapists and child. Video sequences will also be rated based on observation instruments, to assess the quality of relationship.
OP-164

Client experiences with anthroposophic pediatric care in a therapeuticum for children in the Netherlands

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Background: The therapeuticum for children (“Kindertherapeuticum”) is a private anthroposophic healthcare institution that was founded in 1996. The institution has three streams of children for diagnostic evaluation (all children) and therapy (approximately: 25 %): pediatrics, psychiatry and developmental/educational problems. The approach of the institution is characterized by: integration of conventional and anthroposophic methods, multidisciplinary working, and much attention towards the uniqueness of the child by using a qualitative, phenomenological diagnostic method.

Methods: In respectively 2000, 2005 and 2009 a survey was send to all clients: (1) the parents of the children that had visited the institution in the previous 4-5 years and (2) the doctors and anthroposophic therapists that were involved in treatment of the children before and after the visitation of the therapeuticum. The survey contained four categories of questions: client characteristics, experiences with diagnostics and treatment, subjectively experienced effects, and quality of the organization.

Results: Mean response: 54% (2,465 parents, 152 doctors and 294 therapists). Client characteristics: children come from the direct region (43 %), the rest of the Netherlands (55 %) and other countries (2%); age categories of children are: 0-7 (50%), 8-11 (35%), 12-20 (15%); type of problems: psychiatric, psychosomatic or pedagogic (2/3), somatic (1/3). Most parents choose explicitly for an anthroposophic approach (88 %). An increasing number of parents (an estimated 30 %) comes from a non-anthroposophic doctor. Most parents, doctors and therapists are (very) satisfied with the diagnostics and treatment of the institution. More than 2/3 of parents subjectively judge an improvement of the health status, the conduct and the psychological well-being of the child after their visitation. Visitation of health care institutions two months after the visitation of the therapeuticum is very strongly reduced when compared to two months before the visitation. On average there is a 20 % reduction in use of conventional medication after the visitation. Most clients are very satisfied with the quality of the organization.

Discussion: Overall, clients of the therapeuticum for children are (very) satisfied with the offered diagnostics and therapies and the quality of the organization. First practice–based evidence for positive effects of the approach is acquired. Results and implications will be presented.
Efficacy of a Chinese herbal proprietary medicine (Hemp Seed Pill) for functional constipation: a randomized controlled trial

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Functional constipation (FC) is a common clinical complaint. Despite a lack of consolidated evidence, Chinese herbal medicine (CHM) has become a popular alternative treatment for this condition. The aim of this study was to assess, with a rigidly designed study, the efficacy and safety of a CHM proprietary medicine, Hemp Seed Pill (HSP), in optimal dosage for treating FC. This study comprised two parts: trial I, a dose determination study, and trial II, a placebo-controlled clinical study. In trial I, the optimal dosage of HSP was first determined from among three doses (2.5, 5.0, and 7.5 g b.i.d.). In trial II, a randomized double-blind study, the efficacy and safety of HSP for FC patients (Rome III criteria) in excessive syndrome as defined by traditional Chinese medicine (TCM) theory were compared with placebo.

All participants in trials underwent a 2-week run-in, an 8-week treatment, and an 8-week follow-up. The primary end point was the responder rate for complete spontaneous bowel movement (CSBM) during treatment. Participants with a mean increase of CSBM ≥ 1 / week compared with their baselines were defined as responders. Secondary outcome measures included responder rate during follow-up, individual and global symptom assessments, and reported adverse effects (AEs).

The dose of 7.5 g b.i.d. showed better therapeutic effect than that of 2.5 and 5.0 g b.i.d. among 96 subjects (32 per arm) in trial I and was therefore selected for comparison with placebo in trial II. In trial II, 120 subjects were randomized into two arms (60 per arm). Responder rates for the HSP and placebo groups were 43.3 and 8.3 % during treatment and 30.0 and 15.0 % in the follow-up period, respectively ( P < 0.05). Those in the HSP group showed benefit in terms of increased CSBM, relief in the severity of constipation and straining of evacuation, and effective reduction in the use of rescue therapy when compared with placebo.

No serious AE was reported. In conclusion, HSP (7.5 g b.i.d.) is safe and effective for alleviating FC for subjects in excessive syndrome. Optimal dose determination may be crucial for all CHM studies. Data were published in AJG 2011.
OP-042

Hypersensitivity as a target in CAM therapy of functional gastrointestinal diseases: pharmacological data on STW 5

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Introduction: Hypersensitivity of the gastro-intestinal tract is discussed as the most important target for a pharmacological intervention in gastrointestinal diseases like functional dyspepsia and irritable bowel syndrome, which are characterized by abdominal pain as an important symptom. Herbal medicine has shown to be effective in these diseases. For the herbal combination medicine STW 5 (Iberogast®), an antagonizing effect on gastrointestinal hypersensitivity has been shown [1]. The question was, to which extent its most important component, STW 6, an extract of Iberis amara L. [2], is responsible for this effect.

Methods: As a pharmacological model, the colon of C57Bl6 mice was chosen. The colon and its mesenteric nerve was isolated in an organ bath perfused with Krebs solution (32°C, 10 ml*min-1) containing 1 µM nifedipine to eliminate contractility. STW 5 (lyophilized, 57.1 x 10^-3 µg*ml-1) or STW 6 (lyophilized, 21.2 x 10^-3 µg*ml-1) were applied 10 minutes prior to stimulation with bradykinin (0.5 µM), 5-HT (10 µM) or luminal ramp distension from 0 to 80 cm H2O.

Results: Intestinal afferent nerve discharge to 5-HT was reduced to 0.2 ± 0.2 imp sec-1 after STW 6, compared to 5 ± 2 imp sec-1 following vehicle and 3 ± 1 imp sec-1 following STW 5 pretreatment (p < 0.05 STW 6 vs. vehicle). The response to bradykinin was 36 ± 5 imp sec-1 after STW 6 and 38 ± 6 imp sec-1 after vehicle (n.s.). Following STW 5 pretreatment it was reduced to 9 ± 2 imp sec-1 compared to vehicle pretreatment (p < 0.05). Peak afferent nerve discharge frequency at 80 cm H2O was 14 ± 3 imp sec-1 after STW 6, 22 ± 3 imp sec-1 after vehicle and 4 ± 3 imp sec-1 after STW 5 pretreatment (p < 0.05 for both versus vehicle).

Discussion: The Iberis amara extract STW 6 has a particular desensitizing effect in low-threshold mechanosensitive afferents, while STW 5 acts on both low- and high-threshold afferents. Therefore the broader profile of STW 5, possibly mediating its therapeutic effects in irritable bowel syndrome, is in part, but not entirely, based on the effects of STW 6.

Conclusion: Gastrointestinal hypersensitivity is a target of the herbal combination STW 5, an important therapeutic option in CAM therapy of painful functional gastrointestinal diseases.

[1] Reichling J, Saller R Klass Naturheilkld 2002, 9; Suppl. 1, 21-32
Randomized, double-blind, double-dummy, multicenter trial of a herbal preparation of myrrh, camomile and coffee coal compared to mesalazine in maintaining remission in ulcerative colitis

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Background: Aminosalicylates are used as standard treatment for maintaining remission in ulcerative colitis. The herbal treatment with myrrh, dry extract of chamomile flowers and coffee charcoal has anti-inflammatory and anti-diarrheal potential and might benefit patients with ulcerative colitis (UC).

Aims: We compared the efficacy in maintaining remission of the herbal preparation of myrrh, camomile extract and coffee charcoal and an established therapy with mesalazine in patients with ulcerative colitis.

Patients and methods: A total of 96 patients (51 female) with inactive ulcerative colitis (in remission not longer than 12 month - medical history of proctitis n = 13; left-sided colitis n = 52; pancolitis = 31) were included in a randomized, double-blind, double-dummy, multicenter, non inferiority study comparing mesalazine 500 mg three times a day to an oral preparation of 100 mg myrrh, 70 mg chamomile extract and 50 mg coffee charcoal (3 x 4/d) over a time period of 12 month with regard to their efficacy in preventing a relapse of the disease. As primary efficacy criterion non-inferiority of the herbal preparation was defined and accepted, if the colitis activity index (CAI) (calculated at six time points during the 12 month interval) averaged over all visits in the herbal group was \( \leq 1 \) point compared to the mesalamine group. Furthermore, relapse rates, relapse-free times and safety were evaluated, and in addition an endoscopic activity index (Rachmilewitz), the Mayo Disease Activity Index as well as histology was assessed.

Results: The scores of the CAI demonstrated no significant difference between the two treatment groups in the intention-to-treat (ITT; p = 0.121) or per protocol (PP; p = 0.292) analysis as defined as primary outcome criterion over all visits. Furthermore, relapse rates (CAI > 4) did not differ significantly (ITT: mesalazine 19/49 pts versus herbal preparation 25/47 pts; p = 0.156; PP: mesalazine 19/40 pts and herbal preparation 24/42; p = 0.382) under the two treatment modalities. Analysis of relapse-free time showed 275 ± 21 days for mesalazine and 221 ± 20 days (ITT: p = 0.161) for the herbal preparation (PP: 261 ± 24 days for mesalazine and 219 ± 21 days for the herbal preparation; p = 0.299). Safety profile and tolerability were very good for both groups.

Conclusions: The herbal preparation of myrrh, chamomile extract and coffee charcoal shows efficacy and safety in maintaining remission non-inferior to the gold standard mesalazine in patients with ulcerative colitis. It appears to offer an alternative option for maintenance therapy of ulcerative colitis. Further studies should strengthen our findings.
Communication about self-care in traditional acupuncture consultations: the co-construction of individualised advice

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Background and Aim: Knowledge of how self-care advice is communicated by different health professionals is key to improving self-care advice and support. We aimed to identify the characteristics of communication about lifestyle and self-care within traditional acupuncture consultations.

Method: A qualitative study was nested within a co-operative enquiry. The enquiry group was comprised of traditional acupuncture practitioners and researchers. Using a convenience sample of patients attending with a range of conditions, we audio-recorded 27 consultations with 7 practitioners and carried out telephone interviews with 15 of the consulting patients. These were transcribed and analysed by two researchers, using a constant comparative method. The analysis explored each consultation as a trajectory of eight interwoven categories of talk. We identified how ‘self-care talk’ was situated within these trajectories, the content of such talk and who initiated it. Patient’s interview accounts complemented this data.

Results: The consultations contained 130 sequences of self-care talk, which were initiated equally by patients and practitioners. Practitioners more commonly initiated talk about ‘rest & relaxation’ and ‘physical activity’; patients about ‘over-the-counter products’; and talk about ‘diet and eating practices’ and other categories were shared more equally. The amount of self-care talk and whether this was support or specific advice varied between consultations and perhaps between practitioners. However, most sequences involved an interactive discussion. A number of consultations demonstrated a co-construction of self-care talk that was woven throughout the consultation in a way that allowed space for other necessary talk and the acupuncture ‘work’ to take place within the allotted appointment time. In these consultations aspects of self-care were returned to in ways that appeared to build a shared understanding on the basis of other categories of talk, namely ‘symptom’, ‘life-world’ and ‘acupuncture’ talk. This had the effect of individualising the self-care advice and, in many instances, linking it with the Chinese medicine diagnosis.

Conclusions: Our findings demonstrate the importance of self-care talk within acupuncture consultations and indicate the close links with discussions of the patient’s everyday life (‘lifeworld’) and the explanatory theory base. Detailed analysis of the structure of the talk may inform professional development in this area.
An assessment for the occurrences of cardiovascular disease associated with Ephedra: a population-based case-control study

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Introduction: While a large number of adverse event reports, such as cardiovascular disease, regarding herbal ephedra-containing dietary supplements has been filed with FDA, an informed judgment about the potential relationship between ephedra use and the adverse event is relatively unexplored. It was the objective of this paper to determine the risk of cardiovascular disease associated with ephedra-containing products.

Material and Method: The registries for patients with last two years newly diagnosed cardiovascular disease (CVD) in the reimbursement database of illnesses from National Health Insurance in Taiwan during 1996 – 2005 were collected as the cases, while a simple random sample of 50,000 people would be used as controls after excluding patients with cardiovascular disease, including myocardial infarction, stroke, arrhythmias, or death. Potential risk factors, including age, sex, residence, indications for prescribing such ephedra-containing herbs of Chinese herbal products (CHP), and cumulative doses of adulterated herbal supplements potentially containing ephedrine before the development of CVD, were assessed for independent association with occurrences of CVD through construction of multiple logistic regression models. Odds ratios (ORs) and 95% confidence intervals (CIs) were estimated for the association between CHP containing ephedra and the occurrence of CVD.

Results: A total of 49,119 persons (22,481 men and 23,212 women) were included in the final analysis. There were 1,120 newly diagnosed CVD cases and 48,001 controls. Older age and resident in urban area were associated with CVD development. There was a significant reduce of CVD development for consuming ephedra-related CHP. (OR = 0.6, CI = 0.5 - 0.6). Only one (Si Shen Tang) out of total 28 CHP was associated with the risk of CVD development. (OR = 1.2, p = 0.03)

Conclusions: Consumption of ephedra-containing CHP does not increase the occurrence of CVD.
The purpose of this study was to research influence of essential elements dysbalance in human organism on pancreas function and early detection pancreas dysfunction. Dysbalance of essential elements in humans, brings dysfunction of organs and pathological processes. We followed pancreas function disorders connected with elements dysbalance and genes.

We used two non invasive methods: 1/ bio-resonance, registration disturbances of electromagnetic oscillations of different organs and tissues; 2/ elemental hair analyze. Bio-resonance method is based on researches of scientists on the second half of the 20th century, and they proved that living body radiates electromagnetic oscillations in wide frequency spectrum. These oscillations govern all biochemical and morphological processes taking place in organism. Elemental hair analysis is very sensitive method to confirm imbalance of essential elements in organism.

Examinations were conducted on 71 subjects, volunteers, aged 13-76 years (male and female). They were divided in 5 groups, according to level of pancreas dysfunction (1/ without changes in function; 2/ initial compensatory disturbances function without clinical symptoms; 3/ functional compensatory disturbances with symptoms; 4/ pathological disturbances, Diabetes mellitus with therapy; 5/ irreversible changes in tissue) and we followed connected genes. Also we measured concentration of elements in scalp hair.

In the largest number of subjects, early forms of dysfunction of pancreas were discovered: initial compensatory dysfunction without symptoms in 58 % and compensatory disturbances of function with symptoms in 23 %. Also corresponding genes were affected and disturbances from normal range in hair elements concentrations (I, Co, Cu, Se, Zn, MN, Cr, Si, Mg, Ca, K, Na, P, Fe). In all these subjects routine biochemical analyzes and officially used diagnostic methods did not show any abnormality. These two comfortable methods for patients, non invasive, are very helpful for early detection pre pathological stage of health status, to correct disturbance, follow results and to prevent diseases.
Meditation for distressed patients with chronic neck pain: a randomized controlled trial

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Background: Musculoskeletal disorders are the most common cause of disability in Western countries. Recurrent and chronic pain accounts for a significant portion of health-related absenteeism. Preliminary data suggest that stress reduction by meditation leads to pain relief in chronic pain syndromes. We aimed to evaluate the effectiveness of a 8-week meditation program for distressed patients with chronic neck pain compared to home-based exercise.

Methods: Patients with chronic unspecific neck pain and concomitant elevated perceived stress levels were randomly allocated to a meditation group or a home-based exercise group. Subjects of the meditation group attended weekly 90-minute meditation classes over a period of 8 weeks. Patients of the exercise group were requested to practice exercise aiming to relieve neck pain according to a standardized manual. Both groups were instructed to practice at home. Outcomes were assessed at baseline and after the 8-week treatment. Primary outcome was the average neck pain intensity in the last seven days (100 mm visual analog scale). Secondary outcomes included the Cohen Perceived Stress Scale, Maslach Burnout Inventory, State-Trait Anxiety Inventory, Neck Disability Index, Hospital Anxiety and Depression Scale and quality-of-life (Short Form 36 questionnaire).

Results: The trial was completed in April 2011. 70 patients were included and randomized to meditation (n = 35) or exercise (n = 35). 16 patients dropped out due to unwillingness to attend classes or other reasons not related to the study. 54 subjects completed the study, n = 26 in the meditation and n = 28 in the exercise group. Final results will be presented at the conference.

Conclusions: Results of this randomized study will allow to further evaluate the impact of stress reduction by meditation in the management of chronic pain syndromes, i.e. chronic neck pain.
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Additive complex Āyurvedic treatment in patients with fibromyalgia-syndrome compared to conventional standard care alone – design of a controlled clinical non-randomized pilot study (KAFA-Trial)

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Background: Āyurveda is a traditional Indian medicine: as a whole medical system it consists of diagnostic procedures and complex treatments. Āyurveda-treatment is based on āyurvedic diagnosis and may include the following methods: manual therapies, lifestyle and nutritional advice, yoga and purification techniques. In India Āyurveda is often used for the treatment of the Fibromyalgia Syndrome, however, no systematic data is available on its effectiveness as an add-on-treatment compared to Western conventional standard care alone.

Objective: The aim of this study is to evaluate the effectiveness of additive complex āyurvedic diagnosis and treatment compared to conventional standard care alone in stationary patients with Fibromyalgia Syndrome.

Methods and Design: A total of 40 in-patients will be included into this prospective, controlled, clinical, non-randomized observational pilot study. Patients between 18 and 70 years of age, prediagnosed with Fibromyalgia Syndrome, following the criteria of the German Medical Guideline Association AWMF, will be included into two groups. Randomization is not performed due to the trial’s observational character. All 40 patients will receive the individually adjusted complex conventional standard care according to the current AWMF-guidelines including physiotherapy, occupational therapy, specific pain therapy and psychotherapy. In the Āyurveda add-on-group 20 patients will moreover receive individualized treatment according to the Āyurveda diagnosis which may include manual treatments, massages, dietary advice, specific consideration of selected food items, āyurvedic lifestyle & yoga posture advice and daily self-applied massage. Patients of both groups will receive at least 11 hours of intensified in-patient treatment per week according to current DRG requirements for Fibromyalgia Syndrome. Study visits are scheduled at baseline (admission to the hospital) and at the end of their hospital stay (max. 20 days after admission); further follow-up questionnaires will be sent to the patient after 6 months. The primary endpoint is the change in the Fibromyalgia Impact Questionnaire (FIQ) at the end of the in-patient treatment phase. Secondary endpoints are: Functional Hanover Questionnaire (FFBH), State Trait Anxiety Inventory (STAI), Profile of Mood States (POMS), Short Form 36 Health Survey (SF-36), VAS for pain and Likert-Scales.

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Acupuncture for back pain: a prospective cohort study evaluating patient outcomes and their determinants

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Introduction: Psychological factors predict outcomes of conventional back pain treatments. Such factors are often modifiable and can be addressed as part of multidisciplinary treatment, or used to target particular treatments to particular patients, thus improving outcomes for patients. Patients with back pain commonly use complementary treatments, especially acupuncture. Whether and to what extent psychological factors predict outcomes of acupuncture for back pain has not been established. This study tested hypotheses derived from an extended version of Leventhal’s self-regulation theory concerning the role of illness perceptions, treatment beliefs, and coping, in acupuncture for back pain.

Method: 530 adults with non-specific low back pain were recruited to a prospective postal questionnaire study. They were recruited opportunistically as they sought acupuncture treatment from 83 acupuncturists practicing across the UK in different settings (private practice, NHS primary care, NHS physiotherapy, NHS pain clinics). Participants completed questionnaire booklets before commencing acupuncture, at 2 weeks, 3 months, and 6 months follow-up. Validated questionnaires measured socio-demographic characteristics, health, illness perceptions, treatment beliefs and appraisals, coping self-efficacy.

Results: Multivariate linear regression analysis of baseline data examined the predictors of two key variables: back-related disability and expectations of acupuncture. A combination of socio-demographic and psychological factors explained 45% of the variance in back-related disability and 29% of the variance in expectations of acupuncture. Illness perceptions (e.g. seeing one's back pain as threatening) were particularly strong independent predictors of disability. Treatment beliefs (e.g. belief in holistic and natural treatments) were particularly strong independent predictors of expectations.

Conclusions: In patients with low back pain seeking care from acupuncturists, modifiable psychological factors are associated cross-sectionally with back-related disability and treatment expectations. Forthcoming analysis of follow-up data will establish whether such associations hold prospectively and compare the psychological predictors of outcome in acupuncture to those reported in the literature on conventional treatments.
The effects of cupping massage on chronic neck pain: a randomized controlled pilot study

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Question: The aim of the study is to investigate whether five treatment sessions of cupping massage can improve clinical chronic neck pain and subjective well being, and whether cupping massage induced changes in pain related neurophysiologic measures.

Methods: This pilot study comprised 50 patients with chronic non specific neck pain (mean age 53.3 ± 10.4 yrs SD). The patients were examined at baseline and then randomized to treatment group (TG) or standard medical care group (SMC) after the first examination. Both groups received a set of questionnaires and psycho-physical tests for evaluating their perception of pain and sensibility before and after a treatment with five cupping massages. TG received treatment sessions at intervals of two or three days. The patients of SMC received the same investigations like patients of TG, however the treatment started after the second investigation. Questionnaires included questions and visual analog scales (VAS) about the current state of pain, prehistory, expectations and the success of therapy in the treatment group. Further measures included neck pain disability index (NDI), questionnaires regarding pain related to movement, quality of life (SF36) and pain diaries. Neurophysiologic testing consisted of the Quantitative Sensory Testing subtests mechanical detection threshold (MDT), pressure pain threshold (PPT), vibration threshold (VDT) and two-point discrimination (2PD).

Results: Cupping massage led to an average pain relieve of -23.04 ± 27.96 mm VAS for TG whereas SMC showed a smaller reduction in the pain ratings (-6.88 ± 20.16; p = .026). Subjectively perceived neck pain related disability (NDI) scores were small, but very consistent: With 0.03 ± 0.44 the SMC group showed no chance while NDI scores were reduced in the TG (-1.97 ± .44; p = .004). No significant differences were found on the physical or mental Sum Scales of the SF-36, although a strong trend for the physical sum scale was observed. Analyses of the QST subtests are not yet completed, but preliminary calculations revealed that PPT at the location of maximum pain was reduced after treatment.

Conclusion: Five treatment sessions of cupping massage have been shown to improve clinical chronic neck pain and subjective well being. Data on possible changes in QST subtests are likely and these neurophysiologic data will be presented at the conference.

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Spontaneous co-speech hand gestures in patients' complaint presentation and pain description

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Background: Complaints and symptoms are often difficult to put into words. Humans frequently use spontaneous co-speech hand gestures (HG) when talking, especially when describing matters that are difficult to express or verbalize. We aimed to overview and appraise research articles and publications on form, function and meaning of patients’ spontaneous co-speech HG in describing their symptoms quality and their relevance for individualized medicine and patient centered care.

Methods: 10 online databases, several journals and the internet were searched for the combination of “gesture” AND “patient” in “key word, title or abstract” or alternatively in all “text fields”. The references of obtained articles were searched to identify further literature not listed in the databases. Scientific literature regarding patients’ symptom description and spontaneous speech accompanying HG were also included. All publications were critically appraised with quality assessment checklists based on the type of study.

Results: From screening titles and abstracts of 5162 articles and books we included a sum of 31 publications in the review. They consisted of both qualitative and quantitative research studies and were published in a wide range of scientific journals and in scientific monographs. The studies investigated HG in 1) cardiology and their diagnostic value in acute chest pain; 2) in specialised pain ambulances or pain centered research interviews; 3) primary care; 4) psychotherapeutic interactions and 5) homeopathic consultations focusing on a global experience. Patients used HG to indicate the location of pain, demonstrate situations or to characterise a complaints’ quality. The informations conveyed by gesture could be highlighting, additional to or contradicting the verbal utterance.

Conclusion: The reviewed publications showed how patients use HG in presenting their complaints and describing their pain. They support the assumption that HG indeed assist patients in communicating symptoms, pain and illness experience in patient-practitioner interaction or medical interviews. Practitioners and researchers should pay more attention to patients’ HG or else would miss important informations only conveyed in HG. Further research should be informed of previous studies, contemporary standards in gesture research, theories of gesture-speech connection, as well as of research standards in documentation and annotation.
Manual therapy in the treatment of recurrent chest pain

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Acute and chronic chest pain is a major health problem all over the western world. Active approaches are directed towards diagnosis and treatment of potentially life threatening conditions, especially acute coronary syndrome/ischemic heart disease and respiratory diseases. However, according to the literature, chest pain may also be due to a variety of extra-cardiac disorders including dysfunction of muscles and joints of the chest wall or the cervical and thoracic part of the spine. We present a trial on the potential usefulness of manual therapy diagnosis and treatment in patients dismissed from an hospital with recurrent chest pain without a diagnosis of heart or pulmonary based chest pain.

The aims are to investigate in patients suffering chest pain of musculoskeletal origin if manual therapy may be useful in reducing medical visit and hospital admission, whether manual therapy treatments can reduce pain and improve physical function.

This study has included a series of 43 patients discharged from hospital without a diagnosis of cardiac or pulmonary disease. After completion of the hospital's standard diagnostic procedures, trial patients have been examined according to a standardized protocol including a general health examination; and a specific manual examination of the muscles and joints of the neck, thoracic spine, and thorax in order to determine whether the pain is likely to be of musculoskeletal origin. 43 patients underwent a course of manual therapy treatment of up to 5 treatment sessions focusing on high velocity, low amplitude manipulation of the cervical and thoracic spine, and mobilisation.

Outcome measures were pain, physical function, quality of life, cost-effectiveness and hospital re-admissions or medical outpatient visits. 38 patients at 3 and 6 months demonstrated complete recovery and/or absence of significant chest pain; no hospital, emergency department admission or private outpatient visit for chest pain, and improvement in quality of life.

This study may potentially demonstrate that manual therapy is able to treat a subset of patients suffering from chest pain predominantly of musculoskeletal origin among patients discharged from hospital for recurrent chest pain with no apparent cardiac or lung condition. Furthermore knowledge about the benefits of manual treatment of patients with musculoskeletal chest pain will inform clinical decision and policy development in relation to clinical practice.
Experts’ opinions on terminology for complementary and integrative medicine – a qualitative study with leading experts

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**Background:** Integrative medicine is currently the most commonly used term to describe the integration of CAM into conventional medicine. It’s most important feature is the focus on evidence as crucial factor for therapeutic decision-making. Its aim is to seek out the best therapies from all types of medicines and methods that have proven safety and effectiveness in the treatment of the particular condition or health state. However, some uneasiness exists with the term with the most notable critique being that it describes the integration of complementary methods into conventional institutions and into a “conventional framework of thinking” because it accepts the methodology of conventional medicine.

**Methods:** We have conducted semi-standardized interviews with ten experts in the field of CAM and integrative medicine who have leading positions at medical schools or the NIH. Interviews were recorded, transcribed and analyzed using content analysis.

**Results:** Overall terminology was seen as a problem, although all experts agreed that the term integrative medicine describes well what they do or they think is useful for medical care. Interestingly, the experts from Germany understood integrative medicine as a medicine that is conducted by one physician who is well versed in both conventional and complementary medicine, whereas in the US and the UK integrative medicine was seen to be delivered by a multidisciplinary team. Some interviewees used the question of terminology to describe a health care delivery system they would like to see in existence. Based on that vision, they suggested different terms such as “comprehensive health care delivery”, “patient-centered delivery”, or “whole-person care”. These terms were to demonstrate an entirely different mode of health care system as the one in existence today. It was set to start with “health” rather than disease and was to integrate prevention into regular health care delivery, thereby taking serious many of the other medicines that have a holistic approach. All interviewees agreed that positive evidence such as effectiveness and safety had to be the basis for any therapeutic decision-making. Thus for some the goal was to overcome the still existing “conventional” – “non-conventional” understandings in health care.

**Conclusion:** The discussion of the experts demonstrates that the debate is one on the vision of health care delivery in general. It addresses the question of "how health care systems" should look like.
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General complexities, concepts and strategies in CAM research – preliminary results of a review within work package 7 of the EU-funded CAMbrella project

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Objective: A literature review about general complexities, concepts and strategies in research into Complementary and Alternative Medicine (CAM) was conducted within the work package 7 of the EU-funded project CAMbrella. The aim of this review was to evaluate and analyse general issues, concepts, and strategies with regards to research priorities, and research methods in clinical and epidemiological research of CAM therapies worldwide.

Method: Structured literature search for papers published between 1990 and 2010 about research issues like priorities, methodology and study design in CAM was conducted in different databases like Pubmed, Embase among others. Also, experts within the CAMbrella group and the projects’ advisory board contributed relevant papers to this review. Papers which mainly and explicitly address general methodological issues or complexities or concepts or strategies with regards to research methods in CAM-evaluation were included in the review. All identified paper went through a multistage selection process in order to identify paper meeting the predefined inclusion criteria. Included paper went through full-text analysis and major issues and arguments were identified.

Preliminary results: Altogether 158 papers were included in fulltext analysis. A wide range of topics for a variety of different CAM modalities were addressed, for example the use of randomized controlled trials (RCTs) in CAM research, practical problems and possible solutions in studies regarding CAM as well as general frameworks for the choice of research questions and appropriate methods. The preliminary results of this review will be presented at the conference.

Conclusion: The results of this review will serve within the project as basis for the development of a future roadmap for further facilitated research into CAM in Europe.
The development of a professional monitoring infrastructure for anthroposophic art therapy

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Background: Anthroposophic art therapy has been developed in the beginning of the 20th century as a part of anthroposophic medicine. The main therapeutic approaches, therapeutic painting, drawing and sculpturing are used both in somatic and mental healthcare. Within the Evidence Based Medicine development anthroposophic art therapy also needs to monitor the therapeutic processes and its effects and present data to several stakeholders. However, until now there is no clarity which stakeholders (e.g. colleagues, insurance companies) need what type and what quality of information. In addition a professional monitoring infrastructure for art therapy is lacking.

Objectives: The first objective was to map the developed monitoring instruments and infrastructures for art therapy in clinical practice in the Netherlands. The second objective was to map the needs of the stakeholders (‘what information need they for what goals?’). The third objective was to develop a first draft of a monitoring infrastructure for a first specific patient group (psychosomatic and psychiatric patients) based on the results of the mapping of both monitoring instruments and infrastructures, and stakeholders needs.

Methods: A questionnaire was send to all 460 Dutch art therapists who are a member of the Dutch Art Therapy association to map the developed monitoring instruments and infrastructures for art therapy in clinical practice. Stakeholders were interviewed to map the needs of the stakeholders. Based on the results of the survey and interviews and the methodological literature a first draft of a monitoring infrastructure was developed.

Results: The results will be presented at the congress.
Scientific tools, fake treatments, or triggers for psychological healing: how RCT participants conceptualise placebos

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Placebos are an essential tool in randomized controlled trials, where they are used to control for contextual healing effects. Placebos and their effects are also studied from multiple other diverse perspectives, but the perspectives of placebo recipients are seldom considered. Research shows that people form cognitive and affective representations of active treatments such as medicines, and that they use these representations to guide their behaviour; it seems reasonable to suggest that people might also think about and develop representations of placebos.

We adopted a qualitative approach to examine in detail how participants in one RCT (conducted in the USA) conceptualised placebos. 12 people were interviewed 3 times each, at the start, middle, and end of a trial of placebo effects and acupuncture for Irritable Bowel Syndrome (IBS). The interview data were analysed inductively and we identified four ways in which the participants conceptualised placebos: placebos are necessary for research; placebo effects are fake; placebo acupuncture is not real acupuncture; placebos have real effects mediated by psychological mechanisms.

Participants’ conceptualisations of placebos were dynamic and situated in a broader psychological and socio-cultural context. Seeing placebo effects as legitimate seemed to be facilitated by having a more holistic model of healing, viewing IBS as psychological, and seeing acupuncture as involving more than just needles. However, some participants maintained a negative view of placebo effects (e.g. as illusions) that was apparently inconsistent with their other beliefs (e.g. in mind-body healing mechanisms). This may indicate a dominance of negative discourses around placebos at a socio-cultural level. Negative views of placebos are inconsistent with evidence that placebo treatments can have positive effects on patients with IBS (and other conditions).

Future work should review and improve methods of accurately and fully informing potential RCT participants about placebos and their effects.
Meta-Ethnography: concepts of integrative and person-centred medicine from the perspectives of patients

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Background: Personalized medicine in the days of genetic research is seen as molecular biologic specification in individuals, not as individualized care oriented to patients needs in the sense of person-centred medicine. Yet the question can be raised whether this focus can ameliorate health care needs in view of the invested resources. Studies suggest that patients often miss authentically patient-centred care and individual physician-patient interaction and therefore decide to choose complementary and alternative medicine (CAM). By means of a meta-ethnography this project will explore patients’ views about individualized medicine and describe the patients’ perspectives of integrative and person-centred services.

Methods: A systematic literature search of qualitative studies (for ‘qualitative research’ AND ‘CAM’ AND patient decision making OR concepts OR reasons OR patient expectations OR motivation OR attitude OR experiences with OR patient acceptance OR patient participation OR patient-centeredness OR use of OR physician-patient relations OR professional-patient relations) was performed. Studies were assessed using an inclusion/exclusion checklist and a quality score according to an adjusted checklist of Behrens and Langer. The meta-ethnography followed Noblit and Hare’s method to synthesize the key concepts using reciprocal translation synthesis.

Results: 14 electronic databases for 1980 – 2011 have been searched: CAMbase, CAM-QUEST®, API-on®, CINHAL, Cochrane Library, GreenPilot, Heclinet, MedPilot, PubMed, Psynx®, PsyINFO, Sinbad, Somed and DIMDI. 1074 citations were screened, 223 articles met the pre-specified inclusion criteria. PubMed, CINHAL and PsychINFO yielded 85 % of the relevant hits. The major themes highlighting patients’ views about individuated medicine were: personal control, self-empowerment, self-initiated life change, caring and compassion, continuity of the caregiver, spiritual dimensions, equality of relations and shared decision making.

Conclusion: The perspective of patients choosing alternative and complementary medicine regarding individualized care clearly differs from the current idea of personalized medicine. Personalized medicine has therefore to bear in mind the approach of individualized, psychosocial, spiritual and cultural patient needs. The allocation of resources should consider patients needs to enhance a high-quality health care system.
Efficacy of acupuncture in patients with seasonal allergic rhinitis – results of the one year follow-up period within a randomized controlled trial

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Background: Acupuncture (Acu) is widely used to treat seasonal allergic rhinitis (SAR) but the scientific evidence is insufficient. We therefore determined the efficacy of Acu compared to sham acupuncture (Sham) and to rescue medication (RM).

Method: SAR patients age 16-45 with clinical symptoms and IgE-sensitization to birch and grass pollen were randomized in a 2:1:1 ratio to treatment with semi-standardized Acu plus RM (Cetirizine), Sham (superficial needling at non-Acu points) plus RM, or RM alone. Acu and Sham were performed by 51 physicians in 38 outpatient centers in Germany and consisted of 12 treatments over 8 weeks. Primary outcome measures were Rhinitis Quality of Life Questionnaire overall score (RQLQ) and Rescue Medication Score (RMS) in weeks 7 and 8. Secondary outcome measures included the responders to treatment defined as reduction of RQLQ by at least 0.5 compared to baseline. In the second year we preformed a follow-up in weeks 7 and 8 including RQLQ and RMS. All analyses were adjusted for baseline value, study center and region and year of randomization.

Results: A total of 402 patients were recruited from April 2008 to May 2009 and included in the intention to treat population (Acu 206, Sham 97, RM 99; 60 % female, mean ± SD age 33 ±8 years). Compared to Sham and to RM, Acu was associated with significant improvement in RQLQ (mean differences 0.5, 97.5 %CI 0.19-0.81, p = 0.0002, and 0.66, 0.35 - 0.97, p < 0.0001, respectively) and lower RMS (mean differences 1.1, 0.37 - 1.85, p = 0.0004, and 1.5, 0.76 - 2.24, p < 0.0001, respectively). The proportion of responders was 71 % in Acu, 56 % in Sham, and 44 % in RM. The results of the follow-up period in the second year will be presented at the conference.

Conclusion: In patients with SAR Acu was superior in improving disease specific quality of life and reducing use of rescue medication compared to Sham and to RM alone. Results of the one year follow-up period will provide information if there is a long time specific effect of acupuncture in SAR.
Integrative encounters: cultural perspectives on mental health in a north Norwegian community

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**Background:** Unofficial health services exist in many North Norwegian communities, consisting of traditional and religious healers and “modern” alternative practitioners which people actively use or would consider to use when facing illness or crisis. The community of Nordreisa is commonly described as “the meeting of three tribes” - Sami, Kven and Norwegian - and has historically been considered a cultural melting pot. This diversity is also manifested in the use of traditional medicine/CAM. Users of an outpatient clinic in Nordreisa find themselves between different traditional and religious practices/CAM, as well as conventional treatment offered by the clinic. This clinical setting is therefore well suited for explorative studies.

**Objective:** The aim is to describe and analyze the encounters between different medical and cultural contexts in order to identify factors which can contribute to a patient-centred mental health service. The research question to be addressed is: How do patients and therapists relate to the issue of integrating traditional medicine/CAM into the public mental health services, and is such integration possible within “Norwegian/Western” psychiatry?

**Methods:** This explorative project will be performed as an ethnographic fieldwork. Qualitative in-depth interviews and participant observation will be used to investigate this unexplored field of integrative medicine. In addition to patients using the clinic, therapists at the clinic, traditional healers, religious healers and “modern” alternative practitioners will participate. Approximately 30 participants will be included in the study.

**Results:** The empirical and theoretical analysis will explore the encounters between different medical and cultural contexts, both at an individual and structural level. The data collection is in progress and results will be presented in October 2011.

**Conclusions:** Research initiatives are needed to develop a patient-centred mental health service within a region where patients interact with practitioners from different treatment traditions.
Towards a model for integrative medicine in the primary care of patients with chronic joint diseases and allergy

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Background: In the Netherlands, the most frequently used types of Complementary and Alternative Medicine (CAM) among patients with chronic diseases are homeopathy, acupuncture, naturopathy and manual therapies. They are offered by CAM practitioners that practice CAM mostly outside the world of mainstream medicine. CAM use is often unsupervised since the majority of patients never to seldom discuss the use of CAM with their general physician. Patients in the Netherlands would greatly benefit from an integrated model in which CAM offerings are part of mainstream medicine and where disclosure of risks, benefits and level of evidence of CAM as well as credentials of CAM practitioners are sufficiently dealt with.

Objective: The aim of our four-year research project is to develop, implement and evaluate a shared-care model of Integrative Medicine in the Dutch primary care setting for patients with chronic joint diseases and allergy.

Methods: This is the first research project in the Netherlands in which patient organisations, health care providers, health care insurance companies and researchers collaborate to achieve a primary health care approach in which CAM is integrated. The investigative approach consists of four stages; in stage 1 we will investigate the views, needs and preferences of patients with respect to (integrated) health care. Based on this outcome, evidence in literature and CAM-practitioner experiences, an integrated primary care model will be developed (stage 2). The integrated model will be piloted in two primary care centres in the Netherlands (stage 3) and evaluated with respect to outcome, quality of life and cost-effectiveness.

Results and Conclusions: Outcome data will be presented with respect to stage 1; the preferences and needs of patients with chronic joint diseases (≥18 years of age) and parents of children with allergy (<18 years of age) are currently surveyed in a national cross-sectional survey. This comprises a 25-item questionnaire on previous CAM use, experiences with CAM, communication with health care provider and preferences with respect to primary health care approaches. In addition, focus group discussions take place to gather more in-depth qualitative data on patient views, needs and preferences.
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The use of integrative health care among patients with diabetes mellitus in Korea
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Background: Recently due to inconsistent with diabetes medication usage, health care societies have interest in developing more comprehensive intervention and approaches to achieve better diabetes-related health outcomes. Since the use of complementary and alternative medicine (CAM) has been increasingly reported in patients with diabetes mellitus in recent years, it is of importance to understand the advantages and disadvantages of integrating CAM into managing the patients with conventional medical approaches. In Korea, however, little attention has been given to the experiences of the patients in health care sector in Korea. Aim of the study is to assess the prevalence and usage of CAM among the patients of Korea and possible predictors of their use.

Objective: To measure the frequency of Integrative Health Care (IMC) use among patients with diabetes mellitus, to determine demographic characteristics and other factors making it more likely to using IMC, and to find out how benefits, if any, were perceived by patients within a unique health care system in Korea, in which both practitioners of traditional medicine and practitioners of modern Western medicine coexisted.

Methods: The design of the study was descriptive cross-sectional, and data were collected using a 37-items questionnaire. The subjects were three hundred thirteen of patients with diabetes mellitus who visited to a university hospital in Seoul Metropolitan City in Korea. Data were analyzed using ‘SPSS Statistics 18.0 Network Version (on release 18.0.1 of PASW Statistics)’ program. Various statistical methods were used to obtain a profile for participants and the methods most frequently used by users of Integrative Health Care. Logistic regression analysis was employed in order to determine the predicting variables of Integrative Health Care use.

Results: Dietary therapies were the most frequently used CAM method (76 %) among the patients. The prevalence of the use of IHC was 67.4 % among the patients. Results of logistic regression analysis revealed that the variables significantly related with IHC use were age, severity of diseases, perceived benefits of CAM, anxiety level due to diseases, duration of the chronic disease, negatively perceived the treatment used, perceived locus of control.

Conclusions: Patients with diabetic disease, who negatively perceived the effects of hospital treatment, were more likely to use IHC. About 70 % of those using IHC reported, as benefits, blood sugar level control, or feeling of strengthening of body. Thus more comprehensive and holistic approaches should be established to improve better diabetes-related health outcomes, which may benefit patients with diabetic mellitus.
Embedding chiropractic in Indigenous health care organisations: applying the ‘normalisation process model’

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Background and Aim: The ‘normalisation process model’ (May 2006) provides a conceptual framework for understanding the practical problems of embedding and evaluating new complex interventions. We aimed to provide a worked example of using this model to establish, integrate and evaluate a chiropractic service in an Indigenous Australian community.

Method: Over 3yrs, we used action research methods to integrate the chiropractic service, but were still confronted with difficulties in referrals, funding, sustainability and evaluation. We used the model retrospectively, to order this feedback and information. Our data was analysed as it applied to each dimension of model, noting aspects that the model did not encompass. During this process we reworded the dimensions in more everyday terminology. The final analysis focused on to what extent the model helped us to prioritise and systematise our tasks and plans.

Results: The concept of ‘normalisation’ focuses us on the importance of sustainability. The model emphasises the importance of stability and order in health care, both within one-to-one consultations and within the organisation as a whole. It has therefore directed us to consider ways to promote chiropractic as something that will enhance relationships, interactions and procedures and avoid disrupting them. The model also emphasises the importance of chiropractors becoming trusted team members who have acceptable and recognised knowledge and skills: chiropractic practitioners may find a place within the complex occupational web, by being seen to be similar to a well known occupation, such as physiotherapy. However, one dimension from our data, that we have labelled ‘emancipatory’, was absent from the model. Derived from research in the UK, the model conceptualises an intervention as becoming embedded through aligning itself with the status quo, whereas an indigenous culture struggling with a lack of culturally sensitive healthcare also expressed elements of demanding a non-pharmaceutical intervention as an addition to the status quo.

Conclusions: The normalisation process model provided us with a structure for organising previous discussions and tasks and resulted in a number of new insights and questions. We will continue to use it prospectively. In order to make it ‘fit for purpose’ in our particular context we have adapted the language and terminology and suggest that further study of the ‘emancipatory’ dimension is required.
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Integrative approach in diagnoses and treatments of some endocrine diseases

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Introduction: Last few years, growing number of cases of endocrine diseases. In particular, the growing diabetes mellitus and thyroid diseases, especially Hashimoto Sy. And more and more diseases with disturbed functions of two or more endocrine glands with increased levels of antibodies in the serum of belonging to Poliyendokrine Autoimmune Syndrom. BDORT by Dr. Y. Omura is a noninvasive method that can detect early disorders endocrine gland function.

Aim: The aim of our study was to find early signs of diseases of endocrine gland by using Indirect BDORT and to detect risk factors for the development of diseases.

Material and Method: Patients with chronic non-specific symptoms were inspected by BDORT. According to findings, infections were treated by selective drug uptake enhancement method (Y. Omura). Autoimmune disorders detected by BDORT and proved by standard lab-tests, were cured by magnetic water which had previous being treated by MDK chips (made by Salubris, Belgrade)

Results: The largest number of patients had a disorder of endocrine glands and to 2 or more. BDORT indicated gland infection by the mixed infection, the presence of toxins, pathological effects of electromagnetic fields, the existence of chronic emotional stress, but also a lack of iodine. Patients were first protected from pathlogical EMFs, in bedrooms and from cellular phone and computers, and subsequently treated for infection, and then they added the necessary minerals and vitamins, especially iodine source: Oil 80 (Planet of Helath). During 1-2 months long treatments by magnetic water, the levels of different antibodies are decreased on normal level (85-93%), drinking 1-2 liters of water daily.

Conclusion: By performing BDORT and collecting information from all body organs, physician gets more reliable data about possible etiological factors causing certain disease(s). BDORT diagnosis should be followed with standard lab tests and when the results are obtained, possibility to treat etiological factors of diseases is greater. Also, during the diseases treatment, classical therapy should be mixed with Omura’s Selective Drug Enhancement Method, detoxication methods, protection from harmful electromagnetic fields exposure (e.g., by using Guard plus – Salubris made), and the treatment of autoimmune diseases, if any (e.g., by using MDK Chip – Salubris made).
Integrative approach to autism-diagnoses and treatment by bi-digital o-ring test

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Introduction: Prof. Dr. Y. Omura is a founder of new insight in medicine pointing that infections with various infective agents and heavy metal body burden, are among the main causes of diseases onset. As Dr Omura Y. first made research that many neurological disorders as autism and Alzheimers Disease are connected with brain infection mixed with heavy metal (especially aluminum and mercury).

Aim: to present findings obtained by standard laboratory test in children with autism with findings obtained by indirect BDORT in the same subjects.

Material and Method: Following checking health status by standard laboratory test, 10 examinees suffering from autism were treated with detox-items and attended exercises for speech improvement. Also, they had special diet regiment because of allergy presence. No significant improvement were found in these subjects while therapy. Then, they all were examined by indirect BDORT. All patients were treated respecting dr Omura’s Selective Enhancement Drug Uptake Method. Allergy was treated with magnetic water previously treated by MDK-chips.

Results: Indirect BDORT found mixed infection and heavy metal body burden. The most affected zone was hippocampus region where the concentration of heavy metals were the highest. Food allergy was also revealed in these patients as well as heavy metal allergy. Seven children had increased level of beta amyloid 1-42. All of examinees were exposed to pathological electromagnetic waves, had infections of hippocampus and presence of heavy metals. Treatment described above was administered. Pathological electromagnetic waves were reduced by GUARD PLUS protector (made by “SALUBRIS”, Belgrade), mixed infections were cured, and MDK-chips were used for suppression of nutrient allergy. Positive behavioral changes were seen in some patients 7 days following the treatment started and after 3 months, some patients started to talk first words. Aggressive behavior vanished.

Conclusion: BDORT in relation to other tests has an advantage to detect precisely region affected and the kind of infective agents. Also, BDORT can detect the presence of electromagnetic waves, can define what kind of drug should be used, what is the proper dosage and for how long therapy should last. Also, BDORT can point out what kind of food and nutrients can cause allergic symptoms in subjects exposed. By implementation of all above, fast improvement of health can be achieved in patients with autism.
Music therapeutic interventions to affect regulation of severely multiply handicapped adults – a video based qualitative study

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**Background:** The observation of the physical and emotional expression of severely multiply handicapped adults reflects a high prevalence of self-stimulation, stereotypical behavior or self-injurious behavior. Physicians, nurses and therapists have to face great challenges in this context. Insights gained from the area of developmental psychology through infant- and attachment research emphasize the importance of a regulated emotional state especially for the development of interpersonal relationships. A regulated emotional state includes a wide range of flexible ups and downs of tension which is not necessarily aversive. But if tension exceeds an individual threshold, the individual is not able to integrate these high affects and disorganization manifests in physical and motor signs. In therapy it is important to maintain or regain a regulated emotional state as a basis for interaction and any further development.

**Aim:** The aim is to show the effects of developmentally orientated music therapeutic interventions on the behavior of severely multiply handicapped adults, especially concerning affect regulation.

**Method:** Via video analysis the behaviour of a sample (n = 4) of severely multiply handicapped adults is observed in three different situations (music therapy, group situation, a situation without targeting). The focus is the frequency and quality of stress and strain characters. Sequences from music therapy are examined micro-analytically in this respect.

**Results:** We were able to show that music therapy has measurable effects on the physical and emotional expression of severely multiply handicapped adults. Results of the effects of music therapeutic interventions on affect regulation are currently analysed.

**Conclusions:** The study results demonstrate the importance of assessing the physical and emotional expression of severely multiply handicapped adults. Appropriate music therapeutic interventions support the affect regulation and may assist in building an integrative base in a complex therapeutic field.
Complementary medicine in the elderly – level of awareness and use. Results from the KORA-Age project

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Background: Despite the growing proportion of elderly people in many societies there is only limited knowledge of CAM use in old age. Estimates from the U.S. range from 30 to 80%. A German survey published in 2004 - although claiming to be a representative population sample - included only people younger than 69 years. The Cooperative Health Research in the Region of Augsburg (KORA-Age) offers a research platform to investigate this issue in a large-scale sample of elderly people between 65 and 93 years.

Objectives: To provide estimates for prevalence of CAM use in persons with an age of 65 or more, to differentiate current 1-year prevalence and CAM use in younger age, to assess frequency of and experiences with CAM use, and to investigate relations of CAM use to various confounding variables.

Methods: The KORA-Age study comprises participants of the MONICA/KORA studies S1-S4 born before 1944 who were re-examined in 2009. Out of 5,986 eligible former participants, a random sample was drawn stratified by age-group and sex. 1,079 agreed to participate in a detailed medical examination and interview. Questions were presented in structured face-to-face interviews conducted from February to November 2009.

Results: Data on CAM use were available for 1,026 subjects with a mean age of 76 years ranging from 65 to 94 years. 14 % of the total sample was unaware of CAM. Overall prevalence of CAM use was 37 % with minor differences between age-groups but clear differences between male (29 %) and female (44 %) participants. 18 % reported positive experiences in the context of CAM use. With respect to the previous year, 12 % used CAM occasionally and about 10 % used CAM on a regular basis. When asked about past use of CAM (about 25 yrs ago) 14 % reported “yes, occasionally” and 4 % “yes, regularly”.

Conclusions: Findings indicate that awareness of CAM is high even in people 65 years and older. Estimates for the prevalence of CAM use confirm the relevance of this treatment sector for the health care system in old age. While KORA-Age is a population based sample, results should be considered as rough estimates due to a limited capacity to conduct more elaborated questioning techniques. Acknowledgements: Data were derived from subproject 4 of KORA-Age and is funded by the German Fed. Ministry of Educ/Res (01ET0713). The KORA research platform was initiated and financed by the Helmholtz Zentrum München funded by the German Fed. Ministry of Educ/Res and by the State of Bavaria.
Cupping in osteoarthritis of the knee – results of a pilot randomized controlled study


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**Background:** Cupping is a traditional therapy to relieve pain in musculoskeletal diseases. The aim of this exploratory study was to investigate the effectiveness of cupping in relieving symptoms of osteoarthritis of the knee joint.

**Methods:** In a two group, randomized controlled exploratory pilot-study, male and female patients between 40 and 80 years with a clinically and radiologically confirmed osteoarthritis (Kellgren-Lawrence Grading Scale: 2 – 4) and a pain intensity > 4 mm on a visual analogue scale (VAS) were included. Patients were randomized to either 8 sessions of pulsatile cupping plus paracetamol on demand for 4 weeks or waiting list control with paracetamol on demand only. Outcome was measured by Western Ontario and McMaster Universities Osteoarthritis (WOMAC) – score, pain intensity on a Visual Analogue Scale (VAS) (0 = no pain to 10 = maximum intensity) and Quality of Life (SF36) after 4 and 12 weeks. The use of paracetamol was recorded within the 4 weeks treatment period. Analyses on the intention to treat population were performed by analysis of covariance adjusting for the baseline value for each outcome.

**Findings:** 21 patients were allocated to the intervention group (mean age 68 ± SD 7.2 ; 5 male) and 19 patients to the control group (69 ± 6.8; 8 male). We observed significant improvements in the cupping group: The adjusted mean of the WOMAC global score after 4 weeks was 27.7 (95 %-confidence interval 22.1; 33.3) in the cupping group and 42.2 (36.3; 48.1) in the control group (p = 0.0009), and after 12 weeks 31.0 (24.9; 37.2) and 40.8 (34.4; 47.3) respectively (0.0323). Significantly better outcomes in the cupping group were also observed at both time points for pain intensity on VAS and for the SF-36 Physical Component Scale. No significant difference was observed for the SF-36 Mental Component Scale and in the total number of consumed paracetamol tablets between cupping (mean 9.1 ± SD 20.0) and control group (11.5 ± 15.9).

**Conclusion:** Cupping with a pulsatile cupping device seemed to be an effective treatment for osteoarthritis of the knee. Further confirmatory research should include a sham-cupping-device as control group to investigate the specific efficacy of cupping.
Structural brain alterations due to mindfulness meditation – investigation of gray matter volume with voxel-based morphometry

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Background: Mindfulness meditation aims at the cultivation of intense, non-judgemental concentration, heightened awareness and calmness. First studies indicate that meditation may induce permanent brain alterations in prefrontal, orbitofrontal, hippocampal and insular regions. These regions are known to be involved in interoceptive awareness, learning, emotion regulation, and self-referential processing.

Methods: Anatomical magnetic resonance (MR) images from each 10 experienced meditators (minimum of 2 years of experience with 3 hours daily practice, mean practice 2974 ± 1589 hours) and healthy, meditation-naïve control probands matched for sex, age and handedness were obtained using a 3D-T1-weighted MPRAGE sequence at a 1.5 Tesla scanner.

Results: Whole brain analyses confirmed greater gray matter concentration for meditators in the right superior frontal gyrus and right middle frontal gyrus and also revealed enhanced gray matter in the right middle temporal gyrus for the control group. According to initial covariance analyses, the mean value of gray matter concentration in frontal and (para-) hippocampal regions in meditators was predictable by the amount of meditation experience.

Conclusion: The results partly confirm previous studies and suggest a direct causative link between meditation training and structural changes in gray matter concentrations in brain regions involved in higher mental functions and memory encoding and retrieval. Further analyses will complete these initial results.

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Stimulation of gastric slow waves with manual acupuncture at acupuncture points ST36 and PC6 – a randomized single blind controlled trial

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Background: To investigate the effects of stimulated and non-stimulated manual acupuncture at ST36 and PC6 on gastric myoelectrical activity and autonomic function.

Methods: 65 healthy volunteers were randomly assigned to a 1:1:2 ratio to receive either 15 minutes of verum acupuncture (VA) with stimulation followed by 15 minutes of VA without stimulation (nsVA), or 15 minutes of nsVA followed by 15 minutes of VA with stimulation (sVA), or 30 minutes of sham acupuncture (SA). Measures of autonomic function included electrogastrogram, electrocardiogram, impedance cardiography and assessment of blood pressure, breathing frequency and electrodermal activity. Outcome parameters were compared between VA and SA and between sVA and nsVA. The percentage of regular gastric slow waves (normogastria) was defined as the primary outcome.

Key Results: The percentage of normogastria was not significantly different between VA and SA. Differences in secondary outcomes such as power spectrum of gastric slow waves and heart rate variability parameters were pronounced in the comparison of sVA and nsVA. During stimulated acupuncture, the percentage of normogastria was lower (p = 0.033) and the percentage of bradygastria was higher (p = 0.013), systolic blood pressure was lower (p = 0.039) and RMSSD was higher (p < 0.001) as compared to nsVA.

Conclusions & Inferences: Our study suggests that manual stimulation of acupuncture needles affects gastric myoelectrical as well as cardiac activities in healthy volunteers. The effect of stimulation in acupuncture deserves further investigation.
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The effect of arts speech therapy on end-expiratory CO₂ as well as cerebral hemodynamics and oxygenation

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Introduction: Arts speech therapy (AST) is used in anthroposophic medicine. Unlike logopedic speech therapy which focuses on pronunciation, it is used to induce curative processes in various organ systems, e.g. cardio-vascular system or respiratory tract in patients. In AST different kinds of speech exercises are performed under guidance of a licensed speech therapist. Besides indication for clinical effectiveness for various medical conditions e.g. bronchial asthma, previous studies revealed that AST influences the cardiorespiratory system as well as cerebral hemodynamics and oxygenation (CH/COX). The aim of the present study was, for a better physiological understanding, to further investigate effects of AST by assessing changes in CH/COX and the end-tidal CO₂ pressure, which is known to affect CH/COX.

Material and methods: Measurements were performed on 24 adult volunteers during AST (12 men and 12 women). Each measurement lasted 43 min (8 min pre-baseline, 5 min recitation, 5 min recovery, 5 min recitation, 20 min post-baseline,i.e. recovery). For each subject, measurements were performed for 3 different AST tasks (recitation of alliterative (RA), hexameter (RH), and prose (RP) verses) and a control task (mental arithmetic (MA) with voicing of the result) according to a randomized crossover design. Absolute concentrations of oxy-, deoxy- and total hemoglobin ([O₂Hb], [HHb], [tHb]) and tissue oxygen saturation (StO₂) were measured using an ISS OxiplexTS NIRS device. A NIRS sensor was placed on the left and right forehead. End-tidal CO₂ pressure was measured continuously by a Nellcor N1000 gas analyzer.

Results: During recitation: [O₂Hb] and StO₂ decreased significantly by ~1 µM, [HHb] remained the same and [tHb] decreased by ~1 µM during all recitation tasks. CO₂ pressure decreased significantly for all recitation tasks by approximately the same amount. After recitation: (i) [O₂Hb] and StO₂ of the left frontal cortex increased significantly for the MA but not for the recitation tasks. CO₂ pressure resumed baseline quickly for all recitation tasks. [HHb] had a tendency to decrease for RA and RP, while it returned to baseline for RH.

Conclusion: The study showed that AST affects end-tidal CO₂ pressure and CH/COX. The cerebral circulatory changes can mostly be explained by an auto-regulatory response to changes in CO₂ pressure. However, the decrease in [HHb] after RH and RP when CO₂ pressure has returned to baseline may indicate a long-term effect of AST.
Searching for Dr. Supportive. Doctor-patient communication and cancer patients' use of CAM

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**Background:** Use of complementary and alternative medicine (CAM) is an area where patient and medical perspectives often diverge. The quality of doctor-patient communication can be critical in developing patient satisfaction, compliance, and positive health outcomes. It has been argued that we have acquired enough knowledge in general of the value of communication skills, and that there is a lack of studies of communication in context.

**Objective:** The aim is to explore doctor-patient communication from the patient perspective with regard to cancer patients’ choice of CAM as a supplement or alternative to conventional treatment (CT). The research questions addressed are: 1. How have cancer patients who chose to use CAM as a supplement or alternative to CT experienced doctor-patient communication? 2. Did doctor-patient communication influence these cancer patients’ treatment choices? If yes: How and why?

**Material and Methods:** A mixed qualitative design was chosen. Document analysis of text data from 52 Norwegian and Danish cancer patients who reported positive experiences from the use of CAM was used as a basis for strategic sampling as well as a source of extended knowledge. Thirteen of the patients were selected for semi-structured interviews.

**Results:** Both users of CAM as a supplement and alternative to CT searched for doctors with a patient-centred communication behaviour. The patients wanted to discuss, optimize and safeguard their treatment choices. They found that instrumental doctor-patient communication could lead to dissatisfaction, limited treatment options and denial of CT. Their experiences with doctor-patient communication influenced whether they chose to use CAM as a supplement or alternative to CT.

**Conclusions:** Both cancer patients who chose CAM as a supplement and alternative to CT wanted to relate to supportive doctors with patient-centred communication behaviour to safeguard and optimize their treatment choices. Instrumental communication behaviour can potentially lead to mistrust in CT, and health-related risks such as denial of CT can emerge. In doctors’ practices and in the education of doctors a greater awareness of the potential positive and negative outcomes of doctor-patient communication that concern CAM issues could be of importance. These tentative conclusions should be further investigated to develop and safeguard doctor-patient communication with regard to cancer patients’ choice and use of CAM in a society with competing health paradigms.
Impact on medical practice of a new required course on complementary medicines in Lausanne Medical School, Switzerland

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Context: In May 2010 the University of Lausanne, Switzerland, inaugurated a new required course on complementary and alternative medicines (CAM) based on factual scientific knowledge as part of the medical school curriculum. The 2-hour course is included in a general internal medicine module during the 2nd year of the master's degree, just before students begin practical training in hospitals and ambulatory care. The goal is to add in routine physician-patient a question about CAM use and to help future physicians inform their patients about CAM in a professional manner.

Method: A questionnaire was sent through email, with one reminder, to all 6th year medical students one year after the course, while they were dispatched as trainees in medical wards and practices.

Results: 65/135 students answered (37 female and 27 male, mean age 25, range 23 – 28). The mean estimate of the proportion of their patients using CAM is 25 %; 94 % of the students agree that basic knowledge about CAM is important for clinical practice. However, only 49 % say that they know where to find factual information about CAM (as compared to 95 % right after the course and 15 % before), and 23 % actually ask their patients about CAM use (one year earlier they were willing to do so in proportions of 83 % and 97 % resp. before and after the course).

Conclusion: Although the new required course on CAM appears to fulfil students' need, the long-term impact is far from optimal. The required course has now been expanded within basic medical training from 2 to 6 hours, with an optional course of 36 hours. The impact of these courses on internship medical practice should be measured in two years.
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Media focus on complementary medicine – medical students’ perception of the controversial debate in media coverage

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Background: Last year complementary and alternative medicine (CAM) came to the media’s special focus. The reporting ranged from reflection of a favoured medical pluralism to statements of established paramedicine that found its way to medical curricula at German universities.

Aims: We wanted to figure out how medical students perceived the controversial discussion on CAM and evaluate the impact of pre-existing experiences with CAM on their attitude towards core statements of media reporting.

Methods: A questionnaire survey was carried out among medical students in the fifth term. Apart from questions concerning the perception of media coverage, nine key messages were quoted from four essays of different German print media. Personal attitude was evaluated with a Likert-Scale. Statistic analysis was performed with one way analysis of variance and frequency distribution. Reliability analysis via Cronbach’s alpha showed 0.67.

Results: 145 questionnaires (response rate 78.8 %) were evaluated. 46.2 % of all students noticed the discussion carried throughout the media. 71.7 % had pre-experiences with CAM-treatments, 74 % rated their experiences as good to very good. Concerning the headlines and quotes from media coverage, 42.1 % agree that “there is no evidence of benefit for homeopathy”, 31 % disagree. 41.1 % do not support the headline: “German universities teach paramedicine”, 19.3 % are indecisive. 51 % believe that “medical universities cannot deny TCM if a rising number of patients requests it”. 15.2 % believe that “homeopathic drug provings are well represented in double-blind studies”. A significant correlation between own CAM-experiences and the personal tendency of grading the media statements has been shown (p = 0.001), but clear accordance with positive core messages towards CAM was missing. Although there are positive own CAM-experiences the students have the trend to “indecisiveness”. The media’s interest on CAM was mainly rated positive for raising the discussion and encouraging freedom of choice.

Conclusions: In case of positive own experiences the lack of tendency in favour of CAM was surprising. Reasons for the missing positioning remain unclear in this quantitative survey. It might be that clinical proof-of-concept is more important than treatment experience and the own biography is of secondary importance for the assessment. For the profound understanding of missing positioning rather qualitative interviews seem to be suitable regarding further investigation.
Abstracts/ECIM 2011/Oral Presentations/EDUCATION

OP-162

Master’s level education for practitioners: an essential requirement for successful integration?

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Study at Master’s level may arguably have the potential to enrich professionalism, build capacity in the profession and foster critical awareness. For example there is an abundance of anecdotal evidence that undertaking postgraduate research and study at Master’s level significantly changes how teachers view aspects of teaching and learning in their classrooms [1]. Similarly it has been suggested that Master’s level nursing education can lead to increased confidence and self esteem; enhanced communication; personal and professional growth; knowledge and application of theory to practise; and analytical thinking and decision making [2]. As articulated in the national qualification descriptor (UK), graduates of all Master's degrees should be capable of demonstrating a systematic understanding of knowledge, much of which is at, or informed by, the forefront of the discipline, field of study or area of professional practice. They should be capable of demonstrating originality in their application of that knowledge and in addressing problems [3].

In 2006 the University of Central Lancashire (UCLan) began offering an MSc Homeopathy course. Delivered entirely through e-learning the course has attracted students from over 20 different countries. Feedback from the students suggests an impact that far exceeds original expectations of either students or staff. Building on the success of this course, in September 2011, UCLan will be adding MSc Integrated Healthcare and MSc Herbal Medicine to its portfolio of courses. This talk offers a reflective account of the experience of delivering Master’s level education to a global group of practitioners. The development of critical thinking and research skills underpin all other aims in these courses and the potential benefit to professions of improving these skills is considered. Furthermore the importance of Master’s level education for future collaboration and integration is debated.

OP-180

Sculpturing as an approach to train holistic thinking and perception in the medical curriculum

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Introduction: In recent years a development towards an increasing specialization and particularization can be observed in medicine and science. This development is present in research, diagnostics and therapy and also has an impact on teaching and medical curricula. Although highly specialized knowledge is without doubt crucial and beneficial the ability to conceive a subject or person in their respective entirety is likewise essential. Considering a person’s entirety in the sense of a holistic thinking is nowadays primarily found in complementary medicine (CM) and is one of the reasons why patients chose CM. One possibility to acquire and train the ability to think and conceive holistically is to actively participate in arts. This is because working artistically is impossible without the ability to conceive objects in their entirety. This is particularly easily understandable in sculpturing, where a modification of even a detail alters the appearance of the entire sculpture. The aim was to assess whether a sculpturing class promotes holistic thinking and perception in medical students.

Methods: In order to enable students to train their competence in thinking holistically we offer the elective course “Sculpturing in Anatomy” at the Medical School of our University. In this 20 hours class students sculpture with clay different skeletal bones. Anatomical objects are chosen because they have features related to function but their individual form can only be understood and appreciated in the context of the entirety of a living and moving organism. Students experience and train to build and perceive three-dimensionally as well as to become aware of the building process. This enables besides the common static thinking a more processual thinking. Towards the end of the course students reflect on the course in form of an essay or poster.

Results: The contents of these are often surprising. Students appreciate having the opportunity to work with their hands, the calmness of the sculpturing process; name a deepened comprehension of the skeleton, an improved understanding of building processes and a more easy access to learn anatomic terms and biomechanics of the skeleton.

Conclusion: The intended aims of the course can at least in part be achieved. This is particularly interesting and extraordinary because we do not inform the students about the aims prior to or during the course.

Acknowledgement: We thank P. Heusser for initiating the sculpturing class.
A suggested model for constructing an individualized therapeutic plan, in complementary medicine

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Objective: Our purpose is to report the significant elements for the structure of an effective and individualized therapeutic plan, for all the complementary medicine (CM) therapies practicing by professional therapists (especially non doctors).

Introduction: CM therapies are practicing from doctors and non – doctors. Concerning the non medical doctor’s professional therapists, in most of the schools, there is a lack of education concerning history taking and the proper way to construct therapeutic plan.

Method: At this point, we should refer that history taking is assumed to be taken, at first session. Which information does a therapist evaluates: The initial thought of structuring an effective and individualized therapeutic plan should be based on patient’s main demand, namely the main reason of patient’s visit. Moreover, therapeutic plan frames from information delivered from the rest of history taking based on patient’s present health condition, from therapist observation of the patient, and from therapist evaluation and adjustment to his therapy. How should a therapist classify patient needs: CM therapist should be focusing on 1 to 3 patient disorders. Classification of patient health demands deliver from history taking, from the result of scales measurement, from the therapy that therapist practices, and therapist knowledge and experience. How CM therapist structures an effective and individualized therapeutic plan: The structure of an effective and individualized therapeutic plan is limited by : I. the complementary therapy that therapist follows II. the treatment durance III. the contraindications that may occur by the CM therapy IV. the body’s area that CM therapy is applied V. the CM therapist knowledge and experience VI. the body’s area that CAM therapy is applied VII. the CM therapist collaboration with other specialties VIII. the special patient’s groups.

Results and Conclusion: Structuring a therapeutic plan is a complicated procedure that consists of a detailed history taking with all the necessary information about patients health, elements from the patient that CM therapist may need in order to practice his therapy (for example, as it concern reflexology foot diagnosis), therapist communication ability (oral, eye contact and observation as well). Even though, therapist ability to evaluate, distinguish and classify patient needs is important for patient progress, there is a lack in the education in almost all CM therapies. Most of CM therapies schools spend al lot of time analyzing the diseases and disorders and how a therapist should face them according to the therapy he studies, but schools do not have al lot or any class hours, on how a therapist should think, judge and classify patients with more than one disease or disorder, in order for the CM therapist to be able to structure an effective and individualized therapeutic plan. In conclusion we would like to suggest emphasising the history taking education in order each therapist to be able to discriminate and prioritize patient’s symptoms.
Traditional medicine in Serbia - education

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This is the first time that the Law on Health Protection of the Republic of Serbia, of 10.12.2005, has defined the field of Traditional Medicine (TM) within the integrated approach to diagnosis and therapy implementation process. The national strategy on education in this field started with the adoption of the Regulation on detailed conditions, mode and procedure for the performance of the methods and practices of traditional medicine. The conditions for implementation of TM methods and procedures and new methodologies that rely on TM are defined by the Law and the Regulation.

The approved methods and procedures set out in this Regulation are divided into two groups: Diagnostic and therapeutic methods and Methods of health promotion. The sanitary standards, cabinet equipment requirements, staffing profile and the educational minimums are defined by the Regulation. The system of continuing postgraduate medical education is included in the staff education and the Health Council of the Ministry of Health of Serbia holds the accreditation process competency being the highest level Accreditation Board for continuing post-graduate education of health practitioners.

The educational plan foresees the establishment of schools for: ayurveda, acupuncture, traditional Chinese medicine, homeopathy, quantum medicine, chiropractic, macrobiotics, traditional folk medicine. The schools are organized in the form of basic courses, higher-level courses, and the authorized basic and higher-level courses. The Commission on TM of the Ministry of Health of Serbia reviews the work permit applications. The work permit is signed by the Minister of Health. On the basis of this permission, a license that allows the TM medical practice over the next seven years is issued by The Medical Chamber.

Learning complementary and alternative medicine: The evaluation of a mandatory course in training CAM by German medical students

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Courses on complementary and alternative medicine (CAM) have been mandatory at German university medical schools since 2003. Besides the regular lectures on CAM, the curriculum at University Duisburg-Essen includes a mandatory 1-day training in CAM. In this course, medical students learn not only theoretical but also practical basics in European naturopathy, Traditional Chinese Medicine and Mind-Body Medicine mainly focusing on evidence-based data. In 2010, this course was rated best among all 42 mandatory courses in clinical medicine at University Duisburg-Essen.

Methods: After participating in the course, students were asked to evaluate whether they were interested in CAM and whether their interest changed through attendance. On a 6-step Likert scale ranging from “very good” to “unsatisfactory” students also had to rate whether their expectations were fulfilled, they did learn, the training was relevant for clinical practice, the same learning success could be achieved by lectures or new media and the training was profitable to them. The overall quality of the course was assessed, too. Further comments regarding the course could be written in free text.

Results: The course was evaluated by 136 students (86 female, 50 male). 76.5 % of them reported interest in CAM, 44.1 % showed a change in interest through attendance. All outcomes were rated “good” to “very good”. Students reporting interest in CAM rated higher on “expectations fulfilled” (p < 0.001), “did learn” (p = 0.021) and “relevance for clinical practice” (p < 0.001), while students reporting no interest rated more often that their interest in CAM changed through the course (p = 0.021). Female students rated higher on “expectations fulfilled” (p = 0.048) and male students rated higher on “same learning success through new media” (p = 0.038). There were no differences in ratings regarding the overall quality of the course. In their free comments, students most often commended the practical experience and stated changes in attitudes towards CAM.

Conclusions: A mandatory course in CAM was evaluated as being “good” to “very good” by German medical students and rated best among all courses in clinical medicine. Assessments were influenced by gender and interest in CAM. The results suggest that the presentation of evidence-based CAM to students being incurious in CAM leaded to more interest in CAM. The introduced training course in CAM can conduce as a successful model for CAM-lectures in other universities.

PP-188

Complementary and alternative medicine in medical students' compulsory curriculum at the University of Bern, Switzerland

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Background: In Switzerland, a great proportion of the population uses complementary and alternative medical methods (CAM). Due to the high demand and acceptance, two thirds of electors claimed yes for CAM in a public vote in May, 2009. One of the aims of this initiative is integration of physicians’ CAM into both, research and teaching. Additionally, CAM has
great importance in medical general practitioners’ (GP) surgery: A survey of 750 GPs all over Switzerland showed 38% of them practising at least one of the methods themselves or referring patients to colleagues practising CAM. Politically, an effort is made to implement some knowledge of CAM into compulsory teaching of medical students.

**Method:** Since 1995, the Institute of Complementary Medicine KIKOM is integrated into the Medical Faculty of the University of Bern. As an equivalent of an academic chair, it includes four of the five CAM methods most used in Switzerland: Anthroposophic Medicine, Classical Homeopathy, Neural Therapy, and Traditional Chinese Medicine including Acupuncture. According to Bologna principles, students’ time tables were transformed into Bachelor, and Master Courses, and the Dean of the Medical Faculty evaluated existing CAM teaching lessons, and implemented a new concept comprising compulsory lessons, seminars, practical courses, and continuous academic teaching, including bachelor, master, and doctoral thesis.

**Result:** During the first three years, leading to a Bachelor degree, several duty-elective practical trainings were offered. Starting with year three, KIKOM offers at least one compulsory and examination relevant lesson each year. There is no intention to teach practical skills, but students get basic knowledge in the four respective methods needed for qualified caring of patients. But students will be able to participate in academic as well as scientific discussions, and to form their own opinions, and to help patients to make their own decisions. Academic lessons in the third, and fifth year are successfully implemented already, and rated positively by the majority of students. Lessons of years 4, and 6, during master studies, will start in the academic year 2011/2012.

**Conclusion:** Experiences so far tell us, that co-operation in academic teaching is possible between doctors practicing conventional and complementary medicine.
Abstracts/ECIM 2011/Oral Presentations/INTEGRATIVE MEDICINE PATIENT CARE

PP-193

Level of telomers determined as a predictive factor of outcome of infertility treatment; role of pau pereira and rauwolfia vomitoria extracts

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Introduction: Determine the levels of Telomeres (TTAGGG) by Indirect Bi-Digital O-Ring Test BDORT (by Prof. Dr. Omura, NY) in couples who are treated for infertility, we found that if a male or female have low levels of telomere (< 50 ng), is likely to end pregnancies in the first half of pregnancy as intrauterine fetal death or spontaneous abortion. Determine the importance of this factor in reproduction we believe that the concept of Telomere levels comparable to the notion of TCM: Kidney Jing, as the essential factor that is required for the production of gamete quality.

Aim: The aim of our study was to examine the level of telomere, measured with BDORT as an independent factor for the outcome of pregnancy.

Material and method: A few couples who are treated for infertility is examined with indirect BDORT to measure the level of telomere and exclude the existence of infection, hormonal, metabolic changes and the impact of external factors such as pathological form of electromagnetic radiation (EMFs). In couples who had no other risk factors and had low levels of telomere and there was a pregnancy before treatment to raise the level of telomere, there was early termination of pregnancy compared with couples who had high levels of telomere (> 500 ng) and where the pregnancy is presented to the end. Some couples have had three consecutive unsuccessful pregnancy, to only then decided to raise the levels of telomere. For raising the telomere, we used Pau Pereira and Rauwolfia vomitoria extract (Pao V FM V and Rovol capsulae, by Natural Source, NY, USA), which have been tested and confirmed to have a big impact on the stabilization of the genes (Dr. Mirko Beljanski, PhD, Pasteur Institute, Paris).

Results: In pregnant women, where even one of a pair (male or female) had low levels of telomere (< 50 ng), there was an early end of pregnancy. Taking drugs PaoV FM and Rovol V for 30 to 60 days there was a rise Telomere (> 700 ng). In all repeated pregnancies were successfully brought to end and all the children were healthy.

Conclusion: Using indirect BDORT can be measured by the level of telomere in couples treated by infertility. The level of telomere may be a parameter which can be explained in TCM Kidney Jing and that a predisposition to create a healthy and potent oocytes and sperms. The level of Indirect measured Telomere by BDORT before pregnancy may be an important factor in predicting the outcome of pregnancy. Pao Pereira and Rauwolfia vomitoria extract significantly stabilize genes and rise the levels of telomeres in patients and providing prevention, can positively influence on the outcome of infertility treatment and outcome in risk pregnancy.
**PP-199**

**Integrative approach-bi-digital o-ring test (bdort) and prenatal diagnosis**


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**Introduction and aims:** Bi-Digital O-Ring Test, established by Prof. Y. Omura as non-invasive diagnostic method, may be very useful in prenatal diagnosis. Aim of the research is to evaluate the accuracy of indirect Bi-Digital O-Ring Test in determination of fetus gender and to compare the results obtained by BDORT showing pancreatic infection with standard three-hour oral glucose tolerance test (OGTT).

**Material and method:** 149 pregnant women were examined by indirect BDORT. The assistant during the test was female. Slides with human sexual chromosomes were used as referent substances: XX and XY. Slides were produced in the laboratory for Genetics of Mount Sinai Hospital, NYU. 15 pregnant women, between 6th and 11th week of gestational age, were examined prior chorionic villi biopsy and genetic analysis. 134 pregnant women, between 18th and 36th week of gestation, were examined by ultrasonography in order to determine fetus gender. The results obtained from indirect BDORT were compared with the fetus gender following delivery. Also, in patients whom indirect BDORT revealed pancreatic infection, reference slides with acetylcholine (ACh) were applied; the patients showing ACh resonance at 100 pg (BDORT Unit) or less, were referred to lab to perform 3-hour OGTT with 75 g of glucose.

**Results:** The same results of gender determination were obtained by using both BDORT, on one side, and by chorionic villi biopsy and genetic analysis, on the other in vast majority of cases. The diagnosis was missed in three cases and some peculiar information was obtained in five cases. The same results of gender determination by using BDORT on one side and standard methods on the other, were obtained in 94.63%. BDORT showed infection of pancreas in 9 out of 128 pregnant women. The resonance with ACh slides was obtained at 100 pg (BDORT Unit) and less. Those patients referred to lab where 3-hour lasting OGTT was performed with 75 g of glucose. The test was positive revealing glucose intolerance in 8 patients (89%).

**Conclusion:** BDORT may be applied as a screening method to determine fetus gender. Regarding pancreatic infection and ACh, BDORT showed that, besides normal fasting blood glucose level, certain changes in sugar metabolism may be present and, whether ACh is lowered, 3-hour OGTT is recommended. By referring to lab patients with normal fasting blood glucose level and lowered ACh level, physicians may reveal patients with glucose intolerance and preventive measures may be apply.

**PP-210**

**Integrative care in the rehabilitation of people with Multiple Sclerosis – results from a six-year Danish research and collaboration project**

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MS patients, MS patient associations and health care providers within the area of MS are increasingly demanding new types of health care that can meet the complex needs of tomorrow’s chronic patients. This might encompass different concepts of health and disease, diagnostic systems as well as treatment methods and outcomes. Against this background, The Danish MS Society initiated a research project, focusing on integrated care, with the purpose of investigating whether the combination of different treatment perspectives on MS rehabilitation could improve treatment results.

The research project took place from 2004 to 2010. In the project, a team of five health care providers and five practitioners of complementary and alternative medicine (CAM) were set up to work together in developing and offering individual treatment and rehabilitation to 200 people with MS (PwMS) at an MS hospital. A formative evaluation design including an intervention group and a comparison group was employed. Questionnaires from 142 PwMS and qualitative interviews with 59 PwMS were used in the data analyses. Furthermore, interviews with the ten practitioners and notes from 29 collaboration seminars were used in the overall evaluation of the project.

From hospitalization and through an 18-months period, PwMS treated by the integrated team were found to experience a statistically significant different change in quality of life (FAMS total score) compared to PwMS treated within the current ‘best practice’ model. Statistical analyses of the questionnaire data and qualitative analyses of the patient interviews pointed to the fact that many positive treatment results had been obtained on many different levels on the basis of the integrated care approach. A united model was developed by the ten practitioners, illustrating an integrated treatment philosophy. The united model emphasizes the importance of process-oriented factors in the courses of treatment and focus is put on the outcomes that occur over time when strengthened resources and competences work in dynamic interaction with the patient’s own efforts under the right contextual circumstances.

It can be concluded that in many cases an integrated care approach can positively contribute to the treatment and rehabilitation of PwMS by encompassing and combining different treatment approaches and thereby meeting a variety of complex needs among PwMS.
PP-057

Getting started with Taiji – exploring beginners' expectations towards Taiji

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Background: As reported in various clinical trials patients’ expectations have been shown to possess a high influence on treatment results. However, by now little attention has been drawn on subjective expectations in preventive interventions such as Taiji. Taiji is a mind-body practice characterized by sequences of gentle and mindful body movements. It has repeatedly been considered as a valuable intervention for stress management. The aim of our study was to evaluate what beginners without previous practical Taiji experience expect from this mind-body practice in general as well as more specifically with regard to stress management.

Materials and Methods: 74 healthy subjects (22 male and 52 female; mean age = 35.4; SD = ± 7.5) applied for a Taiji beginners course (2 x 1h per week for 3 months) and were asked to write down their expectations towards their upcoming Taiji course. Additionally stress management related expectations were measured by rating 15 expectations on a Likert-scale (six-point rating scale ranging from 1 = “not true at all” to 6 = “absolutely true”) to indicate the degree of correspondence with their own expectations. Descriptive data analysis was employed. Associations between socio-demographic factors and stress management related expectations were analysed by using between group t-Tests.

Results: The expectation most mentioned was “get to know Taiji” (n = 42), followed by “tranquility and peace of mind” (n = 33), “improved handling of stress” (n = 30), “increased body awareness” (n = 26) and “relaxation” (n = 20). Moderate average expectation values were found regarding Taiji related stress reduction (M = 4.44; SD = ± 0.96) and resource activation (M = 4.58; SD = ± 0.68). Subjects without a high-school degree (n = 17) expected a significantly higher stress reduction through Taiji (M = 4.89; SD = ±0.77) than those with a higher education level (n = 57; M = 4.30; SD = ± 0.98; p < .05).

Conclusion: Beginners who are getting started with Taiji mainly expressed knowledge related and mind-body related expectations. Stress reductive expectations were more often mentioned by subjects with less favourable educational background. The consideration of participants’ expectations in future Taiji studies warrants further attention.

PP-058

Flow experience during Taiji practice – an observational study in healthy subjects

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Background: Taiji is a mind-body practice, characterised by gentle and mindful body movements originating from Chinese martial arts. Studies investigating the reasons why people engage into Taiji and maintain their practice routine have emphasised extrinsic motivational outcome related aspects. The relevance of intrinsic motivation (i.e. motivation that comes from inside an individual and is driven by an interest or enjoyment in the performed activity itself) has not yet been examined. The autotelic aspect of intrinsic motivation is an essential precondition for experiencing flow, a state where subjects fully immersed into the performance of an activity report to be highly concentrated, optimally challenged and in control of the action. The aim of our study was to assess to which degree flow was experienced in the course of a 3 month Taiji-beginners class and to examine the relationship between the degree of flow experience at the end of the course and the Taiji practice behaviour.

Materials and Methods: 28 healthy subjects participated in a Taiji beginners course (2 x 1h per week for 3 months). Flow values were measured at week 1, 6 and 12 by using the Flow-Kurz-Skala (FKS) questionnaire. Data were analysed by using ANOVA with repeated measurements, students t-Tests for comparison with normative values, and pearson correlation coefficients were calculated.

Results: In the course of the 12 weeks Taiji training, mean flow values increased continuously (F(1.34, 8.92) = 19.49; p < .001). The mean value for experienced flow during Taiji practice at week 12 (M = 5.54; SD = ±.77) was significantly above the norm value (t = 3.705; df = 27; p < .01). Since average course attendance rate was high (86.8 %), a ceiling effect is assumed, thus flow values did not correlate with course adherence (r = .236; p = .227). However, a significant correlation was found between flow values at week 12 and practice at home (r = .439; p < .05).

Conclusion: Our findings emphasise the potential value of intrinsic motivational aspects inherent in Taiji practice for developing a regular practice routine. The impact of increased flow experience on health related outcome measures, and its relevance in clinical trials is subject of further research.

PP-082

Development and pilot of the LEAP project: an online spirituality based intervention for adolescent depression

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Purpose: Given the growing prevalence of adolescent depression, uncertainties regarding efficacy and safety of conventional treatments and the mounting evidence for a role of spirituality in depression recovery, we set out to develop an online spirituality based intervention for clinically depressed adolescents.
Abstracts/ECIM 2011/Poster Presentations/MIND BODY MEDICINE

Methods: A) Needs Assessment: This included: 1. a literature review, 2. consultations with experts on spirituality and teen mental health and 3. focus groups with youth on media preferences and views on spirituality. B) Framework and Content Development: We compiled an exhaustive collection of spiritual principles from the major traditions of the world, as well as secular organizations, and sorted and categorized these principles until a path of spiritual growth emerged that became the program foundation. Based on the literature review, six key symptoms of teen depression were identified and hypotheses were formulated on how spiritual growth could alleviate these. While the spiritual content development was based on traditional spiritual teachings, materials to bring these teachings to live were largely teen generated. In addition, we included guided imagery and simple meditations tailored towards the program content. C) Website Development: A media company was engaged for the production of the online program. D) Youth Focus Groups: Program content and presentation were focus group tested with youth volunteers.


Conclusion and Future Plans: We produced a youth relevant program to nurture spiritual growth. This program is currently being piloted in a depressed teen population.

PP-083

A lifestyle-based, primary prevention program for Alzheimer's disease

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Alzheimer's disease (AD) is becoming a major global health issue. Its worldwide prevalence is forecast to more than triple during the next forty years and top 115 million by 2050. Since AD develops over decades and treatment options that significantly hinder the disease progression are not on the horizon, the key to lowering the future burden of AD is likely to be primary prevention. We are therefore developing a comprehensive, interdisciplinary and multi-step program whose final goal is to educate individuals about how to best change their lifestyle patterns to lower the risk of developing Alzheimer's disease.

Our approach will include the evaluation and collocation of lifestyle-based risk factors and will focus on the following issue areas. a. Appropriate diet. This will include the evaluation of, for instance, the association of high consumption of omega-3-fatty acids, co-enzyme Q10, a balanced calorie intake, vitamin D/E/C/B12, trace elements and further macro- and micronutrients as well as nutraceuticals, with the incidence of Alzheimer's disease. b. Avoidance of toxins. Heavy metals, e.g. mercury or lead, as well as further environmental pollutants such as radiation by mobile phones will be addressed. c. Physical exercise. We will collate all available information on whether and how much sports or physical exercise may
lower the risk of AD. d. Culture of Consciousness. Meditation, Mindfulness-based stress reduction and cognitive stimulation will be analyzed for potential influence on AD.

Methodologically, the project will be based on systematic reviews of the existing literature, encompassing clinical evidence, but also integrating knowledge from genetics and molecular biology. The resulting reviews will be collated in a popular booklet in order to enable a wide audience to modify their lifestyles with respect to personal preferences. We hope that such an approach will help contain the worldwide spread of Alzheimer’s disease.

**PP-129**

**A clinical study to evaluate the efficacy and safety of Bacopa caplets in memory and learning ability: a double blind placebo controlled study**

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Bacopa has been used in Ayurvedic system of Medicine as a nervine tonic for centuries. Present study was carried out to evaluate safety and efficacy of Bacopa Caplets to improve memory and learning ability in a double blind placebo controlled clinical study. Bacopa caplets were given in a dose of one caplet (750 mg) daily for sixteen weeks. Verbal span test, Verbal working memory task test, and text comprehension tests were used as clinical parameters to assess memory and learning ability in 84 subjects. Bacopa caplets significantly improved these parameters at sixteen weeks of drug therapy.

The drug was well tolerated without any serious adverse effects. It did not change any biochemical parameters. Bacopa caplet appears to be clinically effective in improving cognitive functions without any serious adverse effects.

**PP-145**

**Focus group on a mind body course before the implementation at Lausanne Medical School, Switzerland**

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Context: 54 % of 1st year medical students at Lausanne Medical School report their stress as very high or unbearable. This is probably partly linked with the 75 % rate of failure. According to what is proposed in other universities like Georgetown, Washington D.C., the faculty is considering implementing a mind-body course for students. A focus-group with 3rd year students was organised to get their perception of stress reduction course.
Method: A 45 minutes focus group with 7 third year students (male: 2) was organised in March 2011. Students were asked about their own perception of stress during the 1st year of Medical School and the feasibility of a mind-body course.

Results: Each student reported some kind of stress during 1st year medical school, but not at the same time: some students felt the maximal stress at the very beginning of the year, others during the whole year, but some students felt it around the exam or even after the exam. There is no consensus about what creates stress for the students, but it can be linked with rumours or revisions just before the exams, or personal constraints such as recent arrival in the city or financial problems. All the students in this focus group would have attended a mind-body course. The content of the mind body course should be easy to practice. The fact that it is proposed by the University would be a guarantee of quality. This course should be presented to the students as a way to improve self-confidence and to save time. According to the students implicated in the focus group, 20 to 25 % of students would take part in a mind-body course if it were proposed in a convenient time-slot. The course should not be given by teachers involved in teaching in the first year of medical school.

Conclusion: Even if a mind-body course would be a type of teaching very new and unusual in Lausanne Medical School, the focus-group showed a great interest among students towards its implementation. As the focus group could not be representative of all students, a pilot study will be implemented before proposing a mind-body course to all first year medical school students.

PP-152

Additive complex Ayurvedic treatment in patients with generalized anxiety disorder compared to conventional standard care alone – design of a controlled clinical non-randomized pilot study (BAYA-Trial)

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Background: Ayurveda is a traditional Indian medicine; as a whole medical system it consists of diagnostic procedures and complex treatments. Ayurveda-treatment is based on ayurvedic diagnosis and may include the following methods: manual therapies, lifestyle and nutritional advice, yoga and purification techniques. In India Ayurveda is often used for the treatment of generalized anxiety disorders, however, no systematic data is available on its effectiveness as an add-on treatment compared to Western conventional standard care alone.

Objective: The aim of this study is to evaluate the effectiveness of additive complex ayurvedic diagnosis and treatment compared to conventional standard care alone in stationary patients with generalized anxiety disorders.

Methods and Design: A total of 40 in-patients will be included into this prospective, controlled, clinical, non-randomized observational pilotstudy. Patients between 18 and 70 years of age, diagnosed with generalized anxiety disorders, following the criteria of the German Society for Psychiatry, Psychotherapy and Neurology (DGPPN), will be included into two groups. Randomization is not performed due to the trial’s observational character. All 40 patients will receive the conventional standard care according to the current DGPPN-
guidelines including different forms of psychiatric and psychotherapeutic measures, occupational therapy and physiotherapy. In the Ayurveda add-on-group 20 patients will moreover receive individualized treatment according to the Ayurveda diagnosis which may include manual treatments, oil-dripping-treatment on the forehead, massages, dietary advice, specific consideration of selected food items, ayurvedic lifestyle and yoga posture advice. Study visits are scheduled at baseline (admission to the hospital) and at the end of the hospital stay (max. 30 days after admission); further follow-up questionnaires will be sent to the patient after 6 months. The primary endpoint is the change in the Hamilton Anxiety Rating Scale (HAMA) at the end of the in-patient treatment phase. Secondary endpoints are: Hospital Anxiety and Depression Scale (HADS), State Trait Anxiety Inventory (STAI), Profile of Mood States (POMS), Short Form 36 Health Survey (SF-36), VAS for anxiety and Likert-Scales.

The Trial is supported by Immanuel-Diakonie Group.

PP-167

Survey on hand gestures relevance in patient practitioner communication: a homeopathic example

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Background: A systematic review showed that patients convey important informations in spontaneous co-speech hand gestures (HG) when presenting their complaints and describing their pain experiences. (Practitioners not attending to patients’ HG missed important informations conveyed in HG.) Only a minority of practitioners and therapists were reported to have actively analyzed patients hand gestures during case taking. Sensation method (SM) homeopaths were one of the reported exceptions. This survey was designed to gain a better understanding of the perspective, usage, appraisal and general relevance of manual co-speech gestures by SM homeopaths.

Methods: 94 out of 306 seminar attendants (mean age 49,6 y, 80,9 % female, 57,4 % physicians and 42,6 % healing practitioners) at two seminars on SM homeopathy with varying degrees of expertise, answered a standardized 54 item questionnaire. It covered the topics “formal education and context of work” (15 items), “perspective on, utilization and relevance of gestures in patients’ symptom description” (20 items), “documentation of and sources of knowledge on gestures” (4 items) “homeopathic practise and usage of SM” (15 items) and one short case with gestures depicted and a free text field for comments. For 20 HG related items a factor analysis was performed by means of principal components analysis and varimax rotation in order to arrive at the solution that demonstrates both the best simple structure and the most coherence. 9 items were excluded after reliability analysis due to low item total correlations.

Results: 11 items remaining formed a set of three factors explaining 66.6 % of variance. The first factor with five items describes “Hand gestures in relation to verbal expressions”
(\(\alpha = 0.81\)). The second factor includes four items regarding “Hand Gestures describing the experience of bodily and mental symptoms” (\(\alpha = 0.74\)). The third factor is regarding the “practitioners’ behaviour and active attitude in observing hand gestures” (\(\alpha = 0.86\)).

Conclusions: This survey shows how SM homeopaths actively observe HG and judge them to help patients in expressing their symptoms qualities and illness experience. Whether this view is shared by other physicians or medical professions should be investigated in the future.

**PP-176**

**Wellness care in a chiropractic practice-based research program**

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Chronic diseases (e.g., heart disease, cancer, stroke and diabetes) are the leading causes of death and disability in most industrialized countries. Engaging in healthy behaviors (e.g., reducing smoking, being more physically active, and eating a nutritious diet) and using preventive services (e.g., screening for blood pressure, blood cholesterol and cancer and receiving recommended vaccinations) can reduce morbidity and premature mortality. Congruent with the principles and practice of public health; chiropractic has at its core a theoretical framework of holistic and vitalistic approach to patient care that incorporates a number of prevention and health promotion strategies. Within this paradigm of healthcare is the idea that health is simply not the absence of disease but rather incorporates a state of physical, mental, emotional, spiritual and social wellbeing in the concept of health or wellness. To further explore the concept of “wellness care” in the chiropractic care of children, we undertook a study to determine the components or aspects of wellness care.

**Methods:** This study was approved by the Institutional Review Board of Life University (Atlanta, GA, USA). Our survey of chiropractors and parents of children under care determined sociodemographic information (i.e., age, gender), parental level of education, perceived effectiveness and benefits of care with respect to the physical, mental, emotional, spiritual and social well-being components of wellness care.

**Results:** A convenience sample of 34 parents (30 females; 4 males) participated in this study. Approximately 65% had at least a college education with 88% (N = 30) concurrently under chiropractic care as their child with 79% (N = 27) for “wellness care.” Interestingly, 67% began chiropractic care for a specific complaint or condition, the majority of which involved back pain or headaches. The vast majority (97%) indicated a high perceived effectiveness in the care they received. Furthermore, the vast majority were counseled on the benefits of spinal health (94%), exercise (91%) and proper diet/nutrition (88%) and the health risk of tobacco smoking (55%), obesity/overweight (56%), and alcohol consumption (59%). The parents indicated (strongly agree/agree) that chiropractic care has enhanced/improved their physical (97%), mental (85%), social (76%) and spiritual (62%) wellbeing.

**Conclusion:** There are indications that chiropractors promote aspects of wellness care that involve aspects of prevention and health promotion.
Chronic osteonecrosis of jaw bone (NICO) and RANTES – unknown trigger for breast cancer and multiple sclerosis

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Question: The author observes astounding improvements of systemic complaints after cleaning pain free edentulous areas of the jaw. These areas are defined by fatty-degenerative osteonecrosis of cancellous bone (NICO). Improving complaints include rheumatic, neuralgic, allergic, inflammatory and other systemic diseases. Is there a connection between local osteonecrosis of jaw Bone (NICO), inflammatory immune messengers from osteonecrotic jaw bone and multiple sclerosis, breast cancer and other tumors?

Methods of research: In order to clarify systemic interrelations of NICO, samples of cancellous bone have been extracted from 17 patients. The specimens were analyzed in renowned immunological laboratories in Munich and in Berlin by bead-based multiplex technology and tested for 27 immune messengers. Results: All 17 specimens showed highest concentration for RANTES (CCL 5), FGF-basic and MCP-1. The specific concentration of all 17 samples in RANTES, despite the high number of 27 tested mediators, is a striking figure. The present research is the first to analyze immune messengers within degenerated jaw bone tissue (NICO).

Clinical aspects of the immunological results: Can chronic high RANTES levels in NICO lesions contribute to dysregulation on organs or biological systems in the body? Or: Can -vive versa - cleaning of NICO sites reduce inflammatory signaling by RANTES so far that therapeutic-salutogenetic effects can be observed in the clinical treatment of certain diseases?

Scientific research: The author demonstrates an immunological based explanatory model of multiple sclerosis, breast cancer and other tumors: The findings of the author’s research are linked with scientific knowledge about RANTES. RANTES is found in development of MS, rheumatic arthritis and Astrozyotmas. RANTES is additionally discussed as messenger in breast cancer metastasis. Thus NICO and the implicated immune messengers give a possible complementary and integrative aspect of systemic diseases. The author approaches to a mediator-based hypothesis of systemic interference between NICO of the jaw bone and systemic diseases.

Case histories of several patients are presented with x-rays and individual levels of inflammatory immune messengers in the infected jaw bone areas. Parallel the difficulties of x-ray based diagnosis of NICO are demonstrated. The impressive extents of NICO lesions in the jaw bone are shown.
Low intensity electromagnetic fields suppress tumor's cells growth

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The influence of low-intensity millimeter range electromagnetic radiation on tumors has triggered great interest among researchers mostly due to the absence of harmful side-effects opposed to the widely used X-rays or γ-rays therapy. Unlike ionizing X- and γ-rays, the method proposed here is non-ionizing and hence is completely deprived of any harmful side effects. The present study was undertaken to investigate whether low-intensity (nonthermal) millimeter waves (MMWs) at 42.2 GHz can act on tumor of mice in vivo without cytostatic agents. In case of malignant transformation the cells undergo changes, which lead to uncontrolled cellular proliferation and abnormal differentiation. Besides, the genesis is involved in all aspects of development and growth of the tumor.

Studying the possible structural changes in DNA of tumor cells under the influence of millimeter-radio waves, in the absence of cytostatics, is useful, since the MM-therapy used in complex antineoplastic treatment promotes the reduction of toxic antitumor effect of chemo- and radiotherapy and increasing of its antitumor effect. The process of DNA-methylation is closely related with the appearance of tumors. Imbalance of DNA-methylation is observed in all, without exception, studied neoplasias. The violation of methylation process manifests itself at the early stages of malignant transformation of cells; content of 5-methylcytosine (5MC), which is the only methyl base in DNA of animals and humans, could serve as a diagnostic test for tumor genesis; this opens the possibility for early diagnostics and treatment of disease. Hypermethylation of tumor-DNA, the mechanism of which in many tumors is not clear, destabilizes the secondary structure of DNA as well, what may cause the selective sensitivity of malignant cells toward the influence of MMWs in the absence of chemo- and radiotherapy and to allow receiving of expressed antitumor effect.

The carried out studies revealed the correlation of antitumor activity of MM-therapy with inhibition of methylation of tumor DNA in vivo. It is revealed in our experiments that an half-hour exposure of MM-radiation with incident power density 10 \(\mu\)W/cm\(^2\) and specific absorption rate (SAR) 0.2 W/kg results in the tumor growth inhibition by 33.5 % and a sharp suppression of the level of DNA-methylation 2.5 times. The results obtained in this experiment indicate the prospects of working out the MM-therapy for clinical oncology in the treatment of malignant neoplasms.

Earth magnetic field in cells division and evolution theory of tumor emersion

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Objective: Our theory: The cause of malignant illness is enormous magnetic and changeable magnetic field. This original work explains that magnetic and electro-magnetic forces in cells are resulting vector quantities of the Earth macro-magnetic fields and micro-magnetic-electromagnetic fields from cells. EMF enables division of mother cell into two daughter cells, i.e. the promoter of the cell’s division is the natural EMF. That the above statement is true was proven by Russian experiments which showed that fetus perished in zero EMF. The origin of Crossing-over has been explained, i.e. the EMF enables the exchange of genes on the homologous chromosome segments in north-south and east-west directions. The malignant cell appears only in unnatural EMF, (anomalous increase), as a product of artificial magnetics in the people’s dwelling spaces.

Aim: The goal is to find a correlation between EM-M anomalous zones (Az) and beginning of malignant illness.

Material and Method: This research has been permanent for the last 20 years. We have been examined a couple of hundreds patients with different type of cancer, both sex and all ages. We are presenting now a few cases. In order to achieve the mentioned results, an objective evaluation of the used geophysical method (protonic magnetometer produced in USA and geological compass “Brunton”) applicability was necessary.

Results: All patients improved symptoms and quality of life after spent time in spaces with natural values of EM-M fields.

Discussion: Our research indicates the importance of the magnetic field as an external factor in the formation of malignant disease

Keywords: magnetic field, evolution theory, malignant illness

PP-107

Retrolective studies on the survival of cancer patients treated with mistletoe extracts – a meta analysis

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Background: Studies reveal that cancer patients are actively seeking treatments and coping strategies which might be helpful to extend survival time. In this respect retrolective studies have been applied to examine the therapeutic potential of adjuvant mistletoe treatment.

Material and Methods: The databases PubMED, EMBASE, AMED, and CAMbase were used to identify retrolective studies in mistletoe treatment. Additionally to a review we also carried out a meta-analysis with respect to cancer patients' survival time by a random effects model. Overall estimates of treatment effects were displayed using a forest plot.

Results: A total of 17 articles met the inclusion criteria. From these, 10 duplicates and 3 descriptive literature and popular articles had to be removed, leaving 4 retrolective studies on mistletoe preparations and patients' survival conducted between 1985 and 2002, with a total of 3,324 patients (2,454 per protocol) recruited in 17-35 German and Swiss hospitals, wards and private practices. Meta analysis revealed an overall effect of HR = 0.59 (95 % CI: [0.50; 0.70]) in favour of mistletoe treatment.

Discussion: Although we found a positive treatment effect, there are several methodological limitations with respect to the retrolective study design.
PP-115

Integrative concept in the management of local and systemic advanced breast cancer using components of Āyurvedic medicine – a case report

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In Germany breast cancer has an incidence rate of nearby 60 000 new diagnosed cases each year. Thanks to the successful prevention-projects fortunately patients suffering from highly advanced disease stages at time of primary diagnosis are rare. Therefore complex treatment regimes for these local or systemic advanced cases are challenging both, patient and physician. A complementary approach in this field is suitable for the maintenance or promotion of life-quality, keeping in mind the poor prognosis in stages of disease as mentioned. From this basis our oncological concept “OnkoVeda” includes strategies of Āyurvedic medicine, leading to a holistic concept of modern patient centered oncology. According to the science of Ayurveda the advanced cancer disease is characterized by a serious imbalance of the 3 so called doshas, the basic functional principles of all kind of life. These principles are known as vata, pitta and kapha. First of all the principle of kapha – synthesis- and, on the other side, vata –movement- are especially involved into the pathophysiology of malignancies.

In this report a case of local and systemic advanced breast cancer in a 53 years old female teacher is discussed. For a period of some years before she was admitted in our unit, january 2011, she had tried to manage her situation by changing professional circumstances, adjusting life-style and improving food habits. Combined with an extraordinary declining sight of view to the scientific conventional medicine system she was choosing our hospital – AyurSan Clinic Rotthalmünster, district Passau, Germany – with the option to receive a combined complementary and, if needed, conventional or surgical treatment.

After staging and developing an integrative treatment protocol we started a holistic preparation sequence to optimize the situation before surgery. After 4 sessions of surgical interventions, interrupted by Āyurvedic procedures, the main problem, consisting in a penetrating bad smell due to the tumor necrosis, was solved and a reintegration into the patients social framework was initiated. During the following phase the generalized aspect of the disease, multiple lung metastasis, had to be managed by a combined cytotoxic and Āyurvedic strategy. The Āyurvedic part of this regime included phytotherapy using special medicated oils as well as yoga sessions and meditation. The clinical and mental results of the first postoperative restaging after 6 cycles of chemotherapy and complementary Āyurvedic therapy are shown and discussed.

PP-134

CAM in cancer care within the Joint Action "European Partnership for Action Against Cancer" (EPAAC)
Introduction: The European Partnership for Action Against Cancer was initiated by the EU Commission in September 2009 with the support of more than one hundred stakeholders bringing together the Commission, Member States and their Ministries of Health, patient organisations (ECPC), health professionals, scientists, private industry and civil society. It has embarked on an ambitious agenda of a pan-European collaborative effort to tackle cancer more evenly and effectively across the EU for 3 years. Aim. The aim of the Cancer Partnership is to help all EU countries tackle cancer more evenly and effectively by sharing information, resources, best practice and expertise. In particular: prevention (Health promotion and early detection); Identification and promotion of good practice in cancer-related healthcare; Priorities for cancer research; Health information, collection and analysis of comparable data.

Materials and Methods: Within the work package Health Care (WP7), whose main objective is to identify and assess best practices across European health services, promoting the exchange of experiences focusing on innovative organizational approaches, including patient’s perspective, Tuscany Region has been charged to assess evidence and use of CAM in cancer care and to propose criteria for dissemination of appropriate information. Assessment of dissemination of CAM, review of the evidence and mapping of the EU centres of CAM in cancer care. The evidence of the literature via Medline of CAM therapies (herbal medicine, anthroposophy, homeopathy and acupuncture) in cancer treatment will be reviewed and interactions with chemotherapy will be analyzed. SIGN criteria will be used in grading literature. Finally, a survey to Cancer Units of Hospitals across EU will be realized to identify clinical activities related to integrative medicine.

Results: Two workshops are planned: the first with experts from centres with published experience in CAM in cancer will define the criteria for literature search, survey definition as well as criteria for definition of the mapping the EU CAM in cancer care. Experts from different EU centres and representatives of scientific societies involved in cancer care will be invited to the final workshop in order to discuss the report and a map of the activities will be defined. The final deliverable will be: Use of CAM in cancer care, with evidence reviewed.

Conclusions: Preliminary results will be displayed during ECIM 2011.

PP-207

Reliable evidence-based information on cancer therapies as a tool for facilitating patient-doctor communication

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Reliable Cancer Therapies (RCT) will be presented: a Swiss private non-profit organization selectively funding the development of promising therapies and providing research-based information on cancer therapies. RCT intends to expand reliable treatment options for cancer using a dual approach. Firstly, it will provide patients and their healthcare providers with information on cancer treatments that it has assessed for evidence according to
rigorous standards. RCT also facilitates patient access to information regarding clinical trials which could be a treatment option. Secondly, RCT will selectively provide funding for the clinical development of promising anti-cancer therapies/agents that fall outside the scope of the established clinical cancer research. RCT participates in recognized research through organizations such as the Verelst foundation for uterine cancer, based in Leuven, Belgium (all RCT-projects: http://www.reliablecancertherapies.com/projects).

There is an urgent need for a comprehensive repository of trustworthy information on cancer treatments and investigational drugs. Currently, information on conventional cancer therapies is dispersed and often quite complex. Information from public non-institutional sources is overwhelming, often confusing and in many cases unverified. Evidence-based information of non-conventional therapies that believe or claim to cure cancers needs to be further investigated in a reliable, independent and unbiased manner. RCT is convinced that providing access to the resulting information will facilitate a more open communication between patients and their healthcare providers, so that successful integrative treatment choices can be made.

Reliability: We carry out our retro- and prospective investigations based on a rigorous scientific approach that does not compromise on quality.

Independence: We focus on evidence-based information that is not influenced by political, social, religious or economic interests. RCT is not supported by any interest group, professional organization or product manufacturer. As a non-profit organization, RCT will not promote or commercialize any cancer therapy.

Open-mindedness: We explore all possible treatments – including those outside mainstream medicine – with an open mind and without prejudgment. For more information: www.reliablecancertherapies.com

**PP-208**

Integrative oncology for breast cancer-patients: introduction of an expert-based model

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**Introduction**: Breast cancer is one of the most frequent cancers in the West. Many breast cancer patients unselectively use Complementary and Alternative Medicine (CAM). In this field a very highly specialized knowledge is needed to give recommendations concerning benefits and risks. Our concept of Integrative Oncology for breast cancer patients will be presented.

**Methods**: The Department of Senology and the Department of Complementary and Integrative Medicine at Kliniken Essen-Mitte have established a new concept for Integrative Oncology based on an expert system – SenoExpert. In SenoExpert scientists, surgeons, physicians specialized in CAM and mind-body (MB) instructors work closely together in permanently screening and evaluating current guidelines and scientific literature for
mainstream- and CAM-therapies. Based on current scientific evidence and the special situation of each breast cancer patient, we develop an individualized treatment concept including mainstream- and CAM-therapies. Every patient is offered a consultation with a CAM-physician and a MB-instructor. Additionally, MB-instructors offer modified MBSR-classes (11 weeks, 6 hrs per week) integrating nutrition, exercise, group support and self-care strategies.

Results: From January 2010 to March 2011, 350 primary diagnosed patients with breast cancer were treated in the Department of Senology. 179 patients were seen by CAM-physicians. Most presented with side effects from chemotherapy and endocrine treatment, pain or initial anxiety and depression. Side effects from endocrine therapy were reduced by acupuncture in 70% of our patients. Body acupuncture was applied 327 times, ear acupuncture 740 times. Phytotherapy also helps to reduce side effects from standard therapies. 8 patients were treated with leech therapy for painful hematoma and venous congestion. Neuraltherapy (137 treatments), Gua Sha (81 treatments) and cupping massage were used to reduce symptoms such as pain in scars and generally after surgery. To strengthen the self-healing capacity of the body exercise, yoga, training in MBSR, relaxation and nutrition are part of the concept.

Conclusion: Integrative Oncology for breast cancer patients is well accepted by the majority of patients and is partly paid by German health insurances. In our model, mainly acupuncture, mind/body medicine, neuraltherapy and phytotherapy have been used. Further research is needed to establish integrative oncology as an integral component of cancer.

PP-209

Effects of a mindfulness-based day-care clinic group program on quality of life, psychological health and coping in cancer patients

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Background: Emotional and mental symptoms are common consequences of cancer diagnosis and treatment. Coping with these symptoms seems to be influenced also by locus of health control, spiritual attitudes in dealing with illness, and patients’ interpretation of illness. Mindfulness-based interventions have been shown to improve particularly psychological health in cancer patients. The aim of this study is to investigate the effect of a mindfulness-based day-care clinic group program on quality of life, anxiety and depression in cancer patients, and to evaluate the association with supposed process variables, including coping styles, spiritual attitudes in dealing with illness, and interpretation of illness.

Methods: 120 cancer patients will participate in a mindfulness-based day-care clinic group program, 6 hours per week over 11 weeks. The group program incorporates mindfulness-based meditation, yoga, diet, and lifestyle modification. Outcome measures, including quality
of life (EORTC QLQ-C30), life satisfaction (BMLSS), depression and anxiety (HADS), will be assessed before and immediately after, and at 3 months after the group program. Changes in supposed process variables, including adaptive coping styles (AKU), spiritual and religious attitudes in dealing with illness (SpREUK), interpretation of illness (IIQ), and mindfulness (FMI) will be assessed, as well as the association of these variables with the outcome measures.

Results and discussion: Preliminary results will be presented and discussed. The investigation of quality of life and psychological health and their association with supposed process variables should give a more precise idea of effects and mechanisms of mindfulness-based interventions in cancer patients.


**Abstracts/ECIM 2011/Poster Presentations/PAEDIATRICS**

**PP-010**

**Acupuncture for treatment of hospital induced constipation in children**

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**Objective:** Investigate feasibility and acceptance of acupuncture for the symptomatic treatment of hospital induced constipation in children.

**Study design:** Acupuncture was applied in 10 children with hospital induced constipation using fixed indwelling acupuncture needles (1.5 mm) before starting the conventional local constipation therapy by laxative suppositories. Feasibility was analyzed and effects were recorded by the time children needed to have stool after acupuncture.

**Results:** Acupuncture was feasible in all children and application of the indwelling needles was tolerated without fear. Side effects were not observed. Nearly all children had an acupuncture stool time of less than 2 hours. No patient required conventional local constipation therapy.

**Conclusion:** Acupuncture for the treatment of hospital induced constipation is feasible and acceptable. Suggested effect should be verified in a randomized controlled trial.

**PP-068**

**The Italian paediatrics and CAM**

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The Italian Paediatrics and CAM Tiziana Di Giampietro In the last few years in Italy there has been a sharp increase of CAM requests. A great part of the patients belong to the paediatric area. In Italy, unlike other European Countries, the NHS ensures a qualified assistance to the child at home, given by the Family Paediatrician who provides assistance for both acute and chronic diseases and periodical growth controls until the age of 16. More and more Paediatricians attend schools that teach CAM, and most of them an Homeopathy school. Nearly half of the SIOMI members is a Paediatrician and many of them work in the NHS. We record the results of a national survey regarding CAM and a survey among the Paediatricians in Tuscany Region. Parents are increasingly sensitive towards the choice of therapeutic techniques which cause as little side effects as possible. They address to Doctors expert in complementary therapies and ask the Family Paediatrician to cure their Children with Integrative Medicine choosing the most appropriate treatment, conventional or complementary or both, for the symptoms of the disease in action in the The Italian Family
Paediatricians are associated with the Unions and the most representative is the Italian Federation of Paediatric Medicine (FIMP).

SIOMI has been cooperating for many years with these Unions and more recently also with the Paediatric Italian Society (SIP). There will be a report of the initiatives organized by SIOMI along with the collaboration of FIMP and SIP Paediatricians in order to extend the consciousness of the Integrated Medicine among the Italian NHS Paediatricians. Dr Tiziana Di Giampietro NHS Paediatrician - SIOMI Councilor via Rigopiano 119, 65124 Pescara, Italy e-mail: tiziana.digiampietro@gmail.com

PP-089

Clinical evaluation of traditional chinese medicine holistic treatments on pediatric asthma

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Introduction: Asthma is a prevalent chronic allergic illness of childhood, and is a major public health problem. Apart from the conventional treatment, complementary and alternative medicine has gained a lot of attention nowadays. In Taiwan, the Bureau of National Health Insurance has launched a Traditional Chinese Medicine Holistic Treatment Program (TCMHTP) containing Chinese herbal remedies, acupoints sticking therapy and meridians massage which reimbursed the asthmatic children could receive TCM as an alternative treatment. The purpose of this study was to evaluate the treatment efficacy and look for the possible mechanism of TCM holistic treatments on pediatric asthma.

Materials and Methods: This retrospective study was performed by analyzing an electronic medical record (EMR) dataset of Changhua Christian Hospital in Taiwan during 1/1/2006 and 12/31/2010. Patients with age between 2 and 15 years diagnosed with asthma and participated in TCMHTP were enrolled as study group and those were excluded if they have catastrophic illness such as malignancy, cerebral palsy, or congenital metabolic disease. One control group was randomly sampled from the EMR dataset during the same target period with the same criteria as the study group except to take part in TCMHTP. We investigated the frequency of emergency department visits (EDV), inpatient admission rate (IAR), and length of hospitalization (LH) with primary diagnosis of asthma. We also conduct the spectral analysis of heart rate variability (HRV). Effects of TCM holistic therapies were analyzed by the paired t-test and the variation between different genders was analyzed by the Chi-Squared test. A p-value < 0.05 was considered statistically significant.

Results: 58 patients, including 14 girls and 44 boys were recruited. The average age is 5.67 ± 3.03 years. After TCMHTP intervention, the frequency of EDV descended from 0.97 ± 0.85 to 0.69 ± 1.22 times per year (with p = 0.047) and the IAR decreased from 0.86 ± 0.81 to 0.36 ± 0.77 times per year (with p = 0.001). Furthermore, the average LH reduced from 4.59 ± 4.43 to 1.10 ± 1.86 (with p = 0.000) days per year. Parasympathetically mediated HRV (normalized high frequency power) reduced significantly from 60.42 ± 15.33 to 54.89 ± 16.45 nu (with p = 0.016).
Conclusion: TCM holistic treatments significantly reduced the frequency of EDV, IAR, and LH on pediatric asthma. The vagal tones of the patients undergoing the program become relatively stable simultaneously.
Abstracts/ECIM 2011/Poster Presentations/PAIN

PP-013

The effect of ferula assa foetida gum on phasic pain in mice

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Introduction: Plants of the genus Ferula belongs to the Apiaceae family and has about 130 species that distributed throughout Central Asia and Mediterranean area and grows wildly in Iran and Afghanistan. Ferula assa foetida (FAF) is traditionally considered to be sedative, carminative, antispasmodic, diuretic, anthelmintic, emmenagogue and expectorant. In this study we investigated the antinociceptive effect of FAF gum by a thermal induced pain model in mice.

Materials and Methods: FAF gum was dissolved in distilled water and injected intraperitoneally to mice at three doses (25, 50,100 mg/body weight) 15 minutes before the onset of experiment. Hot-plate test was used to study the analgesic effect of gum as compared with that of the morphine sulfate (8 mg/kg).

Results: 15 min after the treatment the analgesic effect of different doses of FAF was obvious and declined for the next time points except for the FAF 50 % which was elevated again at 60 min after drug administration. The most effective dose of FAF was 50 mg/kg. The percentage of protection against the thermal stimulus at 15min post treatment time point for all doses of FAF were significantly greater than control group. The percentage of protection against heat stimulus at 15 min time point in animals receiving 25 and 50 mg/kg FAF were statistically similar to those who administrated by morphine sulfate.

Conclusion: In this study FAF gum exhibited a significant antinociceptive effect on acute pain in mice.

PP-025

Fasting therapy in osteoarthritis

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Background: The aim of this study was to evaluate the efficacy of fasting therapy according to Buchinger on pain, quality of life, and articular function in patients with osteoarthritis (OA) and to analyse the potential association of the disease duration (≤/> 5 y) with fasting-induced clinical outcome.

Design: This was a prospective uncontrolled clinical study. Inclusion and exclusion criteria for fasting therapy were checked thoroughly and specific recommendations given. Outcomes were assessed on baseline (BL), 1st pre-fast day (1), 5th fast day (8), 4th re-feed day (15) and 1 (I) and 3 (III) months after the dietary intervention.

Setting: The study took place in an academic outpatient specialized center of natural therapy.

Subjects: Sixty patients (50 f, 10 m) with a median age of 60 years (range 37-72 years) with OA (Kellgren stages I-III) of the hand (N = 22), hip (N = 17) and knee (N = 21) were investigated.

Interventions: Patients underwent fasting therapy (intake of 300 kcal/day) for 8 days with 3 pre-fast days and 4 re-feed days simultaneously receiving nutritional/lifestyle education.

Outcome measures: Global intensity of pain (visual analogue scale, VAS); joint pain with activity, at start of walking, at rest (VAS); pressure pain threshold (PPT); articular function (range of motion); health-related quality of life (SF-36); Western Ontario and McMasters Universities Arthritis Index (WOMAC); painDETECT©-questionnaire (Pfizer); analgesics; weight; body mass index (BMI); waist circumference; dietary history; hemodynamic and a variety of serological parameters.

Results: Parameters of pain, quality of life, and articular function improved significantly (p ≤ 0.05); significant reduction in weight, BMI, and waist circumference during fasting and over the complete course of the study (p ≤ 0.05). There was a transient reduction in analgesics in fasting. There was evidence of changes in nutritional habits at follow up. Patients at early stages of OA were less affected by OA symptoms and showed larger improvements than those at advanced stage. Fasting was well tolerated and no serious fasting-related adverse effects, e.g. abnormalities in cardiovascular, metabolic, or blood parameters, were reported.

Conclusions: Medically supervised fasting therapy according to Buchinger can ameliorate symptoms of patients with moderate OA, especially at early stage. These preliminary data should be consolidated in larger cohorts of patients treated in randomized controlled trials.
However, randomized trials demonstrating a therapeutic effect on oxaliplatin's cumulative neurotoxicity are still lacking or ineffective. The oxidative hypothesis is matter of debate. At the state of the art direct data about oxidative damage induced in vivo by anticancer agents are lacking and the efficacy of the available antioxidant compounds are unsatisfactory.

In a rat model of painful oxaliplatin-induced neuropathy (2.4 mgkg-1 i.p., daily for 21 days), we are describing a pattern of molecular and morphological alterations of the nervous system.

In the present study an important component of oxidative stress has been evidenced in the plasma of oxaliplatin-treated rats at day 21th of treatment. Protein oxidation was highlighted by an increase in carbonylated protein levels, whereas the lipoperoxidation was evidenced by an increment of malonyldialdehyde levels. Finally, enhanced levels of 8-OH-2-dG were measured as indicative of DNA oxidation. The same pattern of oxidation was revealed also in the sciatic nerve, and in the spinal cord.

The activity of the natural compound silibinin (from Silybum marianum), in respect to the well known antioxidant α-tocopherol, was evaluated in the oxaliplatin model. Chronic administration of 100 mgkg-1 silibinin or α-tocopherol p.o. once a day, starting from the first day of oxaliplatin injection until the 21th, partially prevented mechanical hyperalgesia. Moreover, mechanical and thermal allodynia were significantly reduced. Antioxidants were also able to improve motor coordination. The antineuropathic effect of both molecules improved by about 50% oxaliplatin-induced behavioural alterations.

Since silibinin and α-tocopherol repeated treatments significantly reduced the oxidative state of the plasma and the nervous system of oxaliplatin-treated rats, it is allowed to think that a relationship between the antihyperalgesic and the antioxidant effect exists. Starting from this evidence, we consider oxidative stress as an important target in oxaliplatin-dependent neuropathy and the research of fully active antioxidant compounds as an attractive therapeutic perspective.

PP-138

Pneumatic pulsation therapy for chronic neck pain. A randomized controlled pilot study

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Background: Pneumatic pulsation therapy is thought to combine the effects of cupping and massage therapy, both of which have been shown to be effective in the treatment of chronic neck pain. Pneumatic pulsation therapy is using a mechanically induced pulsating vacuum to induce an oscillation of the skin and deeper tissue. This study investigated the effect of pneumatic pulsation therapy on chronic neck pain compared to standard medical care.

Methods: 50 patients with chronic non-specific neck pain were randomized to either treatment group (TG) (n = 25) or control group (CG) (n = 25). TG received 5 pneumatic pulsation therapy treatments over 2 weeks using a mechanical device (the Pneumatron®,
Pneumed GmbH, Germany), while CG continued self-directed standard medical care. Main outcome measure was pain intensity in a pain diary (numerical rating scale). Secondary outcome measures included functional disability (NDI), quality of life (SF-36), pain at motion and hyperalgesia. To determine changes in hyperalgesia, pressure pain threshold was measured at pain related sites.

**Results:** TG reported lower pain intensity compared to CG after the first treatment session (p = 0.008). This effect was maintained until the end of the treatment period (p = 0.001). TG reported less functional disability (p = 0.025) and pain at motion (p = 0.004) and improved physical quality of life (p = 0.002). Pressure pain threshold was elevated in the TG compared to the CG (p = 0.002), indicating a reduction of hyperalgesia. No serious adverse events were reported.

**Conclusions:** Pneumatic pulsation therapy appears to be a safe and effective method to relieve pain and to increase function and quality of life in patients with chronic neck pain. Long term effects should be object of further investigation.

This study was supported by Pneumed GmbH, Idar-Oberstein, Germany.

**PP-205**

Āyurvedic marma therapy – treatment of vital points, an effective approach to cure acute and chronic pain syndromes

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Marma therapy, the treatment of special vital points, is one of the ancient approaches of Ayurveda, Indians Traditional Health System. Its origin and first description goes back to Vedic periods and was part of combat techniques and knowledge in martial arts.

The Sushruta Samhita (6th century B.C.), a comprehensive textbook mainly on surgery, describes 107 main points and their importance for health and physiological functions. In today’s ayurvedic treatments these points are more or less included in traditional massage forms or treated similar to acupressure.

Sūkṣma Marma Therapy (Subtle Marma Therapy) is a special and refined form of Marma treatment. It was developed by the author and his colleagues during many years of research, study and practical experience on the basis of traditional Vedic knowledge and classical āyurvedic textbooks.

The very subtle and delicate therapy of special vital points (marmas) and nāḍīs (energy channels) acts on the physical and the emotional level. It has very specific and immediate balancing, pain reducing and healing effects in patients and is also applicable for self-treatment. It turns out to be a very effective approach for acute and chronic pain syndromes.

Sūkṣma Marma Therapy requires āyurvedic skills as well as modern medicinal knowledge, holistic understanding of human physiology, empathy, sensitivity and professional training.

The presentation will give insights into the knowledge and system of marmas and will demonstrate practical applications in different disorders and diseases and shows case examples.
The role of the healthcare sector in patients’ experiences of treatments for back pain

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Background: Patients’ experiences of their treatment may be influenced by the healthcare sector in which treatment is delivered. This study explored the similarities and differences between patients’ experiences of osteopathy and physiotherapy for lower back pain (LBP) when they are delivered in the NHS and private practice.

Methods: A purposive sample of 35 LBP patients who had experienced osteopathy or physiotherapy within the NHS or private practice took part in qualitative semi-structured interviews about their treatment experiences. Data were analysed with thematic analysis and charting techniques adopted from framework analysis.

Findings: Patients experienced mutual and supportive relationships and individualised care within osteopathy treatments in both healthcare sectors and within private physiotherapy; patients consequently appraised these treatments positively. Physiotherapy delivered in the NHS was described as less individualised and relationships were more frequently reported in paternalistic terms, treatment was appraised more negatively. Private and NHS treatments differed in the amount of perceived control available to the patient. Private treatments (but not NHS) were seen as involving financial vulnerability. Patients reported adhering less to treatments and reported worse psychological outcomes from treatment when they appraised their treatment as more paternalistic, less individualised, providing less control, and involving more vulnerability.

Discussion: This analysis suggests that the NHS environment impacts on patients’ experiences of treatment, but that this happens differently within physiotherapy and osteopathy. Reasons for the differences found between the two NHS therapies will be discussed.
Prakriti analysis in Āyurveda: envisaging the construction of validated tools for its practice

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Prakriti has been one among few strongest fundamental constructs of Ayurveda. It specifies that every individual is different in physical, physiological and intellectual pursuits and also that these differences are primarily attributable to the compositional specificity of an individual rendering them so unique. Interestingly, this construct found a wide application in ayurvedic clinical practice by observing that diseases are said to have clear preponderances towards prakriti and also their prognosis. Seeing its importance in identifying the disease susceptibility and also the prognosis, prakriti seem a valuable construct of Ayurveda requiring thorough exploration.

A review of classical literature of Ayurveda reveals that prakriti can be diagnosed on the basis of few physical, physiological or intellectual features which are specific to body composition. It is however observed that this subjective diagnosis of prakriti suffer with substantial inter-rater and intra-rater variability. In literature survey we had not come across any tool of prakriti diagnosis which was validated for its reproducibility once adopted as a help to clinical decision making in Ayurveda. Identifying this limitation, we developed a preliminary form of questionnaire based tool to diagnose the prakriti in clinic and subjected this to a pilot test upon healthy volunteers (n = 45) for seeing it’s inter rater validity. In a correlation coefficient analysis of the scores obtained by individual volunteers through the test done by two independent raters, we were able to identify a strong inter-rater correlation in Vata class of features of prakriti comparing to kapha and Pitta class of features (kapha 0.4074,Pitta 0.5245,Vata 0.8081).

PP-016

Criteria to define and assess initial homeopathic aggravation – focus group interviews with eleven Norwegian homeopaths

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**Background:** Homeopathic aggravation is a temporarily worsening of existing symptoms following the administration of a correct homeopathic prescription. The aggravation indicates a favourable response to treatment and is well known to homeopaths. Patients usually experience such events soon after the administration of the medicine or up to 14 days later. At the moment it is unclear when an initial aggravation becomes an adverse effect, and when it ought to be reported as such. This research is important in order to establish definitions for further research into risk and safety assessment of homeopathic treatment. Results from Systematic Reviews regarding safety conclude that homeopathy in high dilutions, prescribed by trained professionals, are mostly, safe and unlikely to produce severe adverse effects, but there may be aggravations.

**Objective:** Our aim is to define and compose possible criteria that may be a starting point in differentiating adverse effects from homeopathic initial aggravations.

**Methods:** Two focus group interviews were conducted. The groups consisted of five and six experienced Norwegian homeopaths, respectively. The interview guide was developed based on information from a review of relevant literature. The homeopaths were asked to discuss and reflect upon these issues:

1. How do they decide in practice if the initial aggravations are part of a healing process or not?
2. How often do the patients report about adverse effects of the treatment?
3. How do they advice their patients in such challenging situations?

**Results:** The results will be derived from a content analysis. This analysis will explore how homeopaths decide in their practice when an initial aggravation becomes an adverse effect. So far, the analysis reveals that long time experience of the patients’ general health conditions may be a part of this decision.

The data analysis is in progress and will be completed before October 2011.

**Conclusions:** Definitions will be presented in October 2011. This explorative study is an important contribution to an unexplored field of homeopathic risk and safety research.

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**PP-026**

**CAM use: results from a standardized questionnaire in 3 samples – breast cancer patients, high volume users, low volume users**

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**Purpose of the study:** Due to the growing body of data on prevalence of CAM use it is necessary to standardize measurement on an international level. Therefore, an international questionnaire (NAFKAM I-CAM-Q) was published by an international team. We translated the questionnaire into German, pre-tested it and validated it by employing it in 2 studies looking at 3 different samples.

**Methods:** We translated the English questionnaire, adapted it slightly and pre-tested it. The resulting questionnaire was given to breast cancer patients who filled in a paper-pencil version and to a convenience population sample via internet. The internet questionnaire started with the following statement: "In case of illness I rather take CAM first” or “I rather take
conventional medicine first” or “I don’t know”. Thus, we were able to measure CAM use with the same questionnaire in 3 samples: Breast cancer patients, who are known for using a fair amount of CAM after diagnosis, high-volume users (who take CAM first before considering conventional medicine) and low-volume users (who consider conventional medicine first).

Results: In the breast cancer sample the highest use was given for medical CAM specialists (Arzt für Naturheilverfahren, 14 %) and for the non-medical CAM specialist (Heilpraktiker, 8 %); about 31 % of the sample went to one or more CAM providers during the last 12 months. Looking at CAM methods about 29 % used herbs, 7 % used homeopathy and about 6 % used TCM/acupuncture. The highest use of remedies and dietary supplements were given for vitamins/minerals (51 %) and herbs (42 %). The most commonly used self help practices were praying (46 %), relaxation techniques (25 %) and meditation (21 %). In the high-volume user sample 41 % visited a homeopath, 34 % a non-medical CAM specialist and 31 % a medical CAM specialist; about 76 % visited one or more CAM providers during the last 12 month. The most commonly CAM methods were herbs (46 %), followed by homeopathy (34 %). Looking at self help practices, 35 % used relaxation techniques and 25 % did meditation. The low-volume user sample has significant lower rates of CAM-use than the high-volume user sample. The highest use was given for non-medical CAM specialist (12 %); about 31 % went to one or more CAM providers during the last 12 month. Looking at CAM method about 36 % used phytotherapy. The highest rates of remedies and dietary supplements were given for Vitamins/Minerals (38 %) and herbs (35 %). The most commonly used self help practice in the sample of low-volume user was relaxation techniques (26 %).

Conclusion: The CAM use in the breast cancer samples resembles results from other studies in the field from Germany, and in Europe. The use is rather comparable with low-volume users despite being a patient sample highly associated with CAM use. There is a significant and relevant difference between high and low volume users with the low volume users using mainly herbs and vitamins/minerals. Interestingly, also about 1/3 of the low-volume users went to one or more CAM providers within the last 12 months.

PP-029

Lessons to be learned: changing perspectives in acupuncture research methodology translated to osteopathic manipulative therapy clinical trials

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Osteopathic Manipulative Therapy (OMT) research faces many methodological challenges, especially when placed into a research atmosphere dominated by the Randomized Control Trial (RCT), which is agreed on by the medical community to be the “gold standard.” Two central postulates of RCTs are randomization and control. This means patients are randomly assigned to an intervention or control group. The intervention is thus thought to be divided into characteristic (specific) and incidental (placebo, non-specific) effects. But does it make sense to split complex interventions such as OMT into characteristic and incidental effects? Recent research has shown that elements categorized as “incidental” in drug trials are integral to interventions such as acupuncture. Fundamental assumptions underlying the design
of RCTs do not apply to this therapy. Since OMT also cannot separate its characteristic and incidental effects, we may learn something from recently suggested shifts in acupuncture methodology. Acupuncture researchers are proposing to move away from the explanatory design and shift towards pragmatic trials to better study acupuncture as it is actually performed in practice. As a field, they have also developed research reporting guidelines to improve transparency of research design and results. In the same vein, OMT research would also benefit from standardization of research reporting.

Three suggestions to improve research transparency and elucidate research applicability are presented here. The first would be to implement a set of reporting guidelines, specifically tailored to OMT research that would be designed from the CONSORT and STRICTA guidelines. The second would be to use a questionnaire for research participants to determine the believability of the chosen control condition. The third is implementing a 10-factor graphing method designed by Thorpe et al. to consolidate aspects of OMT trial design. This tool will better determine where each study falls on the pragmatic-explanatory spectrum and would also demonstrate the external validity of each study. The goal of these proposed measures is not to dictate research methodology but to increase transparency with clinical trial study design and findings. These tools should improve the quality of manuscript reporting and allow OMT researchers to look objectively at the appropriateness of research paradigms currently employed for OMT research.

PP-033

Consolidated standards of reporting trials (CONSORT) for traditional Chinese medicine: current situation and future development

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The reporting standards for randomized controlled trials were first published in 1996 by a group of scientists under the name “CONSORT,” which means consolidated standards of reporting trials. Revisions followed in 2001 and 2010. A draft of the CONSORT for traditional Chinese medicine (TCM) was published in both Chinese and English in 2007. After publication of the draft, comments were solicited from the medical community. Some papers did raise concerns about which items should be included in the CONSORT for TCM such as the rationale of the trial design, intervention, outcome assessment, and adverse events.

We have now reached the next step which is the finalization of the CONSORT for TCM. Three tasks remain. First, the major changes in CONSORT statement 2010 should be integrated into the CONSORT for TCM. Second, Chinese drugs from minerals and animals should be included in the guidelines. Finally, agreement must be reached among the working groups. Once the draft is finalized, wide dissemination and co-publication will be considered.

PP-039
Making every case worthwhile: multivariate analysis of homeopathic questionnaires regarding everyday polar symptoms

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Background: Millions of successful cases in homeopathy are of no use for the homeopathic method because they are never shared with others. Thousands of shared successful cases render misleading information because they are not properly analysed. If a symptom is seen in a successful case this symptom is hitherto regarded an indication for the prescribed medicine, but this is absolutely wrong. Especially everyday symptoms are misinterpreted this way: due to chance the opposite symptom is also an indication for the same medicine. These are called polar symptoms. We should rely on relative occurrence of homeopathic symptoms, not absolute occurrence. According to Bayes’ theorem a symptom is an indication for a medicine only if it occurs more frequently in the population responding well to a medicine than in the remainder of the population. Frequently occurring symptoms become more unreliable by considering absolute occurrence than peculiar symptoms. On the other hand, frequently occurring symptoms are very relevant because every patient has some of them and they help to reduce the number of possible medicines. They are only useful when several symptoms are combined, which increases the problem. Relative occurrence (prevalence) of symptoms should be systematically assessed, e.g. by questionnaires. It is impossible to interpret such a large amount of data without statistical methods.

Method: All patients filled in a questionnaire considering their basic (polar) symptoms relevant to homeopathic treatment. The answers were checked by the physician. 100 Cases with good reactions to five homeopathic medicines are assessed considering 30 symptoms. A control group was formed by 100 consecutive new patients. Data were analysed by Multivariate Analysis, in this case stepwise Fisher Linear Discriminant Analysis (FLDA).

Outcome: FLDA returned six out of the 30 symptoms that were the most powerful to discriminate between these five medicines and between each medicine and the control group in a clear and familiar output.

Conclusion: Multivariate Analysis is a useful tool to analyse questionnaires with basic homeopathic symptoms. It enables us to discriminate between homeopathic medicines using frequently occurring symptoms. This way every case can become a valuable asset to homeopathy.

PP-072

Investigation of acupuncture sensation patterns under sensory deprivation

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The meridians of acupuncture have been scientifically investigated for more than 50 years. However, no anatomical substrate has been identified so far that could explain the properties that Chinese medicine attributes to these structures. On the other hand, radiation of the
needling sensation (Deqi) along those meridians is a clinical reality. In this study we investigated the incidence and exact spatial patterns of the Deqi radiation using laser acupuncture in a floating tank to reduce environmental sensory input. The idea was that sensory deprivation would improve subjects' ability to distinguish the Deqi sensation from other bodily sensations unrelated to acupuncture. Laser acupuncture was administered in a single-blinded design via fibre optical cables to four acupuncture points (BL67, SP1, LI1, and SI1).

20 healthy subjects took part in the study. After application of the laser optodes to the skin, subjects entered the floating tank, which was filled with skin-warm water, saturated with salt. Furthermore, the tank was sound-isolated and only illuminated by a weak red light. This allowed for tactile as well as auditory and visual sensory deprivation. After 15 minutes of rest laser acupuncture stimulation started with three of the four acupoints being stimulated for two minutes. One of the acupoints served as placebo control and was not stimulated. Each stimulation period was followed by four minutes of rest. After the experiment subjects were asked, which of the points had been stimulated and which not. They were asked to draw their sensations in a body scheme using only dots, lines, and hachures. Finally, they rated their sensations using a visual analogue scale (VAS) and descriptors from the McGill pain questionnaire. “kribbelnd” (“tingling”), “ausstrahlend” (“radiating”), and “sich ausbreitend” (“spreading”) were the descriptors that were most frequently chosen to describe Deqi.

Analysis of the body schemes using a geographical information system (GIS) revealed that subjects's patterns of Deqi radiation were remarkably similar. They followed the courses of the stimulated meridians but also spread to other nearby meridians. Although there were false positives, Fisher's exact test showed that the occurrence of Deqi sensation was related to actual laser stimulation taking place.

PP-102

Evaluation of application etheric oil 68 in the treatment of periodontal disease


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Objective: Epidemiological findings shows that the percentage of people suffering from periodontal disease is 80-90% in the world population after ages 45, and periodontal diseases are the most common cause loss of teeth.

Aim: The purpose of our finding is to evaluate the effect of etheric Oil 68 (Cornus sanguinea, Cornus mas and alcohol, produced from Planet of Health (Ljubljana, Slovenija), in different forms of periodontal disease.

Material and methods: 32 patients ages from 19-56 (18 females and 14 males), are treated for six weeks, local and enteral with etheric oil 68. (3x daily 15 drops enteral and 2x daily 10 drops for dental brushing). Gingival Index (Loe and Silness, 1967) and Periodontal Disease Index (Ramfjord, 1954) are used to evaluate medical effect of etheric oil 68 before and on the end of treatment.

Results: In the beginning of the treatment with the etheric oil 68, value of Gingival Index was 2.5, and on the end of investigations was 0.8. Periodontal Disease Index in the beginning of treatment was 2.6 and on the end was 0.9.
Conclusion: Results show very positive effects of etheric oil 68 in reducing gingival bleeding (inflammation level) and depth of periodontal pockets in all patients.

Keywords: Periodontal disease, Etheric Oil 68, Gingival Index

PP-111

Contralateral homosegmental and ipsilateral heterosegmental effects of stimulations applied by quantitative sensory testing

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Background: Quantitative sensory testing (QST) is a standardized tool that allows for a comprehensive evaluation of sensory detection and pain thresholds. It already has been shown that QST parameters are specific for body regions. Further validation experiments revealed good test-retest reliability within two days and low observer bias. In experimental studies or in clinical trials it is often necessary to perform immediately consecutive QST measurements at various body sites.

Aim: The aim of this pilot study was to evaluate whether stimulations administered by an immediately preceding QST had contralateral homosegmental and ipsilateral heterosegmental effects on sensory perception.

Methods: A series of seven QST measurements at five time points was performed on ten healthy subjects. In order to investigate the contralateral homosegmental effect QST was performed on day 1 at the dominant upper limb (DUL) and on day 2 at the non-dominant upper limb (NDUL) followed by an immediately consecutive measurement again on the DUL. Accordingly, the heterosegmental ipsilateral impact of the QST battery was assessed by conducting a QST measurement at the non-dominant lower limb (NDLL) on day 3 and two QST measurements on day 4 - first on the NDUL and second on the NDLL. In order to control for series effects we performed another QST measurement at the NDUL on day 5 and compared sensory patterns of the NDLL on day 3 and day 4. The washout period between the five time points was at least seven days each.

Results: At the DUL sensory patterns were not significantly different between day 1 and day 2 except for a significant reduction in the cold detection threshold. Between sensory patterns of the NDLL at day 3 and day 4 no significant mean differences were found. Furthermore, warm detection thresholds and heat pain thresholds at the DUL were significantly lower on day 5 than on day 1. At the NDLL thermal sensory limen, heat pain threshold and mechanical pain sensitivity was also significantly lower on day 4 than on day 3.

Conclusions: Our results indicate that sensory stimuli applied during QST measurements might reveal immediate homosegmental contralateral effects on cold detection. Heterosegmental effects seem improbable to occur when immediately consecutive QST measurements are performed. Series effects after weekly repeated QST measurements seem likely to occur. These preliminary findings need to be assessed by further research.
PP-119

Design, implementation and testing of practice-based healthcare programs in anthroposophic healthcare

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Introduction: The evidence based description of healthcare practice in protocols, standards and guidelines has become routine business. The main reason for writing these documents is to ensure that patients get the best possible care available. Such evidence based descriptions are largely lacking in anthroposophic healthcare (AHC). Since this type of healthcare practice is highly individualized, it is believed that these documents are, in most instances, not suitable for this field. However, in order to support professional quality improvement and to provide scientific evidence of the effects of AHC, practice-based AHC programs need to be designed, implemented and tested.

Objectives: The first objective is to design four practice-based healthcare programs (for hay fever, depression, cancer and attachment disorders) that leave the essence of AHC (e.g. individualization and health promotion) intact. The second objective is to implement and test the healthcare programs in practice.

Methods: The design of the healthcare programs is based on scientific literature and expert knowledge. Central questions discussed are: what do healthcare workers generally do with patients suffering from the specified health problems? How is the diagnosis determined and individualized? How is the goal of pharmaceutical or therapeutic treatment determined? How is the therapeutic path individualized? Which different pathways of healthcare exist? What type of therapy is effective? The subsequent implementation of the healthcare programs will be in anthroposophic therapeutics. The effectiveness of the programs will be analyzed in terms of symptom reduction (short and long term), quality of life improvement, patient satisfaction and healthcare costs.

Results: The design of the four practice-based healthcare programs and the monitoring infrastructure will be presented during the congress.

Discussion: The cyclic process of designing, implementing, testing, and subsequent (based on the test results) redesigning of practice-based AHC programs will support the improvement of quality of AHC. Secondly it will provide scientific evidence of optimally organized AHC programs for specific indications.

PP-125

Development and validation of the “Consumer Quality Index – anthroposophic healthcare” to measure patient experiences systematically
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**Introduction:** The professorship Anthroposophic Healthcare has constructed and validated a Consumer Quality Index (CQI) questionnaire concerning patient experiences with their anthroposophic healthcare workers. The evidence based medicine development urged to measure the patient experiences with anthroposophic healthcare scientifically in order to be able to describe the experiences in general and to justify the (supposed) experienced surplus value of the anthroposophic healthcare in communication with governments, politics, health insurance agencies and other relevant stakeholders. The future perspective of the use of the CQI – Anthroposophic Healthcare is its use for quality measurements and in addition for benchmarking of patient experiences between conventional and anthroposophic healthcare.

**Objectives:** The aim of the study is to develop and validate a CQI questionnaire that is able to document patient experiences with anthroposophic healthcare systematically. With this validated measuring instrument the quality of anthroposophic healthcare workers can be compared among workers and patient experiences with anthroposophic and conventional healthcare workers can be compared.

**Methods:** Qualitative construction of the measuring instrument by focus groups of patients of anthroposophic doctors and anthroposophic healthcare workers. Quantitative validation of completed CQI questionnaires. Research population: a random sample of 6000 patients of 20 Dutch general practitioners.

**Analyses:** Psychometric and discriminative statistical analyses (validation). Descriptive statistics of the patient experiences with anthroposophic healthcare.

**Results:** The results with regard to validity of the CQI questionnaire and the patient experiences with anthroposophic healthcare will be presented at the congress.

**Discussion:** With this instrument the anthroposophic healthcare is able to meet the increasing demand for transparency of the quality of healthcare and the future requirements concerning the quality of healthcare, set by the Dutch government. The results of the CQI measurements can be used for specific societal and political demands, for example as information for: - consumer choices - improvement of healthcare by healthcare workers - monitoring by researchers, patient organisations and the government - looking after the interests of the anthroposophic healthcare - validating the quality of anthroposophic healthcare towards governments, politics and health insurance.

PP-157

A novel herbal formulation “LiverCare” differentially regulates primary hepatocyte and hepatocarcinoma cell proliferation in vitro

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Hepatocyte growth factor (HGF) plays an important role in hepatocyte proliferation. HGF expression is regulated by various signalling molecules and nuclear receptors. In the present study, LiverCare (LC) a novel polyherbal formulation was evaluated for its efficacy, using primary rat hepatocytes-non parenchymal cells (NPC) co-culture and human hepatocellular
carcinoma cells (HepG2). The rate of primary hepatocyte co-culture proliferation was significantly and dose-dependently increased by LC as determined by \([3H]\)-Thymidine incorporation into newly synthesized DNA and cell proliferation assay. LC also increased HGF expression in primary hepatocyte co-culture. Albumin and urea content remained constant during proliferation of hepatocyte co-culture in the presence of LC with decreased activity of ALAT. Interestingly, LC inhibited incorporation of \([3H]\)-Thymidine into DNA in HepG2 cells. LC enhanced PPAR-\(\alpha\) expression during hepatocyte proliferation while TNF-\(\alpha\) expression remained unaffected.

In conclusion, our study clearly showed that LC differentially regulates the primary rat hepatocytes and human hepatocarcinoma cell proliferation. LC may be a promising candidate for treating degenerative liver diseases by enhancing liver regeneration.

**Keywords:** Liver care, Hepatocytes, \([3H]\)-thymidine, PPAR-\(\alpha\)-peroxisome proliferator activated receptor alpha, TNF-\(\alpha\)-Tumor necrosis factor alpha, HGF-Hepatocyte growth factor.

**PP-202**

**Determination of vitamin D3 in three high-quality nutritional supplements, using ion-trap liquid chromatography, tandem mass spectrometry**

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**Background:** Supplementation with Vitamin D had gained a renewed curiosity by the public and garnered attention in biomedical research. Vitamin D nutritional supplements are often formulated with heterogeneous matrices, which pose a challenge to the standardization of analytical methodologies. Methodological advances are needed to analyze novel matrices used to formulate and deliver Vitamin D in nutritional supplements.

**Objective and Aims:** We conducted independent analysis of three high-quality vitamin D3 nutritional supplements: a chewable tablet, a capsule and a liquid emulsion. The analysis was initiated to validate three products used in an open-label, randomized, prospective trial of vitamin D3 supplementation in humans.

**Methods:** Commonly used Vitamin D3 nutritional supplements were donated by three different manufacturers. The label claim of each product was 2,000 IU per dosage unit. Light and air exposure was minimized in the preparation of 20-unit composite samples of each product, respectively. Composite samples were analyzed in triplicate, with an additional analysis of spike recovery, using Agilent 500 Ion-Trap LCMS/MS, in APCI positive mode conditions. The spike analyses used neat D3 standard supplied by Accustandard, USA.

**Results:** Vitamin D samples were within the range of +5 % to +126 % of the label claim of 2,000 IU per dosage unit. The mean tablet value was 4,538 IU (SD 623 IU; RSD 13.7 %), with spike recovery of 205.2 %. The mean capsule value was 3,778 IU (SD 401 IU; RSD 10.6 %), with spike recovery of 86.0 %. The mean liquid drop value was 2,103 IU (SD 404 IU; RSD 19.2 %), with spike recovery of 96.5 %.

**Discussion:** The three vitamin D supplements exceed the 2,000 IU label claim. The tablets and capsules were super-potent, and the drops were only slightly above than the label claim. The variability seen was in the matrix not in the method; replicate injections of a mid-calibration standard showed excellent precision. Vitamin D supplements showed wide
variation in measured dose compared to label claim. Greater variation seen in the tablet and capsule formulations may be due to the variability of distribution of active ingredient in solid matrices. Additional analysis of inter-batch and intra-batch variability is ongoing.

PP-204

A comparative effectiveness trial of high-quality vitamin D3 nutritional supplements to replete serum vitamin D

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Background: The importance of vitamin D in the prevention and treatment of human health conditions has gained increased attention in recent years. Currently, few prospective controlled trials have investigated the effect of vitamin D supplementation on measures of cardio-metabolic disease risk. Despite the popular acceptance of vitamin D supplementation for purported health benefits, the dosage and duration of commonly used vitamin D supplements to achieve sufficient vitamin D levels has not been well investigated.

Objective and Aims: The primary aim is to compare the change in serum 25-OHD concentration between three forms of supplemental vitamin D3: a lipid-emulsified form administered in a sesame oil base, a non-emulsified chewable tablet, and a non-emulsified form administered to 25-hydroxycholecalciferol (25-OHD) insufficient < 33 ng/ml (75 nmol/ml) patients. The secondary aim is to compare the proportion of participants reaching an “optimal” 25-OHD concentration ≥ 33 ng/ml (75 nmol/ml) between VitD supplement groups following supplementation. Methods: This three-arm, randomized clinical trial will compare the difference in serum 25-OHD concentration between the three arms at baseline and after random administration of one of the three vitamin D preparations for 12-weeks at a dosage of 10,000 IU VitD per day (N = 60 vitamin D insufficient subjects and N = 30 sufficient controls).

Outcomes: Data included patient demographics, health history, food frequency and sun exposure questionnaires, laboratory values for 25-hydroxy vitamin D, 1,25-dihydroxy vitamin D, serum calcium and phosphate, fasting glucose and insulin, hemoglobin A1c (HbA1c), low density lipoprotein (LDL) and high density lipoprotein (HDL) cholesterol, triglycerides (TAG); and systolic/diastolic blood pressure (SPB, DBP). Nested studies of Klotho protein expression and toll-like receptor-4 expression in macrophages will be completed at the close of the study.

Results: A total of 124 subjects were contacted, of which 99 underwent screening and 19 were found ineligible. Eighty (80) subjects met the inclusion criterion: 45 enrolled, 24 controls, 8 pending screening results, 3 eligible declined enrollment. Eight (8) subjects have completed the full trial. Enrollment was extended to reach the target enrollment (N = 60), with enrollment continuing through May 2011 and study completion expected in August 2011.
Twenty-three per cent of the Swiss adult population are using complementary medicine

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Aim of the study: Various forms of complementary medicine (CM) play an important role in the Swiss health care system, they are appreciated by a majority of the population and mostly used complementarily rather than alternatively to conventional medicine. This study investigates, how many people in Switzerland are actually being treated with CM, and what the most popular methods of CM are.

Data: Data of the Swiss Health Survey 2007 were obtained from the Swiss Federal Statistical Office. This survey is performed every 5 years amongst a sample of the Swiss resident population above 15 years of age. It consists of a telephone interview followed by a written questionnaire (2007: 18,760 and 14,432 respondents, respectively) and includes questions about people's state of health, general living conditions, lifestyle, health insurance and usage of health services.

Results: 23.0% of the Swiss adult population (women: 30.5%, men: 15.2%) used CM during the 12 months before the survey. Homeopathy (6.4%), osteopathy (5.4%) and acupuncture (4.9%) were the most popular methods. The average number of treatments within 12 months for these three methods was 3.1, 3.5 and 6.6, respectively. For treatments with homeopathy and acupuncture, medical practitioners were more commonly consulted than non-medical practitioners, for treatments with osteopathy no difference was found. By means of logistic regression, CM users and non-users were compared. There were significant differences in the use of CM between genders, age groups, levels of education and areas of living. Women, people aged 25 to 64 years, and people with higher education used CM more commonly than men, people below 25 or above 64 years of age, or those with poorer education. Lake Geneva region and central Switzerland had a higher proportion of CM users than the other regions.

Discussion: While 2 years ago, 67.0% of the Swiss population approved a referendum in favour of CM, we find that 23.0% are in fact using it. Current political discussions focus on effectiveness, cost effectiveness and suitability of CM to decide which methods should be permanently covered by the basic health insurance.

Efficacy and safety of meditative movement therapies in fibromyalgia syndrome – a systematic review and meta-analysis of randomised controlled trials
Objective: A systematic review with meta-analysis of the efficacy and safety of meditative movement therapies (Qigong, Tai-Chi, Yoga) in fibromyalgia syndrome (FMS).

Methods: We screened Clinicaltrials.Gov, Cochrane Library, PsycINFO, Pubmed and Scopus (through December 2010) and the reference sections of original studies for MMT in FMS. Randomized controlled trials (RCT) comparing MMT to controls were analyzed. Outcomes of efficacy were pain, sleep, fatigue, depression, health-related quality of life (HRQOL). Effects were summarized using standardized mean differences (SMD [95% confidence interval]). Outcomes of safety were drop out because of adverse events and serious adverse events.

Results: A total of 7 out of 117 studies with 362 subjects and a median of 12 sessions (range 8–24) were included. MMT reduced sleep disturbances (-0.61 [-0.95, -0.27]; 0.0004), fatigue (-0.66 [-0.99, -0.34]; <0.0001), depression (-0.49 [-0.76, -0.22]; 0.0004) and limitations of HRQOL (-0.59 [-0.93, -0.24]; 0.0009), but not pain (-0.35 [-0.80, 0.11]; 0.14) compared to controls at final treatment. The significant effects on sleep disturbances (-0.52 [-0.97, -0.07], 0.02) and HRQOL (-0.66 [-1.31, -0.01]; 0.05) could be maintained after a median of 4.5 (range 3-6) months. In subgroup analyses only Yoga yielded significant effects on pain, fatigue, depression and HRQOL at final treatment. Drop out rate because of adverse events was 3.1%. No serious adverse events were reported.

Conclusions: MMT are safe. Yoga had short-term beneficial effects on some key domains of FMS. There is a need for high quality studies with larger sample sizes to confirm the results.

Development of the electronic materia medica „E-Phatak“ to assist individualized retrieval of remedies in homeopathy

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Background: With a tradition of 200 years of patient care, homeopathy is one of the oldest integrative medical systems in the field of traditional European medicine. An essential part of homeopathic case taking is the conduction of a comprehensive anamnesis followed by individualized finding of a remedy that fits the conditions the patient describes. This is called
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repertorisation and today is done with the help of computer programs using modern database technology.

**Aim:** The E-Phatak project aims at developing and evaluating an electronic Materia medica based on S.R. Phataks “Arzneimittellehre” to complement the existing homeopathic repertory software.

**Methods:** Phataks’ materia medica was ripped into approx. 25,000 sentences which then were processed into an inverted file structure. Using modern Extensible Markup Language (XML) and Extensible Stylesheet Language Transformations (XSLT) together with linguistic algorithms this structure was made searchable. This technical realisation enables the user not only to search within the symptoms but also offers special features like sequential search within the results or the comparison of homeopathic remedies based on Head to Toe Methodology. A first prototype was currently evaluated by a focus group of homeopathic physicians and healing practitioners.

**Results:** Based on the results of published homeopathic cases we were able to reproduce the results of repertorisation with the E-Phatak. Results of the evaluation of the focus group revealed that reduction of remedies by Head to Toe Methodology was ranked lower than the reduction by sequential search. Almost all evaluators found sequential search to be the key feature and the innovative element of the E-Phatak which should be the subject of further investigations and implementations. There was total agreement that E-Phatak is not an alternative but a complement to existing homeopathic repertory software.

**Conclusion:** We were able to show how full text searching in homeopathic text repositories can be achieved using the semantic web standards XML and XSLT. However user demands of day to day practice and terms of information technology have both to be taken carefully into account.

PP-121

**A systematic review of the literature in CAM prevalence as part of the EU CAMbrella collaborative project**

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**Introduction:** CAMbrella is an FP7 funded pan-European research network for complementary and alternative medicine (CAM) aiming to develop a road map for future research in CAM appropriate for EU citizens, governments, health care providers and national research funders. More than 100 million EU citizens are regular users of CAM, largely for the treatment of chronic conditions; therefore CAM is an important issue for patients, health care providers, funders and researchers. CAM use in the EU has increased over the last 25 years but it’s difficult to compare statistics across nationwide surveys due to a lack of standardised terminology however the WHO Centre for Health Development conclude that CAM is highly prevalent. This study reports the interim results of a systematic review of the literature to answer the following research questions; What is the prevalence of CAM in the EU? Which CAM’s are used and for which conditions? What is the quality of the data reporting on CAM use and provision?
Methods: Electronic databases were searched for population based studies across the EU which evaluated the prevalence of CAM. Grey literature was searched via CAM professional bodies. Two researchers determined study eligibility and examined for quality. Data extraction is now underway according to a pre agreed protocol to evaluate study quality and the prevalence of CAM through consultation and over the counter purchase. Types of CAM used and reasons for its use are also being extracted. The quality assessment and data extraction tool was developed from the STROBE criteria for epidemiology and outcome studies. Inter-rater reliability for the quality and data extraction process will be calculated using Cohen’s kappa.

Results: Data collection began in July 2010. The initial search produced 5,599 papers. 2,246 were not CAM related and of the remainder, 189 met the inclusion criteria by title and abstract. The results will be available and analysed by December 2011.

Conclusion: Initial data suggests that some countries will provide good quality information and others within the EU will have little reliable information about CAM use and provision. We suspect there will be large, important gaps in our knowledge of the prevalence of CAM across the EU but knowing and understanding this will allow us to identify where further research is required.

PP-172

Non conventional medicine within the Italian medical profession

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In Italy as in other countries of the European Union, at the present time the juridical/legal status of NCM/CAM is not well established, mainly due to the lack of any national law regulating NCM/CAM professional training, practice and public supply and the absence of government-promoted scientific research in this field.

It can be said that Italian institutions have not yet responded to public demand; similarly, knowledge of NCM among MDs, especially general practitioners, is not as widespread as patient demand would require. In this article we focus the situation of Non Conventional Medicine within the juridical status of the medical profession.

PP-198

Phenomenon of connective tissue disorders

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Objective and aim: High rate of the signs and manifestations of connective tissue disorders (CTD) in the population, especially among young people, changes in clinical course of a wide range of diseases with simultaneous involving several organs into pathologic process, early development of exacerbations and life-threatening complications - all these factors make actual the studying this phenomenon.

Methods and materials: recent literature data on this problem were analyzed.

Results: Adaptation of mankind to the new conditions of existence under the influence of a wide range of difficult environmental, social and other factors has occurred with involving connective tissue that constitutes more than half of body weight and has high flexibility, heterogeneity and adaptability. "Ubiquity" of connective tissue determined multiformity of manifestations, that accompanied these changes. Genetically predetermined defects of various components of connective tissue lead to decrease in its stability, durability, depression of its functions and development of clinical manifestations. Numerous studies have formed the definition of CTD as polygenic multifactorial condition, manifested by internal and external phenotypic signs and clinically important CTD-associated dysfunctions of organs and systems with progressive course. In patients with CTD the most frequently affected organs and systems are: bones and joints, skin, muscle, cardiovascular, gastrointestinal, respiratory, urinary, reproductive system, organs of vision. In patients with involvement of 4-5 and more systems into CTD process the course of disease is more severe, with early development of complications. Phenotypic CTD signs may be missing at birth or have a slight extent and intensity with the subsequent progressive increase in their number and intensity with advancing age.

Conclusions: 1. High rate of CTD manifestations in population and increasing number of life-threatening conditions are revealed against the background of wide range of difficult environmental, social and other factors. 2. The most frequently affected systems of organs are osteoarticular, musculocutaneous, cardiovascular, gastrointestinal, respiratory system. 3. In patients with involvement of 4-5 and more systems into CTD process the course of disease is more severe, with early development of complications. 4. The intensity of manifestation of CTD increases with advancing age.

PP-213

Inflammation in neurodegenerative diseases

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Background: Neurodegenerative disorders have complex disease traits and require a multitarget treatment. Evidences are increasing that inflammatory processes are common a common feature of this group of diseases. Phytopharmaceuticals as multitarget therapeutics may have a therapeutic potential.

Method: We assessed electronic data bases for the key words “inflammation and neurodegenerative diseases” in combination with “multitarget therapy”, “phytomedicine”,...
“phytopharmaceuticals”, “plants” or the term “complex”. Only the latter two terms yielded results.

Results: In general inflammatory processes are regarded as relevant and part of the pathogenesis of neurodegenerative diseases like Alzheimer, Parkinson or amyotrophic lateral sclerosis, but also of neurological disorders like depression. Molecular targets to be treated include the cytokines and chemokines TNF-alpha, IL-6, IL-1β, IL-8, IL-10, CCL-2, CXCL-1, enzymes like COX 1 and 2, but also pathways of oxidative damage (ROS/RNS) which essentially contribute to inflammation. Neuroinflammation, characterised by the appearance of reactive microglial and astroglial cells, can even be triggered by peripheral inflammation. Antiinflammatory treatment approaches with phytopharmaceuticals are so far rare and include e.g. curcumin, willow bark, green tea and omega-3-fatty acids.

Conclusion: Low grade inflammation as part of the pathophysiology of neurological disorders should be assessed and considered in treatment approaches for these disorders. The potential of antiinflammatory multitarget approaches e.g. with phytopharmaceuticals should be systematically investigated.
PP-051

Auricular acupressure can regulate the autonomic nerve system of primiparous women in labor


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Purposes: The purpose of this study was to evaluate the effects of Ear shenmen point (TF4) auricular acupressure on the intensity of anxiety and Heart Rate Variability (HRV) among primiparous women in labor.

Methods: An experimental study with a pretest-and-posttest-control-group design was utilized. They were randomly assigned to either the experimental or the control group. The experimental group received Ear Shenmen point acupressure intervention and the control group received Ear Eyes point acupressure intervention. The intensity of anxiety perception between the two groups was compared in three check points: before intervention, 6~7cm cervical dilation (active phase) and full cervical dilatation. The data were analyzed by Mixed Model in SPSS for Window 7.0 software.

Results: The effectiveness of the Ear Shenmen point (TF4) acupressure was as follows: First, the experimental group had significantly decrease intensity of anxiety perception at 6~7cm cervical dilation (active phase) and full cervical dilatation than the control group. Second, the result proved that acupressing the Ear Shenmen point could increase the activity of parasympathetic nerve system and it could regulate the activity of autonomic nerve system.

Conclusion: The Ear Shenmen point acupressure during the delivery period for primiparous women not only reduced their anxiety at the active phase and full cervical dilation phase, but also calm their HRV by regulating the activity of autonomic nerve system.

PP-087

The immediate effect of electro-acupuncture on balance and gait in stroke patients with spastic hemiplegia

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Stroke is a common problem that results in neurologic and functional deficits. Approximately 30,000 people per year in Taiwan, aged over 35, suffer a first stroke. 80% of stroke patients experience motor impairments, i.e., hemiparesis, poor coordination and gait disturbance. Abnormal spasticity is considered to be the major factor causing these motor impairments.

Acupuncture is one of the main modalities of treatment in traditional Chinese medicine and is a relatively simple, inexpensive and safe treatment. It also has been well-accepted by stroke patients for improving motor, sensation, speech, and other neurological function. Electro-acupuncture (EA) has the same effects as traditional acupuncture.

Thirty subjects from the rehabilitation clinics in Changhua Christian Hospital of Taiwan, aged 45 to 75 years who suffer a first stroke within 6-24 months, were enrolled in a single blind study and randomly assigned to study and control group in equal number. Acupoints applied on patients are affected ST-36 with mid-portion of the tibialis anterior muscle belly and GB-34 with mid-portion of the Peroneus muscle belly.

All subjects (both group) underwent regular rehabilitation programs. Moreover, The Park-Sham Device (PSD) was used in this study. Only in the study group, Electro-acupuncture was given. Objective laboratory evaluation including computerized gait and balance test and dynamic foot pressure analysis is used to compare the effects of EA between these groups.

The results show significant differences in the degree of asymmetry in GRF in spastic hemiplegia after electroacupuncture treatment. Since that there is no significant improvement in the functional parameters of gait and balance, the results might provide alternatives for further intervention of rehabilitation program.

PP-116

Intensity and duration of needling sensations – a pilot study in osteoarthritis patients

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Objectives: Many acupuncturists claim that the deqi or needling sensation is the crucial ingredient of a successful acupuncture. In order to study acupuncture in an fMRI scanner it is necessary to know more about the intensity and time course of this subjective sensation. Thus we set out to study systematically various features of deqi in a blinded setting.

Methods: In a cross-over design 36 patients suffering from osteoarthritis of the knee (OA-k) or the thumb (OA-t) came in our department for two sessions within 14 days. They received real acupuncture (RA) in one session and were treated with the blunt Streitberger Needle (SN) which is not penetrating the skin in the other session. Patients were blinded to the condition which was at random order. Only one needle at one acupuncture point (GB34 for OA-k and LI 4 for OA-t) was inserted. One minute after the insertion the needle was manipulated by the acupuncturist for 15 seconds. The patient was then asked to indicate how
long sensations elicited by the manipulation were continuing and to rate the intensity on a VAS. This procedure was then repeated for 30 min in total, having up to 9 manipulations per patient and session. At the end of the session patients filled in the Southampton Needling Sensation Questionnaire (SNSQ) describing the intensity of needling sensations on the two factors aching and tingling and the overall painfulness of deqi.

**Results:** A test comparing the two groups (either RA first or SN first) demonstrated that there was no carry-over effect between the two sessions. We found a significant difference between the two groups regarding the needling sensations reported by the SNSQ (p = .007). We could not replicate the partial correlations between the two factors of the SNSQ and the overall pain. We report intra-personal and inter-personal variation regarding the time-course and the intensity of the deqi sensation in a descriptive manner.

**Conclusion:** Needling sensations are elicited by both real acupuncture and Streitberger Needle. But the qualities of the sensations are clearly different. A German translation of the SNSQ questionnaire elicited a different correlation pattern and thus demonstrates the difficulties to translate notions describing individual sensations.

**PP-184**

**Evaluating different placebo interventions in acupuncture research**

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The primary objective of the study is to investigate the feasibility of a study design examining whether one-treatment acupuncture prevent nausea in early pregnancy. A second objective is to explore a study design investigating whether a patient is capable of discriminate the needle effect (de qi) comparing real acupuncture needle and sham acupuncture needle. A third objective is investigate if the design of a study give reason to estimate the effect size of expectation comparing real acupuncture/sham-acupuncture with inert sham laser.

The study is planned as a pilot study including 20 women in each of the three study groups, all-together 60 pregnant women. Intervention will consist of standardised 15 minutes stimulation of acupuncture point pericardium 6 by either two acupuncture needles, two sham acupuncture needle or two sham laser devices. The women will record their daily symptoms during a 4 day run-in period, and thereafter a 4 day follow up after treatment according to previous research methodology.

The results from the study could be important for planning of future studies where the blinding issue with regard to acupuncture is challenged.
Effects of anthroposophic rhythmical body oiling on symptoms of stress and wellbeing in children and youth with mild ID and psychiatric disorders

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Background: One of the main therapeutic instruments of anthroposophic nursing is rhythmical body oiling. This is gentle rhythmic application of specific plant oils for specific indications. The general aims of rhythmical body oiling are: balancing the physiological processes of the organism, restoring energy, and supporting the body’s own healing process. Despite excellent clinical experiences, until now no outcome studies have been executed.

Objective: To investigate the effects of rhythmical body oiling on symptoms of stress and well-being in ‘problematic youth’: children with mild intellectual disabilities, psychiatric problems and in most cases traumatic experiences.

Method: A quasi-experimental study with two groups of 30 children and youth (8-18 years of age) each. The groups are matched on sex, age and psychiatric classification. Experimental treatment: 12 sessions with rhythmical body oiling followed by bed rest and storytelling; a total of 30 minutes per session, two sessions per week. Control treatment: treatment as usual and, as in the experimental condition, 12 sessions with 30 minutes bed rest and storytelling. Measured indicators of stress and well-being: heart rate, respiratory rate, body temperature, heart coherence (a stress related indicator, measured with a sensor at the earlobe and a specific computer program). All indicators were measured at the start and at the end of each session, in both the experimental and control group.

Results: Both groups demonstrate positive results on all measured indicators. However, there is a statistically significant difference between the experimental and the control group in all measured indicators in favor of the experimental group. Results will be presented.

Discussion: this outcome study provides first empirical evidence of the positive effects of rhythmical body oiling. Further effect studies are indicated.
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Background: In short and simplified terms anthroposophic care integrates conventional medicine with the unique aspects of care developed by Dr Rudolf Steiner and the inclusion of selected complementary therapies such as massage, natural remedies, art and music therapy. This type of anthroposophic integrative medicine in Sweden (AIMS) has been provided since the 1980s supported by permits from the Swedish Government. There has been little scientific investigation into the potential cost-effectiveness of AIMS compared to conventional care based on Swedish registry data.

Aim: To explore Swedish registry data of costs and effects for patients treated with AIMS compared to matched controls that have received conventional care.

Methods: A retrospective comparative analysis of registry data (health care utilisation, drug utilisation, quality of life/EQ5D, sick-leave, mortality) for patients managed with AIMS vs. matched controls managed with conventional county council care. Data will be gathered from registries managed by Stockholm county council, the National board of health and welfare and the National health insurance organisation. Standardised statistical procedures including multivariate regression analyses will be used to analyse differences between groups.

Relevance: This study will for the first time compare the potential differences in clinical and cost-effectiveness of AIMS vs. conventional care based on Swedish registry data. The results may facilitate the generation of research hypotheses as well as to inform health care reform and decision making processes in the Swedish health care system. A further ambition is to use the results to estimate proper sample size and power for a large scale randomised clinical trial investigating the comparative effectiveness of AIMS vs. conventional care in the management of select groups of patients.

PP-108

Prescribing practices in a German network of anthroposophic physicians for the treatment of patients with depression: a prospective observational study

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Background: Depression is a major and increasing public health problem worldwide. In primary care conventional treatments are often accompanied by prescriptions of complementary and alternative medicine (CAM).

Aim: This study aims at investigating depression treatment strategies among physicians specialized CAM by analysing prescribing patterns.

Methods: 22 primary care physicians in Germany participated in this prospective, multicentre observational study. Prescriptions and diagnoses were reported for each consecutive patient. Data were included if patients had at least one new diagnosis of depression according to the 10th revision of the International Classification of Diseases
during the study period (ICD10: F32 or F33). Multiple logistic regression was used to determine factors associated with a prescription of any antidepressant medication.

Results: From 2004-2008 a total of 2444 patients with depression were included (mean age: 49.1 years (SD: 15.4); 77.3 % female). Depression was classified as depressive episode (88.3 %) and recurrent depressive disorder (11.7 %). The most frequent co-morbidities were cancer (14.4 % of all patients), coronary heart disease (8.3 %), and diabetes mellitus (7.1 %). 8.3 % of all patients were classified as multi-morbid. In total, 2645 prescriptions of antidepressants for 833 patients were reported. The phytopharmaceutical Hypericum perforatum was the most frequently prescribed antidepressant over all (44.6 % of all antidepressants), followed by amitriptyline (16.1 %). The likelihood of being prescribed an antidepressant medication was not significantly different for persons who had a co-morbid condition compared with those who did not have a co-morbid condition after controlling for age, sex, and co-morbidities (adjusted OR (AOR) = 1.01; CI: 0.81-1.26). But there were significant differences according to individual co-morbidities. The AOR for receiving any antidepressant medication was greater than 1 for the co-morbidity cerebrovascular disease (AOR = 1.76; CI: 1.12-2.76). Patients who had cancer were significantly less likely to be prescribed an antidepressant medication than those who had no cancer (AOR = 0.75; CI: 0.57-0.97).

Conclusion: This study provides a comprehensive analysis of everyday practice for treatment of depression in primary care in physicians with a CAM focus. Further analysis regarding co-morbidity, co-medication and the occurrence of critical combinations are of high interest to health services research.
**PP-153**

**Āyurvedic management of jalodara (Hepatic Cirrhosis Complicated with Ascites): a non-randomized, observational clinical trial**

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**Background:** Hepatic cirrhosis is one of the leading causes of death worldwide. In Āyurveda this condition is labeled jalodara and it is described under the superordinate disease group of udara roga, characterized by abdominal distension due to abnormal peritoneal accumulation e.g. ascites. Jalodara is an udara roga which comprises advanced hepatic cirrhosis associated with ascites. Hepatic cirrhosis is a main condition behind the manifestation of ascites.

**Objective:** We aimed to evaluate the principle potential of the traditional āyurvedic approach for the overall clinical outcomes in hepatic cirrhosis.

**Methods:** An observational clinical study of 56 patients of jalodara was conducted at P.D. Patel Āyurveda Hospital, Nadiad, India. Patients were treated with vardhamāna pippalī (Piper longum powder in increasing and tapering dose pattern), followed by mild purgation and the administration of the herbal compound preparation punarnavādi kvātha, and a mixture of bhūmyāmlakī (Phyllanthus urinaria), śarapunkhā (Tephrosia purpurea), śvetaparapāṭi (contains ammonium-chloride, potassium-nitrate and alum) and bhṛṅgarāja (Eclipta alba) for a period of 6 weeks.

**Results & Discussion:** The results showed significant improvement in various clinical outcomes, including patient-symptoms and liver functions. The prognosis of the patients, assessed by the Child-Pugh prognostic grade score, also improved significantly. Further randomized studies on Āyurveda in hepatic cirrhosis are warranted.
Possibilities of homeopathic treatment for minor-grade cervical cytology abnormalities

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Cervical cancer prevention strategy is surgical excision of precancerous lesions. But surgical procedures of cervix can increase premature birth probability. That’s why non-surgical treatment of those lesions is preferred. The aim of the study is to evaluate effectiveness of homeopathic treatment for minor cervical intraepithelial lesions compared to usual follow up.

\textit{Material and methods:} Study design – clinical trial using historical data basis. Study groups formed from the female patients of Lazdynai outpatient clinic if their Pap smears have been taken between 01.07.2004 and 31.12.2010. Inclusion criteria: 1) first time cytologically diagnosed low-grade squamous intraepithelial lesion (LSIL) or atypical squamous cells of undetermined significance (ASCUS) (if human papillomavirus (HPV) was detected), 2) at least one follow-up smear, 3) no surgical interventions on cervix. Study group (got homeopathic treatment, \( n = 12 \)) and control group (usual follow up and anti-inflammatory treatment, if necessary, \( n = 18 \)) were formed from 30 cases, that met inclusion criteria. Homeopathic treatment consisted of 1) Detox-Kit, 2) Gynäcoheel, 3) Galium-Heel for 6 weeks. Follow-up smears were taken every 4-6 months. Recovery rates in study and control groups were compared. Recovery criterion – the last Pap smear during the observation period is normal. The result was also compared between users and non-users of hormonal contraceptives.

\textit{Results:} Recovery rate was 75% in study and 55% in control group. Among users of hormonal contraceptives recovery rate in study group was 75% and only 20% in control group. Among non-users it was respectively 75% and 66.7%. However due to the small number of cases the result was not statistically-significant. Homeopathic treatment was well tolerated. There was only one case of skin rash during the treatment which regressed spontaneously after the use of prescribed medications was ceased for a while. The treatment was continued when the symptoms passed.

\textit{Conclusions:} Homeopathic treatment can be recommended for the treatment of patients with minor-grade cervical cytology abnormalities. Hormonal contraception shouldn’t be recommended for those patients.
PP-182

Determinants of patients' choice of their family GP according to his prescription preferences towards homeopathic and complementary medicines: results of the EPI3 nationwide survey

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Background: While literature has mainly evaluated the comparability of patients seeking access to conventional and homeopathic practice by confronting them, no study has also documented in the particular context of French health care provision, determinants of patients increasingly choosing family GPs that combine both conventional and alternative therapies prescriptions in their daily practice.

Methods: The EPI3 study was a nationwide observational survey of a representative sample of general family GPs and their patients. Certified homeopaths (GP-H), regular prescribers of homeopathic medicines in a mixed practice (GP-MP) and those who strictly practice conventional medicine (GP-CM) had been identified using a two-stage, stratified, random sampling method. Patients completed a questionnaire on socio-demographics, lifestyle, beliefs toward complementary alternative medicines (CAMBI) and quality of life using the Short Form 12 (SF-12) questionnaire. Diagnoses were recorded by the physician. Associations between patients’ determinants and type of practice were estimated using multivariate logistic regressions and adjusted for risk factors.

Results: A total of 804 family GPs and their 6379 patients were recruited during a one day survey survey with on-site assessment by trained interviewers: 26.5 % visiting a GP-CM, 50.0 % a GP-MP and 23.5 % consulting a GP-H. As compared to patients visiting GP-CM, similar characteristics, lifestyle and medical conditions were found in patients referring to a GP-MP. Patients attending GP-H were younger, had higher educational attainment and overall had healthier lifestyles than GP-CM patients, higher confidence into alternative treatments (OR = 3.43, 95 % CI [2.97-3.97]), higher physical but lower mental status. Patients referring to a GP-H were more likely to exhibit chronic disorders such as osteoarthritis and joint diseases (OR = 1.29, 95 % CI [1.07-1.56]) or depression (OR = 1.38, 95 % CI [1.15-1.65]) whereas patients from the GP-H were less likely to have acute diseases such as cardiovascular disorders (OR = 0.67, 95 % CI [0.56-0.81]) or acute respiratory diseases (OR = 0.69, 95 % CI [0.52-0.91]).
Conclusions: The EPI3 survey is the first study to highlight that homeopathic medicines prescriptions are now commonly integrated in French general practice and that patients choosing family GPs who combine both unchallenged biomedicine and comprehensive individualised therapies are not different than those who visit conventional GPs.
The Tibetan herbal formula padma digestin modulates gastrointestinal motility in vitro

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\textbf{Background:} Symptoms of functional gastrointestinal disorders are prevalent and have a high impact on quality of life, but treatment options are limited. Padma Digestin is a formula originating from Tibetan Medicine. It is used in maldigestion and dyspeptic symptoms but the exact mechanisms of action are not yet known.

\textbf{Aim:} To examine the in vitro effects of Padma Digestin on smooth muscle motility of different gastrointestinal segments.

\textbf{Methods:} The effects of the ethanolic extract of Padma Digestin (8.16 mg/ml or 81.6 mg/ml) on contractility and susceptibility to acetylcholine (ACh) were analyzed in muscle strips of cardia, antrum, pylorus, duodenum, jejunum, ileum and colon of male Wistar rats.

\textbf{Results:} Compared to control the Padma Digestin extract had pro-contractile effects in antrum smooth muscle strips. It decreased sensitivity to ACh in cardia and increased it in antrum and pylorus strips. In intestinal segments spontaneous contractility was inhibited in duodenum and jejunum strips as was reactivity to ACh in jejunum strips. In colonic samples, Padma Digestin inhibited spontaneous and Ach-stimulated contractility in the low dose but seems to have increasing effects in the high dose.

\textbf{Conclusion:} Padma Digestin extract has region-specific effects on contractility and excitability of gastrointestinal smooth muscle. The demonstrated effects are known to promote gastric emptying and intestinal absorption and suggest a positive effect in functional dysmotility of the upper gastrointestinal tract. The results thus support the traditional use of Padma Digestin in maldigestion and functional gastrointestinal disorders.
Modulatory role of Bauhinia variegata against sodium arsenite induced genotoxic and biochemical changes in mice

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Introduction: Bauhinia variegata a species of flowering plant belonging to the family Leguminosae, grows widely in India and is known for its pharmacological properties. In the present investigation ethanolic leaf extract of this plant has been tested for its possible antioxidant activity during sodium arsenite induced toxicity in mice compared to suitable controls.

Methods: Twenty animals were randomized into two groups of 5 and 15 mice each and were treated as below for 1 month: Group I: no treatment (control) Group II: arsenic treated, as sodium arsenite 200 ppm in drinking water. After 1 month, arsenic exposed mice were divided into three groups of five mice each and given following treatment consecutively for 5 and 10 days. Group II a: Mice were fed chronically fed 1:20 alcohol to distilled water (‘vehicle’); Group II b, c: 150 mg/kg leaf extract of Bauhinia variegata (oral), once daily for 5 and 10 days.

Results: Feeding of Bauhinia variegata leaf extract to Group II b and c mice considerably reduced genotoxicity and modulated favorably some marker enzymes when compared to controls (p \textless 0.05 to p \textless 0.001). A similar trend was also observed in histological analysis of the hepatic tissues.

Conclusion: Alcoholic leaf extract of Bauhinia variegata have potential to be used as complementary and alternative medicine in arsenic induced toxicity, particularly as supporting palliative measures. Further, independent investigations from other laboratories are encouraged to confirm and refute our findings.

Antibacterial, antifungal and antimutagenic activity of Unani herbal drug Swertia chirayita linn (Chirayita)

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Introduction: The importance of Integrative Systems of Medicine has now been recognized worldwide. Herbal drugs are playing an important role in healthcare programs in the world. Herbal medicines also play a great role in the development of primary health care because of
their effectiveness with safety and lesser side effects. The increasing incidence of infectious diseases necessitates to search for effective and safe natural remedies for health ailments and this gives an objective to find out herbal anti-microbial drug and follow the theme of World Health Day, 2011 “To Combat Drug Resistance”.

The present study was aimed to explore the antibacterial, antifungal and antimutagenic activity of a well known Unani drug Swertia chirayita Linn. (Chirayita).

**Material and Methods:** Kirby Bauer’s Disk Diffusion Method was used according to CLSI Guidelines by W.H.O. to explore antibacterial and antifungal activity against various bacterial and fungal isolates of clinical origin. The activity was compared with the standard drug and Plane control i.e. the solvent used. The prepared plates were incubated at 37°C for 24 hrs. The antibacterial activity was evaluated by measuring the Zone of Inhibition - ZOI (in mm.) of drug extract. Minimum Inhibitory Concentration (MIC) was also screened. Ames test was performed using tester strains S.typhimurium TA97, TA98 and TA 100 to identify its antimutagenic activity. All the experiments were conducted in triplicates and in sterilized conditions.

**Results:** The results were analyzed statistically by using ANOVA. It was found that Chirayita was effective against a large number of microbial strains i.e. among gram positive strains S.aureus (MIC-19.53 µg/ml), S.mutans (MIC-156.25 µg/ml), S.epidermidis (MIC-625.0 µg/ml), and among gram negative strains P.vulgaris (MIC-625.0 µg/ml) and fungal strain C.albicans (MIC-19.53 µg/ml). Results of the present investigation indicate that S.chirayita possesses antimicrobial properties against tested micro-organisms. Antimutagenic Inhibition of tester strains was found as 98 % inhibition was seen against TA100 while 85 % against TA 98 and 68 % against TA97 tester strain.

**Conclusion:** This study concludes that S.chirayita Linn. is effective against microbial organisms like S.aureus, S.mutans, S.epidermidis, P.vulgaris and C.albicans. And also has a potent antimutagenic activity. However further clinical studies are needed in this direction so, that it can be used safely and effectively as ‘herbal antibiotic’.

**PP-041**

**Influcid in feverish infections: results of a randomized, international, controlled clinical trial**

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Upper respiratory tract infections (URTI) represent the most frequently occurring illness in the world. Although uncomplicated URTI are usually self-limited illnesses, they cause considerable costs in terms of inability to work and are therefore a major public health challenge.

As there is no approved specific therapy for URTI, treatment mainly focuses on symptomatic relief. Most URTI remedies may produce side effects that contribute to increased health-care costs. There is a continuous interest in the identification and clinical evaluation of alternative therapies with a favorable risk-benefit profile.
Influcid, a homeopathic medicinal product composed of six active substances (Aconitum D3, Bryonia D2, Eupatorium perfoliatum D1, Gelsemium D3, Ipecacuanha D3, Phosphorus D5), may provide this profile.

A randomized, controlled clinical study was performed to evaluate the efficacy and tolerability of Influcid tablets in patients suffering from URTI with flu-like symptoms. Treatment with Influcid in addition to standard symptomatic medication was compared to treatment with standard symptomatic medication alone. Standard symptomatic medication (Paracetamol, Ambroxol and/or Oxymetazoline) was offered to the patient at the discretion of the investigator depending on the symptoms of the patient.

Body temperature and URTI symptoms of patients were followed up for 14 days, whereby URTI symptoms were recorded by using the short version of an illness-specific questionnaire, the Wisconsin Upper Respiratory Symptom Survey (WURSS-21). Response at day 4 was evaluated as primary objective and has been defined as absence of fever and the absence or very mild degree of symptoms (assessed by WURSS-21).

A total of 523 patients aged 1 – 65 years were included in 22 centers in Germany and Ukraine. Inclusion has been stratified according to age groups. 50 % of the included patients were younger than 12 years. Patients’ recruitment took place between November 2010 and April 2011. Response at day 4 differed highly significant in favor of the Influcid-group (mean difference 8.6 %; 95 % CI: 2.9-14.4; p = 0.0018). Significant difference in response persisted until day 11. Simultaneously cumulated dosages, average dosage per day as well as duration of symptomatic medication intake were significantly lower in the Influcid study group. Taking into account its favorable safety profile, Influcid could be a gentle and effective additional treatment option of URTIs.

PP-053

Retrolective study of STW 1 in diseases of the locomotor system in a medical specialist practice

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Degenerative joint diseases are of increasing relevance in an ageing population. The efficacy of STW 1 (Phytodolor®), a fixed herbal combination phytomedicine containing extracts from trembling poplar, common ash and goldenrod, used in therapy of painful diseases of the support and locomotor system has been shown in a large number of clinical studies [1] and also in metaanalyses [2,3].

Aim of the study was to document the use of STW 1 in a specialist medical practice. Using an extensive case report form, data from 300 patients have been included into this retrolective study. Analysis of variance with repeated measures was conducted (SPSS 15.0). 63 % of the patients had a spinal cord syndrome, 28 % gonarthrosis. 72 % of them have been treated with STW 1 (4 x 30 drops), 14 % with diclofenac (75 mg) and 14 % with ibuprofen (600 mg). It could be shown, that symptoms of patients treated with STW 1 improved significantly. This was the case for subjective symptoms, as pressure induced pain and impaired motility, as well as for objective parameters (walking distance, manual force, ascending stairs). The efficacy of
STW 1 (4 x 30 drops) was comparable to or even tended to be better than diclofenac (75 mg) and ibuprofen (600 mg). The improvement of symptoms continued over the whole observational period (up to 18 month). The same was the case with CRP.

Tolerability of STW 1 was distinctly and significantly better than that of diclofenac and ibuprofen, especially regarding gastrointestinal symptoms. With STW 1, no drug interactions or habituation were observed.

These data demonstrate that the phytomedicinal approach, and especially STW 1 (Phytodolor®), has significant advantages over standard NSAIDs in clinical practice, and that its therapeutic potential has often been underestimated in the past. They encourage a broader use of this phytomedicine.

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References:

PP-055

Medical care of patients with moderate depression under hypericum extract STW3-VI (900 mg daily) compared to selective serotonin reuptake inhibitors in routine outpatient treatment – a prospective health services research study in Germany

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Objective: The primary objective of this study was to investigate the effectiveness of a hypericum extract STW3-VI (900 mg daily) therapy compared to any selective serotonin reuptake inhibitor (SSRI) by analyzing quality of life, tolerability, patient compliance and related costs of the therapeutic alternatives.

Methods: A non-interventional, prospective, observational study was performed and the effectiveness of both treatment groups assessed by the “Quick Inventory of Depressive Symptomatology” (QIDS) at different time points. Tolerability was calculated by adverse event (AE) rates. Additionally, effectiveness, tolerability and compliance were assessed on a 5-point scale. To assess the relevance for health economics, a cost-benefit and a cost-effectiveness analysis were conducted.

Results: After 6 months of therapy, mean QIDS values decreased by 8.8 (HE) and 9.7 points (SSRI), respectively, and effectiveness was assessed as very good or good. Tolerability was significantly better for STW3-VI than for SSRI. The incidence of AEs was comparable in both groups. Patient compliance increased in the STW3-VI group at the end of the study. While differences in efficacy were only marginal, the therapy with STW3-VI was more cost-effective and gained more quality adjusted life years (QALYs). This indicates a better cost-benefit relation of STW3-VI when compared to SSRI (based on QALYs and total costs).

Conclusions: Non-inferiority in effectiveness of STW3-VI compared to SSRI was proven. Moreover, significantly superior tolerability and compliance of STW3-VI compared to SSRI
were demonstrated. Thus, the benefit of this more cost-effective phytotherapeutic alternative treatment was confirmed. Disclosure statement: This study was supported by Steigerwald Arzneimittelwerk Darmstadt, Germany

PP-065

Immunomodulatory properties of a lemon-quince preparation (Gencydo®) as an indicator of anti-allergic potency

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Introduction: Gencydo®, a combination of lemon (Citrus limon) juice and aqueous quince (Cydonia oblonga) extract has been used traditionally in anthroposophical medicine for treating patients with allergic rhinitis or asthma. Because there are no reports about the mode of action, we investigated the anti-allergic effects of this preparation in vitro by using cell lines and primary cells in various biological and immunological endpoints.

Materials and Methods: The release of soluble mediators from basophilic cells, mast cells and lung epithelial cells, which are essential for the initiation of early- and late-phase allergic reactions, was analyzed in relation to the synthetic anti-allergic drugs azelastine and dexamethasone. In addition, the impact of Gencydo® on the viability and activation of GM-CSF-activated eosinophil granulocytes was investigated.

Results and Discussion: Gencydo® reduced the degranulation and histamine release of IgE-activated basophilic cells and mast cells and inhibited the IgE- and PMA/A23187-induced increases in IL-8, TNF-α and GM-CSF production in mast cells. The effects were comparable to that of the used concentration of azelastine and dexamethasone. Furthermore, Gencydo® partially blocked eotaxin release from human bronchial epithelial cells, but has no impact on the viability and activation of GM-CSF-activated eosinophil granulocytes.

In conclusion, these results give a rational base for the topical use of Gencydo® in treatment of allergic disorders through the down regulation of soluble mediators, which are essential for the initiation and maintenance of allergic reactions.

PP-071

Toxicity matters: assessment of genotoxicity of herbal medicinal products with a coordinated approach

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**Background:** The fear, that complementary medicines could cause cancer, can be a deeply disturbing cause of concern in both patients and therapists. Therefore, in the European Union the availability of valid data on genotoxicity, which allow the identification of a cancerogenic potential of herbal drugs, is a precondition for the marketing authorisation of herbal medicinal products (HMPs) in traditional or well established use.

**Objective:** In European regulatory guidelines prepared by the Committee for Herbal Medicinal Products, the responsible committee of the European drug regulatory agency EMA, a test strategy has been defined, giving a pragmatic framework on how to assess the potential genotoxicity of HMPs and how to interpret the results.

**Methods:** The procedure begins with the Ames test. In case of a positive result, it is followed by a mammalian cell assay, and, if a still positive result is obtained, *in vivo* genotoxicity tests are performed. In order to reduce the number of extracts of the herbal drug to be tested, a bracketing and matrixing approach has been proposed.

**Results:** According to this test strategy, already genotoxicity tests for 30 HMPs, including e.g. St. John’s wort, caraway, melissa, garlic, ginkgo and hawthorn have been conducted within a joint project of several manufacturers of HMPs, coordinated by Kooperation Phytopharmaka, Bonn, a scientific society in the field of HPMs. The project was performed in accordance with modern regulatory guidelines including those of EMA.

**Conclusion:** The project has broadened the knowledge about the safety of important herbal drugs used in Europe and allows meeting current regulatory requirements. Results are delivered to the cooperation partners for use in regulatory applications and can help preventing unfounded fear of carcinogenicity of the respective HMP. Further cooperation partners are welcome.

**PP-073**

**Acute hepatitis associated with use of green tea and oral contraceptives: a case report**

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The potential health benefits associated with green tea (Camellia sinensis) consumption have been partially attributed to the antioxidative properties of polyphenols, particularly to catechins, among which Epigallocatechin-3-gallate (EGCG) is the most effective. Unfortunately, some reports of adverse effects, mainly hepatitis, associated to the consumption of green tea preparations (extract or infusion) have been published. Case presentation A 42-year-old woman with jaundice was admitted to the Gastroenterology Unit of Careggi University Hospital of Florence. Laboratory analysis revealed total bilirubin level 31 mg/dL, direct bilirubin 21 mg/dL, aspartate aminotransferase, 1447 U/L; alanine aminotransferase, 1618 U/L and a liver biopsy showed hepatocellular necrosis and mixed inflammatory infiltrate. An extensive diagnostic workup discarded any other known etiology for her liver disease. Viral serology for active hepatitis A, B, C, and extensive toxicology
screening were all negative. A detailed history revealed that the patient had been drinking Japanese matcha green tea (micronized water-soluble powder of Camellia sinensis) every other day for 10 days. Green tea was withdrawn and liver functions tests normalized within some months. Discussion Although tea beverages have been consumed for almost 50 centuries, the co-assumption of green tea and oral contraceptive needs to be considered potentially hepatotoxic since being involved in some cases of toxic hepatitis. The mechanism of toxicity of green tea is unclear, the possibility of idiosyncratic, or immune-mediated mechanism, was suggested. Animal experiments and clinical trials have shown some evidence of a green tea interaction with CYP3A4, also mediating the oxidative metabolism of the oral contraceptive. A possible explanation may be that green tea (EGCG) inhibits the metabolic degradation via CYP3A4 of oral contraceptives with consequent increased bioavailability and relative toxicity. This case report could confirm that green tea, even conventional infusions, may induce severe acute mixed liver injury in predisposed individuals. A possible pharmacogenetic predisposition (e.g. green tea/oral contraceptive interaction) as well as possible contaminations during the growth of the leaves or during production of the product were investigated with appropriate techniques. Results of these investigations will be reported in the present communication.

PP-074

Potential interactions between synthetic drugs, herbal medicine and dietary supplements during preoperative anaesthesiological assessment


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Patients who need surgery use herbal medicines (HM) much more often than the general population and adverse reactions were reported frequently during the perioperative period. Here we report results of a survey aimed at evaluating the potential interactions among prescribed drugs, HMs and/or other complementary alternative medications used concurrently by patients during preoperative anaesthesiological assessment. Method The sample population consisted of patients admitted to 3 Tuscany hospitals in order to undergo a surgical intervention. Data were collected by means of a semi-structured questionnaire. Potential drug-herb interactions were identified using Micromedex® database, and through searches of MEDLINE® database. Results On the basis of 478 (83.5 %) entered the analysis according to data quality checking, 238 patients use HRS, fifty-six (23.5 % of 238 )could not be considered because they missed the type of HRs being consumed. Among 182 evaluable patients 174 (95.6 %) were at least exposed to one synthetic medications and natural product concurrently, these were detectable for potential interactions and 55 (30.2 % of 182) were exposed to one potential interaction; 42 with HMs and seventeen with dietary supplements, four both. Univariate models did not show any significant predictors among age, gender, level of education and operator class of risk . Potential interactions that have been identified by our analysis. In our study 18.2 %, (10/55) of patients were exposed to one potential interaction with antiplatelet and anticoagulant drugs; 12.7 %, (7/55) with oral hypoglycemic; 12.7 %, (7/55) with antiarrhythmic and cardiotonic drugs; 20 %, (11/55) antihypertensives; 10.9 %,
(6/55) with benzodiazepines; antidepressants; 7.3 %, (4/55) corticosteroids; 3.6 %, (2/55) thyroid and anti-thyroid hormones. Discussion In the case of prospective surgery or a physical examination to be performed under anaesthesia, the interactions between herbs, drugs, and anaesthetic techniques may be numerous because the high number of active principles contained by certain herbal-based products. Natural products should therefore be subject to careful attention on the part of the anaesthetist, who should determine their suspension if necessary.

**PP-076**

*Anti-oxidative and anti-inflammatory effect of the herbal preparation Canephron®N*

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**Background:** The urinary tract acts as a prominent bacterial port of entry into the human body. Diverse infectious and inflammatory diseases involve tissue destruction induced by oxidative stress and generation of nitric oxide (NO). This study aimed (i) to evaluate the radical scavenging and NO formation - inhibitory activity mediated by the commercial herbal medicinal product Canephron®N (CaN) and its individual components (i.e. Levisticum officinale (LO), Centaurium erythraea (CE) and Rosmarinus officinalis (RO)) and (ii) to correlate the results with the total phenolic contents.

**Materials and methods:** Hydroethanolic extracts (50 % v/v) of CaN, LO, CE and RO were provided by Bionorica SE. The total phenolic contents were determined by Folin-Ciocalteau method, anti-oxidative ability by DPPH assay and the formation of NO in the supernatants of LPS-stimulated RAW 264.7 cells using Griess reagent. Dexamethasone (DEX) at 1 µM concentration was used as positive control. Cytotoxicity was measured by WST-1 assay.

**Results:** In CaN, LO, CE and RO, the total content of phenolic substances equalling 1 mg/ml of gallic acid (GA) was determined as 324, 52, 250 and 586 mg/l, respectively. The phenolic compounds rutin and quercetin produced signals equivalent to 1 mg GA of 632 and 1228 mg/l. The amount of inactivated DPPH was proportional to the total amount of phenolic compounds and is expressed as scavenging concentration 50 % (SC50). In detail, RO possessed the highest anti-oxidant activity (52 µg/µl) followed by CaN (101.7 µg/µl), CE (151.7 µg/ml) and LO (285 µg/ml). Notably, for the antioxidants vitamin E and C and the phenolic substances quercetin and rutin SC50 values of 4.4, 6.8, 8.0 and 35.3 µg/ml, respectively were found. CaN and its components exerted concentration-dependent inhibitory effects on NO formation at non-cytotoxic concentrations (90 % inhibition for CaN and RO at 250 µg/ml). In detail, SC50 values of 107, 115, 247 and 75 µg/ml were found for CaN, LO, CE and RO, respectively.

**Conclusion:** CaN and its single components exert radical-scavenging activity and inhibit the generation of NO. The antioxidant activity correlated with the total amount of phenolic substances (RO > CaN > CE > LO) suggesting that this class of compounds is responsible for this activity. In contrast, for the inhibition of NO formation also other groups of compounds could be responsible.
An investigation on the perception of the risk on the use of medicinal plants commonly used and sold by herbalists in tuscany


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Background: The herbalist represents a professional figure that is responsible for educating and making sure that the patient uses correctly medicinal plants. The objective of the present study was to evaluate the perception of the risk from the herbalists on the use of plants generally used and sold in the herbalist’s shops.

Method: The investigation was conducted “de visu” by means of a questionnaire. For each studied product/plant (Allium, Aloe gel, citrus aurantium, Cimicifuga, Escolzia., antraquinones laxatives, propolis, echinacea, Harpagophytum and Ginseng) and for some specific clinical effects. The herbalist was asked to indicate the exact proportion of risk across a simple Visual Analogic Scale. A group formed by 10 experts in this area was used as a control group.

Results: In this study 159 in 185 herbalists assisted in the inquiry. The herbalists considered plants and natural products more secure in respect to experts, in exception to plants containing antraquinones. Nevertheless, such differences were not statistically significant. With regard to Garlic, the herbalists showed a perception of the general (middle) risk but much lower in respect to the experts (Median: 2.1 and 4.6, respectively). It also emerged that graduated herbalists and herbalists with exception of 10-year-old of working experience had a perception of risk similar to that of the experts. For Citrus aurantium the herbalists were perfectly in line with the experts, considering the general risk being middle of the plants (4.0 and 5.6, respectively) and recognized that the possibility that such plants could give unfavorable cardiovascular reactions. In this case there were differences between the herbalists with more than 10 years of working experience or less. For Cimicifuga it has emerged that the herbalists, in agreement with the experts, considered this plant generally to be of middle risk (3.5 and 4.1 respectively), but did not know the possible unfavorable effects being derived from its utilization, in fact consider gastritis, allergy and liver damages as low risk. Finally, half of the herbalists interviewed reported to having had unfavorable reports of adverse reactions from actual customers. Considering that in 8 years only about 500 reports were obtained from the National Phytovigilance System, the discrete number of adverse reactions reported by the herbalist’s in this study demonstrates that a majority of the signals were generally omitted by herbalists.
PP-078

Similasan® arnica plus spray homeopathic remedy promotes the wound healing of 3T3 fibroblasts in in vitro scratch assay

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Background: Homeopathic preparations of Arnica montana, Calendula officinalis or Hypericum perforatum are frequently used remedies to promote wound healing. While their effect on wound healing using preparations at pharmacological concentrations was supported in several in vitro and clinical studies investigations of herbal homeopathic remedies on the wound healing process are rare. The aim of this study was to investigate the efficacy of the commercial homeopathic remedy Similasan® Arnica plus Spray (Similasan AG, Jonen, Switzerland), an ethanolic (22 % m/m) preparation of Arnica montana D4, Calendula officinalis D4, Hypericum perforatum D4 and Symphytum officinale D6 (0712-2) on the wound healing in cultured NIH 3T3 fibroblasts.

Materials and Methods: We investigated the cell proliferation, migration and wound closure promoting effect of the preparation (0712-2) and its potentized hydroalcoholic solvent (0712-1) on NIH 3T3 fibroblasts. Cell viability was determined by WST-1 assay, cell growth using BrdU uptake, cell migration by transwell chamber assay and wound healing by CytoSelect™Wound Healing Assay Kit. All assays were performed in controlled, blinded manner at least in three independent experiments. In some experiments 22 % (m/m) non potentized alcohol (0712-3) was also investigated.

Results: Preparations (0712-1), (0712-2) and (0712-3) were investigated at 1/10; 1/100 and 1/1000 dilutions. Cell viability was not affected by any of the three substances. Substances (0712-1) and (0712-2) showed no stimulating effect on cell proliferation as measured by BrdU uptake. After 24 h treatment the migrated cells were quantified. The preparation (0712-2) exerted a stimulating effect on cell migration: 31.7 % vs 15 % solvent (0712-1) at 1:100 dilutions (p < 0.05). Positive control 2 ng/ml EGF increased migratory activity of cells by 57.2 %. Substance (0712-3) had no influence on cell migration. Preparation (0712-2) differed significantly from (0712-3), however there was no significant difference between the (0712-1) and (0712-3). The homeopathic remedy (0712-2) at 1:100 dilution showed wound healing promoting effect comparable to the positive control (5 % FCS). Mean wound closure reached 59.5 % by (0712-2) and 63 % at positive control. Solvent (0712-1) caused 22.1 % wound closure and differed significantly from (0712-2).

Conclusions: Our results demonstrate that the Similasan® Arnica plus homeopathic remedy exerted wound healing potential, which is a result of increased ability of fibroblasts to migrate without affecting cell proliferation.
**PP-079**

**Alternative treatments of anorectal fistulas: intrafistular injection of Argentum metallicum/Quarz, a case report**

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An anorectal fistula is an abnormal channel originating from the anus or rectum and usually reaching the skin near the anus though occasionally it can reach other organs, such as the vagina. Anorectal fistulas are common among people suffering from anorectal abscesses, IBD (Chron, Ulcerative Colitis), proctitis \cite{1}. Treatment may involve surgery, but some incruent alternatives are now available. The spontaneous healing of anorectal fistulas in Crohn’s disease, is a very rare event and also pharmacological therapy results often ineffective. We report the case of a 46-year-old woman affected by Crohn’s disease, previously treated with mesalazine, in follow up, seen at our hospital for anorectal fistula. We proposed to the patient an alternative therapy: intrafistular injection of Argentum metallicum/Quarz. The patient was assessed with rectoscopy and echo-endoscopy, repeated also after the treatment.

Our purpose was to find new non-invasive alternative treatments to heal non-complicated anorectal fistulas. After a six months treatment, with a single weakly intrafistular injection of the drug, we observed the complete closure of the fistula and no side effects. The results of this experience seem very promising. From those findings, although only a single case has been treated, we consider this procedure worthy of attention and we plan to continue to treat a larger number of patients.


**PP-084**

**Selenium for the primary prevention of Alzheimer’s disease**

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Alzheimer’s disease is the most common form of dementia. Globally, there are 35.6 million people with dementia in 2010, with the numbers more than tripling by 2050. This highlights the need for effective treatment and prevention. Selenium is an essential trace...
element with multiple biological functions including crucial roles in many anti-oxidant enzymes. Increasing evidence suggest that an appropriate dietary intake of selenium may be crucial for healthy ageing and an important player in Alzheimer’s diseases. Therefore, we conducted a systematic review on the literature to answer the question whether selenium supplementation may be beneficial for preventing or treating age-associated cognitive decline or Alzheimer’s disease.

We identified 9 placebo-controlled studies (6 were multiple supplement trials including Se, 1 was ongoing), 4 prospective, 4 cross-sectional, 15 case control, 24 autopsy studies and as well studies in animals and cells. In total, our review shows that the current state of knowledge provides no evidence for a role of selenium in the treatment of Alzheimer’s disease, but allows speculation on a potential preventive relevance. This is substantiated by evidence from molecular biology, leading to a mechanistic model of the role of selenium in Alzheimer’s disease. In light of the subclinical deficiency of selenium which is assumed for Germany, Switzerland and other countries, our findings suggest that an appropriate diet of selenium may play a relevant role if one aims to reduce the future rise in the prevalence of Alzheimer’s disease.

PP-097

Cold pressed and essential oils in treating psoriasis vulgaris


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Objective: Psoriasis is a chronically often genetically determined skin condition. It appears in the form of clearly encircled plaques of different shape and size, reddish in color, covered with whitish layers.

Aim: To establish the efficiency of the usage of cold pressed and essential oils in treating psoriasis vulgaris.

Material and Methods: Volunteers are carefully watched for a year. Each examinee is familiarized with the protocol of the study and is asked for written approval. The protocol prescribes that at the beginning and at the end of the research, lab analysis should be done and photos of the skin changes should be taken and also the data about the sex, age etc should be recorded for later statistical processing. The remedies-cold pressed and essential oils produced in a natural way and by nanotechnology (by the firm Linum, Conoplja, Serbia) are given to the patients to be used in two ways: orally (combination of nut and sesame cold pressed oil) or by application onto the skin all over the body, the face, and the scalp (combination of macerate and cold pressed linseed oil with addition of lavender essential oil). All the examinees are explained the importance of adequate nutrition – no animal proteins during the treatment. The treatment lasts for three months with check ups every 14 days, and then check ups every 30 days for the following 9 months.

Results: Here we present the case of a patient with Psoriasis vulgaris, 36, treated by a remedy on cold pressed linseed oil basis by application onto the skin (which originally was supposed to be taken orally 3x1 teaspoon daily, but because of the hard taste it has not been used in that way).

Conclusion: Positive results in treating the shown case encourage us for further researches and usage of this kind of treating the patients with psoriasis.
Stress and the stomach: the effect of a herbal medicine, STW 5, in a pharmacological model of stress-induced functional dyspepsia

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Psychological factors, especially stress, are known to play an important role in functional gastrointestinal diseases. Based on the good correlation between stress and functional dyspepsia (FD), different animal models for FD have been developed. Animals subjected to psychological stress either during the neonatal period or in adulthood were found to develop gastric motor dysfunction resembling symptoms of FD. In the present study, two models for stress-induced functional dyspepsia were performed in order to choose the more adequate one for testing sensitivity changes of the fundus to various mediators and the effects of treatment with STW 5 (an herbal combination preparation) on the observed changes. In one model, maternal separation (1) was performed on weanling rats starting from postnatal day 2 for 3 h each day for 3 weeks. Rats were then allowed to mature to an adult age. The other model was that of restraint stress (2,3). Adult animals were restrained for 90 min/day for 1 week. The animals of both models were eventually sacrificed, the stomach fundus was isolated and its sensitivity in vitro to carbachol, potassium chloride, serotonin and adrenaline was tested. The sensitivity of the fundus strips from restrained rats towards these agents, partly representing autonomic responsiveness, was more depressed than those from maternally separated ones. That model was therefore chosen to test the efficacy of STW 5 in restoring sensitivity to the agents mentioned. A group of animals received STW 5 orally once daily for 2 weeks before subjecting them to restraint stress. Treatment with STW 5 was effective in normalizing the depressed responses exhibited by animals subjected to restraint stress. Samples of blood were taken to assess levels of CRF and ghrelin. The findings throw further light on the mechanisms underlying the therapeutic usefulness of STW 5 in functional dyspepsia, especially when triggered by psychological stress.

References:

A systematic review of the effects and working principles of Citrus/ Cydonia comp. for seasonal allergic rhinitis

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Abstracts/ECIM 2011/Poster Presentations/VARIOUS TOPICS – PHYTOTHERAPY II

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Background: Citrus/ Cydonia comp. is an anthroposophic medicine that has been prescribed for seasonal allergic rhinitis (SAR) for more than 85 years. Several case reports, surveys, in-vitro studies, cohort studies and a randomized trial have been executed to study the clinical and immunological effects of Citrus/ Cydonia comp. on SAR. In addition, by using the Goethean phenomenological method, qualitative studies on the working principle of the remedy have been performed. However, until now a review of all the evidence on the effects is lacking. In addition, the qualitative results of the study on the working principle have not been tested.

Objectives: The first objective is to provide a systematic review of the current (quality of the) evidence of the clinical and immunological effects of Citrus/ Cydonia comp. on SAR. The second objective is to give an overview of and subsequently test the results of the qualitative studies on the working principle of the remedy by comparing them to the results of the empirical outcome studies.

Methods: For the systematic review on the effects we performed a relevant literature search in databases (e.g. PubMed, Google Scholar, Internet) on (combinations of) search terms: Citrus, lemon, Cydonia, quince, Gencydo, (seasonal) allergic rhinitis and hay fever. After selecting the studies (population, intervention, outcome and study design) a quality assessment was performed and the evidence was summarized. Categorization of the body of evidence was performed by using the GRADE categories. For the study on the working principle at first we searched and subsequently reviewed the relevant literature. Then we compared the qualitative results to the empirical clinical and immunological effects to determine the accordance between qualitative and empirical results.

Results: Since the study is not finished yet, the results will be presented at the congress.

Conclusion/ discussion: Implications of the results for both clinical practice and scientific research will be presented.

PP-128

Efficacy and safety of a herbal formulation in benign prostatic hyperplasia: a single blind, randomized, placebo controlled study

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Benign prostatic hyperplasia (BPH) is a condition intimately related to ageing. Currently available treatment options for the management of BPH have various limitations and associated adverse effects. A polyherbal formulation is claimed to be beneficial in patients with benign prostatic hyperplasia. This single blind, placebo-controlled study evaluated the clinical efficacy and safety of polyherbal formulation in BPH.

Material and Methods: A total of 60 patients who were diagnosed as BPH and who were willing to give informed consent were included in the study. At the randomization visit, a detailed medical history was obtained and the patients underwent a thorough systemic examination and digital rectal examination. Routine blood, urinalysis and serum levels of
prostate specific antigen were carried out. Abdominal pelvic ultrasonography was done at entry and after completing. The severity of the urinary parameters was evaluated using American Urological Association symptom score. Patients were randomized using random table into either polyherbal group (n = 30) or placebo (n = 30). Each patient received either polyherbal formulation or placebo in a dose of 2 capsules twice a day with meals for two months. All adverse events reported by the patients or observed by investigators were recorded. Statistical analysis was done according to the intention-to-treat principles.

**Results:** Fifty-six patients completed the study. There was a significant improvement in the mean AUA symptom score, PVR urine volume urinary hesitancy, intermittent flow, straining during urination, sense of incomplete micturition and frequency of night-time urination, in the polyherbal formulation group. Four patients from the placebo group withdrew from the study due to lack of benefit to the treatment.

**Conclusion:** The beneficial clinical efficacy of polyherbal formulation observed in this study in the management of BPH could be due to the synergistic actions of its potent herbs. This polyherbal formulation was well tolerated, effective and safe.

**PP-130**

Use of a multivitamin, mineral and herbal supplement to improve memory, mood and stress

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With aging of the world population, there is demonstrated age-associated cognitive decline and a rising prevalence of depression and anxiety. Population studies show that vitamin deficiency, cardiovascular disease, elevated homocysteine and cellular metabolic dysfunction are risk factors for cognitive decline, dementia and other pathological conditions of aging. Growing evidence indicates that dietary supplementation and selected vitamins and minerals may improve risk parameters and consequently improve cognitive function. A series of experiments have been conducted investigating the role of nutrients and herbs on mood, stress, memory and cognition: 1. The effects of a multivitamin/mineral/herbal supplement on mood and stress in a group of healthy older male volunteers. This RDBPC trial of 50 men, aged 50-69 years were supplemented for a period of 8 weeks. 2. A RDBPC trial was undertaken to investigate the effect of 16 weeks multivitamin (at levels above recommended daily intakes)/mineral/herbal supplement on cognition in 56 elderly women. Cognition was measured with a battery of memory and attention tasks designed to be sensitive to age-related reduction to fluid intelligence plus a measure of verbal recall. Biochemical measures of a number of nutrients, homocysteine, markers of inflammation, oxidative stress and blood safety parameters were carried out. Results were assessed at baseline and after 16 weeks of treatment. 3. Role of Pinus radiata bark extract formulation. A RDBPC study investigated the effects on cognitive performance of a 5 week supplementation with Enzogenol\textsuperscript{®} Pinus Radiata bark extract containing flavonoids\textsuperscript{53}. Forty-two males aged 50-65 years with a BMI > 25 were studied. This series of studies have demonstrated that a multivitamin/mineral/herbal supplement a) May improve alertness, reduce depression, anxiety and stress in non-depressed
older adults b) May benefit memory performance in elderly women of risk in cognitive decline c) Pinus radiata bark extract can improve cognition in elderly men.

PP-189

Integrative medicine with Ayurveda in a general practice for 25 years - ethical background and cost effectiveness

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Many doctors suffer from burn out syndrome. One reason besides long working hours may be the load of work not connected to the doctor’s original aspiration when starting to study medicine and to the background developed in medical education. The traditional Ayurvedic literature gives an ethical background for working in a relaxed manner and in accord with the innermost desire of the doctor to bring true health to the patient. These texts give the advice that the doctor has to first take care of himself in terms of knowledge, continuous medical education and personal health in order to be an example to his patients. Some of the most important suggestions from the texts are given.

One factor that is very important for the effect of greater job satisfaction is that Ayurveda is health oriented as opposed to modern medicine that is strictly disease oriented.

Ayurveda was integrated in a General Practice 25 years ago. This model is successful on several levels: on the level of income for the doctor, on the level of medical outcome for the patient and on the level of cost effectiveness for the public health insurance. Statistical material is presented to support this outcome. Examples of the clinical diagnoses most frequently and successfully treated in general practice are given, also a glimpse of the patient categories coming for ayurvedic and integrative treatment.

If time allows, a few case studies can be given.

PP-194

The safety of fennel tea: epigallocatechin gallate and phenolic compounds discovered in fennel tea inhibit estragole toxicity

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The alkenylbenzene estragole is a natural constituent of several herbs including fennel, basil, anise, and tarragon; it is also present in food as a result of the addition of essential oils as flavoring agents. Estragole has been shown to be hepatocarcinogenic in rodent species at high-dose levels. Translation of these results into the likelihood of formation of DNA adducts, mutation, and ultimately cancer upon more realistic low-dose exposures remains a challenge. Safety of fennel tea especially during pediatric age is particularly debated. The main active constituents of fennel, which include anethole and other terpenoids are found in its volatile
oil. They may inhibit spasms in smooth muscles, such as those in the intestinal tract and in fact is used in treatment of dyspepsias such as mild, spastic gastrointestinal afflictions, fullness and flatulence.

Estragole is not directly toxic but it must undergoes 1’-hydroxylation by cytochrome P450 enzymes. Further bioactivation to 1’-hydroxyestragole requires the involvement of sulfotransferases converting 1’-hydroxyestragole to 1’-sulfooxyestragole, which is unstable and degrades in aqueous environment to a reactive carbocation that is capable of binding covalently to different nucleophilic molecules including glutathione, RNA, and DNA. The results of our original research performed by PROSAD innovative technology, demonstrated by means of liquid chromatography-mass spectrometry the discovery of two new important constituents in fennel tea, epigallocatechin gallate and nevadensin (waiting definitive confirmation) that at very low concentrations inhibit estragole toxicity by interference with sulfontrasferases.

The presence of fennel tea epigallocatechin gallate was confirmed by tandem MS / MS and MSN. Safety of fennel tea is based on: a) absence of any human clinical and epidemiological toxicity of estragole; b) presence of more substances with anticancer and chemopreventive activities, such as quercetin, anethole and limonene; c) inhibition of estragole bioactivation by epigallocatechin gallate and its phenolic compounds.

**PP-214**

*St. John’s wort extract: activity in psychic stress*

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**Background:** Psychic stress is a widespread problem with high socioeconomic impact and may even trigger psychic depression. The St. John’s wort extract STW 3-VI (SJW) is effective as a phytotherapeutic agent for the treatment of mild to moderate depression, as has been shown by clinical studies [1,2], and confirmed by a recent Cochrane metaanalysis [3].

**Method:** For other antidepressants an impact on psychic stress is known. Therefore a systematic review of publications on relevant mechanisms of action of this extract has been conducted.

**Results:** In a study in the open field model of acute psychic stress in mice [3], stress-induced hyperthermia was used as main parameter. Treatment with SJW (250 and 500 mg/kg b.w., p.o.), with several of its flavonoid constituents, and with diazepam (5 mg) as a positive control, significantly antagonized stress reactions. A second study [4] has been conducted in a chronic restraint stress model in rats (1h for 21 consecutive days), with SJW (250 and 500 mg/kg; p.o.) and fluoxetine (10 mg/kg, p.o.) significantly improving open field activity and biochemical parameters, which had been impaired by stress. In this study [5] hypothalamic and hippocampal tissues were analyzed using a gene chip (Affimetrix Rat Genome 230 2.0), showing that stress is differentially regulated genes in comparison to the control group, whereas treatment with fluoxetine in stressed animals and treatment with 250 mg/kg and 500 mg/kg differentially influenced several pathways providing a link to the pathogenesis of stress and depression.
**Conclusion:** The results point to a potential usefulness of SJW not only in depression, but also in the prevention and treatment of psychic stress.


**PP-215**

**Antidepressant effect of willow bark extract and its fractions**

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**Background:** While the anti-inflammatory and analgesic properties of willow bark (WB) extracts are known since a long time [1], additional antidepressant effects have been suggested only recently [2]. To understand these effects and their underlying potential mechanisms of action, the dose-effect relationship of WB extract STW 33-I (Proaktiv®) and four fractions separated by polarity [3] was studied in the Porsolt Swimming Test (FST), the locomotor activity and the serotonin metabolism of the brain in rats.

**Methods:** Male Sprague Dawley rats (n = 6/group) were treated for two weeks once daily per os with STW-33-I (15, 30, 60 mg/kg b.w.) and with fractions in comparison to vehicle and imipramine (20 mg/kg b.w.). On day 15 the FST and locomotor activity were monitored. After further four days, neurotransmitter concentrations were determined in frontal cortex, hypothalamus, hippocampus and striatum.

**Results:** A significant shortening of the cumulative period of immobility was seen after treatment with 15, 30, 60 mg/kg b.w. of the extract, with the strongest effect (48 % reduction) with 30 mg/kg, while higher doses were ineffective. Locomotor activity was not increased, allows the conclusion on an antidepressant effect. The effects of the fractions were best in doses equivalent to the lowest extract dose tested. The aqueous fraction in a dose as low as 1.5 mg/kg was more effective than imipramine, 20 mg/kg b.w.. In addition, significant effects on 5-HT levels in the hippocampus were found.

**Conclusion:** The WB extract STW 33-I showed an antidepressant effect in doses even below those known to have anti-inflammatory effects. This could be of relevance for its clinical efficacy in musculoskeletal pain.

**Dedication:** This contribution is dedicated in memoriam to Prof. Dr. Hilke Winterhoff, Institut für Pharmakologie und Toxikologie, Westfälische Wilhelms-Universität, Münster, Germany, who passed away on May 9, 201.
Evidence for efficacy and effectiveness of the MORA bioresonance method in smoking cessation

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\textit{Background:} For more than thirty years MORA bioresonance therapy (classical bioresonance therapy) is used by naturopathic practitioners all over the world for a broad range of indications (e.g. allergic diseases, rheumatic diseases). Since 2007 until today (2011) one of the authors (EI) applies this therapy concept in his clinic for smoking cessation, and assesses its practical effectiveness at the same time. Over the course of one year (2008 until 2009) the Faculty of Medicine of the University of Istanbul (Department of Pulmonary Diseases) verified in a clinical trial the efficacy of the MORA bioresonance method for smoking cessation as well. None of the scientists in this study had any previous experience regarding the device’s use and respective method.

\textit{Patients and Methods:} In the retrospective, non selective, uncontrolled study of EI 4733 participants were treated with the bioresonance method and evaluated accordingly (including drop outs). The main outcome was the rate of smoking cessation for: One week, one month and three months after therapy start with bioresonance. In the prospective, placebo controlled, randomized and double-blind study of the Faculty of Medicine 189 participants were treated with bioresonance in the same manner of EI’s study. The main outcome was the rate of smoking cessation for: One week, two weeks, one month and one year after therapy start with bioresonance. The smoking anamnesis and basic demographic characteristics were documented in both studies.

\textit{Results:} In the uncontrolled study the rate of smoking cessation after one week was 80.1 \%, after one month 62.1 \% and after three months 48.2 \%. The results of the placebo controlled double blind study regarding the smoking cessation rate in the active bioresonance group (respectively the sham bioresonance group) were: 77.2 \% (rsp 54.8 \%) after one week (p = 0.001), 62.4 \% (rsp 34.4 \%) after two weeks (p < 0.001), 51.1 \% (rsp 28.6 \%) after one month (p = 0.002) and 28.6 \% (rsp. 16.1 \%) after one year (p = 0.04).

\textit{Conclusion:} Two complementary studies show evidence for significant efficacy respectively a high practical effectiveness of the MORA bioresonance therapy in smoking cessation.
Eurythmy therapy for essential hypertension - a pilot study

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Introduction: Although eurythmy therapy (ET) has been used amongst others in the treatment of hypertension (HT) for more than 80 years, there are as yet no studies on its effectiveness on this type of disease. However, it has been shown that ET can increase HRV compared to ergometric training. High HRV is considered to be a predictor of reduced cardiovascular mortality.

The objective of the study: Does 10-week ET impact HT? What is the extent of the effect? The study also explores the impact of ET on State-autonomous Regulation (S-aR), Self-regulation (SR), Internal Coherence (ICS) and Quality of Life (HLQ).

Methods: Consecutive inclusion of 9 subjects (6 f, 3 m, 64 years, SD 8.26) with essential HT via GP surgeries. Inclusion criteria: Constant RR medication from 4 weeks before the start of the study until the end of the study. ET is carried out daily for 10 weeks, with weekly instruction as well as a home based programme with 6 defined exercises. 24 hr RR is measured and patients are given the inventory questionnaire both before and after the intervention.

Results: Parameters of the 24 hr RR measurements show a likely but not significant improvement (e.g. mean arterial pressure Z = 1.07, p = 0.28). Improvements have been measured for S-aR, especially for the subscale on “rest/activity regulation”, for SR and for the subscale “initiative and interest” of the HLQ (all Z >-2.023; p < 0.045). The ICS does not improve significantly (p = 0.12). Patient documentation shows improvements in such as vitality, motivation and equilibrium.

Conclusion: A 10-week ET does not result in a significant improvement in blood pressure. Despite the small group size, S-aR, SR and the subscale “initiative and interest” of the HLQ improve significantly. 8 out of 9 patients continued with ET of their own accord after the end of the study, which shows high patient satisfaction. It remains to be seen whether significant improvements in HT can be achieved with larger group size or longer therapy period respectively.

PP-045

Effects of dance as primary prevention and health promotion program

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Abstracts/ECIM 2011/Poster Presentations/VARIOUS TOPICS – THERAPEUTIC METHODS

**Background and Objective:** Dance (movement) therapy is defined as ‘the psychotherapeutic use of movement as a process which furthers the emotional, social, cognitive, and physical integration of the individual’. It is believed to have a positive impact for people with social, physical or psychological impairments. Our objective was to assess the effects of dance as a primary prevention and/or health promotion program for adults and children in comparison with other programs or no intervention (e.g. waiting list).

**Methods:** A systematic search was carried out in the electronic databases MEDLINE (Pubmed) and PsycINFO for the time period 1995-2011. References of all identified articles were screened. In addition, a hand search was conducted in further journals and dance therapists were contacted for supplementary and also unpublished studies. All interventional and observational study designs, published in English or German were considered. For randomized control trials (RCTs), the quality of the studies was assessed by the Jadad Scale.

**Results:** Out of the 7 identified studies, 5 were RCTs with patient samples ranging from 37 to 101 persons. They came predominantly from the USA (n = 3) and examined the effects of dance as primary prevention for adipositas in childhood (n = 1), reduction of cardiovascular risk factors (n = 2) and improvement of quality of life (n = 2) in elderly. Four RCTs were of good quality (Jadad Score 4); most studies used established validated instruments for outcome assessments. Dance (movement) therapy had a positive impact for socially weak girls, improving daily activities and decreasing bodyweight as well as for elderly, decreasing psychological distress and increasing quality of life. Folkloric and aerobic dances improved balance and coordination in elderly. Overweighted patients showed a higher motivation to participate in activities after the study program.

**Conclusion:** There seems to be some evidence that dance (movement) therapy and folkloric dances are beneficial in primary prevention, particularly for socially weak girls and elderly with higher cardiovascular risks. However, further research, especially RCTs with larger sample sizes, longer treatment periods and active control groups, are needed to gain more profound insight into the efficacy of dance therapy for primary prevention and health promotion programs.

**PP-047**

**Bodily experiences in various systems of treatment among patients with breast cancer**

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**Background:** Women diagnosed with breast cancer are frequent users of complementary and alternative medicine (CAM). They often have complex reasons for, and experiences from, their use of CAM. The meaning and importance of bodily experiences with regard to patients’ treatment choices are so far almost unexplored elements in CAM use.

**Objective:** The aim is to explore bodily experiences among women who were using CAM as a supplement or alternative to conventional treatment (CT) during their breast cancer continuum. The research question to be addressed is: What is the meaning and importance of bodily experiences among women diagnosed with breast cancer who are users of CT and/or alternative therapies?
Abstracts/ECIM 2011/Poster Presentations/VARIOUS TOPICS – THERAPEUTIC

METHODS

Material and Methods: A mixed qualitative design was chosen. We had access to a material of 19 Norwegian and Danish breast cancer patients who had reported positive experiences from the use of CAM during their cancer trajectories. Document analysis of text data from the 19 women was used as a basis for strategic sampling. Ten of these women were selected for semi-structured interviews, while three were selected for a focus group interview. Four of the 13 selected women had decided to use alternative therapies as an alternative to CT at the start, while nine decided to use CAM as supplement or alternative to CT at various stages of their cancer trajectories. Three of the women used CAM recommended by their oncologists.

Results: Bodily experiences and embodied knowledge were of vital importance to the women in the material both before medical diagnosis and as users of CAM as an alternative to CT. The women using CAM as a supplement to CT related to bodily experiences and embodied knowledge, as well as to medical expertise based on knowledge from effect studies of bodies of unfamiliar others. Bodily experiences and embodied knowledge was important in their communication with doctors with regard to their choice and use of CT.

Conclusions: The results suggest that bodily experiences were particularly important when the women where positioned outside conventional health care prior to medical diagnosis and as users of CAM as alternative to CT. Based on the empirical patterns, we introduce three modes of embodiment with regard to bodily experiences and the use of CAM: the body as a right, a gauge, and a guide. Cancer patients’ positioning between various systems of treatment should be further explored from a bodily perspective to safeguard and optimize patients’ treatment choices.

PP-066

Integrated clinical Evaluation of traditional Chinese medicine and conventional medicine on diabetic patients

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Introduction: In traditional Chinese medicine (TCM), examination of the tongue plays an important role in diagnosis. The characteristics of the tongue (e.g., color of the tongue body, tongue fur, teeth-marked tongue) provides some clues and prognosis, which are considered a reflection of the body’s internal condition. Diabetes mellitus is a metabolic disorder of hyperglycemia, which lead to damage the kidneys, eyes, nerves, blood vessels, and heart. Long standing hyperglycemia can also be associated with buccal alteration. The purpose of this study was to survey on tongue image associated with type 2 diabetic mellitus.

Methods: High resolution digital camera was used to record tongue images in standard imaging environment. Participants were divided into two groups. A total of 166 subjects with DM (n = 119, M/F = 56/63), and healthy group (n = 47, M/F = 14/33) were included for tongue examination in order to clarify tongue characteristics. Tongue characteristics are tongue body, tongue color, fur, fur color, blood stasis, and dry tongue or not. Some of DM patients attended the Quality-based Payment Program for Diabetes Care and others didn’t. HbA1c and other healthy marker were monitored.

Results: The average ages of the diabetes group and healthy group were 61.9 ±11.2 years and 38.8 ±13.7 years. DM patients have some significant characteristics including enlarged
tongue (p = 0.042), yellow coating (p < 0.001), thick fur (p = 0.001), slimy fur (p < 0.001), and dry mouth (p = 0.034). Instead, xerostomia or red tongue (p = 0.139) was not significantly revealed in our observation. Diabetic patients received medical care from coordinated team have lower HbA1c than non-receiving Quality-based Payment Program for Diabetes Care (HbA1c 7.21:8.06, p = 0.04). In total of 119 DM patients have most common co-morbidity in cancer, hypertension, and hyperlipidemia.

**Conclusion:** These findings suggest that yellow coating and thick fur could reflect an abundance of inner heat in diabetic patients. However, blood stasis in diabetic patients would be attentive because of its vascular complications. There may also be a potential role for the tongue examination and other TCM diagnostic tools in identifying DM patients.

**PP-086**

**Integrative approach of assisted reproductive technology (ART) techniques and Traditional Chinese Medicine (TCM)**

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In 2004 the assisted reproductive medical department of the university hospital of Bonn integrated a practice for tradition Chinese medicine (TCM) in their department to treat several patients complementary. Since that time the amount of patients constantly grew, so that in 2010 a second physician was included in the practice. The call for integrative treatment seems to be connected with the demanding physical and psychological effects of the reproductive medicine and the relatively low success rate (10-30 %) in elderly woman undergoing ART (assisted reproductive technology). Data concerning the enhancement of integrative treatment is under evaluation. Furthermore under integrative treatment side effects of Gonadotropin stimulation, such as: headaches, sleeping disorders, mood swings, tiredness, distension of lower abdomen and/or breasts can be reduced or avoided.

In Order to create a quality standard in integrative medicine and ART/TCM the “Deutsche Gesellschaft für Reproduktionsmedizin- DGRM” (German society for reproductive Medicine) started in 2009 in cooperation with several specialists – including: Franziskus Sulisty o, Stefan Englert, Tanja Emde and Kerstin Friol – a postgraduate training for practitioners of traditional Chinese medicine. During the one year training physicians are undergoing a detailed education in TCM and ART and the integrative approach of both. After passing the final exam the participants will be named on the DGRM's web page.

**PP-096**

**Colitis ulcerosa – integrative treatment**

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**Objective:** The research paper describes a many-year medical treatment of a girl, between the age of fifteen and twenty-three. The girl comes from the divorced and feuding parents.

**Aim:** In the course the illness’s progression and the application of the various treatment’s methods, one gains an insight into the personality disorder and psychosomatic dynamics of the pathology.

**Methodology and the results:** In the course of the initial two and a half years of her illness, the girl had been ineffectually treated by the immunosuppressive therapy against the Colitis Ulcerosa. She was given 10 blood transfusion units, but in spite of that, she was still having between five and ten painful blood-filled stools a day. Once an excellent student, she soon abandoned her regular education. She was then treated by 10 cycles of Micro resonant therapy (MRT), each ten-day-long, so the bleeding was halted during the very first cycle. However, each of her return from her father to her mother resulted in a recidivism, due to which a colostomy was applied. At a later stage was developed the depression with a suicidal tendency. Treated by a psychotherapy and antidepressive medicaments, the girl succeeded to improve her family relationships, resume her part-time education and enroll in the graphic studies. However, the intensive fears, forced actions and hallucinations significantly decreased only by the administration of a homeopathic therapy.

**Conclusion:** A complex symptomatology of the Colitis Ulcerosa required the application of classic medicamentosa, surgical therapy and psychotherapy, MRT and homeopathic therapy so that the patient could gradually abandon psychosomatic pathology, improve her personal betterment and social adaptation after the dramatic progress of the illness.

**PP-103**

**Influence long term microwave radiation (MW) from mobile phone on some tissue of rats**

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In this paper analysed effects long term electromagnetic radiation from commercial mobile phone on tissue rats. Especially analysed influence on two organs: brain and liver.

Experiments were performed on 84 adult male Wistar Albino rats (6–8 weeks old, 150 g), bred at the Vivarium of the Institute of Biomedical Research, Medical faculty, Nis.

We formed four experimental groups. Each group consisted of 21 animals, situated in 3 cages by 9 animals in each. I group (control)-animals treated by saline, intraperitoneally applicated everyday during follow up, II group (Mel)-everyday treated rats with melatonin (2 mg kg–1 body weight i.p.), III group (MWs)-MWs exposed rats, IV group (MWs + Mel)-MWs exposed rats treated with melatonin (2 mg kg–1 body weight i.p.) The animals were exposed by MW for 20, 40 and 60 days (4 h/day during light period). The MW was produced by a mobile test phone (NOKIA 3110) connected to a Communication Test Set with PC and appropriate software module. MW exposure was performed in the same room where all animals were housed. Mobile phone, as a source of MW radiation an electromagnetic near-
field signal for GSM at 900 MHz was used. Electrical field was estimated from $E = 9.88 \text{ V/m}$ to $18.356 \text{ V/m}$ and magnetic field $B = 4.68 \mu\text{T}$ to $8.69 \mu\text{T}$. The whole-body SAR was estimated as $0.043\text{–}0.135 \text{ W/kg}$. For electromagnetic simulation are applied FDTD which solves Maxwell’s equations in the time domain. Authors used model of phone and voxel model of rats to determine components of electromagnetic fields in rat’s tissues and SAR. This fact correlated with biochemical result of experiments.

MW significantly decreased thymocytes’ proliferation, induced by ConA ($p < 0.01$) and increased apoptosis, detected using the Annexin V-FITC/PI detection kit ($p < 0.001$). DNA fragmentation in exposed thymocytes is probably triggered by the increase activation of alkaline-DNase I and acid-DNase II ($p < 0.05$). Melatonin was found to be effective on MW induced injury of thymocyte: (1) increase thymocyte proliferation ($p < 0.05$), (2) decreased apoptotic rate of thymocytes ($p < 0.001$), (3) decreased DNase I and DNase II activity ($p < 0.01$).

**PP-105**

**Sexual weakness and infertility: mind-body traditional Israeli medicine**

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Israel is known for a variety of medicinal plants, extremely rich with some 2,700 flora species, those have been used for centuries. Among Arab and Jewish villages coexist ethnic groups which still use traditional folkloric medicine, mainly based on native plants. During the 20th century, Jewish immigration particularly from Yemen and Morocco brought folk remedies and natural medicine with them. However, most of the professional practitioners of traditional medicine remaining today are local Arabs, Druses and Bedouins. Personal ethnobotanical surveys conducted on traditional medicine in the region reveal current knowledge for the use of local plants for treating infertility and sexual weakness both in women and men.

Treating and preventing infertility are significant in the Middle East as women’s social status is closely related to their procreation potential. Childbirth and rearing are regarded as family commitments and not just biological and social functions. The Druses, who live on mountain Hermon, have used the root of "Zallouh" (Ferula hermonis) for generations. They claimed that both men and women can benefit from its aphrodisiac and stimulating properties and that elderly people find it particularly energizing and revitalizing. Also, Camelthorn "Akol" root (Alhagi maurorum) considered as a sexual stimulant and aphrodisiac, mainly for young men. The fruits of Mandrake "Yabrouh" (Mandragora autumnalis), also called love apples, were believed to increase women's fertility for containing estrogen like substances. Furthermore, Date palm "Tal' al nakheel" (Phoenix dactylifera) have been cultivated in the Middle East for over 6,000 years. Their pollen grains have been used by local Jewish healers to improve women's fertility and considered a tonic and aphrodisiac. Moreover, it was scientifically proven that date palm pollen seems to cure male infertility by improving the quality of sperm parameters. Thus, folkloric medicine in the region provides a natural solution for common cases of infertility and sexual weakness by the use of local medicinal plants.
PP-117

The global patient's illness representations as a dialectic referent: analysis of the articulation of a plurality of voices in a Canadian integrative health care clinic

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In the past decade, North America has witnessed the emergence of integrative healthcare (IHC) clinics, in which practitioners of different clinical backgrounds (alternative and biomedical) offer “holistic care” in a spirit of cooperation centered on the “whole person”. Despite a growing research interest on this kind of organisation, no study has yet to analyze in situ the negotiation of viewpoints in the IHC process, taking into account the patient's illness representations, and even less to situate this dynamic in its sociocultural context.

During a field study in a Canadian IHC cooperative, grouping together 14 alternative and biomedical practitioners, the therapeutic experiences of 15 participants were examined. The objective of this study, in addition to its ethnographic dimensions, was to identify and analyze the factors that either foster or impede articulation of viewpoints in an IHC process centred on the person. The conceptual framework, with its innovative dynamic use of individual explanatory models (iEM) and semantic networks concepts, made it possible to analyze the interaction between the perceptions of the actors involved in the health care process.

The data analysis show that the patient’s illness representations could provide to practitioners a dialectic referent thus reducing some constraints relating to idiomatical and epistemological diversity encountered in these types of organizations. One of the theoretical contributions of this study is that it refines our understanding of the concept of iEM stressing, among other things, their polymorphic nature. We propose a concept of plurivocality to illustrate that patient may use a "plurality of voices" and embody "different characters", according to the context in which they "tell the story" of their illness. The overall analysis of this plurality may illustrate complementarities between discourses, offering a global overview of the needs of individuals and their experience of illness that might be at the base of the IHC process.

Beyond the fact that it’s in keeping with a central postulate of IHC, recognizing the importance of the patient’s viewpoints also appears to facilitate the transition from multidisciplinary to interdisciplinary team work, a fundamental process for development of this new care paradigm.

PP-126

Network chronic bowl disease first community and integrative research concept

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Network chronic bowl disease First community and integrative research concept In Herne specialists of gastroenterology, gynaecology, rheumatology, surgery and further more
combined with general practitioners and their patients for a network. The network tends to spread knowledge and arise new scientific outcome all together with the patients, who should become experts for their own disease. First steps taken, are going to be “Case-conferences” among committed doctors, a health record in the patients ownership, patient seminars and a conference addressing all persons involved in the network. 112 patients with chronic bowel disease between 19 and 70 years of age, 59 female and 53 male, have declared to become a member of this network. A survey taken with the HADS-form determined the extent of anxiety and depression. Evaluating 57 forms until now resulted that one third of all interviewees suffers from anxiety, and 12 % suffer from depression. Pilot project patient seminars A five evening patient seminar was realized as a pilot project. It pursued an integrative strategy. The seminar focused on the patient’s self-experience and experiencing self-regulation by the patients in combination with the information of somatic experts. Due to this attitude it was supported by doctors from a wide spread of disciplines. In these points the seminar differs from a disease centric self-awareness group or a self-help group. Predominantly the attendees depicted disturbance in their life quality depending on anxiety for bad smelling (ablutomania with loss of social achievements), diarrhoea, job loss, poverty and side-effect of new therapies. Evaluation results Eight attendees answered a poll taken with the HADS-D-form before and after the seminar. Prior to the seminar the anxiety scale value of 5 attendees was noticeable, afterwards only of three of them. Three participant’s depression value was observable, afterwards only of 2. The average anxiety value among all attendees (minimum 0, maximum 21) decreased from 11.3 to 9.4. In personal view of the attendees the following statements were fundamental: • It was helpful to tell from your own. • The participation of several specialists was helpful. • Exchanging with others was helpfully.

All patients agreed that attending the seminar reduced their anxiety.

Conclusion: In an integrative concept, the cooperation between psychosomatic and somatic specialists can guide the patients to more self-efficacy. This traces back to the fact that there are synergetic effects between qualified information, the doctors caring attitude and a guidance to exposure the own disease.

Case report of a patient suffering from cervical focal myelopathy, treated with reflexology

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Objective: The case report refers to a male adult, 58 years old, suffering from focal myelopathy of cervical spine, who received a focused therapeutic treatment with reflexology, in order to reduce the symptoms.

Case presentation: In May 1998 M.M. presents difficulty in walking, tremor and numbness at lower limbs. After visiting a neurosurgeon and taking a magnetic evaluation he was diagnosed of cervical disk herniation with myelopathy. The doctor proposed immediate surgical treatment. Following the surgery M.M. presents appreciable reduction of symptoms. In August 2009 he presents deterioration of the symptoms. More analytically: numbness at the lower limbs, particularly in the right leg, gait impairment with difficulties in walking and tremor, especially after exercise. The patient was examined by a neurosurgeon independently
of us and he suggested immediate surgical intervention for his myelopathy. MM decided to follow an alternative treatment of his problem, and he chose reflexology. The therapeutic design was focused on reducing the major symptoms: reduction of numbness in right leg, improvement in walking, reduction of lower limbs tremor and a general relaxation of the body. He received a focused medical reflexology treatment, in order to reduce the symptoms, and offer him relief. MM’s treatment plan was completed in 12 weeks (11 sessions). During the treatment, his progress was evaluated by an assessment of a 10 cm scale. The assessment measurement was taking every 3 reflexology sessions. Based on the above evaluation we planned the frequency of the sessions, according to patient needs and progress.

Treatment: M.M. decided to be treated by a physical alternative treatment and he chose reflexology. Reflexology is a complementary method of treatment which according to WHO belongs in traditional healing methods (empirical therapy). The therapeutic plan was 2 sessions weekly for the first 3 weeks, 3 sessions in the next 2 weeks, followed by 2 sessions every 15 weeks and conservative session monthly. His treatment was completed in 12 weeks. His doctor (neurosurgeon) reported in the follow up of the patient that he does not need to undergo the operation and suggested to continue conservatively.

Treatment outcomes: his reflexology treatment began on 24/11/09 and ended on 25/11/10 with very interesting outcomes. There were 11 sessions in 12 weeks. According to the measurements done and the patient’s statements all his symptoms were improved.

Conclusion: This case report suggests that reflexology constitutes an effective alternative method in reducing the symptoms of focal myelopathy. This potential, needs to be further evaluated.

PP-177

Expression of antioxidant enzymes in diabetic patients on integrative treatments

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Objectives: Our study has investigated whether the mRNA expression of several antioxidant enzymes (EC-SOD, GPx, CAT) is influenced by diet alone or polyphenol supplements in a diabetic population vs control. We selected a product used in the traditional Romanian culture, balsamic vinegar from apples enriched with blackcurrant extract, with a total popyphenol content of 36 mg/10ml, determined by the Folin-Ciocalteu method. The HPLC analysis of the total product revealed anthocyanins 2000 ppm, flavanols/flavonoids/catechines 400/200/1000 ppm, tannins/pectines 1000 ppm.

Material and method: Twenty patients with diabetes and 10 healthy controls were selected (10M, 10F). The patients were under standard medication recommended by guidelines, but glycemic and lipid control was not achieved to target. The patients were randomized into two groups: gr1 (n = 10) on diet, gr2 (n = 10) on diet+polyphenol supplements. After a 14-day wash-out period, the patients were given a diet designed for a calories intake of 35 Kcal/kg body weight/day, constant for fats and fiber, meat 150 g/day (chicken, fish, beef), that also included 30 ml of balsamic vinegar with blackcurrant extract in gr. 2. We compared the antropometric parameters, glycemia, insuline, IR-HOMA, lipids and oxydative stress at
inclusion and after one month between the two groups. The control group served for comparison of antioxidant enzyme expression.

**Results:** The most efficient lowering of glycemia was obtained in gr 2, from 108.9 to 95.7 mg/dl (p = 0.0001). TG also decreased significantly in gr 2 from 210.84 to 152.43 mg/dl (p = 0.003). The most efficient lowering of oxidative stress was obtained in gr.2 from 354.87 to 230.14 UFORT (p = 0.0002). In gr1 the EC-SOD mRNA significantly decreased (p = 0.012) but CAT and GPx mRNA were not significantly modified in this group vs controls. In gr2, at enrollment, the expression of EC-SOD mRNA was significantly increased when compared with controls. CAT and GPx mRNAs expressions were lower than in controls. After the diet+polyphenols supplementation, the CAT and GPx mRNA expressions were significantly lower than in controls (p = 0.02, p = 0.044 respectively) and EC-SOD mRNA expression was also decreased (p = 0.001).

**Conclusions:** The results obtained in the present study demonstrate safety, tolerability and efficacy of a bioactive extract rich in polyphenols. Diabetic patients should use functional products in their daily diet in order to enhance the effect of recommended medications.

**PP-183**

**Integrative smoking cessation**

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**Background:** Smoking cessation is probably the most important life-style change for health improvement. As many patients find it difficult to change or end their smoking-habits, all initiatives are welcome to reduce risk for health related illness and disease.

**Method:** Smoking cessation enforced by medical personnel in a group setting has been arranged at Vitalisklinikken, an integrative clinic in Harstad, North-Norway. Groups of 8-10 smokers get together in groups and during a 12 week period, there are 5 group meetings. In an integrative setting, the treatment consists of medicine for nicotine addiction in combination with acupuncture and psychological behavioral life-style advice.

**Results:** Our combination of therapies in an integrative setting has proved to give a high success rate in which almost every participant has success in their attempt to quit smoking.

**Conclusions:** Vitalisklinikken has developed a method with a high success-rate that easily could be implemented in an integrative setting in general practice.