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Oral Abstracts

Oral Abstract Session 01: Clinical Trials

OA01.01
Disodium EDTA Chelation for Post Myocardial Infarction Patients

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Purpose: Chelation therapy with disodium ethylene diamine tetraacetic acid (EDTA) has been used to treat atherosclerosis for over 50 years without proof of efficacy. The Trial to Assess Chelation Therapy (TACT) was designed to define the risks and benefits of this therapy.

Methods: TACT was an NIH-sponsored double-blind factorial trial in which 1,708 post-myocardial infarction patients age 50 or older were randomized to receive 40 infusions of a chelation solution (3 grams EDTA, 7 grams ascorbate, B-vitamins, electrolytes, and heparin) versus placebo, with a second randomization to oral vitamins and minerals or an oral placebo. Primary endpoint was a composite of mortality, myocardial infarction, stroke, coronary revascularization, or hospitalization for unstable angina. This report describes the intent-to-treat comparison of EDTA chelation versus placebo.

Results: The median age was 65 years, and the qualifying myocardial infarction occurred a median of 4.6 years prior to enrollment. The median duration of follow-up was 55 months. The five-year Kaplan-Meier estimates of the primary endpoint were 32.8% for the chelation group and 38.5% for the placebo group (hazard ratio 0.82, 95% confidence interval 0.69–0.99, p = 0.035). The effect of EDTA chelation on the non-fatal components of the primary endpoint was consistent with its overall effect (no single component dominant). Expanded analyses of diabetics demonstrated a significant risk reduction by EDTA (25% vs 38%, HR 0.59 (0.44, 0.79), p < 0.001). Patients with prior myocardial infarction demonstrated a 37% reduction in risk (p = 0.003). There was no interaction of chelation therapy with oral vitamins and minerals, nor with randomization at a conventional cardiology site or an alternative medicine site.

Conclusion: The 10-component disodium EDTA chelation infusion reduces clinical events in patients with a history of MI. Further research to understand mechanisms of action and potential applicability to patients should be carried out. Pre-specified subgroup analyses suggest interesting avenues for further research.

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OA01.02
Oral High-Dose Multivitamins and Minerals Alone and in Combination with Chelation Therapy for Coronary Disease: A Randomized Clinical Trial

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Purpose: The vitamin component of the Trial to Assess Chelation Therapy (TACT) assessed whether oral multivitamins reduced cardiovascular events, and augmented any benefits of chelation.

Methods: TACT was a double-blind placebo-controlled two by two factorial multicenter randomized trial. 1708 patients, age ≥50 years and ≥6 weeks post myocardial infarction, with creatinine ≤2.0 mg/dL were randomly assigned to EDTA chelation or placebo infusions plus 6 caplets of a 28-component multivitamin and multimineral mixture or oral placebo. The composite primary endpoint was total mortality, recurrent myocardial infarction, stroke, coronary revascularization, or hospitalization for angina. This analysis compares the 4 factorial groups.

Results: Median age was 65 years, with 18% female, 31% diabetic, 83% prior coronary revascularization, and 73% on statins. Median LDL was 84.9 mg/dL. The primary endpoint occurred in 230 (27%) patients in the active vitamin group and 253 (30%) in the placebo group (HR 0.89, 95% CI 0.75–1.07, p = 0.21). In the analysis of the factorial groups, the primary endpoint occurred in 108 (26%) of patients in the chelation + high-dose vitamin group, and 139 (32%) in the placebo infusin + placebo vitamin group (HR, 95% CI 0.74 (0.57, 0.95); p = 0.016). The secondary clinical endpoint (cardiovascular mortality, myocardial infarction, or stroke) occurred in 39 (9%) of chelation + multivitamins and in 58 (13%) of placebo + placebo (p = 0.045). The point estimates for each component of the combined endpoints were all <1.0 and consistent with the overall effect.

Conclusion: In post-MI patients on evidence-based therapies, high-dose oral multivitamins and multiminerals did not produce a significant reduction in cardiovascular events. However, the
additive effect of the combination of oral vitamins and chelation therapy was significant and of potential clinical relevance. Our findings in TACT offer several opportunities for novel research programs that may eventually lead to important therapeutic insights for treatment of CAD.

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AOA0.03
Chiropractic for Hypertension in Patients (CHiP): A Pilot Randomized Controlled Trial

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Purpose: Bakris et al. reported dramatic blood pressure (BP) lowering effects resulting from an upper cervical manipulation technique (NUCCA) in narrowly selected patients with Stage 1 hypertension. Our study compared BP changes between a similar but more commonly used upper cervical technique, Toggle Recoil (TR), and a sham intervention (SI) in a more generalizable sample.

Methods: We conducted a 2-arm pilot RCT with participants age 21 to 75 with documented pre- to Stage 1 hypertension who saw the doctor of chiropractic (DC) twice weekly for 6 weeks. Participants and BP assessors were blinded to treatment, while DCs were masked to BP outcomes.

Results: We screened 681 volunteers and randomly allocated 51 participants (24 TR and 27 SI; 59% males; mean age 58; mean BMI 31.3). At the first visit, pre/post adjusted mean systolic BP decreased 0.9 mmHg in the TR group and 5.5 mmHg in the SI group; diastolic BP increased 1.4 mmHg in the TR group and decreased 2.2 mmHg in the SI group. From baseline to week 6 (primary endpoint), adjusted mean systolic BP increased 0.6 mmHg in the TR group and decreased 4.2 mmHg in the SI group; diastolic BP increased 0.5 mmHg in the TR group and decreased 1.3 mmHg in the SI group; and the between group adjustment mean difference in systolic BP was 4.8 (95% CI: −0.4, 10.0). No between group differences were statistically significant.

Conclusion: We did not see the dramatic changes in BP reported in the Bakris et al. study; the differences we did observe were in favor of the sham. Our results provide more questions than answers about the value of spinal manipulation for the treatment of hypertension. We propose that basic science research is needed to understand the potential mechanisms of action before further clinical investigations are initiated.

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AOA0.44 LB
Catechol-O-methyltransferase Associated Risk of Cardiovascular Disease Is Modified by Treatment with Vitamin E

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Purpose: Despite the lack of conclusive evidence of efficacy from well-designed clinical trials, the use of vitamins remains widespread. With recent reports of possible harm, the debate has shifted from benefits relative to placebo, to concerns about safety. Few studies have investigated the effect of genetic variation on treatment responses to vitamin E. Genetic variation is considered an important factor in heritability of CVD and treatment response. Catecholamines like epinephrine play a key role in cardiovascular function and are metabolized by catechol- O-methyltransferase (COMT). The effect of genetic variation in COMT on CVD outcomes in women treated with vitamin E is not known.

Methods: The Women’s Health Study (WHS) is a large prospective placebo-controlled trial of incident CVD prevention with random allocation to aspirin and vitamin E and 10 years follow-up. The Women’s Genome Health Study (WGHs), a large subset of the WHS for genetic analysis provided a unique dataset to examine the effects of the COMT rs4680 polymorphism.

Results: The rs4680 high-activity val allele was protective for incident CVD among women in the placebo arm (HR[95%CI] = 0.66[0.51–0.84], P = 0.0007) such that val homozygotes had a 56% lower rate of major CVD relative to low-activity met homozygotes. The rs4680 protective association was abolished by randomized allocation to vitamin E such that val homozygotes experienced higher rates of major CVD with vitamin E compared to placebo (HR[95%CI] = 1.50[0.83–2.70], P = 0.180), while met homozygotes experienced lower rates (HR[95%CI] = 0.53[0.34–0.84], P = 0.023) thus revealing a significant interaction between COMT and vitamin E (P = 0.004).

Conclusion: Common COMT polymorphism association with CVD risk and differential effects of vitamin E treatment suggests novel aspects of CVD pathophysiology. In an era where the use of vitamins is under debate, this study highlights the importance of considering genetic composition in evaluating clinical efficacy of vitamins and using pharmacogenomics to guide the development of smarter, individualized strategies for treatment and prevention.

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Oral Abstract Session 02: Health Services Research

OA0.02.01
A National Assessment of the Usage, Cost, and Reimbursement of Unconventional Medical Laboratory Tests

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Purpose: A growing number of unconventional medical laboratory tests have emerged and are anecdotaly popular among CAM-oriented practitioners. In the United States, millions of unconventional medical laboratory tests are ordered annually, though no high quality data exist regarding practice patterns, cost, or reimbursement. To our knowledge, this is the first study...
to formally assess and characterize the usage of unconventional medical tests in the United States.

Methods: A cross-sectional survey among licensed healthcare professionals associated with 12 national CAM/integrative medicine organizations using an anonymous, online survey instrument. Participants were queried on the types and rationale regarding unconventional medical laboratory tests, reimbursement status, use in pediatric patients, and demographics.

Results: Responses from 638 participants were recorded. The average age of survey participants was 46 years of age, with an average of 12.6 years of practice. The most frequently used medical laboratory tests included stool analyses, urine neurotransmitter assays, organic acid tests, salivary hormone assays, and urine heavy metal tests. 26–35% of adult patients receive unconventional laboratory tests, while 31–46% of tests are used in children. 61% of providers use unconventional tests with pediatric patients for a variety of indications. 40–53% of adult tests were reimbursed by third parties, with private insurance, and Medicare being the predominant payers.

Conclusion: These data provide insights to the practice patterns and reimbursement status of this burgeoning clinical practice. Unconventional tests are often utilized in chronic conditions without reliable mainstream treatments. Further study on the validity of the most prevalent tests can provide greater insights to the clinical utility of unconventional medical laboratory testing.

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OA02.02
Costs of Complementary and Alternative Medicine for Cancer Survivors in the United States: Results from the 2012 National Health Interview Survey

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Purpose: While it is known that a high percentage of cancer survivors use complementary and alternative medicine (CAM), little is known about the financial implications of such use. We sought to determine cancer survivors’ annual out-of-pocket spending on CAM.

Methods: Data from the Adult Alternative Medicine questionnaire of the 2012 National Health Interview Survey (NHIS) were used to estimate out-of-pocket CAM costs among individuals with a history of a cancer diagnosis. The analysis was limited to adults with a history of cancer, excluding non-melanoma skin cancers. Statistical methods were used to account for NHIS’s complex sampling methods. We performed a multivariate analysis to determine factors associated with the highest quartile of CAM spending.

Results: We identified a cohort of 3,102 cancer survivors, of which 78.1% reported having used at least one CAM modality over the past 12 months. We estimated that adult cancer survivors in the United States spent $9.0 billion in total on out-of-pocket CAM use in 2012. Over two thirds of this total was spent on the purchase of vitamins and minerals ($6.2 billion), over 15% ($1.4 billion) was spent on herbs and non-vitamin supplements, and over 5% ($0.5 billion) was spent on massage. Breast cancer survivors were estimated to be the highest spending group, totaling $1.6 billion in out-of-pocket CAM costs over the past 12 months. Among all users, median annual cost of CAM use was estimated at $140. Compared to those who did not report CAM use due to their cancer diagnosis, survivors who reported using any CAM for cancer have 4.6 times the odds of being a high spender (p = 0.0028).

Conclusion: The total 2012 out-of-pocket CAM costs for cancer survivors in the United States are estimated to be $9.0 billion—7% of the estimated $125 billion for cancer survivors’ yearly health care costs.

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OA02.03
Morbidity and Management Patterns of Traditional Chinese Medicine (TCM) Primary Care in Hong Kong Population

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Purpose: Primary health care plays an important role to the health of the population by managing more than 90% of the illnesses. There was a lack of information on the morbidity pattern and management process despite 8815 of Chinese Medicine Practitioners (CMP) providing primary care to Hong Kong population. This study aims to determine the morbidity pattern and the management process of CM in primary care in Hong Kong.

Methods: A cross-sectional study of prospective recording of all clinical encounters that presented to the participating CMP were collected for four seasons in 2012. All health presenting problems were coded by IPCP-2 and the national classification of disease and Zheng of CM. The prevalence was expressed in percentage distribution.

Results: 55,312 subjects’ health encounters were collected from 260 CMP in 2012. Females were more likely to consult CMP than males (67.0%). Most subjects (64.0%) consulted for a chronic problem whom were elderly. By IPCP-2 coding, the respiratory (24.9%, R) and musculoskeletal (22.7%, L) problems were the most common complaints, especially cough (11.7%, R05) and low back symptoms/complaints (6.6%, L03). By national classification of diseases, internal diseases (65.1%) were the most commonly diagnoses. The top 3 diseases were muscle/tendon-related illnesses (9.4%), flu-related illnesses (8.8%) and cough (6.2%). By national classification of Zheng (i.e., syndrome differentiation), organs and channels-and-collaterals syndromes (40.5%) were the most common Zheng. Chinese herbs were
commonly used as management treatment by CMP together with lifestyle advices. For musculoskeletal problems, massage or acupuncture were adopted instead.

**Conclusion:** This was the first study to investigate the morbidity patterns in Hong Kong managed by CMP with the parallel coding from both ICPC-2 and national classification of diseases and Zheng (i.e., syndrome differentiation) from TCM aspect. Several factors have contributed to the difference of morbidity and management patterns.

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**OA02.04**

**Health Care Utilization for Pain and Stress Patients Following Integrative Care Compared to Conventional Care: A Swedish Registry Analysis**

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**Purpose:** Our previous national registry analysis showed that prescription drugs and costs significantly decreased for integrative care (IC) pain and stress patients and significantly increased for matched conventional care (CC) patients. The purpose of this study was to explore the same cohort of patients regarding the number of revisits for target diagnosis following IC or CC.

**Methods:** Retrospective analyses of national high quality registry data 2005 to 2010. Patients from the IC and CC cohorts were matched on ICD-10 diagnoses M79 (pain) and F43 (stress), age, gender, socio-demographics. Revisits for target diagnosis was analyzed within 90 and 180 days after the first observed inpatient visit with M79/F43 for anthroposophic integrative care (IC) and conventional care (CC).

**Results:** 90 days after index visits: 5.3% (58/1094) of CC pain patients vs. 2.4% (5/213) of IC pain patients, group difference 3.6% (p = 0.079), had 1 revisit with the M79 diagnosis. 14.0% (222/1589) of CC stress patients vs. 3.7% (6/161) of IC stress patients, group difference 10.3% (p = 0.000), had 1 revisit with the F43 diagnosis. 180 days after index visits, 6.5% (71/1094) of CC pain patients vs. 2.4% (5/213) of IC pain patients, group difference 4.1% (p = 0.022), had 1 revisit with the M79 diagnosis. 15.0% (238/1589) of CC stress patients vs. 5.0% (8/161) of IC stress patients, group difference 10.0% (p = 0.001), had 1 revisit with the F43 diagnosis; 2.9% (46/1589) of CC stress patients vs. none (0/161) of IC stress patients, group difference 2.9% (p = 0.031), had 2 revisits with the F43 diagnosis.

**Conclusion:** Our national registry analysis shows that revisits for target diagnosis of pain and stress were significantly less for IC pain and stress patients compared to matched CC patients. Future analyses include measures of national savings in relation to health care utilization, sick leave, and co-morbidity.

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**OA03.01**

**Histone Modifications in Phenethyl Isothiocyanate-Treated Cancer Cells May Contribute to its Chemopreventive Effects**

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**Purpose:** Site-specific histone modifications are key epigenetic regulators of gene expression impacting cancer etiology. Dynamic effects of phytochemicals and dietary compounds on histone tail modifications remain relatively unexplored. Phenethyl isothiocyanate (PEITC) is a common phytochemical derived from cruciferous vegetables like broccoli and cress. Our observations show promising anti-inflammatory and chemo preventive properties of PEITC. We also report novel, dynamic, site-specific chemical changes to histone H3 in a gene-promoter-specific manner, associated with PEITC exposure in colon tumor-derived epithelial cells.

**Methods:** For all data derived from mRNA and protein expression analyses, functional assays, chromatin immunoprecipitation experiments, as well as a 90-day in vivo chemoprevention experiment, a statistical significance (one way ANOVA) of p < 0.05 was considered.

**Results:** The time- and concentration-dependent effects of PEITC on histone modifications (di- and tri-methylations of lysine (K)-9 and lysine (K)-27 and acetylation) and gene expression changes (genes with key functions in inflammation and cancer signaling) were achieved at low, non-cytotoxic concentrations, in contrast to the higher concentrations necessary to halt cancer cell proliferation likely mediated by caspase-dependent apoptotic signaling. H3K27me3 (repressive mark) states inversely correlated with STAT1, NFkB1, and IL8. H3-Ac (activation mark) levels were positively correlated with MMP7 expression modulation by PEITC. For CD40 and CCL2, no correlation was observed. In vivo, PEITC-enriched diet was effective in preventing colon tumor initiation in pre-fed mice but did not significantly reduce tumor load when administered after carcinogen challenge and tumor initiation.

**Conclusion:** Presence as well as absence of correlation between gene expression and histone modifications indicates a possible selective gene-specific function of PEITC at the epigenetic level. Increased understanding of specific epigenetic alterations by dietary compounds may provide improved chemopreventive strategies for reducing the healthcare burden of cancer and the same strategy may be applied to other chronic human diseases. The work is supported by NIH [R00AT4245] and SDAES [328100/318000] to MD.

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**OA03.02**

**The Alterations of Damage-Repair Related Signals in Hippocampal CA3 Region of Chronic Stress Rats after Electric-Acupuncture (EA) Treatment**

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**Purpose:** To investigate alterations of IL-6, IL-1β, TGF-β1 expressions in hippocampal CA3 region of chronic restraint stress rats.

**Methods:** A total of 19 Sprague-Dawley Rats were divided into three groups, with 4 male and 3 female in model group, 4 male and 3 female in treatment group and 2 male and 3 female in control group. For model group, chronic restraint stress model

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was induced by restraining rats with wire fences, 9am-3pm per day, for 21 days; for EA group, treatment was conducted prior to restraint, acupoints GV20 and GV29 were selected, 2/100Hz, 1 mA, 15 min per time, for 21 days; for control group, no induction and treatment were conducted. Immunohistochemistry is applied to detect the expression of IL-6, IL-1β and TGF-β1 in hippocampal CA3 region.

Results: Based on IOD calculation and analysis, 21 days after chronic restraint stress stimulation, IL-1β level in stress group increases obviously compared to those in control group and EA group (p < 0.01), while differences between EA group and control group are not statistically significant (p > 0.05). The expression of IL-6 in stress group rises substantially in contrast to that in control group (p < 0.01) and EA group (p < 0.05). TGF-β1 in stress group improve greatly compared to that of control group with significant differences (p < 0.01), but no differences are found compared with EA group (p > 0.05).

Conclusion: The results indicate that EA treatment induces the alterations of inflammatory cytokine expressions in hippocampus of chronic restraint stress rats. The probable mechanism is: through inhibiting excessive stress, alleviating inflammatory damage, promoting cellular interaction and activating function, EA can stimulate the self-modulation, restore the micro-environment balance to achieve anti-depression effects.

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OA03.03
Ginko Biloba (EGb 761®) Augments the Repair and Regeneration Process by Enhancing Neurogenesis after Experimental Stroke in Mice
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Purpose: Studies have underlined the importance of repair mechanisms in the recovery phase of stroke. Neurogenesis in response to brain injury is one of the regeneration processes that, if enhanced, may offer better stroke treatment alternatives. In the present study, we were interested to study whether ginkgo biloba (EGb 761) could protect mice from stroke and enhance neurogenesis.

Methods: EGb 761 was administered to mice for 7 days before surgery for pre-treatment paradigms. In another cohort of mice, EGb 761 was immediately administered 4h after pMCAO and continued for 7 days. For neurogenesis experiments, sham, vehicle, EGb 761 post-treated, and HO1-/- mice were injected with 100µL of BrdU (10mg/mL of conc.) at 4h following surgery and then continually for 7 days.

Results: In the present study, we were interested to study whether EGb 761 could protect mice from permanent middle cerebral artery occlusion (pMCAO) and enhance neurogenesis. EGb 761 pre- and post-treated mice had lower infarct volume and improved motor skills with enhanced proliferation of neuronal stem/progenitor cells (NSPCs) at 24 h and 7 days post-treatment. Nitrin-1 and its receptors (DCC and UNC5B) that mediate axonal attraction and repulsion were observed to be over-expressed in NSPCs only, implying that nitrin-1 and its receptors might have partly played a role in enhanced neurogenesis. Interestingly, in heme oxygenase 1 knockout mice (HO1-/-), neurogenesis was significantly lower than in vehicle-treated mice at day 7. Furthermore, EGb 761 post-treated mice also demonstrated heme oxygenase 1 (HO1)-activated pathway of phosphorylated glycogen synthase kinase 3-α/β (p-GSK-3α/β), collapsin response mediator protein 2 (CRMP-2), semaphorin3A (SEMA3A), and Wnt, suggesting probable signaling pathways involved in proliferation, differentiation and migration of NSPCs.

Conclusion: Together, these results propose that EGb 761 not only has antioxidant, neurogenic and angiogenic properties, but can also augment the repair and regeneration mechanisms following stroke.

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OA04.02
Can We Teach Empathy?: Evidence from the Evaluation of a Course Titled “Compassion in Medicine”

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Purpose: Empathy plays an important role in patient care. However, multiple studies indicate that empathy declines as health care providers progress through their professional education. Evidence-based educational interventions are needed to foster empathy among health professional students. The present study evaluated a 10-week course titled “Compassion in Medicine” aimed to foster compassion and empathy among pre-health undergraduate students at the University of California Irvine.

Methods: Surveys were administered to students enrolled in “Compassion in Medicine” (n = 135) preceding and following the course. Students enrolled in “Introduction to Global Health” (n = 108) were used as control subjects. Students’ level of empathy was evaluated using the Jefferson Scale of Empathy (JSE)-Health Professional Student Version; level of compassion was evaluated using the Santa Clara Brief Compassion Scale (SCBCS). Other demographic variables were also included in the survey to control for confounding effects. A generalized estimating equation was used to evaluate longitudinal changes of scores within students from week-1 to week-10 between the two courses.

Results: GEE model analysis shows that subjects from “Compassion in Medicine” yielded significantly greater post-course incremental scores on JSE, in reference to “Intro to Global Health” (GEE group x time interaction coefficient: 7.08, 95% CI: 1.6–12.6), when adjusted for age, gender, year in school, intention to become a physician and baseline SCBC score.

Conclusion: Courses such as “Compassion in Medicine” could be an effective educational intervention for fostering empathy among pre-health professional students; however, longitudinal study is needed to evaluate the prolonged effect of the intervention. Also, students’ self-selection to enroll in each class could be a serious bias in our study.

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OA04.03
Impact of Changes in Mindfulness on Perceived Stress and Empathic Concern in Medical Students

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Purpose: Recent reports indicate that mindfulness training decreases burnout and improves physician empathy and well-being. Medical students also suffer from burnout and exhibit declines in empathy, perhaps related to their stress level. Yet most medical curricula lack interventions that foster mindfulness, which may improve student stress management and coping. The aim of this study was to determine whether a mind-body medicine skills course would alter mindfulness in medical students and affect their stress and empathy.

Methods: Georgetown University SOM offers an 11-week experiential course in mind-body medicine (MBM) to expose first-year medical students to various mind-body approaches (e.g., meditation, autogenic training, guided imagery). The group sessions, led by 2 trained facilitators, involve sharing openly and listening without judgment. Data were obtained in 118 first-year medical students who completed survey instruments before and after participating in the MBM course. Instruments included Perceived Stress Scale (PSS), Freiberg Mindfulness Inventory (FMI), Positive and Negative Affect Scale (PANAS), and the Interpersonal Reactivity Index (IRI).

Results: Significant increases (P < 0.001) were observed in mindfulness (FMI), positive affect (PANAS) and empathic concern (IRI), while significant declines were seen in perceived stress (PSS), in negative affect (PANAS), and in personal distress in response to distress in others (IRI). Furthermore, the changes in perceived stress and affect were significantly correlated (P < 0.001) with improvements in mindfulness.

Conclusion: A one-semester course in mind-body medicine skills during the first year of medical school is effective in enhancing traits such as mindfulness, positive affect and empathic concern, while reducing students’ perceived stress and negative affect. Further, the mindfulness level was an important predictor for the changes in perceived stress and affect. Fostering mindfulness through an experiential mind-body medicine skills course may help decrease medical student stress and enhance emotional intelligence. Such curricular interventions may promote better physician-patient communication and improve the quality of health care.

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OA04.04
A Longitudinal Study of Well-Being, Burnout and Emotional Intelligence in Family Medicine Residents
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Purpose: The goals of this study are to: 1) examine longitudinal changes on dimensions of well-being among family medicine residents; and 2) examine the impact of burnout on mindfulness and emotional intelligence at graduation.

Methods: Residents graduating in 2011–2012 (n=172) were assessed at the beginning of the first and second years of residency and graduation. Measures included perceived stress, burnout (emotional exhaustion, depersonalization), depression, positive and negative affect, and life satisfaction. Emotional intelligence included empathic concern, perspective taking, empathic distress, attention to feelings, clarity of feeling experience, and repair of emotions. Mindfulness and gratitude were also assessed.

Results: In longitudinal analyses, emotional exhaustion, depersonalization, positive affect, and life satisfaction deteriorated between the first two years of residency. Emotional exhaustion and depersonalization remained elevated at graduation. Analyses comparing longitudinal trajectories by marital status revealed that single residents were more likely to remain distressed at graduation, while married/cohabitating residents returned to pre-residency levels on all well-being measures. Furthermore, well-being was higher at graduation for married/cohabitating residents than singles. Emotional intelligence, mindfulness, and gratitude were compared against burnout levels at graduation. All of the models were statistically significant, except attention to feelings. Residents in the “at risk” burnout group had lower levels of emotional intelligence, gratitude, and mindfulness than residents in the low risk group. The moderate risk group scored between “the low” and “at risk” groups; however, these differences were only significant for gratitude. Moderate risk residents had more gratitude than the at risk residents.

Conclusion: While burnout increases and well-being decreases by the second year of residency; some measures of well-being return to pre-residency levels by graduation. However, burnout remains elevated. Furthermore, burnout appears to have a substantial impact on residents’ emotional intelligence and mindfulness as they enter their career as practicing physicians.

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OA05.02
Characteristics of Acupuncture Treatment Associated with Outcome: Analyses of 17,922 Patients with Chronic Pain in Randomized Controlled Trials
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Purpose: Recent evidence shows that acupuncture is effective for chronic pain. However we do not know whether there are characteristics of acupuncture or acupuncturists that are associated with better or worse outcomes.

Methods: An existing dataset, developed by the Acupuncture Trials’ Collaboration, included 29 trials of acupuncture for chronic pain with individual data involving 17,922 patients. The available data on the characteristics of acupuncture included style of acupuncture, point prescription, location of needles, use of electrical stimulation and moxibustion, number, frequency
and duration of sessions, number of needles used and acupuncturist experience. We used random-effects meta-regression to test the effect of each characteristic on the main effect estimate of pain. Where sufficient patient-level data were available, we conducted patient-level analyses.

**Results:** When comparing acupuncture to sham controls, there was little evidence that the effects of acupuncture on pain were modified by any of the acupuncture characteristics evaluated, including style of acupuncture, the number or placement of needles, the number, frequency or duration of sessions, patient-practitioner interactions and the experience of the acupuncturist. When comparing acupuncture to non-acupuncture controls, there was little evidence that these characteristics modified the effect of acupuncture, except better pain outcomes were observed when more needles were used ($p < 0.01$) and, from patient level analysis involving a sub-set of five trials, when a higher number of acupuncture treatment sessions were provided ($p < 0.001$).

**Conclusion:** There was little evidence that different characteristics of acupuncture or acupuncturists modified the effect of treatment on pain outcomes. Increased number of needles and more sessions appear to be associated with better outcomes when comparing acupuncture to non-acupuncture controls. This suggests that dose of acupuncture could be more important than previously thought. Trials that can evaluate the potentially small differences in outcome associated with different acupuncture characteristics are likely to require large sample sizes.

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### OA05.04
**Acupuncture Related Integrative Treatment for Low Back Pain: A Systematic Review and Meta-Analysis of Randomized Controlled Trials**

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**Purpose:** A literature search of 8 English and 4 Chinese databases for RCTs evaluating the effectiveness of integrative treatments for musculoskeletal related LBP was conducted. Reporting/methodological quality and relevant clinical characteristics were assessed, extracted by two researchers, with consensus by a third reviewer and meta-analyses conducted.

**Results:** Initially 1470 English and 3358 Chinese studies were identified. Screening titles/abstracts gave 218 English and 739 Chinese articles. After inclusion and exclusion criteria, 13 English, 46 Chinese articles remained (22 acupuncture). Acupuncture combined with traction was the most popular treatment in China (8/17); for other countries acupuncture plus usual care (4/5) was the most popular combination. Favourable improvements were shown in integrative treatments (acupuncture combined with traction/medication/epidural injection/usual care) over conventional medicine (CM) alone – with traction: 5 studies: $n = 450$, visual analogue scale (VAS), standardized mean difference (SMD) $-1.43$, 95% CI $[-1.69, -1.18]$, $p = 0.18$, I² = 34%; 2 studies: Japanese Orthopaedic Association (JOA) score, SMD $0.52$, 95% CI $[0.02, 1.01]$; modified JOA, [SMD 2.50, 95% CI [1.82, 3.19]] with medications: 3 studies: $n = 234$, VAS, SMD $-0.89$, 95% CI $[-1.17, -0.62]$, $p = 0.38$, I² = 2%; 2 studies: $n = 142$, Oswestry pain disability index score, SMD $-1.04$, 95% CI $[-1.40, -0.69]$, $p = 0.72$, I² = 0%; with EI: 1 study: VAS, SMD $-1.67$ $[-2.36, -0.97]$; 1 study: JOA score, SMD $-1.93$ $[-2.44, -1.41]$ and positive results comparing acupuncture plus usual care. Minimal safety data was generated. Chinese studies had poorer reporting/methodological quality.

**Conclusion:** Previously effectiveness of IM has been inadequately evaluated. Variations in terminology/policy/registration
OAA06.01
Meditation-Based Mantram Repetition Program for Veterans with PTSD: A Randomized Controlled Trial in the VA Healthcare System
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Purpose: Few complementary and alternative approaches are offered for symptom management of posttraumatic stress disorder (PTSD) in Veterans receiving care at the Veterans Affairs (VA). Even fewer approaches have been empirically tested as evidence-based treatments (EBT). EBTs are required in clinical practice as part of the VA’s mental healthcare system redesign. This study sought to establish the efficacy of the Mantram Repetition Program (MRP), a portable practice of repeating a mantra or sacred word/phrase, slowing down, and practicing one-pointed attention, as an EBT for Veterans with PTSD. Our earlier research showed MRP was effective when compared to usual care.

Methods: A randomized controlled two-site clinical trial was conducted to compare MRP to an EBT developed by the VA’s National Center for PTSD, present-centered therapy (PCT). Veteran participants diagnosed with PTSD were randomly assigned to MRP (n = 25) or PCT (n = 20), both delivered in an individual treatment format according to standard protocols in 8 weekly, 60-minute sessions. PTSD diagnosis and symptom severity were measured at baseline and post treatment by the Clinician Administered PTSD Scale (CAPS).

Results: Veterans randomized to MRP experienced greater reduction of PTSD symptoms relative to Veterans who received PCT (p = .003). While Veterans in both groups experienced PTSD symptom relief, improvement in CAPS scores of Veterans receiving MRP was more than twice as large on average than those in PCT (M = 31.28 versus M = 13.50). Even when controlling for Veterans’ baseline spiritual wellbeing scores, the effect of MRP on CAPS scores remained significant (p = .0005).

Conclusion: The significant impact of an 8-week session of MRP on Veterans’ PTSD symptoms argues for widespread implementation and sustainability studies across VA HealthCare System. While EBTs like PCT are effective for PTSD, our results reveal even greater improvement in symptomatology for Veterans receiving MRP. Provider training and Veteran peer-support are methods for disseminating these findings and implementing successful onsite programs.

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OAA06.02
Tai Chi Practice Is Associated with Increases in Spirituality, Which Predicts the Reduction of Depression Symptoms in Heart Failure Patients
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Purpose: Heart failure (HF) affects 5 million North Americans (York et al, 2009). Depressive disorders are present in up to 40% of HF patients (Norra et al, 2008), which are associated with increased mortality, clinical events, and re-hospitalization (Rutledge et al, 2006). Yet the efficacy of antidepressant therapy in heart disease patients has had limited effects on reducing depressive symptoms. Meanwhile, research suggests that Tai Chi is effective in reducing depressive symptoms in HF patients (Redwine et al, 2012). However, the mechanisms are not clearly understood. The present preliminary study sought to determine whether changes in spirituality and mindfulness are related to reductions in depressive symptoms in HF patients practicing Tai Chi.

Methods: Thirty HF patients (mean age = 67.5, S.D. = 9.4) were randomly assigned to Tai Chi, Resistance Band training or usual care. Participants completed the Five Facets of Mindfulness Questionnaire (FFMQ), Functional Assessment of Chronic Illness Therapy-Spiritual Well-being Scale (FACIT-SP), and Beck Depression Inventory (BDI) pre- and post- the 16-week intervention period.

Results: There was a significant group X time interaction for Awareness of Activities (sub-measure of mindfulness) (F = 5.94, p = .023, partial eta squared = .10) and spirituality (F = 5.52, p = .028, partial eta squared = .22), with Tai Chi participants increasing from pre- to post-intervention compared with control groups. For the Tai Chi group, alterations in depression symptoms (F = 7.12, p = .028, partial eta squared = .47) were predicted by changes in spirituality (t = -4.16, p = .006, R squared change = .40) but not Awareness of Activities (p = .66).

Conclusion: These findings suggest that spirituality and aspects of mindfulness increase with Tai Chi training in HF patients. However, only changes in spirituality were related to reductions in depressive symptoms associated with performing Tai Chi.

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OAA06.03
The Impact of Tai-Chi on Cognitive Performance in Older Adults: A Systematic Review and Meta-Analysis
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Purpose: Summarize and critically evaluate research on the effects of Tai-Chi on cognitive function in older adults.
Methods: Electronic literature searches were conducted using PubMed/MEDLINE and 3 additional medical databases from inception through March 2013. Search terms were tai-chi, tai-ji, tai-chi chuan, memory, cognition, cognitive decline, and brain function. Studies where cognitive measures were examined as outcomes in relation to a Tai-Chi intervention were included. Results: Twenty eligible studies with a total of 2,533 participants (mean age 73y) were identified that met inclusion criteria for the systematic review: 11 randomized controlled trials (RCTs), 1 prospective non-RCT, 4 observational studies, and 4 cross-sectional studies. Overall quality of RCTs was modest, with 3 of 11 trials categorized as high risk of bias. Meta-analyses of outcomes related to executive function in RCTs of cognitively healthy adults indicated a large effect size when Tai-Chi was compared to non-intervention controls (Hedge’s g = 0.90; p = 0.043) and moderate effect size when compared to exercise controls (Hedge’s g = 0.51; p = 0.003). Meta-analyses of outcomes related to global cognition in RCTs of cognitively impaired adults (mild impairment to dementia) showed smaller but statistically significant effects when Tai-Chi was compared to both non-intervention controls (Hedge’s g = 0.35; p = 0.004) and other active interventions (Hedge’s g = 0.30; p = 0.002). Findings from non-RCTs add further evidence that Tai-Chi may positively impact these and other domains of cognition. Conclusion: Tai-Chi shows potential to enhance cognitive function in older adults, particularly executive functioning and in individuals without significant impairment. As a multimodal mind-body exercise that incorporates physical, cognitive, social, and meditative components in the same activity, Tai-Chi may impact cognitive function via a diverse and potentially synergistic set of mechanistic pathways. In addition to the need for larger and more methodologically sound trials, future research should focus on the potential of Tai-Chi to offer benefits superior to interventions that target only single pathways. Contact: Peter Wayne, pwayne@partners.org

OA06.04 Evaluation of an Integrative PTSD Treatment Program
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Purpose: Advancement is occurring in the search for effective, evidence-based treatments for Post-Traumatic Stress Disorder (PTSD). One innovative program—the Warrior Combat Stress Reset Program—at Fort Hood is showing promise for reducing the symptoms of PTSD, anxiety, and depression through its integrative approach combining traditional individual and group therapy with complementary and alternative medicine (CAM) treatments (e.g., Acupuncture, Reiki, Reflexology, Yoga). The objectives of the evaluation were to: 1) Analyze retrospective patient outcomes data and 2) Collect qualitative data from stakeholders including patients, family members, providers, and hospital leaders to identify mechanisms accounting for success or failure of the program.

Methods: A mixed-methods program evaluation examined current treatment and practice of CAM for PTSD in conjunction with traditional therapies. Treatment outcomes were analyzed for 764 soldiers who attended the 3-week program between 2008 and 2013 and participated in more than 20,000 CAM sessions. It was also of interest to evaluate health impacts of CAM sessions and to explore data to determine which patients benefited the most from treatment. Interviews were conducted with 59 stakeholders and topics included program structure, logistics, implementation issues, replicability, and patient acceptability and satisfaction.

Results: Results indicate significant reductions in PTSD symptoms (PTSD Checklist-Military version; p < .001), anxiety (Beck Anxiety Inventory; p < .001), and depression (Beck Depression Inventory II; p < .001) from pre- to post-treatment. Outcome analysis by year indicates steady improvements in treatment gains for these major outcomes over time. Analyses also suggest that CAM sessions may have an impact on traditional treatment effectiveness, patient adherence, loss to follow-up, and number of required sessions.

Conclusion: This integrative PTSD treatment program for active duty soldiers demonstrates statistically and clinically significant improvements in PTSD, depression, and anxiety with high satisfaction among patients, providers, and family members. Mechanisms for success and suggestions for improvement and replication will be discussed.

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Oral Abstract Session 07: Integrative Medicine in Clinical Care

OA07.01 Complementary and Alternative Medicine Interventions for Perioperative Symptoms: A Comparative Effectiveness Study
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Purpose: Perioperative symptoms such as pain and anxiety are common and often sub-optimally treated. Therefore we conducted a pragmatic trial to evaluate whether complementary and alternative (CAM) treatments can improve such symptoms in the perioperative setting.

Methods: Patients 18 years old and above that were referred to CAM consultations by the surgery department’s medical staff were allocated to standard of care (SOC group) or CAM treatments on top of standard of care (CAM group). Treatment allocation was determined according to patient preference and practitioner availability. Patients in the CAM group received 15–30 minute treatments of acupuncture, reflexology, or guided imagery. The primary outcome variable was change from baseline in visual analogue scale scores (0–10) for pain and anxiety. Patients and practitioners were also asked to report any side effect they attributed to the CAM treatment.

Results: A total of 1127 patients were enrolled between June 2010 and September 2012. 916 patients were assigned to the CAM group with 1214 CAM treatments provided, and 211 patients were assigned to the SOC group. Patient socio-demographic characteristics were similar in both groups. Primary outcome measures were significantly improved in the CAM group compared to the SOC group with a mean difference for pain −2.17 ± 2.4 vs −0.29 ± 2 (P < 0.0001) and anxiety −2.23 ± 2.76 vs −0.03 ± 2.54 (P < 0.0001). Certain CAM treatments showed more effectiveness than others for specific symptoms. No significant adverse events occurred in the CAM group.

Conclusion: CAM treatments in addition to standard of care provide short-term relief from common perioperative symptoms. Larger studies with longer follow-up are needed to confirm these benefits.

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OA07.02
Effects of Integrative Medicine on Pain and Anxiety Among Oncology Inpatients
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Purpose: To evaluate the provision of integrative medicine (IM) services on pain and anxiety in hospitalized oncology patients in a large Midwestern hospital.

Methods: Retrospective, observational data obtained from electronic health records (EHR) identified patients with an oncology ICD-9 code (140.0–239.9) who were admitted to the hospital between July 1, 2009 and December 31, 2012. Primary outcomes were change in patient-reported pain and anxiety. Patients rated pain and anxiety levels before and after IM treatments using a numeric rating scale (0 to 10), with higher scores indicating higher levels of pain and anxiety.

Results: There were 22,791 different hospital stays among 16,191 unique oncology inpatients. A total of 5,299 documented IM therapy sessions occurred among this oncology patient population; 1,663 oncology inpatients (10.3%) received at least one documented IM therapy (mean IM visits 2.8, SD 2.6). Of these 5,299 IM visits, 3,456 (65.22%) were bodywork, 302 (5.70%) were mind-body, 620 (11.70%) were therapies derived from Traditional Chinese Medicine, and 921 (17.4%) were a combination of these three categories. Pre- and post-treatment pain scores obtained from 1,781 of the 5,299 IM visits indicated a 47.2% (SD 36.0; p < 0.001) reduction in pain after IM therapy, whereas pre- and post-therapy anxiety scores obtained from 1,216 IM visits demonstrated a 56.6% (SD 30.7; p < 0.001) reduction in anxiety after IM therapy. Forthcoming analyses with additional EHR data will provide an opportunity to delineate specific oncology patient populations benefiting from IM.

Conclusion: The provision of IM services to oncology inpatients resulted in a statistically significant decrease in pain and anxiety scores. Additional research should also include pain medications and changes in these medications as additional measures. Generating additional evidence of the effectiveness of IM for pain/anxiety in oncology inpatients would advance scientific knowledge and potentially impact practice patterns.

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OA07.03
An Integrative Cardiac Wellness Program Improves Clinical Outcomes
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Purpose: To evaluate the effects of an established Integrative Cardiac Wellness Program (ICWP) for elective cardiothoracic surgery patients on postoperative recovery, bleeding risk, satisfaction and participation in rehabilitation programs.

Methods: ICWP participants enrolled over 3 years were compared with a historical control group receiving usual care at the same hospital in the previous 3 years. Data were collected from medical records, a survey and interviews. Patients enrolled at pre-admission clinics commenced oral metabolic supplements (coenzyme Q10, magnesium orotate, alpha lipic acid, omega 3 fatty acids) taken up until the day of surgery, then recommenced postoperatively for another 4 weeks. Between postoperative days 3–7, patients received individualized health education from a nutritionist, then a phone call post-discharge.

Results: Data from 922 patients were analyzed. Of the ICWP cohort, 176 were coronary artery bypass graft (CABG) patients and 161 valve surgery patients. ICWP participants (n = 337) were well matched with historical controls (n = 585) for age, gender, history of hypertension, diabetes, hypercholesterolemia and smoking. Multivariate analysis was used to adjust for other differences between active and control groups. Compared to usual care, ICWP CABG patients had a significant 42% relative reduction for post-surgery inotropic support (p < 0.001) and ICWP valve surgery patients had 40% relative reduction (p = 0.02) Total blood loss in the ICWP group was increased by a clinically insignificant 150 ml (p < 0.001). Importantly there were no significant differences in the incidence of serious bleeding events between active and control groups, defined as return to theater due to hemorrhage or blood transfusion requirement. Staff and ICWP patient feedback was positive and a 46% increased attendance at rehabilitation programs was achieved compared to controls (p = 0.033).

Conclusion: The Integrative Cardiac Wellness Program is safe, improves postoperative heart function, is well accepted by patients and increases attendance at rehabilitation.

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OA07.04
The Effects of Adjuvant Whole-Systems Traditional Chinese Medicine on In Vitro Fertilization Live Births: A Retrospective Cohort Study
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Purpose: In vitro fertilization (IVF) patients may elect adjuvant treatment from an acupuncturist and receive Whole Systems Traditional Chinese Medicine (WS-TCM). The combined effects of these treatments, however, are largely unknown. In this retrospective cohort study, live births were compared among fresh, non-donor IVF patients who elected WS-TCM pre-treatment which included acupuncture the day of ET, or elected standardized acupuncture only before and after embryo transfer (ET), or received usual IVF care.

Methods: The records of 1,069 fresh, non-donor IVF patients were reviewed. The main outcome measure was live birth. Secondary outcomes were biochemical pregnancy and miscarriage rates. Outcomes were compared among three groups: (1) WS-TCM group elected treatment prior to ET, in which they
could receive acupuncture, Chinese herbs, dietary and/or lifestyle recommendations as appropriate, and acupuncture before and after ET (N = 119); (2) Acupuncture (ACU) group elected adjuvant acupuncture only before and after ET (N = 370); and (3) Usual Care group (UC) received no additional treatment (N = 580). Outcomes were compared using logistic regression with covariates of antral follicle count and number of embryos transferred.

Results: Live births were higher in the WS-TCM group (N = 73, 61.3%) compared to the ACU group (N = 188, 50.8%; OR = 1.53, 95% CI 1.01–2.34), and the UC group (N = 280, 48.3%; OR = 1.77, 95% CI 1.15–2.72). Biochemical pregnancies were lower in the WS-TCM group (N = 3, 2.5%) compared to the ACU group (N = 35, 9.5%; OR = 0.24, 95% CI 0.07–0.82), and UC group (N = 49, 8.4%; OR = 0.28, 95% CI 0.09–0.91). There was no difference in miscarriages between the WS-TCM group (N = 7, 5.8%) and the ACU group (N = 27, 7.3%; OR = 0.53, 95% CI 0.24–1.21), or the UC group (N = 62, 10.7%; OR = 0.65, 95% CI 0.32–1.46).

Conclusion: WS-TCM may improve the odds of live birth in fresh, non-donor IVF cycles, and reduce biochemical pregnancies compared to usual care or acupuncture on the day of ET alone. More rigorous research is needed to confirm these findings.

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Oral Abstract Session 08: Research Methodology

OA08.01 Improving the Patient-Reported Outcome Experience for Participants and PI’s: Feasibility and Validity of PROMIS

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Purpose: Patient-reported outcomes (PROs) quantify a person’s experience with their health and the effect of treatment on how they feel or function. As the patient is the only reliable source of this information, PROs are important research outcomes. Because traditional clinical outcomes are often unavailable or inappropriate for many complementary and alternative medicine (CAM) trials, PROs are particularly valuable for CAM clinical research. However, administering and scoring questionnaires requires considerable effort and time. The Patient Reported Outcomes Measurement Information System (PROMIS) could considerably reduce administrative obstacles and lessen survey burden for participants. The purpose of this study was to assess the feasibility and validity of PROMIS compared to commonly used pen and paper legacy measures for collecting PROs in clinical research.

Methods: Cross-sectional survey; 133 participants with confirmed MS completed legacy surveys and PROMIS Computerized Adaptive Tests (CATs) for depression, anxiety, pain, fatigue, and physical function. A multitrait-multimethod analysis was conducted and verified with confirmatory factor analysis.

Results: PROMIS surveys asked fewer questions and required substantially less time to complete than legacy scales. Correlations between PROMIS and corresponding legacy measures were large (0.67 to 0.87). Multitrait-multimethod criteria were generally well met, providing good evidence of convergent and discriminant validity of PROMIS measures. Confirmatory factor analysis returned a chi-squared statistic of χ²(25) = 43.22, p = 0.013; a Goodness-of-fit index of 0.940; and RMSEA index of 0.074; indicating good fit to the observed MTMM matrix.

Conclusion: Results provide evidence of construct validity for a variety of PROMIS questionnaires. Several aspects of PROMIS CATs make them an important resource for CAM clinical trials, including: (1) substantially less time required to complete, (2) reduced missing data, and (3) automatic scoring referenced to the general population. Findings support the use of PROMIS in clinical research with MS and may have broader implications for other research populations, as well.

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OA08.02 Mixed Methods in CAM Research: A Systematic Review of Studies Published in 2012

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Purpose: Mixed methods research uses qualitative and quantitative methods together in a single study or a series of related studies. This systematic review aimed to review the prevalence and quality of mixed methods studies in complementary medicine.

Methods: All studies published in the top-10 integrative and complementary medicine journals in 2012 were screened (n = 2349). The quality of mixed methods studies was appraised using a published tool designed for mixed methods studies, the Mixed Methods Appraisal Tool. Two researchers conducted the screening and quality appraisal.

Results: 4% of papers (95 out of 2349) reported mixed methods studies, 80 of which met criteria for applying the quality appraisal tool. The most popular formal mixed methods design was triangulation (used by 74% of studies), followed by embedded (14%), sequential explanatory (8%) and finally sequential exploratory (5%). Quantitative components were generally higher quality than qualitative components; when quantitative components involved randomized clinical trials they were of particularly high quality. Common methodological limitations were identified. Most strikingly, none of the 80 mixed methods studies addressed the philosophical tensions inherent in mixing qualitative and quantitative methods.

Conclusion: Research published in complementary and alternative medicine journals could benefit from more use of mixed methods research designs. The quality of mixed methods research in these journals would be enhanced by addressing philosophical tensions and improving reporting of (a) analytic methods and reflexivity (in qualitative components) and (b) sampling and recruitment-related procedures (in all components).

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OA08.03 Measuring the Healing Context in CAM: Progress on Developing Patient-Reported Measures of Nonspecific Contributors to Treatment Outcome

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**Purpose:** In its 3rd strategic plan, NCCAM identified goals for future research, including “better understanding of the contributions of both specific and nonspecific effects influencing outcomes.” We present progress to date on our NCCAM-funded project, The Healing Context in CAM: Instrument Development and Initial Validation, which will measure nonspecific factors from the patient’s perspective.

**Methods:** We used PROMIS® methodology to develop patient-report measures of nonspecific factors that may influence healing, such as perceptions of the provider and healthcare environment, treatment expectations, and spirituality and optimism. We conducted 6 focus groups of CAM and conventional medicine patients, interviewed 22 CAM experts, and evaluated existing questionnaires. Through an iterative approach involving writing, rewriting, and revising items based on feedback from patients, we developed a set of item banks containing a total of 296 items. The items were tested on an Internet sample of 1400 adults who had experienced CAM or conventional treatments, and on a Pittsburgh sample of 257 patients who had started a CAM or conventional treatment for any non-acute condition within the previous 4 months. Data analysis included exploratory factor analysis (EFA), confirmatory factor analysis (CFA), and item response theory (IRT). Additionally, 221/257 of the Pittsburgh sample rated their Clinical Global Impression (CGI) of improvement 6 weeks after completing the item banks.

**Results:** EFA and CFA retained 250 items and identified 5 factors: 1) Patient-Provider Relationship + Healthcare Environment, 2) Optimism, 3) Spirituality, 4) Pro-CAM Attitudes, and 5) Treatment Expectations. IRT analyses resulted in retaining Healthcare Environment as a separate construct. Patients’ IRT theta scores for all factors except Spirituality were significantly greater than SH (p < 0.01). Determinants of Responders in a Dose-Response Trial of Spinal Manipulation for the Care of Chronic Low Back Pain

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**Purpose:** The aim of this secondary analysis is to identify determinants of success of spinal manipulation (SMT) for the treatment of chronic low back pain (cLBP). We randomized 400 cLBP patients to receive 18 sessions of lumbar SMT or a light massage control scheduled over 6-weeks; with SMT at 0, 6, 12, or 18 of the visits. Patients were followed for 52-weeks. Successful response to treatment is defined as a 50% improvement in pain measured with the 100-point modified Von Korff Pain Scale. Three-quarters of the data-set is used to develop the predictive models with stepwise logistic regression. Investigated determinants of successful response are baseline measures of pain, disability, outside care, health status, age, gender, relative confidence in SMT/massage, any previous SMT/massage care, and time-point. Secondarily, models are validated on the remaining data with sensitivity and specificity.

**Results:** Determinants associated with improvement across all time points included number of weeks since baseline, dose, number of comorbidities, number of treatment visits, confidence in physician’s ability to treat cLBP, and the EuroQol question about self-care at baseline with p-values of 0.048, < 0.001, 0.020, 0.080, 0.100, and 0.046 respectively. 50%-improvement in pain, across all time points, was predicted best, using forward stepwise selection, by treatment and lower number of comorbidities. An increase in dose increased successful recovery with an OR per increase of 6 treatments of 1.32 95%CI[1.11, 1.57, p=0.002]. And an increased count of the number of comorbidities prevented recovery at an OR per 1 comorbidity of 0.82 95%CI[0.69, 0.97; p=0.025].

**Conclusion:** These findings will assist with developing models for predicting which cLBP patients would especially benefit from SMT.

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**OA08.04**

**Oral Abstract Session 09: Clinical Trials**

**OA09.01 LB**

**Mindfulness Training Versus Sleep Hygiene for Insomnia Symptoms in Older Adults: A Randomized Controlled Comparison Trial**

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**Purpose:** Adequate sleep is vital to our survival, yet sleep problems grown in common with age. About 50% of people aged 55+ years experience insomnia weekly. Given that sleep problems often go untreated in older adults, and untreated sleep problems increase the risk for morbidity and all-cause mortality, effective treatments for sleep problems are a priority to improve the health of our aging population. This randomized controlled comparison trial examined the relative efficacy of two 6-week interventions (mindfulness meditation training, MT vs. sleep hygiene, SH) on sleep, inflammatory markers, and brain morphology.

**Methods:** Participants (N=49) were ages 55–90 (M=66.27, SD=7.43). Inclusion criteria: currently active insomnia symptoms, age in years > 55, and agreeing to randomization. Exclusion criteria: current inflammatory disorder, illness, or infection, current practice of mediation, depression, cognitive impairment, class II or greater obesity, current sleep apnea diagnosis, inability to speak English, and current smoking and/or substance dependence. The UCLA IRB approved study procedures. Measures included self-reported sleep, fatigue, and peripheral blood mononuclear cell levels of Nuclear Factor-kappa B. Brain images were acquired on a 1.5T Siemens Sonata scanner using an 8-channel head coil and a T1-weighted MPRAGE sequence.

**Results:** Forty-three (88%) participants completed the trial. ITT analyses showed that both groups reported improved sleep and SF-12 levels post-intervention. Sleep improvements in the MT condition were significantly greater than SH (p<0.02). Fatigue symptoms improved only in the MT group (p<0.01). Significant
OA09.02 LB
A Randomized Controlled Trial of a Mindfulness-Based Intervention for Metabolic Health in Obese Adults

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Purpose: To estimate the long-term effects of adding mindfulness-based eating and stress management practices to a diet-exercise program on metabolic risk factors in obesity.

Methods: We randomized 194 adults (BMI > 30; 80% female) to a diet-exercise program with or without mindfulness-based eating and stress reduction components. Programs were matched for diet-exercise guidelines. Both arms received 17 group sessions over 22 weeks and were followed for 18 months from intervention initiation. Intent-to-treat analyses were conducted with all available data.

Results: Participants in the standard (n = 94) and mindfulness (n = 100) arms had similar baseline mean BMIs (35.6 and 35.4), fasting glucose levels, insulin resistance as assessed by homeostatic model assessment (HOMA), and triglyceride/HDL ratios. Change in weight (standard vs. mindfulness) was -4.4% vs. -5.5% at 6 months (p = .19) and -3.6% vs. -5.3% at 18 months (p = .21). Change in fasting glucose was 0.74 vs. -0.17 mg/dl at 6 months (p = .46) and 3.11 vs. -0.44 mg/dl at 18 months (p = .017), change in HOMA was 0.00 vs. -0.28 at 6 months (p = .32) and 0.50 vs. -0.11 at 18 months (p = .08), and change in triglyceride/HDL ratio was -0.15 vs. -0.58 at 6 months (p = .019) and 0.09 vs. -0.33 at 18 months (p = .036). In secondary analyses, we found evidence that metabolic outcomes differed among the 3 mindfulness-group instructors. For example, ANOVA for 18-month weight change by instructor group was significant (p = .049). Follow-up tests revealed that weight change for participants led by instructor A was -3.3% vs. -7.3% for those led by instructors B & C (95% CI: -0.5, -7.8, p = .03).

Conclusion: We observed clinically significant improvements in metabolic health indices related to insulin resistance and lipids consistent with improvement of the metabolic syndrome and a non-statistically significant trend toward improved weight loss maintenance in the mindfulness arm. Mindfulness enhancements to diet-exercise programs may improve long-term metabolic health in obesity.

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OA09.03
Preliminary Clinical Trial of Integrative Therapy for Patients with Severe Tinnitus: Findings from an NIDCD-Funded R21

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Purpose: Tinnitus is a common problem for which there is no universally effective treatment, and an estimated 1.2 million individuals are not able to benefit at all from current, widely used treatment strategies. Sound-based and educational therapies (SBE) are the focus of most approaches but appear to be inadequate for those with significant non-auditory aspects of tinnitus (e.g., anxiety, depression, interference with daily life). Given the emerging evidence of Integrative Medicine (IM) to enhance mood, decrease distress and empower patients to cope more effectively, this NIDCD-funded R21 evaluated the possibility that an IM approach targeting treatment of the non-auditory aspects of tinnitus is more effective in alleviating tinnitus symptoms when added to current commonly applied SBE therapies, compared with SBE alone.

Methods: Participants (N = 49) with debilitating tinnitus [i.e., Tinnitus Handicap Inventory (THI) score ≥ 38] were randomized in a 1:3 ratio to either SBE (n = 15) or SBE + IM (n = 34) groups followed over 9 months (i.e., pre-, immediate post-, and 3 mo post-intervention). Using intention-to-treat principles, we employed a 2-level mixed effects model to examine the effect of intervention group on intercept and THI change over time.

Results: As expected, baseline THI scores (B = 62.0, SE = 2.34, p ≤ .001) did not differ by group (p > .10), and both groups significantly improved over the course of the study (B = -2.7, SE = 0.7, p ≤ .001). Moreover, compared to SBE alone, those in the SBE + IM group exhibited even greater improvement (B = -1.7, SE = 0.8, p ≤ .05). In addition, the study tested the feasibility and acceptability of the IM approach, as measured by enrollment, adherence to various treatment components, and by patient report of satisfaction with each component. While enrollment targets were surpassed with excellent adherence in the experimental group, retention was problematic, particularly in the control group.

Conclusion: Although SBE alone significantly reduces tinnitus symptoms, the addition of IM treatment to SBE results in further symptom reduction.

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OA09.04
Management of Gulf War Syndrome Symptoms with Acupuncture: Findings of a Wait-List Controlled RCT

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Purpose: Gulf War Illness (GWI), or chronic multisymptom illness (CMI), is a complex illness characterized by a diverse clinical presentation, that may include fatigue, sleep and mood disturbances, cognitive dysfunction, and musculoskeletal pain.
First defined by the Centers for Disease Control and Prevention (CDC) after the first Gulf War (Operation Desert Shield/Storm), it is commonly seen with a highly individualistic presentation, associated with clusters of symptoms and comorbid medical diagnoses. Our study team recently completed a wait-list controlled RCT project, funded by the Department of Defense (W81XWH) and with the aim of assessing the effectiveness of acupuncture in the treatment of Gulf War Illness.

**Methods:** Because GWI is a complex illness with multiple manifestations, our treatment plan offered tailored individualized treatments to target the symptoms most important to the subjects. Subjects (n = 104) were assigned to either 6 months of biweekly individualized acupuncture or 2 months of wait list followed by 4 months of weekly individualized acupuncture treatments. Our main outcome is the physical component subscale of the SF-36, but we also included validated measurements to capture changes in specific GWI symptom (such as sleep problems) as well as the patient-centered form, the MYMOP. Measurements were conducted every 2 months. We judged all SF-36 comparisons for statistical significance using paired Student’s t-tests.

**Results:** Overall, grouping the weekly and biweekly groups together, improvements were statistically significant by the 6 month measurement timepoint (p = 0.028), but analyses by treatment group suggest that this result may be led by individuals in the biweekly treatment group. For the biweekly treatment group, scores from time 1 (mean score = 48.5) to time 4 (mean score = 75.7) did improve with statistical significance (p = 0.003). A seven point improvement in this physical component of the SF-36 is also clinically significant.

**Conclusion:** Individualized acupuncture treatments may be an effective therapy for GWI.

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**OA10.02**

**From Community Need to Classroom Intervention: Fuel for Learning—A Nutrition/Stress Reduction Intervention Delivered Via DVD**

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**Purpose:** Over the past three decades, the prevalence of childhood obesity has tripled among children in the United States. Behaviors associated with the prevention of childhood obesity have been identified, but finding appropriate avenues for teaching children these behaviors has proven challenging. A classroom-based DVD curriculum, Fuel for Learning (FFL), was designed to address obesity and stress behaviors.

**Methods:** A quasi-experimental non-equivalent wait-list control group design was used in six 3rd grade elementary school classrooms in two schools: treatment (n = 82), control wait-list (n = 80). The FFL curriculum consisted of 50 minutes of mindfulness-based movement and appreciative inquiry exercises/week, and 35 minutes of nutrition instruction/week, delivered via DVD with the classroom teacher as facilitator. Psychosocial stress-related classroom behaviors and self-efficacy regarding dietary behavior were evaluated pre and post the 8-week intervention. Overall change scores for intervention and control wait-list groups were compared using a multivariate analysis of variance (MANOVA) to account for variance in school, classroom, and intervention. Classroom behavior (Connor’s Behavioral Checklist – Self Report and Teacher Scale) was used to gauge behavioral changes impacted by stress.

**Results:** Significant differences were found in teacher-rated classroom behavior concerning the children’s inattention (p = 0.023) while the child-rated scale showed changes in classroom hyperactivity behavior (p = 0.045), in addition to the child reported changes in self-efficacy concerning dietary behavior (p = 0.020) for the intervention group only.

**Conclusion:** This pilot study of FFL indicates the intervention’s potential as a pragmatic approach to deliver stress reduction strategies related to behaviors involved to academic achievement (hyperactivity and inattention) and to psychosocial factors important to obesity prevention, self-efficacy. Both teachers and
students noted significant classroom behavioral differences. FFL may be an effective classroom intervention that effectively addresses the community need of obesity and stress prevention. The DVD format of FFL increases the dissemination potential of introducing these important psychosocial skills.

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**OA10.03**

Mind in Labor: Effects of Mind/Body Training on Childbirth Appraisals and Pain Medication Use During Labor

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**Purpose:** Fear of childbirth poses substantial risks to healthy adjustment across the perinatal period. Fear of childbirth includes maladaptive appraisals of pain (e.g., pain catastrophizing) and of one’s ability to cope with childbirth (i.e., low childbirth self-efficacy). Fear of childbirth predicts lower pain tolerance and greater use of pain medication in labor. Fear and pain in labor may increase the likelihood of unwanted obstetric interventions, such as emergency Cesarean section, lead to a reduction in birth satisfaction, and, in severe cases, can lead to post-traumatic stress symptoms following birth. Mindfulness training – long used as a method for promoting coping with chronic pain and recently shown to be beneficial for acute pain – provides a novel and potentially promising strategy for preparing women for childbirth.

**Methods:** In a small, randomized controlled trial (N = 30), we tested the impact of “Mind in Labor (MIL): Working with Pain in Childbirth,” a brief, 3rd trimester childbirth education program that teaches mindfulness skills for coping with childbirth pain and fear. We compared MIL with an active comparison condition of high quality childbirth education that had no mind/body focus. Participants completed pre-/post-course and post-birth questionnaires and granted access to their medical record data. Participants completed pre-/post-course and post-birth questionnaires and granted access to their medical record data.

**Results:** After receiving the intervention, MIL participants showed increased childbirth self-efficacy (p = .04) and a trend toward lower pain catastrophizing compared to controls. Epidural anesthesia rates were comparable across conditions, but fewer MIL participants used systemic opioid analgesia during labor (Fisher’s exact test p = .119). MIL participants had significantly lower depression symptoms post-course than controls; the difference grew in magnitude postpartum; (p = .04).

**Conclusion:** With over 3.99 million births in the United States per year, innovative and accessible interventions for addressing childbirth fear and pain are critically needed. Our results suggest that relatively brief mind/body training may address this need.

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**OA10.04**

Increases in Mindful Eating Predict Reductions in Consumption of Sweets and Desserts: Data from the SHINE Clinical Trial

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**Purpose:** Many researchers hypothesize that increased consumption of sugar and sweet foods has contributed to more than 60% of the U.S. population being overweight or obese. Psychological stress and lack of conscious attention to food choices may be factors driving non-homeostatic eating and over-consumption of sweets. We hypothesized that increases in mindful eating would lead to decreases in consumption of sweets. We examined this hypothesis using data from the SHINE trial (weight loss results presented elsewhere), which compared a standard diet and exercise program to an enhanced program that included mindfulness-based eating and stress reduction components (SHINE With Awareness; SWA).

**Methods:** Obese adults (N = 194, 36 M; mean BMI = 35.5) were randomized to receive the standard diet and exercise program or SWA. Both arms received one all-day and 16 evening group sessions over 22 weeks. Participants completed the Perceived Stress Scale (PSS), Mindful Eating Questionnaire (MEQ), and the Block Food Frequency Questionnaire at baseline, 6 months (i.e., post-intervention) and 12 months (i.e., ~ 6 months post-intervention).

**Results:** Changes in psychological stress (PSS) from baseline to 6 and 12 months were not statistically significant predictors of changes in eating sweets and desserts in either group. Among participants in SWA (but not in the standard program) increases in mindful eating (MEQ) from baseline to 6 and 12 months predicted reductions in eating sweets and desserts at 6 months (β = −0.270, p = .007; 95% CI [−0.798, −1.331]) and 12 months (β = −0.217, p = .020; 95% CI [−0.623, −0.550]), respectively. Models did not evidence reverse causality; i.e., changes in eating sweets did not significantly predict changes in mindful eating (MEQ).

**Conclusion:** Increasing mindful eating may support lasting reductions in the consumption of sweets and dessert foods among obese people.

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**Oral Abstract Session 11: Clinical Manual Therapies**

**OA11.01**

Structural Integration for Chronic Low Back Pain: A Randomized, Open Label Pilot Clinical Trial

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**Purpose:** To obtain preliminary data comparing Structural Integration (SI), an alternative method of manual therapy and movement education, when combined with usual care (outpatient physical therapy) (SI + UC) versus usual care alone (UC) as treatments for chronic low back pain (cLBP).

**Methods:** Forty-six men and women aged 18–65 with cLBP of > 6 months duration, not attributed to neoplasm, infection or systemic inflammation, and with average pain over the past six
Results: Differences in change scores across treatment groups for the primary and secondary outcomes were in favor of SI+ UC. The primary outcome, a Wilcoxon rank sum comparison of intention-to-treat (ITT) changes in disturbingness of pain over the past week, patient rated on a visual analogue scale (0–100 mm), gave a difference of −25, p = 0.070. The same comparison per protocol (n = 29) gave a −29 difference, p = 0.035. The secondary outcome was the same test applied to the Roland Disability Questionnaire scores (0–24), where the ITT difference was −2, p = 0.007, and the per protocol difference was also −2, p = 0.032. The same test per protocol gave differences in median change scores in favor of SI+ UC for Global Satisfaction with Care (p = 0.004) and the Bodily Pain sub-scale of SF-36 health status inventory (p = 0.022). Study related adverse events in both groups were predominantly mild to moderate with none severe, and self-limiting.

Conclusion: SI+ UC might have a significantly greater therapeutic impact on cLBP than UC alone, with a low burden of associated discomfort. However, the observed superiority of SI+ UC might be due to larger placebo and time and attention effects versus UC alone.

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OA11.02 Craniosacral Therapy for the Treatment of Chronic Neck Pain: A Follow-up Study
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Purpose: Clinical experiences suggest Craniosacral Therapy (CST) as a treatment option for chronic pain management, especially in its non-specific manifestation. However, evidence is limited to observational studies and randomized controlled trials with inadequate control designs. Long-term examinations are missing completely. Therefore this study aimed to report on follow-up data of a randomized controlled trial in chronic non-specific neck pain. The primary outcome was a Wilcoxon rank sum comparison of intention-to-treat (ITT) changes in disturbingness of pain over the past week, patient rated on a visual analogue scale (0–100 mm), which had demonstrated short-term efficacy of CST on pain, disability, quality of life, pressure pain sensitivity, and body awareness.

Methods: Chronic neck pain patients were reassessed 3 months post intervention. During the active study period, blinded patients received standardized CST or light touch sham treatment 8 times once a week. The primary outcome was pain intensity on a 100mm-visual analogue scale. Secondary outcome measures were pain intensity related to motion, pressure pain sensitivity, neck pain-related disability, quality of life, anxiety and depression, stress perception, physical well-being, pain acceptance, body awareness, and global impression of improvement. ANCOVAs for follow-up analyses were conducted on a multiple imputed sample of all 54 randomized patients.

Results: Intention-to-treat analyses revealed robust follow-up results for most of the previously significant group differences including reduction in pain intensity (p = .003) and pain related to motion (p = .020) as well as improvement in disability (p = .006), physical quality of life (p = .000) and patients’ global impression (p = .029). Pressure pain sensitivity and body awareness were no longer significant. Only at follow-up, levels of anxiety were significantly less in the CST than in the sham group (p = .020). No group differences were found for depression, stress perception, mental quality of life and well-being, and pain acceptance.

Conclusion: Study results indicate that Craniosacral Therapy is more effective in relieving chronic non-specific neck pain and in improving physical quality of life than an active attention-control condition, even 3 months post intervention.

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Purpose: Pain is a frequent problem in the neonatal intensive care unit (NICU), with infants receiving an average of up to twelve painful procedures daily. While many studies have examined the effects of massage therapy on pain-related outcomes in neonates, few have examined other integrative care therapies, and even fewer have included objective, physiological outcomes. The purpose of the current observational study was to examine the associations between integrative care therapies and physiological and therapist-reported pain and presentation outcomes among hospitalized neonates.

Methods: We conducted a retrospective review of a clinical database obtained in a naturalistic, practice-based study of integrative care therapies at a large, Midwestern pediatric hospital. Before and after delivering integrative care therapies, therapists rated neonates' pain and presentation levels. Neonates' heart rate and oxygen saturation were recorded pre-post therapy. Paired-samples t-tests were used to examine the associations between integrative care therapies, pain and presentation ratings, and neonates' heart rate and oxygen saturation.

Results: Of 186 participants (Mage = 68 days), 58% were male (N = 108) and 67% were Caucasian (N = 125). Fifty-seven percent (N = 106) received massage and healing touch, and 12% received some other therapy combination. The remainder received a single therapy, mostly massage (N = 42) or healing touch (N = 12). From pre-post intervention, neonates' heart rate significantly decreased (M = 156 vs. M = 140 per min; t(159) = 16.6, p < .001) and oxygen saturation significantly increased (M = 95.0% vs. M = 97.4%, t(160) = -10.4, p < .001). Therapist-reported pain (M = 2.8 vs. M = 0.2; t(170) = 11.9, p < .001) and presentation ratings (M = 3.2 vs. M = 1.0; t(72) = 14.5, p < .001) significantly decreased pre-post intervention.

Conclusion: Delivery of integrative care therapies in the NICU was associated with improvements in pain, presentation, heart rate, and oxygen saturation among hospitalized neonates. Limitations notwithstanding, these preliminary results suggest that integrative care therapies may be a useful adjunct to pain and overall management in the NICU. Further controlled research including an active control group is warranted.

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OA11.05 LB
Effectiveness of Integrative Medicine for Pain Relief: Use of CMS Major Diagnostic Categories to Identify Responsive Inpatient Populations

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Purpose: Integrative medicine (IM) reduces pain in hospitalized patients. However, a barrier to expanding IM to additional hospitals is the difficulty of identifying clinical populations that best respond to integrative therapies. Overcoming this barrier is challenging, given the paucity of large-scale IM inpatient programs capable of this research. In this retrospective study, we assessed the overall effectiveness of IM provided by the Penny George Institute (PGI) for pain management and then analyzed by clinical populations.

Methods: Data were collected from 7/1/09–12/31/12 and include 12,899 admissions where pre-IM intervention pain > 0 and both pre- and post-intervention pain scores (0–10 verbal scale) were available. Dataset also included EPIC-based EMR variables (demographics, diagnoses). CMS major diagnostic categories (MDCs) were calculated by dividing ICD-9CM principal diagnoses into mutually exclusive clinical populations.

Results: Pre-IM intervention pain scores averaged 4.84 (SE = .03) and pain change averaged 2.07 points (SE = .02). Identification of MDCs with large samples resulted in the following MDCs suitable for analysis: “Musculoskeletal System and Connective Tissue” (n = 4,058), pre-IM intervention pain of 4.98 (SE = .04) and -1.90 (SD = .03) pain change, “Factors Influencing Health Status” (n = 1,796), pre-IM intervention pain of 4.78 (SE = .09) and -2.21 (SE = .05) pain change, “Pregnancy, Childbirth and Puerperium” (n = 1,467), pre-IM intervention pain of 3.78 (SE = .07), and -2.33 (SE = .05) pain change, “Circulatory System” (n = 1,101), pre-IM intervention pain of 4.88 (SE = .09) and -2.23 (SE = .06) pain change, and “Digestive System” (n = 1,030), pre-IM intervention pain of 5.02 (SE = .09) and -2.05 (SE = .06) change. Compared with “Pregnancy, Childbirth and Puerperium”, all MDCs had statistically higher pre-IM intervention pain scores (p < .001). Compared with “Musculoskeletal System and Connective Tissue”, 4/5 MDCs had statistically larger post-IM pain decreases (p < .001).

Conclusion: Widespread provision of IM across an entire hospital by the PGI offers a unique opportunity to identify differential patterns of responsiveness by clinical populations. Future PGI research will examine the pattern of responsiveness over the hospital stay.

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OA12.01
Pressure to Perform: CAM Providers’ Perceptions of Pressure to Demonstrate CAM Effectiveness

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Purpose: Shifting public opinion and policy regarding the effectiveness of different CAM modalities may influence client perceptions of CAM, but also providers’ views of their own practice. According to Self-Determination Theory (SDT) health-care providers who feel pressure to demonstrate the effectiveness of their practice will adopt a controlling rather than an autonomy-supportive (AS) motivational orientation (MO) towards clients. The aim of this study was to examine perceived pressure to demonstrate modality effectiveness among CAM providers, the correlates of feeling pressured, and qualitatively explore the source of perceived pressure.

Methods: 750 CAM providers (M age = 47.18, 72.8% female) recruited from CAM association lists and websites completed questions about their practice, and the degree to which they felt pressure to demonstrate the effectiveness of their primary CAM practice on a scale from 1 to 10. They also reported the source of this pressure via an open-ended question. Four scenarios describing client interactions were rated for appropriateness with response options reflecting a high AS to a high controlling MO.

Results: A MO index was created with higher values reflecting greater AS. 47.6% reported feeling pressure to demonstrate practice effectiveness. A one-way ANOVA, F(8, 624) = 2.62, p < .01, revealed that those who practiced Cranial Sacral Therapy
reported the least pressure to demonstrate effectiveness (M = 2.45), whereas those who practiced Chiropractic (M = 5.72), Naturopathy (M = 5.83), and Reiki (M = 6.33) reported more pressure. Age was the only demographic variable associated with pressure perceptions (r = -.14). Greater pressure was also associated with less client AS. Thematic content analysis revealed the general public as the most common source of pressure (33.9%), and the medical community as the least mentioned source (14.7%).

Conclusion: Our findings suggest that some CAM providers feel pressured to prove that their modality is effective, and that this pressure may impact how they interact with their clients.

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OA12.02
Ethical Dilemmas and Scientific Misunderstandings: Exploring General Practitioners’ Views on Placebo Effects
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Purpose: Surveys show general practitioners (GPs) use placebos in clinical practice. Reported prevalence rates for such placebo prescribing vary widely. This study aimed to explore GPs’ perspectives on clinical uses of placebos in more depth using qualitative methods.

Methods: We conducted a web-based survey of 783 UK GPs’ use of placebos in clinical practice. The survey showed that 97% of UK GPs have used placebos in clinical practice, and that pure placebos are used rarely but impure placebos are more common. This paper expands our understanding of these results by reporting a qualitative descriptive analysis of written responses (“comments”) to three open-ended survey questions.

Results: Comments were classified into three categories: defining placebos and their effects in general practice; ethical, societal and regulatory issues faced by doctors; and reasons why a doctor might use placebos and their effects in clinical practice. GPs typically defined placebos as lacking something, be that adverse or beneficial effects, known mechanism of action, and/or scientific evidence. Some GPs defined placebos positively as having potential to benefit patients, primarily through psychological mechanisms. GPs described a broad array of possible harms and benefits of placebo prescribing, reflecting fundamental bio-ethical principles, at the level of the individual, the doctor-patient relationship, the National Health Service, and society. While some GPs were adamant that there was no place for placebos in clinical practice, others focused on placebo effects, and saw these as ubiquitous and potentially beneficial in primary care. GPs’ comments also revealed some misunderstandings about placebo effects.

Conclusion: This study has elucidated specific costs, benefits, and (for some, insurmountable) ethical barriers to placebo use as perceived by a large sample of UK GPs. Stand-alone qualitative work would provide a more in-depth understanding of GP’s views. Continuing education and professional guidance could help GPs contextualize their knowledge of placebos and their effects.

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OA12.03
The Association Between Women’s Choice of Birth Setting and Their Use of CAM During Labor and Birth
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Purpose: Contemporary maternity care often means women are able to choose a number of settings for their birth including hospitals, birth centers, and community settings. There is also evidence that many women utilised complementary and alternative medicine (CAM) during pregnancy and birth. The purpose of this study is to examine the association between women’s choice of birth setting and their use of CAM during labor and birth.

Methods: Longitudinal data from a sub-study of women (n = 2445) from the nationally-representative Australian Longitudinal Study of Women’s Health (ALSWH) was analyzed for relationships between women’s birth setting (hospital, birth center, or community) and their demographics, attitudes towards maternity care (including CAM), and use of CAM during pregnancy and birth.

Results: The characteristics associated with women’s choice of birth setting include some demographic features such as employment status, health care subsidy, and level of education. Women’s birth setting choice was also linked to a preference for CAM practitioner by women birthing in birth centers and community settings. In contrast, women birthing in hospitals held more positive views towards obstetric care. There was a higher use of CAM during pregnancy by women birthing in birth centers and community but this was not consistent across all CAMs investigated. Naturopaths, herbal medicines, homeopathy and flower essences were more commonly used by women birthing in community compared with those in a birth center. There was also a higher rate of CAM use for intrapartum pain management for women birthing outside of a hospital setting, although women attending a birth center were more likely than those birthing in community to use pharmacological pain management techniques.

Conclusion: There are characteristic differences between women birthing in different birth settings which seems to be influenced as much by preference for maternity care and interest in CAM use as it is by demographics.

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OA12.04
Cancer Patients’ Stories about CAM-Use: The Ongoing Work to Shape as Good a Life as Possible During Cancer Illness and Treatment
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Purpose: The purpose of this paper is to give a qualitative analysis of how and why 5 patients treated for colorectal cancer related to CAM during a one year illness trajectory.

Methods: The data are drawn from the Norwegian arm of the international mixed method “PATH-study” (Patients Accounts
of Trajectories to Healing’), which included 9 patients diagnosed with colorectal cancer. The patients selected had finished operation at the hospital. They were interviewed every third month during one year, they wrote diaries and answered questionnaires. Each row of qualitative interviews contains many small stories about events, relations and actions during the one year process. We will present shortened edited versions of the stories of the five patients who integrated some kind of CAM in their work to live as well as possible and to get well. The presentation and analysis of stories are inspired by Arthur Frank's perspectives on illness stories and socio-narrative analysis.

**Results:** The 5 stories of CAM-use differed both in actions and in reasons for action. They showed differences and nyances in what, when and for how long the patients used CAM, and if and in what ways the use changes during the one year process. The analysis of the five stories will be connected to Mol’s perspective on ‘the logic of care’, which sees patients as members of their caring team, and care as an interactive, ongoing, open-ended process that may be shaped and reshaped depending on results.

**Conclusion:** The analysis contributes to nuancing the category ‘CAM-user’. The analysis of the stories illustrates different processes of relating to and including CAM into the care among cancer patients. The study underlines the need to be attentive to different ways of relating to and using CAM in cancer patients work to shape good a life as possible during treatment.

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### Oral Abstract Session 13: Clinical Research: Yoga

#### OA13.01

**The Safety of Yoga: A Systematic Review of Case Reports and Case Series on Adverse Events Associated with Yoga**

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**Purpose:** While yoga is gaining increased popularity in North America and Europe, its safety has been questioned in the lay press. The aim of this systematic review was to assess published case reports and case series on adverse events associated with yoga.

**Methods:** Medline/Pubmed, Scopus, CAMBase, IndMed and the Cases Database were screened through August 2013. A specific cases was regarded as ‘yoga’ if it was a) explicitly labeled as yoga, b) labeled as a specific yoga practice, and/or c) the described practice clearly resembled typical yoga practices. Adverse events were classified as yoga-associated if they appeared in temporal connection with yoga practice and/or a causal relationship was assumed in the report.

**Results:** Out of 741 records, 37 case reports and 2 case series reporting a total of 78 cases were included. Eleven cases had medical preconditions, mainly glaucoma (n = 3; 3.8%), and osteoporosis (n = 3; 3.8%). Pranayama (n = 4; 5.1%), hatha yoga (n = 3; 3.8%), and Bikram yoga (n = 3; 3.8%) were the most common yoga practices; headstand (n = 11; 14.1%), forceful breathing (n = 4; 5.1%), shoulder stand (n = 3; 3.8%), and lotus position (N = 3; 3.8%) were the most common yoga postures and breathing techniques cited. Twenty-eight adverse events (36.8%) affected the musculoskeletal system; 14 (17.9%) the nervous system; and 9 (11.5%) the eyes. Sixteen cases (20.5%) reached full recovery; 9 cases (11.5%) partial recovery; 1 case (1.3%) no recovery; and 1 case (1.3%) died. Fifty-one cases (65.4%) did not report clinical outcomes.

**Conclusion:** As with any physical or mental practice, yoga should be practiced carefully under the guidance of qualified instructors. Beginners should avoid extreme practices such as headstand, lotus position and forceful breathing. Individuals with medical preconditions should work with their physician and yoga teacher to appropriately adapt postures; patients with glaucoma should avoid inversions and patients with compromised bone and other musculoskeletal disorders should avoid forceful yoga practices.

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#### OA13.02

**Is Yoga Really Dangerous? A Systematic Review of Adverse Events Reported in the Medical Literature**


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**Purpose:** Determine the nature and risk of adverse events (AE) associated with yoga practice.

**Methods:** PubMed was searched for primary source citations containing the term “yoga” from inception through July 2013, excluding those that only involved meditation or breathing. We reviewed all randomized and quasi-randomized controlled trials (RCT/QRCTs), classified purpose as health promotion (preventive) or treatment of a health problem (therapeutic), control groups as active (e.g., exercise) or inactive (e.g., usual care), and AEs as present, absent, or not mentioned. Non-randomized/uncontrolled studies, surveys, case series, and case reports (non-RCT/QRCTs) were reviewed if AEs were suggested by the title/abstract. AEs were classified as requiring medical care (serious) or not serious. The association of AEs to yoga practice was classified as definite, possible, unlikely, or unknown.

**Results:** Of the 1456 citations fulfilling inclusion criteria, 199 were RCT/QRCTs. Of these, 28 included information about the presence or absence of AEs. In five therapeutic RCT/QRCTs, AEs were reported in 6.3% of yoga, 9.7% of active control, and 0.2% of inactive control participants. In 23 preventive RCT/QRCTs, AEs were reported in 0.4% of yoga, 1.6% of active control, and none of inactive control group participants. Most AEs were transient musculoskeletal injuries; one was serious (cervical radiculopathy) and none required hospitalization. Among 1256 non-RCT/QRCTs, only 28 mentioned AEs (total AEs: 222). However, only 29 AEs were definitely/probably associated with yoga and, of these, only 7 required hospitalization (arterial dissections/occlusions [2], rectus sheath hematomas [2], elevated muscle enzymes, neuropathies, seizures).

**Conclusion:** AEs were rarely mentioned in the yoga literature. When reported, AEs were usually non-serious, similar in frequency in yoga and active control groups, and rarely required hospitalization. Caution is still warranted to prevent musculoskeletal and nervous systems AEs, particularly when yoga is used for therapeutic purposes. Only large population-based studies will provide complete information about yoga-associated AEs.

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OA13.03
Effect of Restorative Yoga vs. Stretching on Salivary Cortisol and Psychosocial Outcomes in Individuals with the Metabolic Syndrome: The PRYSMS Randomized Controlled Trial

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Purpose: Chronic stimulation and dysregulation of the neuroendocrine system by stress may cause metabolic abnormalities. We determined whether cortisol and psychosocial outcomes would improve with a restorative yoga (relaxation) or a low impact stretching intervention for individuals with the metabolic syndrome.

Methods: We analyzed data from a 1-year multi-center randomized controlled trial (6-month intervention and 6-month maintenance phase) of restorative yoga (RY) vs. stretching (S). Participants completed surveys to assess depression, social support, positive affect, and perceived stress at baseline, 6 and 12 months. We collected saliva for cortisol analysis. Multivariate GEE/GLM regression models compared changes in cortisol and psychosocial outcomes by intervention group, controlling for study site, medications (antidepressants, hormone therapy), BMI and baseline values.

Results: Complete data was available for 146 of 180 study participants, 77 in RY and 68 in S. After 6 months, there were decreases in cortisol in S compared to the RY group. The relative decrease in waking salivary cortisol was: 1.9 mmol/l (95% confidence interval: 0.2; 3.6, p = 0.004), waking +30 minutes was 1.9 mmol/l (−0.3; 4.2, p = 0.09), waking +60 minutes was 1.4 mmol/l (−0.6; 3.5, p = 0.16), and evening cortisol was 2.3 mmol/l (0.7; 4.0, p = 0.005). For psychosocial outcomes, there was a trend toward increased positive states of mind with S at 1 year (0.12; −0.3; 0.01, p = 0.07) but little evidence of change between groups for the other scales. Perceived stress decreased by 1.5 points (−0.3; 3.3, p = 0.11) at 6 months in S, and by 2.0 points (0.1; 3.9, p = 0.04) at 1 year compared to RY.

Conclusion: We found significant decreases in many cortisol-related outcomes in the S group compared to the RY group. Concordantly, scores on the Perceived Stress Scale also decreased in the S group. Group support during the interactive stretch classes may have led to some of these observed changes.

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OA13.04
Pilot Trial of an Integrative Yoga Program Designed by a Delphi Method for People with Moderate Disability Due to Multiple Sclerosis

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Purpose: There is a great need for research on yoga in multiple sclerosis (MS), due to widespread use, anecdotal evidence of benefits, and little formal research. The purpose of this pilot trial was to assess feasibility and measure selected physical, mental, and biological effects of a yoga program designed for people with moderate disability due to MS.

Methods: A modified Delphi process with a panel of experts from across health care fields and yoga training, and people with MS who have taken yoga, was utilized to help design the yoga program. Fourteen women, ages 34–64 (M = 53.5, 2–26 years since MS diagnosis (M = 13.9), and a score of 3–6 (M = 4.67) on the Self-Report of MS disease severity, completed 8-weeks of two 1.5 hour classes/week, yoga philosophy, breathing, postures, relaxation, meditation, tracked home practice, and assessments at 0, 9, and 16 weeks.

Results: Significant improvements (week 9 vs. baseline) were measured in: 25’ timed walk (p = 0.001), 9-hole peg test (dominant hand) (p = 0.014), 6-minute walk distance (p = 0.004), 5-times sit-to-stand (p = 0.001), standing backward reach (p = 0.028), 12-item MS Walking Scale (p = 0.009), MS Quality of Life Inventory (MSQLI); Mental Component Summary scale of SF-36 (p = 0.001), and four subscales: vitality (p = 0.001), social functioning (p = 0.003), role-limitations due to emotional problems (p = 0.007), and mental health (p = 0.016), the Modified Fatigue Impact Scale (p = 0.003), and physical (p = 0.003), cognitive (p = 0.003), and psychosocial subscales (p = 0.007), MOS-Pain Effects Scale (p = 0.042), Bladder Control (p = 0.028), Impact of Vision Impairment (p = 0.040), Perceived Deficits Questionnaire (PDQ) (p = 0.02), and three subscales: Attention/Concentration (p = 0.033), Prospective Memory (p = 0.028) and Planning and Organization (p = 0.038); Mental Health Inventory (MHI) (p = 0.003) and three subscales: Anxiety (p = 0.001), depression (p = 0.005) and positive affect (p = 0.016). Qualitative results, circulating biomarkers and gene expression are being analyzed.

Conclusion: This pilot trial indicates potential benefits in physical, mental and quality of life parameters of a specifically designed yoga program for individuals with moderate disability due to MS.

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OA14.01
A Comparison of Chiropractic Manipulation Methods and Usual Medical Care for Low Back Pain: A Randomized Controlled Clinical Trial

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Purpose: The primary aim of this study was to compare manual and mechanical methods of spinal manipulation (Activator) for patients with acute and sub-acute low back pain. These are the two most common methods of spinal manipulation used by chiropractors, but there is insufficient evidence regarding their comparative effectiveness against each other.
Our secondary aim was to compare both methods with usual medical care.

Methods: In a randomized comparative effectiveness trial, we randomized 107 participants with acute and sub-acute low back pain to: 1) usual medical care; 2) manual side-posture manipulation; and 3) mechanical manipulation (Activator). The primary outcome was self-reported disability (Oswestry) at four weeks. Pain was rated on a 0 to 10 numerical rating scale. Pain and disability scores were regressed on grouping variables adjusted for baseline covariates.

Results: Manual manipulation demonstrated a clinically important and statistically significant reduction of disability and pain compared to Activator (adjusted mean difference = 7.9 and 1.3 points respectively, P < .05) and compared to usual medical care (7.0 and 1.8 points respectively, P < .05). There were no significant adjusted mean differences between Activator and usual medical care in disability and pain (0.9 and 0.5 points respectively, P > .05).

Conclusion: Manual manipulation provided significantly greater short-term reduction in self-reported disability and pain compared to Activator and usual medical care. University of Pittsburgh IRB approval: PRO10040327. This work was supported by an award (R00AT004196) from the National Institutes of Health (NIH) National Center for Complementary and Alternative Medicine (NCCAM).

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OA14.03
The Effect of Self-Administered Acupressure on Chronic Pain in Breast Cancer Survivors

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Purpose: There are nearly 3 million breast cancer (BC) survivors in the United States. Chronic pain and sensory disturbances after BC treatment is common, occurring in approximately 50% of patients, and can persist for years. Chronic pain in BC survivors is associated with fatigue, sleep disturbances, mood disorders, and decreased quality of life. Current treatments for chronic cancer pain have limited efficacy and/or unacceptable side-effects, and as such there is a tremendous need for new treatments in this area.

Methods: We examined the effect of 6 weeks of the effects of two types of self-administered acupressure (stimulating {SA} and relaxing {RA}) compared to standard of care (SC) in 105 (39 randomized to SA, 33 to RA and 33 to usual care) chronically fatigued BC survivors who reported ≥ 3 on the Brief Pain Inventory’s (BPI) average pain subscale and who were from an ongoing randomized clinical trial on acupressure for persistent cancer-related fatigue. The BPI severity and interference pain subscales were used to determine changes in pain. Analysis of variance (ANOVA) was performed on mean differences of changes in pain scales by time and group.

Results: Baseline pain severity scores are 4.6SA, 4.2RA, 4.6 UC (10 point scale) and baseline pain interference scores are 3.0SA, 4.5RA, 4.3UC (10 point scale). There was a significant decrease in pain severity (p = <0.01; 1.4SA, -1.3RA, -1.1RA, 0.8RA, 0.03UC; 10 point scale) and pain interference (p = <0.01; -1.4SA, -1.3RA, -1.4SA, -1.3RA, 0.1UC; 10 point scale) in the combined acupressure group compared to UC.

Conclusion: In this preliminary analysis two types of self-administered acupressure engender a greater analgesic response for clinical pain as compared to UC in fatigued BC survivors. These findings should be interpreted with caution given our small sample size and diverse types of pain. More rigorous studies are recommended.

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OA14.04 LB
Impact of Outpatient Massage on Symptom Expression in Cancer Patients and Caregivers

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Purpose: Massage as a manual therapy has shown benefit for symptomatic relief in cancer patients and their caregivers. We
explored the impact of a single massage session on self-reported symptoms in an outpatient setting at a large academic cancer center.

Methods: Data were reviewed from massage sessions (30 or 60 minute duration) at our Integrative Medicine Center outpatient clinic from May 2011 through December 2013. Participants completed a pre- and post-massage symptom assessment instrument, the Edmonton Symptom Assessment Scale (ESAS); 10 symptoms, scale from 0–10, where 10 is most severe). ESAS subscales analyzed included Physical Distress (PHS; range 0–70), Psychological Distress (PSS; range 0–30), and Global Distress (GSD; range 0–100). Data were analyzed pre and post scores using paired t-tests.

Results: Our analysis included data collected from 1529 massage visits (mean 2.59 visits/person). The most frequently reported symptoms at initial massage (first visit) included: Sleep 82.7%, Well-Being 82.7%, Fatigue 79.6%, Pain 67.7%, and Anxiety 62.7%. Symptoms with the highest scores (score ≥3; means) at initial massage included: Sleep [3.8; n = 480]; Fatigue [3.3; n = 491]; and Well-Being [3.2; n = 480]. An initial massage session resulted in a significant decrease in GSD [22.8 to 12.3], PHS [15.4 to 8.7], and PSS [7.3 to 3.7] (all p’s < 0.0001). A single massage (including first and follow up visits; n = 1529) resulted in a statistically and clinically significant reduction (decrease in symptom score ≥ 1; means) in symptom expression for Fatigue [−1.20], Well Being [−1.14], and Pain [−1.08] (all p’s < 0.0001).

Conclusion: A single 30- or 60-minute massage session resulted in acute relief of self-reported symptoms in patients and caregivers. Further study is warranted to gain insight into the potential benefits of massage in relieving symptom distress in cancer patients and caregivers, the temporal nature of the effects, and the necessary frequency to maintain effective symptom control.

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OA15.01
Effects of Eight-Week Meditation Training on Hippocampal Volume: A Comparison of Mindful Attention Training and Cognitively-Based Compassion Training

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Purpose: The hippocampus is an important brain region that atrophies with chronic stress and aging. Previous studies indicate that hippocampus gray matter concentration is higher in experienced meditation practitioners and may increase after participation in Mindfulness-Based Stress Reduction (MBSR). Here we investigated changes in hippocampal volume in healthy subjects following two different meditation-based interventions: Mindful-Attention Training (MAT) and Cognitively-Based Compassion Training (CBCT) and evaluated whether changes were associated with amount of practice time.

Methods: As part of a larger randomized controlled trial, healthy adults without prior meditation experience were randomized into 3 arms: MAT, CBCT, or an active control intervention (health education course). Each group met for 2 hours per week for 8 weeks. MAT and CBCT participants kept a log of their meditation practice. We collected high-resolution anatomical brain scans before and after each intervention on a subsample of participants. Longitudinal changes in hippocampal volume were measured using the FreeSurfer longitudinal toolbox, a validated method for computational neuroanatomy with high test-retest reliability.

Results: There was no main effect of either intervention on hippocampal volume (paired t-test, p > 0.3 in each group). However, in the MAT group, practice time was significantly correlated with increased hippocampal volume (r = 0.82, p < 0.05, N = 13), even after removing one outlier subject with very high practice (r = 0.58, p < 0.05, N = 12). The CBCT group showed no significant effect of practice (r = 0.01, p > 0.9, N = 14).

Conclusion: Our study indicates that Mindful-Attention Training may promote neuroplasticity in the hippocampus in healthy subjects who engage in regular meditation practice over the course of 8 weeks. These findings confirm and extend similar findings with MBSR. Future research is needed to test these effects in clinical populations with hippocampal volume reduction, such as in major depression.

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OA15.02
Mindfulness-Based Cancer Recovery (MBCR) and Supportive Expressive Therapy (SET) Maintain Telomere Length (TL) and Cortisol Slopes Relative to Control in Distressed Breast Cancer Survivors

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Purpose: Group psychosocial oncology interventions including Mindfulness-Based Cancer Recovery (MBCR) and Supportive-Expressive Group Therapy (SET) can help breast cancer survivors decrease distress and influence cortisol levels, but their impact on Telomere Length (TL) and cortisol together has not been studied. The objective was to compare the effects of MBSR and SET to a minimal intervention condition on TL and cortisol profiles in distressed breast cancer survivors who were part of a larger randomized controlled trial.

Methods: MBCR focused on training in mindfulness meditation and gentle Hatha yoga while SET focused on emotional expression and group support. Both groups included 18 hours of contact time. The control condition was usual care plus a one-day 6-hr stress management seminar. Blood and saliva samples were collected pre-and post-intervention. The primary outcome measures were relative telomere length as measured by the T/S ratio and cortisol slopes across four daily measures averaged over three days. Secondary outcomes were self-reported mood and stress symptoms.

Results: Ninety-two distressed breast cancer survivors with a diagnosis of Stage I-III cancer who had completed treatment at least three months previously participated. Using analyses of
OA15.03
Signal Processing and Machine Learning of EEG and Respiration Changes During Mindfulness Meditation State
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Purpose: Mindfulness meditation (MM) has increasing evidence of benefit for a variety of health conditions. EEG changes have been noted short-term during a meditation session as well as long-term from continued practice. Most studies examine EEG changes alone and do not include other physiological measures. The purpose of this study was to analyze EEG and respiration changes during meditation using advanced signal processing techniques and machine learning.

Methods: EEG and respiration data were collected and analyzed from novice meditators after a 6-week one-on-one MM intervention previously reported on (Wahbeh et al., 2012). The meditation was a guided mindfulness of breath meditation delivered with an audio recording; no specific instructions to slow breathing were given. Research participants were relatively healthy adults aged 50–75 years. EEG and respiration signals together had a higher discrimination accuracy than using the EEG or respiration signal alone.

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OA15.04
Do Complexity-Based Measures of Sway Inform Long- and Short-Term Effects of Tai Chi Training on Balance in Healthy Adults?
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Purpose: Diminished control of standing posture, as indicated by traditional measures of postural sway, including increased center-of-pressure (COP) displacements and sway speed, is associated with falls in older adults. Tai Chi (TC) is a multisystem intervention that reduces fall risk, yet its impact on traditional sway measures is inconsistent. We hypothesized that TC improves the integrated function of multiple control systems influencing balance, which can be quantified by a multi-scale “complexity” measure of postural sway. We evaluated both traditional and complexity-based measures of postural sway to characterize the short- and long-term effects of TC training on postural control in healthy older adults.

Methods: We conducted a two-arm wait-list randomized clinical trial to evaluate short-term (6 months) TC effects, and a cross-sectional comparison of TC naïve and expert (24.5 ± 12 yrs experience) groups. COP was assessed on a force-plate with eyes-open (EO) and eyes-closed (EC), a more challenging condition. Traditional (sway speed) and complexity-based (multi-scale entropy, MSE) measures quantified antero-posterior postural control.

Results: At baseline, TC experts (n = 27, age: 62.8 ± 7.5 yrs) had greater sway speed, compared to TC naïve adults (n = 60, age: 64.5 ± 7.5 yrs) under EC condition (P = 0.026). However, compared to TC naïve adults, MSE of TC experts exhibited greater COP complexity under both EO (P = 0.056) and EC (P = 0.007) conditions. After 6 months of TC, TC naïve adults showed non-significant trends towards increased sway speed vs. controls, while COP complexity increased with EC (P = 0.018). Similar non-significant trends occurred with EO. Complexity outcomes were generally more highly correlated than sway speed with functional measures (e.g., maximum walking speed).

Conclusion: Complexity-based measures of COP provide information regarding the impact of long- and short-term TC training on integrated postural control. MSE measures appear to be more sensitive to both the short- and long-term effects of TC than traditional measures of sway speed, especially under more challenging postural control conditions.

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Oral Abstract Session 16: Herbal Medicines: Basic and Clinical

OA16.01
An Innovative Combination Phytotherapy Derived from Viscum Album L. Is Effective in Treatment in Acute Myeloid Leukemia

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Purpose: Aqueous Viscum album L. extracts (VAE) are widely used in complementary cancer therapies. Due to their low solubility, triterpene acids, which are known to possess anti-cancer properties, do not occur in aqueous extracts in significant amounts. Using cyclodextrins it was possible to solubilize mistletoe triterpene acids and to determine the anti-cancer properties in different myeloid leukemia cell lines (AML).

Methods: The experimental extracts contain either mistletoe lectin-I and viscotoxins (viscum) or solubilized oleanolic- and betulinic acids (TT) and more interestingly, a combination thereof (viscumTT). The cytotoxicity of increasing concentrations of VAE preparations was tested in U937 and HL-60 cells in vitro. Apoptosis was determined using mitochondrial membrane potential measurement, Annexin/PI, Western blot analysis and caspase assays. A NOD/SCID model of HL-60 was used to test efficacy and mechanisms of treatment with lectin- and triterpene-containing preparations in vivo. NOD/SCID mice were treated six times intravenously with TT, Viscum or ViscumTT.

Results: TT as well as Viscum inhibited cell proliferation and displayed impairing cytotoxic properties in vitro. The Annexin/PI and mitochondrial potential measurements indicated a dose-dependent induction of apoptosis. Furthermore, the combination of both extracts (ViscumTT) acted significantly synergistic compared to the single agent treatment in HL-60 cells. Combined with the caspase activity and caspase inhibitor assays, the results revealed a caspase-8 and -9 mitochondrial dependent pathways for Viscum, TT and ViscumTT. The in vivo experiment showed that treatment of mice with viscum and the ViscumTT combination prolonged the mean survival significantly compared to control group.

Conclusion: Taken together, we could demonstrate that this new formulation “viscumTT” of aqueous mistletoe extracts and triterpene acids can induce apoptosis in leukemia cells via the intrinsic and extrinsic signaling pathways. Based on these data we assume that Viscum album L. extracts containing triterpene acids may possess impressive therapeutic potential.

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OA16.02
The Characterization and Therapeutic Development of Natural Products from E. Officinalis: An Ayurvedic Medicinal Plant Used to Treat Diabetic Eye Disease

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Purpose: The medicinal plant Emblica officinalis has been used for a thousand years as an Indian Ayurvedic preparation to treat diabetes and promote overall eye health. In the eye, human aldose reductase (AKR1B1) metabolism of glucose to sorbitol is linked to cataract formation and retinopathy. We have isolated and characterized β-glucogallin (BGG) from E. officinalis, as a potent and selective inhibitor (IC50 = 8 µM) of AKR1B1 in vitro. In addition, we determined that BGG was effective at preventing the pathology of diabetic eye disease by blocking 80% of sorbitol accumulation, under hyperglycemic conditions, in cell based assays and in lenses from an AKR1B1 transgenic mouse strain cultured ex vivo.

Methods: Thus, we began a medicinal chemistry campaign based on the pharmacophore of BGG to develop more potent AKR1B1 inhibitors while maintaining the specificity for AKR1B1 over other aldose reductase family members. During our studies we observed that the ester linkage of BGG is labile in aqueous solutions. We report the design of six new linkages (ether/triazole/amide) and structure activity relationships, introduced via high yielding efficient syntheses, replacing the labile ester and an original 2-step (90% yield) preparation of BGG. Inhibition of AKR1B1 was assessed in vitro (recombinant enzyme), with Raw264.7 macrophages, and using the ex vivo lens organ culture model.

Results: The most promising lead was the amide-linked glucoside (BGA), which displayed activity identical to BGG and was synthesized in 3 steps (79% yield). The stability of BGG and BGA, in aqueous sulfuric acid solutions (pH = 0.33) at 80°C, was investigated using quantitative HPLC. We found that BGG completely decomposed within 30 minutes. Conversely, 96% of BGA remained intact after 6 days under the same conditions.

Conclusion: With comparable activity to BGG and greatly improved stability, BGA becomes an attractive therapeutic lead toward the treatment of diabetic eye disease.

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OA16.03
A Randomized Placebo Controlled Trial of Rhodiola Rosea and Sertraline for Major Depressive Disorder

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Purpose: Rhodiola rosea (R. rosea), a botanical of both western and traditional Chinese medicine, has been used as a folk remedy for improving stamina and reducing stress. Few controlled clinical trials have examined R. rosea for its putative antidepressant action in major depressive disorder (MDD). In this study, we seek to gain preliminary safety and efficacy data on R. rosea compared to sertraline (a conventional antidepressant) and placebo.

Methods: We conducted a 12-week, randomized, double-blind, placebo-controlled, parallel group trial. Drug-free subjects with mild to moderate MDD were randomized to either R. rosea extract 340–1,360 mg daily; sertraline 50–200 mg daily, or placebo for 12 weeks. The primary outcome measure was changed over time in the mean 17-item Hamilton Depression (HAMD) Rating score. Mixed-effects models were used to evaluate the primary end point. Adverse events were evaluated and compared using Fisher’s exact test. Analyses were also performed under blinded conditions.
**Results:** 57 subjects were enrolled. Mean age was 45.0 (SD 15.5) years: 26 (45.6%) females, 68.4%/31.6% White/Non-white. There were statistically non-significant differences in the change in HAMD-17 favoring sertraline followed by R. rosea, and placebo ($p = 0.79$). The mean (SD) reduction of the HAMD-17 score in R. rosea was 6.5 (4.9) points (Cohen’s $d = 1.33$). A greater proportion of subjects (63.2%) experienced study related adverse events in the sertraline group versus R. rosea (30.0%) or placebo (16.7%), $p = 0.012$.

**Conclusion:** In this preliminary trial, R. rosea had similar effects on depression, but significantly fewer adverse events, versus sertraline. We will discuss implications for patient-centered comparative effectiveness herbal research.

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**OA16.04**

Study of NHP-Drug Adverse Reactions (SONAR) in Patients Seeking Mental Health Services

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**Purpose:** To investigate the rates of adverse event(s) (AE) associated with natural health product (NHP) use, prescription drug use and concurrent NHP-drug use in individuals within the community setting seeking mental health services through active surveillance.

**Methods:** Participating clinicians from mental health clinics in the Edmonton, Alberta and the surrounding area asked individuals seeking mental health services through self-referral or referral by a health care provider about (i) prescription drug use, ii) NHP use and iii) experiences of AEs during a telephone intake process.

**Results:** Over 48 weeks (July 3, 21012 to May 31, 2013), a total of 1480 patients were screened across six clinic sites. Overall, 672 patients reported taking prescription drugs only (45.8%; 95% CI: 43.3–48.4), 79 reported taking NHPs only (5.4%; 95% CI: 4.3–6.7), 279 reported taking NHPs and drugs concurrently (19.03%; 95% CI: 17.1–21.1) and 436 (29.7%; 95% CI: 27.46–32.13) reported taking neither. In total, 147 patients reported an AE, representing 10.7% (95% CI: 8.6–13.3), 2.5% (95% CI: 0.6–9.6), 25.5% (95% CI: 20.7–30.9) and 0.46% (95% CI: 0.11–1.81) of each population, respectively. Compared with prescription drug use, patients reporting concurrent prescription NHP-drug use were 2.8 times more likely to experience an AE (OR; 95% CI: 2.0–4.1; $p < 0.001$).

**Conclusion:** Nearly a fifth of patients seeking mental health services within the community take NHPs and prescription drugs concurrently; these patients are also at a greater risk of experiencing an AE than those taking prescription drugs only. Active surveillance provides a valuable means of detecting such AEs and can be incorporated into the medical histories obtained by mental health clinicians.

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POSTER ABSTRACTS

BASIC SCIENCE

P01.01
Effect of Spinal Manipulation Thrust Duration on Trunk Mechanical Activation Thresholds of Nociceptive Specific Lateral Thalamic Neurons

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Purpose: High velocity low amplitude spinal manipulation (HVLA-SM) has been clinically shown to increase mechanical pressure pain thresholds via unknown physiologic mechanisms. Evidence points to the involvement of central nervous system pain processing and modulation centers. The thalamus is a key pain processing center. The objective of this study was to determine if HVLA-SM thrust duration alters trunk mechanical activation thresholds of nociceptive specific (NS) lateral thalamic neurons.

Methods: Extracellular recordings were obtained from 18 NS lateral thalamic neurons in 9 normal anesthesized Wistar rats. Activation thresholds to electronic von Frey anesthesiometer (rigid tip) mechanical trunk stimuli in three directions (dorsal-ventral, 45° caudal, 45° cranial) were determined prior to and immediately following the dorsal to ventral delivery at the L5 vertebra of 3 HVLA-SM thrust durations (time-control=0, 100, 400ms). Mean changes in mechanical trunk activation thresholds were compared using a mixed model ANOVA and one-sample t-tests.

Results: Using the mixed model ANOVA analysis, there were no differences of changes in NS lateral thalamic mechanical activation thresholds between the timed-control and both the 100 or 400ms HVLA-SM thrust durations. Due to the variability experienced, changes in mechanical trunk activation thresholds were subsequently analyzed with parametric one-sample t-tests to determine whether there were significant change differences in the 100 and 400ms mean thrust durations when compared to the observed value for the timed-control (0ms). Changes in mechanical trunk activation thresholds increased significantly (t = 2.2, df = 17, p < .05) only following the 400ms thrust duration compared to the 0ms thrust duration in the 45° caudal testing direction.

Conclusion: This study suggests that HVLA-SM thrust duration may increase mechanical activation thresholds of NS lateral thalamic neurons when tested in the 45° caudal direction. Due to variability, these results need to be extended in a larger study.

Acknowledgment: This work was supported by a grant from the Australian Spinal Research Foundation to WRR.

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P01.02
Effects of Instrument-Assisted Spinal Manipulation on Lumbar Muscle Spindle Response in an Animal Model

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Purpose: To determine how instrument-assisted spinal manipulation affects muscle spindle discharge following thrusts delivered at different magnitudes.

Methods: Muscle spindle activity from the L6 spinal root was recorded in 7 anesthetized cats prior to and after spinal manipulative thrusts were delivered to the L7 vertebra using 2 clinical instruments (the PulStar™ and Activator™). Both instruments were used in 3 cats. Typically, 3 thrusts at each of 3 peak magnitudes were delivered with 5 minute intervals between thrusts. Spindle activity was determined in the absence of any contact during 2 secs prior to and immediately following the manipulative thrust. Mean frequency (MF), mean instantaneous frequency (MIF), and time until first action potential (AP) following the thrust were determined.

Results: Change from baseline discharge during 2 sec after thrust (n = 21, \( n = 18 \)) Change from baseline discharge during 2 sec after thrust (n = 6, \( n = 9, \ n = 8 \)) PulStar™ Activator V™ 5 lbs\# 10 lbs\# 15 lbs\# Setting 1* Setting 2\# Setting 3\# Mean MF (SEM) 6.8 (1.2) 7.0 (1.4) 6.7 (1.7) 1.0 (0.2) 3.8 (1.9) 4.2 (1.8) Mean MIF (SEM) 5.2 (0.9) 5.6 (1.1) 5.6 (1.1) 4.8 (1.5) 0.7 (0.2) 2.8 (1.4) 4.1 (1.9) Time to 1st AP (ms) (SEM) 308.3 (0.1) 317.6 (0.8) 378.4 (0.1) 40.2 (0.01) 366 (0.2) 600 (0.01).

Conclusion: The PulStar™, regardless of thrust magnitude, yielded similar changes in mean MF and mean MIF values suggesting a possible ceiling effect on muscle spindle discharge. With the Activator™ instrument, changes in both mean MF and mean MIF were graded with thrust magnitude. This is the first report about the effects of clinically used manipulation instruments on paraspinal muscle spindle activity. Further investigation is needed to extend these findings and to determine any clinical significance. This work was supported by NIH grant KO1AT005935 to WRR and instruments were kindly provided by Sense Technology Inc. and Activator Methods®.

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P01.03
Exploring the Modern Contents of Dysfunction of “Liver Housing Blood” Based on Hierarchical Cluster

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Purpose: To explore the modern contents of dysfunction of “Liver housing blood” which is a classical theory of Traditional Chinese Medicine (TCM).

Methods: Make a cross-sectional clinical survey for the liver cirrhosis in 9 study centers of China, collect symptoms and signs related to “Liver housing blood” according TCM four diagnostic methods, and laboratory findings and imaging related to blood circulation according to western medicine, adopt hierarchical cluster to explore their potential relationship.

Results: Three main clusters were acquired: the first included Edema, dark complexion, thirsty, decreased urine output and elevated prothrombin time ratio, reduced Potassium levels; the second contained yellow complexion and reduced percentage of lymphocytes, widened portal vein diameter; the third one...
composed of abdominal veins, become thin, black sublingual bruising, dry and rough coating and reduced mean platelet volume, reduced serum chloride level.

**Conclusion:** Dysfunction of “Liver housing blood” dysfunction possessing three meaning: blood stasis, blood deficiency and yin deficiency. The first cluster denoted blood stasis might result from elevated prothrombin time ratio and reduced potassium levels; the second cluster indicated blood deficiency is closely related with reduced percentage of lymphocytes and widened portal vein diameter; the third cluster showed that reduced mean platelet volume and reduced serum chloride level might result in yin deficiency. Thus, the dysfunction of “Liver housing blood” could be interpreted by the above laboratory findings and imaging.

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**P01.04**

**Analyze and Compare Different Stages of Hepatic Cirrhosis of the Tongue Picture**

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**Purpose:** Analysis and comparison of patients with liver cirrhosis compensatory and decompensatory phase distribution of tongue.

**Methods:** Use the cross-sectional survey of clinical epidemiology research methods, acquisition met the inclusion criteria patient’s general condition information, symptoms, signs, and input the data by Excel, were analyzed using SPSS17.0 statistical software.

**Results:** © The compensated, decompensated patients with pink tongue (33.55%, 30.00%), white fur (60.70%, 60.08%), thin fur (72.44%, 58.09%), moist fur (78.07%, 74.09%) was found in high. © Dark red tongue, tough tongue, bulgy tongue, wide of sublingual vein, varicose sublingual vein, purple dots or spots on the tongue, thick fur, greasy and putrid fur, exfoliating fur had significant difference in two patients (P<0.05), and all with decompensated ratio is high.

**Conclusion:** The changes of tongue picture can reflect the severity of hepatic cirrhosis in a certain extent.

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**P01.05**

**Bromelain Reduces FceRI Expression on Humanized Rat Basophil Leukemia Cells**

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**Purpose:** Bromelain (sBr), an extract from the pineapple, is used to treat inflammatory diseases such as arthritis, allergy and asthma. sBr has been shown to impart immuno-modulatory effects in a murine model of allergic airway disease (reducing lung eosinophils, CD4 + T cells and Th2 cytokines) and reduce CD25 (IL-2a receptor) expression on CD4 + T cells in vitro. An important target in allergy treatment is IgE, its receptors and signaling products produced via IgE cross-linking. The purpose of this study was to determine sBr’s effect on FcεRI (hFcεRI) expression using a humanized rat basophil leukemia cell line (RBL-SX38) and test the hypothesis that sBr treatment of RBL-SX38 cells would reduce expression of hFcεRI.

**Methods:** Cultured RBL-SX38 cells were assessed for growth, viability expression of FcεRI and functional IgE binding. RBL-SX38 cells were treated overnight (in triplicate) with media alone, sBr (1–100mcg/ml) or E64-inactivated-sBr (Replicate experiments performed). Post-staining with human IgE (Alexa488, HE1) and anti-hFcεRI (PE, AER-37), cells were acquired on LSRII and analyzed with FlowJo. Slides were prepared via CytoSpin (Thermo-Shandon) and treated with DAPI for fluorescence microscopy. Digital images were acquired with BX53F Olympus microscope and analyzed using CellSens Dimension software.

**Results:** The expression of hFcεRI on RBL-SX38 cells and functional binding of IgE was confirmed (via fluorescence microscopy). sBr treatment significantly reduced hFcεRI expression on RBL-SX38 cells in a dose dependent manner. Representative data includes: Control Cells-alone (MFI FcεRI=11,379), sBr 1mcg/ml (MFI FcεRI=12,684) sBr 100mcg/ml (MFI FcεRI= 950), E64 + sBr 100mcg/ml (MFI FcεRI=10,612); Significant differences were found via ANOVA and p<0.0001 comparing control to sBr 100mcg/ml treatment group via Tukey’s post-hoc analysis.

**Conclusion:** sBr reduces hFcεRI expression in a cell line engineered to mimic human basophils, indicating that it may have therapeutic potential in allergy. Future experiments will determine sBr’s effect on both IgE binding to the hFcεRI and downstream IgE mediated histamine release.

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**P01.06**

**D.C. Electric Field Related to Tai Chi-Induced Bio-Electrical Changes Affects Actin-Based Movement of Fibroblasts and Cancer Stem Cells in Culture**

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**Purpose:** We have previously found that Tai Chi practice elevates blood flow measured with laser Doppler flowmetry and electrical flow measured as pre-polarization conductance at jing-well acupoints with Motoyama’s single square voltage pulse method. This study investigates how the bioelectrical change might affect cellular function by examining the effects of D.C. electrical field on cell cultures.

**Methods:** 3T3 fibroblasts and lung cancer stem cells were grown on a glass cover slip which formed the top surface of a chamber regulated at 37°C for time-lapse digital photomicroscopy. A constant current from a power supply was passed through the growth medium to expose the cells to a fixed D.C. field. The distance and directionality of cellular movement were measured by tracking the center of the nucleus.
Results: 3T3 cells and lung cancer cells exposed to a field of 0.2/0.4/0.6 V/mm were measured at 60/120/180 mins. Migration distance (μm range) and directionality towards the cathode increased with time and field strength. Reversing the polarity produced the opposite directionality. In additional experiments on cancer cells, 1 μmol cytochalasin D (inhibits actin filament assembly) inhibited the electric field effect while 20 μM cisplatin (arrests cell cycle) and 50 mM verapamil (blocks calcium channels) had no effect. Cancer cells that had taken up silica-coated nanoparticles that were negatively (Si@RuNPs-COOH) or positively charged (Si@RuNPs-NH2, Si@RuNPs-OH) responded to the electric field in the same way as control cells.

Conclusion: This study shows that low level D.C. field can induce actin-based movement of normal and cancer cells towards the cathode in a time and dose dependent manner. While the relationship between electrical conductance and electric field in the human body remains undefined, these results suggest that changes in bioelectrical properties induced by Tai Chi practice might have physiological consequences at the cellular level.

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P01.07 Evidence for Phytochemical Synergism in Classical Chinese Herbal Pairs
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Purpose: In classical Chinese medicine, herbs are predominantly prescribed in pairs within the context of a larger herbal formula. The biochemical framework for why these pairs exist has not been fully evaluated. Current botanical medicine research has predominantly investigated herbal constituents in isolation and not the chemical interactions between herbs when extracted together. This study aims to investigate the potential synergistic relationship between three herbs commonly found in pairs within classical Chinese medicine.

Methods: Dried herbs were decocted in deionized water for 30 minutes at 100°C either independently or in pairs of Licorice with Ginger and Licorice with Bupleurum, at differing ratios. The supernatant from the decoction was centrifuged and filtered for remaining botanical particles and analyzed by high performance liquid chromatography (HPLC). Peak area, retention time, and peak shape were collected and compared between samples of single herbs and the herbal pairs.

Results: Overall, Licorice, Ginger and Bupleurum, when decocted in pairs rather than in isolation, showed differences in peak areas causing increases and decreases in peak area, and new peak formation.

Conclusion: Decoction in pairs versus single decoctions showed variation in the chemical signature indicating potential synergy among classical Chinese medicine herbal pairs. Future studies are needed to determine the chemical structure of these novel peaks, as well as their potential for clinical application.

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P01.08 The Joint Moment Distribution of the Lower Extremity During Tai Chi Chuan
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Purpose: Tai Chi Chuan (TCC) exercise is becoming an increasingly popular complementary and alternative approach for both healthy people and patients with a variety of medical conditions in the United States. As a form of physical activity, TCC is a continuous, slow rhythmic and bipedal movement, and this requires TCC to control joints at ankle, knee and hip in a coordinate manner. Few studies have investigated the multi-joint coordination and distribution of lower extremity joint moments during TCC. To better understand the biomechanics of TCC, the purpose of study was to determine the vertical support moment synergy during TCC (simplified 24 yang style forms) and compared to normal gait.

Methods: Ten healthy TCC practitioners performed normal walking and TCC while data were collected using high-speed motion capture system integrated with force plates. The joint distributions of the ankle, knee, and hip were calculated by ratio between individual joint moment impulse and total support moment impulse. A paired t-test (p < 0.05) was used to compare TCC with normal walking.

Results: TCC was predominated by the contribution of the knee (ankle: 32.78 ± 2.25%; knee: 58.68 ± 1.84%; hip: 8.54 ± 1.91%) whereas the ankle was the primary contributor to support in normal walking (ankle: 67.86 ± 2.76%; knee: 26.18 ± 2.69%; hip: 5.96 ± 1.83%). The contributions of all three joints were significantly different (p < 0.05) between TCC and normal gait.

Conclusion: This study demonstrates that TCC places a high mechanical demand on the knee. The high stress the knee experiences during TCC supports benefits of TCC on increasing knee range of motion, knee muscle strength for healthy people. It also suggests as a potential therapy for people with joint disease, such a high mechanical demand placed on the knee is concerning.

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P01.09 Complementary and Conventional Medicine Use Among Youth with Recurrent Headaches
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Purpose: To identify prevalence and patterns of complementary and alternative medicine (CAM) use among youth with recurrent headache (HA) and evaluate associations with co-occurring health problems and limitations as well as with the use and expenditures for conventional medical care.

Methods: Variables were constructed for youth age 10–17 using linked data from the 2007 National Health Interview Survey and the 2008 Medical Expenditures Panel Survey. Bivariate, logistic and two-part regression analyses were employed.

Results: Of the 10.6% of youth experiencing HA, 29.6% used CAM, rising to 41% for the many HA sufferers who also
P01.10  
The Role of Meal Replacements in Regulating the Hedonic Brain Network of Appetite  
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**Purpose:** Obesity has become a public health crisis, not sparing a quickly expanding population of older adults. Obesity is a major risk factor for chronic disease; thus, there is a growing need to understand the etiology of food consumption among older adults. Important to this research direction is the role that liquid meal replacements (MR) have in calorie-restricted diets for weight loss. We hypothesize that MR beverages modulate a hedonic brain network of appetite (HBN-A) and decrease state-craving.

**Methods:** The sample included (n = 14) obese, older adults. The participants completed two visits. During each visit, participants consumed a calorie-controlled breakfast. After a 2.5 hour fast, participants either consumed a can of BOOST™ (MR beverage) or an equivalent amount of water. On both visits, an MRI scan was performed and the Food Craving Questionnaire (FCQstate) was administered. Functional brain networks were created for each individual. Hubs-of-interest for the HBN-A were defined as regions of interest with a greater number of connections in the fasting condition (p < 0.10). To fully characterize the HBN-A, the direct and indirect connections among these hubs were quantified between conditions.

**Results:** In investigating the HBN-A, we found that in the fasting state, brain networks had hubs in the following regions: anterior cingulate cortex (ACC), amygdala, insula, right hippocampus and superior temporal pole. Importantly, all interconnections among these five hubs were greater in the fasting condition than the MR condition. For direct connections, the effect sizes ranged from 0.44 to 1.11; whereas, for indirect connections, the effect sizes ranged from 0.77 to 1.19. We also show that when individuals consume a MR beverage, they also report significantly less craving.

**Conclusion:** In summary, we found that MR beverages downregulated the HBN-A after a short-term fast in older, obese adults. Additionally, the consumption of MR beverages also lowered craving, reinforcing their value in weight-management programs.

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P01.11  
Studies of a Human Bioenergy Field Using a Torsion Pendulum Balance  
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**Purpose:** It has long been assumed that human bioenergy fields would consist of components of the electromagnetic spectrum, such as photons. An alternate hypothesis is that instead of photons, the bioenergy fields consist of a form of energy that can push against physical objects, as in psychokinesis. This hypothesis was tested using a torsion pendulum balance consisting of a steel mesh hemisphere suspended above a subject by a nylon monofilament. Twisting motions of the hemisphere were monitored with high precision by a video camera. Analysis of the data demonstrated that the effects were dramatic and of substantial magnitude. The force against the pendulum was chiral in that the center of oscillation shifted dramatically away from the natural center. Fast Fourier Transform analysis demonstrated that the pendulum oscillated with many new frequencies. Experiments using hemispheres constructed of alternate materials, such as organic coco fiber, establish that no magnetic forces are involved. Static charges have also been eliminated as a source of these phenomena. One of the most intriguing aspects is that the effects exerted by the subject on the pendulum persist for 30–60 minutes after the subject departs from the pendulum. These persistent effects suggest the subject has altered the pendulum so that the effects are somehow retained within the molecular/atomic structure of the steel mesh or coco fiber hemisphere. Some of these results have been published in the peer-reviewed Journal of Scientific Exploration, Journal of Scientific Exploration, Use of a Torsion Pendulum Balance to Detect and Characterize What May Be a Human Bioenergy Field, Vol. 27, No. 2, pp. 205–225, 2013.

**Methods:** Bioenergy forces were measured using a torsion pendulum balance.

**Results:** Subjects exerted profound effects on the pendulum.

**Conclusion:** A torsion pendulum balance can detect and measure many novel aspects of a chiral force exerted by a human bioenergy field.

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P01.12  
Transient Receptor Potential Cation Channels and Cytokines Are Involved in Topical Long-Teng-Tong-Luo Gel Inhibition of Bone Cancer Pain  
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**Purpose:** Cancer pain management remains a challenge for which Chinese herbal medicine might be useful. The aim of this study was to explore spinal mechanisms of one such preparation, Long-Teng-Tong-Luo (LTTL) gel, a seven-herb compound, on bone cancer pain.
Methods: A bone cancer pain model was made by inoculating the tibias of female rats with Walker 256 cells (3.5 × 10^5 in 6 μl of vehicle). LTTL gel or inert gel, 0.5 g/cm2/day, was applied to the skin of tumor-bearing tibias for 21 days beginning a day after inoculation. Antagonists were given intrahydraulically. Mechanical allodynia, a decrease of mechanical threshold, was assessed with von Frey filaments. Thermal hyperalgesia, a decrease of hind paw withdrawal latency (PWL) to noxious thermal stimulation, was determined. Spinal interleukin-17A (IL-17A) mRNA and protein were respectively measured with real time PCR and enzyme-linked immunosorbent assay. Transient receptor potential (TRP) channel expression in dorsal root ganglia (DRG) was detected with immunofluorescence staining. Data were analyzed with repeated measure analysis of variance (ANOVA) or one-way ANOVA.

Results: Data show that mechanical threshold and PWL significantly (P < 0.01) increased in LTTL-treated rats compared to those in the vehicle group, substantiating that the gel alleviated cancer-induced mechanical allodynia and thermal hyperalgesia. LTTL treatment also inhibited cancer-enhanced expression of spinal cord IL-17A and TRP cation channel subfamily members V 1 (TRPV1), TRPV4, and TRPA1 in lumbar DRG. TRP antagonists at 10 μg (i.t.) significantly attenuated mechanical allodynia, thermal hyperalgesia, and IL-17A expression, indicating that TRP channels facilitate spinal IL-17 expression and cancer pain. IL-17A antibodies inhibited cancer pain, suggesting that IL-17A promotes such pain.

Conclusion: As prior study showed that LTTL suppresses osteoclast activity in cancer-bearing bone, we conclude that the gel inhibits cancer pain by blocking such activity, consequently decreasing TRP and IL-17A action.

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P01.14
Symptom and Pathologic Features of Hyperuricemia Combined with Abdominal Obesity Quail Model with Chinese Medicine Symptom Categorization Method
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Purpose: To investigate the symptom and pathologic features of hyperuricemia combined with abdominal obesity quail model induced by high purine diet.

Methods: 36 French male quails were randomly divided into three groups: control group, model group and chicory treated group. The control group quails were fed normal diet; model group and chicory treated group quails were fed high purine diet. Body weight, serum uric acid (UA), abdominal fat mass, the enzyme activities of acetyl-CoA carboxylase (ACC), xanthine oxidase (XOD) and adenosine deaminase (ADA) were determined. Furthermore, the Chinese Medicine symptom categorization of different group quails was collected according to the four diagnose methods of Traditional Chinese Medicine, such as inquiring the living environment, etiological factors, treatment; inspecting the fecaluria characteristics and tongue pictures; listening and smelling the bird sound or fecaluria odour, and so on.

Results: Body weight in model group had no changes. Serum UA level in model group was increased significantly on 14th, 21st day. Abdominal fat mass and abdominal fat ratio were increased in the model group quails. The fecaluria of model quails became noncoagulative and with offensive odor on 17th, 30th day. The tongues of model quails became pale, with the index of r and red area ratio decreased on 22nd, 32nd day. Serum UA level and abdominal fat ratio in chicory treated group was decreased vs model group. Humid weight of fecaluria in chicory treated group was increased, the water content of fecaluria decreased in contrast. The activities and protein expression of ACC and XOD were increased in model group quails. And chicory inhibited the activities of ACC and XOD.
Conclusion: High purine diet (Indulgence in a rich fatty and sweet diet) can induce hyperuricemia combined with abdominal obesity quail model. The characteristics of this animal model were similar with Spleen-deficiency and Phlegm-dampness syndrome categorization system.

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P01.15
Chinese Herbal Prescription Yinqiaosan Suppresses Influenza-Virus-Induced Pro-Inflammatory Cytokines by Inhibiting the Activation of MAPKs and NF-κB in Human A549 Cells

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Purpose: Influenza virus infection can cause severe pneumonia and death. During replication Influenza virus activates the Raf/MEK/ERK-cascade and the transcription factor NF-κB. Both result in virus supportive and anti-viral effects by inducing expression of pro-inflammatory cytokines. Yinqiaosan (YQS) is a traditional Chinese medicine (TCM) prescription that has been used for several hundred years by the Chinese community, which is widely used for treating influenza-virus-induced inflammatory responses including bronchitis, tracheitis, pneumonia, pharynx ache, headache, catarrhus and so on. However, no studies have been undertaken to investigate whether YQS inhibits the inflammatory activity of activated human lung epithelial cells. The aim of this study was to examine whether YQS modulates inflammatory reactions using human lung epithelial cell line A549.

Methods: A549 cells were infected with influenza virus strain PR/8/34. The inhibitory effect of YQS on pro-inflammatory cytokine gene expression and production by stimulated A549 cells was measured by quantitative RT-PCR, and cytokine-specific ELISA assays, respectively. Western blotting was used to analyze the effect of YQS on the activation of ERK in influenza-virus stimulated A549 cells. Effect on the activity of NF-κB was measured with an ELISA-based highthroughput screening system. Significance of differences from control values were analyzed by means of standard statistical methods.

Results: YQS significantly decreased influenza-virus stimulated inflammatory gene expression and production of IFN-beta, MCP-1 and interleukin (IL)-6 in A549 cells. The inhibitory effect of YQS on the pro-inflammatory cytokines was ERK dependent. In addition, YQS suppressed the NF-κB activation induced by influenza-virus in human lung epithelial cells.

Conclusion: These novel pharmacological actions of YQS provide new suggestion that YQS may be of therapeutic use for the treatment of influenza-virus induced inflammatory diseases by suppressing ERK and NF-κB activation.

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P01.16
A Combination of Triterpene Acids and Mistletoe Lectins Induces Highly Effective Apoptosis in Ewing’s Sarcoma

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Purpose: Aside from Osteosarcoma, Ewing’s Sarcoma is the most abundant form of bone sarcoma in children and adolescents. This malignancy derives from a mesenchymal stem cell and is associated with poor therapeutic outcome and prognosis. Viscum album L. extracts (VAE) are popular in complementary cancer medicine but little is known about its effects on pediatric Ewing’s Sarcoma cells. The biologically effective components of mistletoe include hydrophilic lectins (ML) and viscotoxins and hydrophobic triterpene acids. Triterpene acids are difficult to extract and hardly solubilized in water. All commercially available VAE are water-based. By using cyclodextrins it was possible to solubilize mistletoe triterpene acids (mainly oleanolic acid) resulting in a VAE with high levels of triterpene acids and ML in combination (ViscumTT).

The objective of this work is to study the effects of VAE composed of ML and viscotoxins (Viscum) or triterpene acids (TT) and the combination ViscumTT on Ewing’s Sarcoma cell lines in vitro for the first time.

Methods: Human Ewing’s Sarcoma cell lines were treated with ML and/or triterpene acids containing VAE. Effects on proliferation were measured by CASYCounter and WST assays. Apoptosis induction and its mechanisms were analyzed by Western blotting and flow cytometry using Annexin/PI, Caspase-8/9, staining and JC-1.

Results: VAE composed of triterpene acids (TT) or ML and viscotoxins (Viscum) induce apoptosis dose-dependently in Ewing’s Sarcoma cells. The proliferation is inhibited as well. In addition, their combination (ViscumTT) shows synergism in apoptosis induction and anti-proliferative effect. The apoptosis mechanism is the subject of current investigation.

Conclusion: A new VAE formulation containing ML and solubilized triterpene acids (ViscumTT) shows high anti-tumor effectiveness in vitro and may represent a new promising therapy option in pediatric Ewing’s Sarcoma. Therefore the therapeutic effect of ViscumTT should be evaluated in vivo.

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P01.17
Far Infrared Emitted by Bioceramics Reduces Mechanical and Thermal Hyperalgesia in an Animal Model of Chronic Inflammatory Pain

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Purpose: This study evaluated the effect of far infrared emitted by bioceramics in a BioPowerTM Bioceramics Pad against mechanical and thermal hyperalgesia as well as paw temperature increase and edema formation in a mice model of inflammatory pain.

Methods: Experiments were conducted with male Swiss mice (30–35g) after approval of the University of South of Santa Catarina Ethics Committee. The animals underwent intraplantar injection of Freund’s complete adjuvant (CFA, 20 μl - 70%) and for treatment a BiopowerTM Bioceramics Pad (80% BioCorn PVC - 20% Bioceramic materials) was placed inside the animals
box. After 24h of exposure to the product, mechanical and thermal hyperalgesia was assessed as response frequency to 10 presentations of a 0.4g von frey filament or by hot stimuli applied to the animals right hind paw (Hot Plate Method). Evaluations were performed daily for 10 days. After evaluation the animals were placed in their boxes and re-exposed to the Pad until the subsequent evaluation (24 hours later). In addition, edema formation and hind paw temperature were evaluated on experimental days 1, 3 and 10 with a micrometer and a digital thermometer, respectively. Control animals were placed on a Sham Pad (100% BioCorn PVC without bioceramics) and underwent the same experimental protocol.

Results: Acute exposure to the BioPowerTM Bioceramics Pad induced analgesia which lasted for 2 hours (P<0.001 - maximum inhibition of 53±11%). Chronic treatment reduced mechanical hyperalgesia on all evaluation days and thermal hyperalgesia on days 1 and 3. In addition, the treatment decreased paw temperature on days 1 and 3. 8±1% (P<0.001) and 5±1% (P<0.05) but did not affect edema formation.

Conclusion: Far Infrared emitted by a BioPowerTM Bioceramics Pad reduced mechanical and thermal hyperalgesia of inflammatory origin as well as paw temperature increase induced by intraplantar injection of CFA in mice.

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P01.18
Effect of Far Infrared Emitted by Bioceramics on Parameters of Physical Performance in Mice

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Purpose: To evaluate the effect of Far Infrared therapy emitted by bioceramics on parameters of physical performance in mice subjected to a swimming protocol.

Methods: Experiments were conducted with male Swiss mice (30–35g) after approval of the University of South of Santa Catarina Ethics Committee. The mice were randomly divided into 2 groups and subjected to a 30min 21 day swimming protocol. For treatment a BioPowerTM Bioceramics Pad (80% BioCorn PVC - 20% Bioceramic materials) was placed inside the animals box for three weeks. Control animals were placed on a Sham Pad (100% BioCorn PVC without bioceramics) and underwent the same experimental protocol. At the end of each week body weight and food and water intake were measured and an exhaustion test was conducted in which the mice were put to swim until exhaustion with a charge of 5% of body weight tied to their tail. Point of Exhaustion was determined when the animal could not maintain its head out of the water surface for more than 5 seconds. At the end of third week right hind limb grasping strength was conducted using a strain gauge force feedback system and the gastrocnemius muscle weight was assessed with an analytical scale.

Results: Far infrared emitted by a BioPowerTM Bioceramics Pad increased time to reach exhaustion in forced swimming test (133.1%, 60.4% and 90.83% in weeks 1 to 3) but did not affect body weight, water or food consumption. Although gastrocnemius muscle weight was not affected, BioPowerTM Bioceramics Pad increased hindlimb grasping strength in 6.6%.

Conclusion: Far Infrared therapy emitted by a BioPowerTM Bioceramics Pad increased hindlimb grasping strength and time to reach exhaustion of mice subjected to a three week swimming protocol. These results could indicate increased resistance, muscle endurance, overall stamina (energy levels) or a combination of these factors.

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P01.19
Comparative Cardioprotective Effects of Crataegus Monogyna, Cornus Mas and Prunella Vulgaris on Neonatal Rat Cardiomyocytes

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Purpose: Our study aimed to compare the cardioprotective effect of three medicinal plants traditionally used in Romanian folk medicine: Cornus mas, Crataegus monogyna and Prunella vulgaris, on neonatal rat cardiomyocytes, both in normoxic and hypoxic conditions. As most previous studies have focused on fruits, our investigations aimed to fingerprint and quantify the polyphenol compounds in aqueous leaf extracts, based on HPLC-DAD-ESI(+)-MS analysis.

Methods: The total polyphenol content of each plant extract was determined using the Folin-Ciocalteu reagent. The hearts from 270 newborn Wistar rats (1–2 days old) were excised and collected in ice cold sterile PBS. Ventricles were minced and inserted in trypsin solution (0.25%) for cell dissociation. The cell suspension was subjected to centrifugation (2000 rpm, 15 min, 4°C), the infranatant was mixed with growth medium and 96-well mobile/non-mobile plates were prepared (2×104cells/well). The plates were incubated at 37°C (95% O₂, 5% CO₂) for 72 hours. Consecutive dilutions (from 0.01 mg polyphenols/ml to 0.0001 µg polyphenols/ml) of each aqueous extract were used for treating the cells while undergoing hypoxic/normoxic conditions vs control. Viability measurement was performed using calcein and PI-digitonine staining. The plates were analyzed using the FLUOstar Optimia plate reader and data was evaluated using GraphPad Prism 5.

Results: Both Crataegus monogyna and Cornus mas showed cardioprotective effect. Prunella vulgaris had no significant effect on cell viability. In hypoxic conditions, Cornus mas which had the highest polyphenol concentration, increased cell viability by 19%, compared to control. In normoxic environment, the viability was increased by 11%. Crataegus monogyna increased viability by 17% in hypoxic conditions, and by 11% in normoxic environment, compared to control.

Conclusion: To our knowledge, this is the first study assessing the cardioprotective effect of Cornus mas. Purified fractions of flavonoids and polyphenols from Cornus mas and Crataegus monogyna extracts will need further study for explaining this cardioprotective effect.

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P01.20
Therapeutic Touch Modulates Immune Function and Inhibits Metastasis but Not Primary Tumor Size in a Breast Cancer Model in Mice

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Purpose: We assessed the effect of Therapeutic Touch (TT) on development of tumors, metastasis and changes in immune phenotype in a well-accepted breast cancer metastasis model in mice.

Methods: Mice were randomly assigned to three groups; n = 16/group. Cancer group 1 received TT for 10 minutes twice a week. Cancer group 2 received mock-TT for 10 minutes twice a week. Control group 3 received saline injections. Cancer was induced by cell (thioguanine-resistant cell line 66cl4 derived from 4T1 mouse mammary carcinoma) injection into foot pads. Culture of foot-pad draining popliteal lymph node (PLN) cells, in the presence of 6-thioguanine, allows survival of metastasized cells, and colonies can be counted as metastatic index. At 26 days, tumor volume was determined and serum collected for determination of 32 cytokines/chemokines. Spleens and PLN were isolated, processed for metastasis assays and immune cell phenotype via flow cytometry. Statistical analysis was performed by ANOVA followed by Bonferroni post-test.

Results: Breast cancer tumors developed in each injected foot pad with no significant differences in tumor size or mouse weight between groups. A significant increase in 10 cytokines was noted in mice with cancer compared to saline-injected mice. TT significantly decreased IL-1beta, MIG, and MIP-2 to control levels. In mice with cancer there was a significant increase in % macrophages (CD11b+) and activated lymphocytes (B and T cells). TT significantly modulated % macrophages and lymphocytes (CD4+CD44hiCD25+, CD4+CD44loCD25, CD4+CD44hiCD25− and CD4+CD44loCD25+), compared to mock-treated and control mice. A significant decrease in metastasis was found with TT compared to mock-treated mice.

Conclusion: We conclude that TT had significant effects on immune responses by down-regulating serum cytokines, macrophages, and modulated lymphocyte subsets. TT also significantly reduced metastasis but not primary tumor size in this breast cancer model.

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**P01.22 LB**

Effect of Compound Qin Qing Liquids on AMPK Protein Levels in Kidney Tissue of Rat Uric Acid Nephropathy Model

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Purpose: To investigate the effects of compound Qin Qing liquid (AMP-activated protein kinase, AMPK) protein expression levels in rat kidney tissue of high uric acid kidney injury, and study in molecular mechanisms of compound Qin Qing liquid in inhibiting high uric acid kidney injury.

Methods: SD rats were randomly divided into control group, model group, positive group, and high-, medium-, low-dose groups of Chinese medicine. The molding method was gavage adenine and feeding yeast. Control group and model group were daily gavaged with distilled water (10ml/kg·d), positive control group was daily gavaged with allopurinol by 9.33 mg/kg. High-, medium-, low-dose group of Chinese medicine was daily gavaged with Compound Qin Qing Ligui by 3.77/(kg·d), 1.89/(kg·d), 0.09/(kg·d), ig 6 weeks. Some rats of each group were sacrificed at the 4th and 6th week, and their kidney were taken for observing the protein expression of AMPKα1 and AMPKα2 by western-blot and immunohistochemical staining.

Results: Protein levels of AMPKα1 and AMPKα2 were significantly up-regulated by compound Qin Qing Liquids.

Conclusion: The main molecular mechanisms of compound Qin Qing liquid inhibited immune inflammatory injury in high uric acid kidney tissue may be associated with the activation and increases expression of AMPK.

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**P01.23 LB**

Food Reactivity on the ALCAT Leukocyte Activation Test Is Associated with Upregulation of CD11b on T Cells

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Purpose: The ALCAT food sensitivity test is based on leukocyte activity in the presence of food antigens, though the underlying cellular and molecular steps have not been fully identified. We quantified activation markers on peripheral blood lymphocytes (PBL) from healthy volunteers in response to “severe intolerance” or “no reaction” foods on the ALCAT test.

Methods: Reactivity of PBL from 10 volunteers to 200 antigens was determined by ALCAT testing. On a subsequent day, PBL from the same volunteers were exposed to a single “severe intolerance” and “no reaction” food extract, or left untreated. Flow cytometry (FACS) was performed to examine activation markers CD69 and CD11b after gating on T cells (CD3+ and either CD4+ or CD8+), B cells (CD19+), neutrophils (CD66b+ CD16+), monocytes/macrophages (CD14+ CD16+), eosinophils (CD66b+ CD16−) and basophils (CD123+ CD66b− CD16−).

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P01.24 LB
Anticancer Activity of Gerbera Jamesonii on A549-Adeno-Carcinomic Human Alveolar Basal Epithelial Cell Line An In Vitro Study
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Purpose: Current therapy for lung cancer includes chemotherapy, radiotherapy and surgery that are effective but associated with significant morbidity. Many compounds isolated from plants against cancer are found to have toxic behavior as compared to crude extract of same plant from which compounds are isolated. It forces to find a potential plant that can be used in crude form for treatment of cancer without showing any toxicity to normal body cells.

Methods: Fingerprinting of MeGj was done by HPTLC for standardization. Cytotoxicity of MeGj was examined in lymphocytes (5FU as positive control) and A549 cells by dye exclusion assay using trypan blue and MTT assay at 24 and 48 hrs. The effect of MeGj on intracellular level of oxidative stress in A549 cells was determined at 24 and 48 hrs by analyzing the activity of SOD and Catalase enzyme. MeGj in apoptosis was evaluated by studying apoptotic parameters such as alteration in cell morphology under phase contrast microscopy, change in morphology at nuclear level by staining cell with 4’6-diamino-2-phenylindole (DAPI), measuring DNA damage by comet assay and determining Caspase 3 activity at exposure period of 48 hrs. The anti-metastatic property was studied by performing wound healing assay.

Results: MeGj did not show any cytotoxicity on lymphocyte cells at three different concentrations (500, 1000, 1500 µg/ml). MeGj showed dose and duration-dependent reduction in cell viability and cell growth and an increase in SOD activity as compared to control and inactivation of Catalase activity. At 48 hrs of exposure MeGj showed cell rounding, cell shrinkage, cytoplasmic membrane irregularity, chromatin fragmentation and condensation, DNA damage, high Caspase 3 activity and showed inhibition of cell migration at highest dose (1500 µg/ml).

Conclusion: It is concluded that MeGj possesses anti-proliferative and anti-metastatic activity on A549 and nontoxic to lymphocytes, making it a promising agent for further evaluation.
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P01.25 LB
The Effects of Chinese Herbal ShenQi Decoction on Insulin Resistance and Lipid Profile in Genetically Diabetic KK-Ay Mice
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Purpose: Genetic factor and diet intake are important for diabetes development. The present pilot study was to perform the effects of ShenQi Decoction (SQD), a Chinese herbal medicine, on blood glucose, insulin resistance and lipid profile in genetically diabetic KK-Ay mice.

Methods: Male mice were divided into two groups and administrated with present (HFD + SQD) or absent of SQD for 6 weeks. The body weight, the concentration of fasting glucose, insulin, total cholesterol, triglyceride, high-density lipoprotein (HDL), and the homeostasis model assessment of insulin resistance (HOMA-IR) were determined before and at the end of the 8th, 11th, and 14th week of the experiment.

Results: As a result, the fasting blood glucose, total cholesterol, HDL, triglyceride, body weight, and HOMA-IR of HFD were higher than that in ND. However, insulin of HFD was less than that in ND. Furthermore, total cholesterol, HDL, triglyceride, and HOMA-IR of HFD + SQD were lower than that in HFD after 3 weeks of SQD administration. Moreover, the concentration of fasting glucose of HFD + SQD was lower than that in HFD after 6 weeks of SQD treatment.

Conclusion: Although HFD increased the blood glucose and lipid levels, which lead the diabetes onset earlier in genetically diabetic KK-Ay mice, SQD might inhibited and delayed the HFD-induced-diabetic severity and development.
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P01.26 LB
Effect of Electroacupuncture Intervention on the Behavior and the Expression of β-site Amyloid Cleavage Enzyme 1 in Cerebral Cortex of SAMP8
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Purpose: To observe the influence of electroacupuncture (EA) on the behavior and the expression of β-site amyloid cleavage enzyme 1(BACE-1) in cerebral cortex of SAMP8, so as to explore its mechanism underlying relief of Alzheimer’s Disease (AD).
Methods: SAMP8 mice were randomly divided into model, medication and EA groups. SAMR1 mice were used as the control group. Mice of the medication group were treated by oral administration of donepezil (0.92 mg/kg). EA was applied to “Baihui”(GV20) and “Yin tang”(EX-HN3), and then swift pricked “Shuigou”(GV26). The learning memory ability of mice was detected by using Morris Water Maze. The expression levels of Aβ and BACE-1 in cerebral cortex were assayed by immunohistochemistry and fluorescent quantitative real-time PCR.

Results: Compared with the control group, the escape latency was significantly higher as well as the expression levels of Aβ and BACE-1, but target quadrant swimming time, swimming distance and velocity were shorter in the model group than in the model group (P<0.05); while in comparison with the model group, swimming distance velocity and the Aβ expression of the medication and EA groups were obviously decreased, the same as the expression of BACE-1 and BACE-1mRNA in EA groups (P<0.05).

Conclusion: EA can effectively improve learning memory ability of SAMP8 mice which may be closely associated with their effects in restraining the expression of Aβ and BACE-1 in cerebral cortex.

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P01.27 LB
Evaluation of Adaptogenic Potential of Curcuma Longa and Zizyphus Mauritiana Against Acute Noise Stress Induced Changes in Guinea Pigs

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Purpose: Noise stress has been inevitable in modern life and it can cause disorders of nervous, endocrine and cardiovascular systems. Curcuma longa (CL) and Zizyphus mauritiana (ZM) are claimed to have anti-stress, antioxidant and free radical scavenging activities. Adaptogenic potential of these 2 herbs was tested with acute noise stress induced changes in Guinea pigs, keeping Diazepam as a positive control.

Methods: Guinea pigs of 32 to 36 weeks age weighing 600 to 800 gm were divided in to 8 groups (N=4) 1 normal control, 1 noise control, 1 drug control, 2 herb control and 3 trial groups (herbs and drug + noise). After 7 days of herbal and drug treatment by forceful feeding to respective groups, on day 8, four groups (Noise control and 3 trial groups) were subjected to 100 Db industrial noise with frequency ranging between 8 to 50 kHz, for 4 hours in morning. Blood was collected one hour after noise stress for measuring cortisol level, plasma glucose, leukocyte count and neutrophil function by NBT reduction, and candida phagocytosis assay thereby evaluating the effects of drug, herbs and noise plus herbs/drug on the above parameters.

Results: Diazepam and CL reduced the cortisol level; while CL and ZM raised phagocytic %. Acute noise stress caused leucopenia, increased cortisol level, increased plasma glucose level and enhanced the neutrophil function. Cortisol level as well as plasma glucose were most consistently prevented from rising by both herbs and diazepam. CL and ZM prevented significant leucopenia. Both herbs prevented the noise induced enhancement of neutrophil functions superior to diazepam.

Conclusion: CL and ZM do have anti-stress properties like Diazepam but without causing sedation; with efficacy differing marginally for different parameters tested, suggesting different complex mechanisms of actions. CL and ZM showed intrinsic powerful immunostimulatory activity as compared to Diazepam as an added benefit.

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P01.28 LB
Pao Pereira Extract Inhibits the Growth of Hormone Refractory Prostate Cancer Cells by Suppressing NFkappaB Signaling

Abstract Withdrawn

P01.29 LB
Pao Pereira and Rauwolfia Vomitoria Plant Extracts: Anti-Ovarian Cancer Effects and Potentiation of Carboplatin

Abstract Withdrawn
Abstract Withdrawn

(continued)

P01.30 LB

Influence of Electro-Acupuncture on Endothelial Cells in the Hippocampus of Rats with Chronic Stress Depression

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Purpose: The change of brain micro-environment has been reported following use of acupuncture, and endothelial cells is an important part of it. This study was using biotin label-based antibody array, and concerning about the functional changes of endothelial cells in the hippocampus of chronic stress depression model rats, attempts to explore the role and mechanism of Electro-acupuncture (EA) in the micro-environment of brain.

Methods: 40 Sprague-Dawley rats were randomly devided into four groups: blank, model, model + EA, and model + fluoxetine. Using chronic stress combined with solitary raising methods to establish rat depression model: food-break (24h), water-break (24h), turn night into day (24h), Cold water swimming (10°C, 5min), heat stress (45°C, 5min), clip tail (3min), bounding (3h). EA and fluoxetine intervention were using 1 hour before the modeling. EA was given at points Baihui (GV20) and Yintang (Extra) for 20min (antidementia prescription, ZJ-12H) once a day; 4) Pulsed electro-acupuncture group (n = 10): SAMP8 mice were treated with Pulsed electro-acupuncture alone, which were stimulated the same acupoints for 20min (215HZ,LH-202H) once a day; 5) Donepezil hydrochloride group (n = 10): SAMP8 mice were treated with Donepezil hydrochloride (0.92 mg/kg) once a day. After 15 days, Morris water maze was implemented to assess the learning and memorizing abilities of mice, and the Aβ1–40 and Aβ1–42 levels of the Serum β-amyloid protein in SAMP8 mice were detected with Enzyme-linked immunosorbent assays.

Results: 1. Experimental animals in Donepezil hydrochloride group, Pulsed EA group and Music EA group showed a decrease in both latency time and swimming distance (P < 0.05) while no significant decrease in Model group; 2) With the decrease in Aβ1–40 and Aβ1–42 protein levels, mice in Donepezil hydrochloride group, Pulsed EA group and Music EA group had a significant difference (P < 0.05) compared with the Model group; 3) The reduction of Aβ1–42 protein level in Music EA group was more significant (P < 0.01) in the EA groups.

Conclusion: Both Music electro-acupuncture and Pulsed electro-acupuncture could improve the learning and memorizing abilities of SAMP8 mice, to some extent, may be able to help prevent Alzheimer Disease. Moreover, the regulating effect of Music electro-acupuncture on β-amyloid protein level is much greater than Pulsed electro-acupuncture, this might be one of the important advances of Music electro-acupuncture.

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P01.32 LB

Effects of Music Electro-Acupuncture on the Expression of Monoamine Neurotransmitter in Different Encephalic Regions in Chronic Unpredictable Mild Stress Depression Model Rats

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Purpose: This study aimed to observe the effects of Music electro-acupuncture on the expression of 5-hydroxytryptamine (5-HT), Dopamine (DA) and Noradrenalin (NE) levels in frontal lobe and hippocampus in chronic unpredictable mild depression model rats, and then investigate the efficacy and biological mechanism of Music electro-acupuncture in therapeutic intervention of depression.

Methods: Forty male Sprague-Dawley rats were randomly divided into four groups: Normal control, Model, Fluoxetine and Music electro-acupuncture group (n = 10). Rats were treated with the chronic unpredictable mild stress stimulation combined solitary feeding for 21 days excepted rats in Normal control group. Music EA (ZJ-12H) was stimulated at Baihui (GV20) and Yintang (Extra) for 20min once a day (2V, 1mA), while selected “antidepressant prescription” as music prescription. Fluoxetine was given at the dosage of 10mg/kg. Music EA and Fluoxetine were administrated 1h before modeling. Behavior changes were detected through open-field test, sucrose intake test and body weight measurement. Neurons were counted under microscope after Nissl’s staining of hippocampal tissue. 5-HT, DA and NE were increased significantly in Fluoxetine and Music electro-acupuncture group (P < 0.05). Results of Nissl’s staining displayed in the Model group, the hippocampal neurons were loose in arrangement and partially absent, while in Fluoxetine and Music electro-acupuncture group the neurons were clear in shape and lined in order. Contents of frontal lobe and hippocampal’ 5-HT, DA and NE were increased significantly in Fluoxetine and Music electro-acupuncture group (P < 0.05). Compared with Fluoxetine group, contents of 5-HT increased significantly in Music electro-acupuncture group (P < 0.05).

Conclusion: Music electro-acupuncture could have a positive effect to improve behavior characteristics and hippocampal neuronal structure in depressive rats. The regulating effect of Music electro-acupuncture on raising monoamine neurotransmitter levels is much better than Fluoxetine. Results from the present study indicate that Music EA could be a potential efficacious therapeutic technique for treating depression.

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P02.02

Does Wet Cupping Improve Depression and Anxiety?

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Purpose: Metabolic syndrome is characterized by the presence of 3 clinical features: abdominal obesity, dyslipidaemia, high blood pressure and glucose intolerance. Some studies have shown that metabolic syndrome is also associated with depression and anxiety. Cupping has been shown to have beneficial effects on psychological wellbeing by improving factors such as anger, hostility, depression, and anxiety. Hence, this study aimed to investigate the effects of wet cupping on depression and anxiety in patients with metabolic syndrome.

Methods: Patients with metabolic syndrome (n = 136, aged 18 to 65 year) were included in this study. Ten patients were excluded due to history of hemophilia, systemic disorder, infectious disease, stroke, heart attack, type 1 diabetes, secondary dyslipidemia, renal dysfunction, epilepsy, and drug therapy. Patients were randomly divided into two groups: a control group (n=63) and an experimental group (n=63). The experimental group was treated with dietary advice plus wet cupping. The patients in the control group were given dietary advice alone. Treatment was given for 3 months. Depression and anxiety were assessed by the Hopkins questionnaire at the baseline, 6 and 12 weeks after treatment. Data were analyzed using SPSS software and a repeated measurement ANOVA.

P02.01

The Pilot Study of Traditional Chinese Medicine in the Treatment of Stable Bronchiectasis by N-of-1 Trials

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Purpose: Traditional Chinese Medicine (TCM) stresses syndrome differentiation and individualized treatment. The aim of this study is to compare the efficacy of individualized herbal decoction with fixed decoction on stable bronchiectasis patients.

Methods: We conducted N-of-1 trials (single-patient, double-blind, randomized, multiple crossover design) in 3 patients with stable bronchiectasis. Following a run-in period, individualized herbal decoction and fixed decoction were given for 2weeks to 2 patients and 3 weeks to 1 patient, in pairs (for up to 3 pairs). The primary outcome was the change of the symptoms score in the Visual Analogue Scale (VAS) documented in the patients’ diary. Secondary outcomes were 24 hours sputum volume and medication preference. A clinical significance criteria was stipulated.

Results: Three patients (one male and two female) entered the formal N-of-1 RCT. All the three patients completed 3 treatment pairs. In the analysis of individual N-of-1 trials, no significant differences were seen between individualized herbal decoction and standard decoction in symptoms score, and 24hours sputum volume. However, one patient had definite preference for the individualized herbal decoction over the standard one with the confirmation after breaking the code.

Conclusion: This pilot study showed that N-of-1 trial may be feasible and useful in evaluating the efficacy of herbal decoction in patients with stable bronchiectasis. It also provided us some insights on designing and conducting relevant future studies.

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Results: There were no significant correlations between depression and anxiety with weight, body mass index, and lipid profile ($P > 0.05$) but there was a significant association between psychological parameters with blood pressure, age and gender ($P < 0.05$). There was a significant variation in anxiety scores between times ($P < 0.001$) but this did not differ significantly between groups ($P = 0.78$). There was also a significant variation in depression scores between times ($P < 0.001$) although this did not differ significantly between the two groups ($P = 69$).

Conclusion: Wet cupping does not appear to be useful for the treatment of psychological factors such as anxiety and depression in patients with metabolic syndrome.

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P02.03
A Randomized Controlled Trial of Acupuncture for Chronic Low Back Pain

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Purpose: Chronic Low Back Pain is a common condition and acupuncture is widely sought for the treatment. In the current study, we examined the efficacy of adding confluent acupuncture points related to day time to the regular body acupuncture in patients with chronic low back pain and the persistence of effects in comparison with regular acupuncture.

Methods: Sixty patients were randomly divided to two groups to receive acupuncture. The case group received Routine Acupuncture protocol (RA) while the control group received RA plus acupuncture in confluent points related to time (TA). The change in patients’ Visual analog scale (VAS) score, the number of therapy sessions needed, the absent days count during treatment period and 12 weeks post-treatment, and the relapse of pain during 4 and 12 weeks follow-up.

Results: VAS decreased from $69.6 \pm 7.9$ to $11.8 \pm 4.9$ in case group and from $69.2 \pm 8.0$ to $15.7 \pm 10.0$ in control group ($P = 0.001$). The number of therapy sessions was less in case group ($8.1 \pm 2.0$) than control ($10.1 \pm 2.0$, $P < 0.001$). The case group showed less absent days than control ($0.5$ vs. $1.4$) and pain relapse ($4$ vs. $7$) at $12$ weeks follow-up ($P = 0.03$ and $P = 0.04$). In total, VAS decreased from $69.4 \pm 7.9$ before the first session of acupuncture to $13.8 \pm 8.0$ after the last session ($P < 0.001$), and number of therapy sessions needed for pain relief was $9.1 \pm 2.2$.

Conclusion: Accompanying the routine acupuncture with confluent points attributed to time, enhance the efficacy of the treatment and its persistence in patients with cLBP.

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P02.04
Characteristics of the Authors and Intervention Heterogeneity in Acupuncture Cochrane Systematic Reviews

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Purpose: To investigate the characteristics of the authors of acupuncture Cochrane systematic reviews, and to know the heterogeneity of acupuncture interventions in meta-analysis.

Methods: Searching “acup*” and “acupuncture” in “record title” in Cochrane Library (2013 January) for published full Cochrane reviews. Author information, health conditions, types of acupuncture, meta-analysis information was abstracted and analyzed.

Results: 1. Outline: 40 Cochrane reviews were identified (1 was withdrawn), 39 reviews were included. They were published in 2008–2013. 8 groups, including Menstrual Disorders and Subfertility group (5), Musculoskeletal group (4), Pain group (4), stroke group (3) etc., published 62% of the reviews. Authors from 13 countries contributed. China mainland (10), Australia (8), Hong Kong (6), United Kingdom (6), US (4), Canada (3), GER (2). International author groups: 18 (46%) reviews. 2. Background of authors: Authors of 25 (64%) reviews could not be identified to have acupuncture related education or practice background judged by the information provided in the reviews. 6 (15%) first authors published 15 (38%) reviews, Among them, 4 authors published 11 reviews for almost totally different Cochrane groups. Only 2 of the 13 reviews that didn’t involve Chinese language reviewers searched Chinese databases. 3. Meta-analysis: None of the reviews defined acupuncture as the same. 13 reviews didn’t have any specified limitation on the needle types and methods of stimulations. 28 reviews conducted meta-analysis, 16 (57%) of which included different types of acupuncture into one meta-analysis. In the other 12 (43%) reviews conducted subgroup analysis according to different types of acupuncture.

Conclusion: Acupuncture systematic reviews were mainly written by authors from 13 countries. Acupuncture education or practice background of the authors should be provided adequately. As well as the clinical heterogeneity caused by disease conditions, the heterogeneity caused by acupuncture types and stimulation methods should also be considered carefully when conducting a meta-analysis.

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P02.05
Acupuncture for Melasma in Women: A Systematic Review of Randomized Controlled Trials

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Purpose: To assess the effectiveness and safety of acupuncture for melasma in women.

Methods: Randomized controlled trials (RCTs) on acupuncture for melasma in women were included. PubMed, the Cochrane Library, and Chinese databases (CNKI, VIP, CBM and Wan Fang) were searched till July 2013. Two authors extracted data and conducted the quality assessment independently. RevMan 5.1.7 software was used for data analysis. We adopted the STRICTA checklist to assess the reporting quality of the acupuncture interventions used in the trials. Traditional Chinese medicine syndrome differentiation, acupuncture treatment principles and acupuncture points used were analyzed, too.

Results: 6 RCTs involving 468 women were included. The methodological quality of trials was generally poor in terms of randomization, blinding and intention-to-treat analysis. Meta-
analyses showed acupuncture was significantly better than oral
Vit C plus Vit E on increasing the number of cured patients
(affected area decreased >90%) (RR 2.94, 95%CI 1.11 to 7.79,
p = 0.03), and improved patients (affected area decreased
>30%) (RR 1.36, 95%CI 1.14 to 1.64, p = 0.0008). Number of
insertion, unilateral or bilateral and practitioner background
were not reported sufficiently. Depression of liver qi, deficiency
of spleen and kidney was the major symptom patterns. SP6,
ST36, SP10 and RN6 were the main points used. Five of the six
included studies adopted the local encircling needling technique
to the affected areas on the faces together with the traditional
hand needling techniques applied to the acupoints on the limbs
and trunks. No severe adverse events reported in the included
trials.

Conclusion: Acupuncture appears to be beneficial to the mel-
asma women in terms of symptom improvement. The symptom
patterns of melasma and the acupuncture treatment principles
were highly consistent within the included studies. But the evi-
dence is insufficient to draw a confirmative conclusion.

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P02.06
Improving Inter-Rater Reliability of TCM Diagnosis
Through the Use of Biomarkers and Other Methods
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Purpose: Our study aimed to assess the inter-rater reliability
of TCM diagnosis of people with prediabetes and to document any
relationships between biomarkers and TCM syndromes.

Methods: Twenty-seven participants diagnosed with predia-
betes by blood test were enrolled in the study. Participants were
diagnosed using nine TCM patterns by two independent TCM
practitioners.

Results: Where there was exact agreement on TCM diagnosis
of PDN, acupuncture point selection, and acupuncture frequency.
Eight differential diagnostic categories of PDN emerged from the literature and interviews: four cate-
gories of Deficiencies (of Yin, Yang, Qi and Blood) and four
categories of Excesses (of Damp, Qi and Blood, Damp-heat, and
Stomach heat). Based on consensus among senior acupunctur-
ists, the final new protocol consists of 8–12 acupuncture points
selected according to (1) ‘branch’ presentation based on location
of neuropathic symptoms and (2) ‘root’ presentation based on
eight TCM differential diagnoses. Data from 62 clinical trials of
PDN indicated variation in acupuncture dose and frequency.
Studies in the U.S. offered acupuncture once or twice per week
with 10–20 total treatments with equivocal effects. Most RCTs
in China offered acupuncture on a daily basis, with total treat-
ments ranging from 15–60 with therapeutic benefits.

Conclusion: Using a treatment manualization approach, we
triangulated data on TCM diagnosis and treatment for PDN,
ensured that our protocol is representative of acupuncture
practice, and identified inconsistencies in acupuncture frequency
in prior RCTs. A pilot RCT is planned to determine optimal
frequency of acupuncture treatments for PDN, usability of the
point selection protocol, and effects of group acupuncture on
PDN.

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P02.07
Protocol Development of Group Acupuncture Treatment
for Painful Diabetic Neuropathy Using Treatment
Manualization
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Purpose: Treatment manualization has been successfully ap-
plied in acupuncture trials as a means of standardizing protocols
while maintaining the flexibility of individualized treatments.
We used treatment manualization to develop a protocol of group
acupuncture for painful diabetic neuropathy (PDN).

Methods: Following established guidelines, we conducted: (1) a
systematic review of acupuncture and PDN including studies
carried out in China, (2) interviews of US-based acupuncturists
on traditional Chinese medicine (TCM) diagnoses and treatment for
PDN and (3) a focus group and interviews with senior US-based
acupuncturists to reach consensus and to ensure that the protocol
is consistent with how TCM is actually practiced.

Results: Treatment manualization methods yielded key findings
on TCM diagnosis of PDN, acupuncture point selection, and
acupuncture frequency. Eight differential diagnostic categories
of PDN emerged from the literature and interviews: four cate-
gories of Deficiencies (of Yin, Yang, Qi and Blood) and four
categories of Excesses (of Damp, Qi and Blood, Damp-heat, and
Stomach heat). Based on consensus among senior acupunctur-
ists, the final new protocol consists of 8–12 acupuncture points
selected according to (1) ‘branch’ presentation based on location
of neuropathic symptoms and (2) ‘root’ presentation based on
eight TCM differential diagnoses. Data from 62 clinical trials of
PDN indicated variation in acupuncture dose and frequency.
Studies in the U.S. offered acupuncture once or twice per week
with 10–20 total treatments with equivocal effects. Most RCTs
in China offered acupuncture on a daily basis, with total treat-
ments ranging from 15–60 with therapeutic benefits.

Conclusion: Using a treatment manualization approach, we
triangulated data on TCM diagnosis and treatment for PDN,
ensured that our protocol is representative of acupuncture
practice, and identified inconsistencies in acupuncture frequency
in prior RCTs. A pilot RCT is planned to determine optimal
frequency of acupuncture treatments for PDN, usability of the
point selection protocol, and effects of group acupuncture on
PDN.

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P02.08
Who Might Benefit from Acupuncture for
Musculoskeletal Pain: Results from a Student Clinic
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Purpose: The same acupuncture treatment is not equally ef-
fective for every patient. This report focuses on patients’ base-
line characteristics that are related to greater or lesser positive
outcomes from acupuncture treatments.

Methods: This secondary analysis study looks at 42 patients
who i) completed an initial and 6th week follow-up “Measure
Your Medical Outcome Profile” (MYMOP) form and ii) had
diseases of the musculoskeletal system and/or connective tissue
as the main complaints on their health history form and iii) visited
the New England School of Acupuncture (NESA) main
clinic site in Massachusetts, USA in 2011.

Results: Patients were mostly female (67%) and White (74%) with
76% having at least a college education. Certain baseline
patient characteristics showed statistically significant relation-
ships with symptom outcomes, as measured by the MYMOP
after short term acupuncture treatments. For example, in patients
with musculoskeletal conditions, higher baseline pain score was
significantly related to greater improvement over 6 weeks of treatment.

**Conclusion:** We found some potential variables that are related to acupuncture treatment outcomes in patients with musculoskeletal conditions. The findings may not apply to other treatment of different conditions. Potential confounders and biases are discussed.

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**P02.09 Local Effects of Acupuncture on the Median and Ulnar Nerves in Patients with Carpal Tunnel Syndrome (CTS): Study Design and Preliminary Results**

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**Purpose:** The purpose of this mechanistic study is to use electrophysiologic measurements such as nerve conduction studies (NCS) and quantitative sensory testing (QST), to assess the local, nerve-specific effects of 3 acupuncture modalities on two anatomically distinct nerves in the forearm (Median and Ulnar nerve) in subjects with CTS. We expect to see a greater response in the diseased nerve (Median), compared to the healthy one (Ulnar).

**Methods:** Participants with CTS are randomized to 3 intervention groups – manual, low- and high-frequency electroacupuncture. In Week 1, baseline NCS and QST measurements are obtained in both nerve territories, followed by acupuncture to the Median nerve (pericardium channel points) and to the Ulnar nerve (heart channel points), one week apart, order counterbalanced. Acupuncture is followed by repeat NCS and QST measurements for both nerves. In Week 2 repeat baseline QST and NCS measurements are obtained, followed by acupuncture to the nerve not treated in Week 1 and post-acupuncture NCS and QST measurements to both nerves.

**Results:** 3 pilot participants have been tested to date. In Pilot1 acupuncture caused 66% improvement of the Median cold detection threshold, but not in the healthy Ulnar nerve, with corresponding 60% increase in Median compound muscle action potential (CMAP) amplitudes. In Pilot2 acupuncture induced restoration of Median Sensory Nerve Action Potentials (SNAP), which had been missing at baseline due to CTS. In Pilot3 acupuncture caused improvements in Median nerve cold (3%) and vibration (55%) sensation, with corresponding increases in Median motor and sensory nerve conduction velocities (NCV). Ulnar sensory NCV and SNAP amplitude also increased with acupuncture. All 3 subjects reported symptomatic improvement.

**Conclusion:** Acupuncture appears to have nerve-specific affect on the Median and Ulnar nerves in the forearm, which can be measured using NCS and QST. These effects will be fully assessed upon completion of the study which plans on 36 participants.

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**P02.10 The Effects of Wet Cupping on Serum High-Sensitivity C- Reactive Protein and Heat Shock Protein 27 Antibody Titers in Patients with Metabolic Syndrome**

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**Purpose:** An increased level of serum heat shock proteins (Hsps) is reported in patients with metabolic syndrome. Expression Hsp and inflammatory markers can affect by cupping and traditional Chinese medicine. By considering, there is a little data to investigate effects of cupping on markers of inflammation and Hsp proteins hence, the objective of this study was evaluation of the effects of wet cupping on serum high-sensitivity C- reactive protein (hs-CRP) and Hsp 27 antibody titers in patients with metabolic syndrome.

**Methods:** Serum hs-CRP and Hsp 27 antibody titers were assessed in samples from 126 patients with metabolic syndrome (18 to 65 years of age) at the baseline, 6 and 12 weeks after treatment. One hundred twenty-six patients were randomly divided into the experimental group treated with wet cupping combined with dietary advice, and the control group treated with dietary advice alone. Eight patients in case group and five subjects in control groups were excluded from the study. Data was analyzed using SPSS 15 soft ware and a repeated measure ANOVA.

**Results:** Serum hs-CRP titers did not change significantly between groups (P >0.05) and times (P =0.07). The same result was found for Hsp 27 titers (P >0.05).

**Conclusion:** Cupping does not have a considerable effect on serum hs-CRP and Hsp 27 antibody titers in patient with metabolic syndrome.

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**P02.11 Systematic Review of Acupuncture Versus Medication for Migraine Prophylaxis**

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**Purpose:** This project aims to systematically compare the evidence for the use of acupuncture relative to pharmaceutical medications in the prevention of migraines. Systematic literature searches of PubMed (Medline), Embase, Web of Science, were conducted from the 1940s, 1973, and 1985 respectively, to present.

**Methods:** Studies were included if they were prospective control-comparison, using acupuncture for migraine prophylaxes in an English-speaking adult population, and with relief of migraine frequency as a primary or secondary outcome measured on an established scale. Methodological quality was evaluated using the modified Scale for Assessing Scientific Quality of Investigations for Complementary and Alternative Medicine (SASQI-CAM).

**Results:** Of the 169 papers identified by database searches, 9 met our inclusion and exclusion criteria. Six of these papers received a SASQI score >10 and were deemed of sufficient quality to be included in the review. All of these selected quality papers demonstrated prevention of migraine symptoms either equal to or greater than common pharmaceutical treatments. These medications include beta-blockers (metoprolol), anti-seizure medications (topirimate), and calcium-channel blockers (flunarizine). Standardized acupuncture was used in most of the...
P02.12
Association Between Acupuncture Needling Sensation (de-qi) and Local Skin Blood Flow in Healthy Subjects: A Single-Blind, Randomized Controlled Trial

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Purpose: De-qi refers to sensations generated by needle insertion into an acupuncture point. De-qi sensation is believed to be associated with the treatment effects of acupuncture and the increase of local blood flow, although some patients may find the sensation uncomfortable. This study aimed to assess the association between the strength of de-qi sensation and local skin blood flow in healthy subjects.

Methods: Forty-five healthy subjects were randomized into real acupuncture (RA) (n = 15), Park Sham acupuncture (SA) (n = 15), and non-needling control (CO) (n = 15) groups. A single acupuncture session was conducted on the right LI4 point, involving manual stimulation and 10-minute needle retention. De-qi sensation was assessed immediately after the removal of needles, through the use of the Southampton needle sensation questionnaire. Recording of local skin blood flow within a 2cm diameter of the ipsilateral LI4 area was performed intermittently with the Laser Doppler blood perfusion imager, lasting from just before the intervention until the end of the trial. Correlations between changes in skin blood flow and the strength of de-qi were assessed.

Results: The median change of local skin blood flow from baseline to post-treatment was 48.85, 48.20, and −0.59 arbitrary units (AU) in the RA, SA, and CO groups, respectively. The median total sensation scores in the three groups were 10, 3, and 0 of 51 points, respectively. No significant correlation was found between total sensation score and change of skin blood flow in the RA or SA groups (0.1059 of Spearman’s rho, p = 0.57).

Conclusion: The data suggest that there is no association between de-qi sensation and local skin blood flow during acupuncture in healthy adults. The role of de-qi sensation in physiological changes and clinical outcomes should be further investigated in future acupuncture trials.

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P02.14
Therapeutic Effect of Acupuncture Combined with Exercise Therapy on Patients with Low Back and Leg Pain

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Purpose: To observe clinical therapeutic effect of acupuncture at Fengfu (DU16) combined with exercise therapy on patients with low back and leg pain.

Methods: 50 outpatients with low back and leg pain were investigated, including lumbar disc herniation (n = 31), knee arthropathy (n = 9), displacement of atheteic sacroiliac joint (n = 3), acute waist sprain (n = 3), ankle sprain (n = 2) and heel pain (n = 2). Fengfu was chosen as the only acupoint, the acupuncture manipulation consisted of lifting-inserting and "the phoenix unfolds its wings" were operated after insertion. Treatment was given for once: exercise of the affected part ( 5 minutes) after manipulation (1 minute), 3 times. We evaluated the therapeutic effect based on standard of clinical control, significant effective, effective and ineffective.

Results: The cure rate was 34%, the significant effective rate was 42%, the effective rate was 24%; the total effective rate was 100%.

Conclusion: Our small-scale clinical observation indicates that acupuncture combined with exercise treatment could improve low back and leg pain after single therapy.

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**P02.15**

**Effects of Different Frequencies of Electroacupuncture on Blood Glucose Tolerance Patients**

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**Purpose:** To investigate the clinical efficacy of electroacupuncture (EA) at different frequencies for patients with impaired glucose tolerance (IGT).

**Methods:** 120 outpatients with IGT were randomly divided into four groups: control (n=30), EA-5Hz (n=30), EA-50Hz (n=30), and EA-100Hz (n=30). Bilateral Pishu (BL20), Shen-shu (BL23), Zusanli (ST36) and Sanyinjiao (SP6) were chosen as the main acupoints. Treatments were given for 60 days, 1mA and 20 minutes every day. The body mass index (BMI), fasting blood glucose (FBG) and 2-hour post-prandial blood glucose (2hBG) were detected by BAYER Blood Sugar Analyzer; glycylated haemoglobin (HbA1c) was detected by enzymatic assay, indexes were detected before and after treatment.

**Results:** The detection indexes’ levels showed no differences among the groups at baseline (P>0.05). In EA-5Hz group, the levels of 2hPBG and HbA1c were significantly lower than those of control group (P<0.01 and P<0.05), as well as BMI and FBG showed no differences. There were no statistically significant differences among EA-50Hz, EA-100Hz and control groups.

**Conclusion:** Our comparative effectiveness clinical trial indicates that electroacupuncture at 5Hz for patients with IGT may be better in reducing the levels of 2hPG and HbA1c than higher frequency.

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**P02.17**

**Bee Venom Acupuncture for Central Post-Stroke Pain**

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**Purpose:** Stroke is major cause of mortality and disability worldwide. central post-stroke pain(CPSP) refers to pain initiated or caused by a primary lesion or dysfunction of the central nervous system after stroke. This study aimed to summarize and evaluate the evidence for the effectiveness of bee venom acupuncture (BVA) for CPSP.

**Methods:** Eight databases (MEDLINE, EMBASE, The Cochrane Library, Chinese Database and 4 Korean Medical Databases) were searched from their inception through May 2013 without language restrictions. Randomized controlled trials (RCTs) were included if BVA was used at acupoints as the sole treatment or as an adjunct to other treatments for CPSP.

**Results:** A total of 58 possibly relevant articles were identified, of which 2 RCTs met our inclusion criteria. 2 RCTs that assessed effect of BVA compared with saline injection were included. One RCT reported significant difference in pain reduction, whereas the other RCT did not show. All trials employed appropriate sequence generation methods. One RCT reported allocation concealment, whereas the other RCT did not. All trials did not provide detailed information about blinding.

**Conclusion:** This review does not provide evidence to support the routine use of BVA for CPSP. Further studies are needed to draw firm role of BVA for CPSP. Future trials about this topic must be conducted with large samples and rigorous study designs for certainty.

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**P02.16**

**A Clinical Comparative Research of Electroacupuncture and Auricular Point Sticking Therapy in Patients with Impaired Glucose Tolerance**

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**Purpose:** To investigate the efficacy comparison of electroacupuncture and auricular point sticking therapy in patients with impaired glucose tolerance (IGT), and find effective method in curing IGT.

**Methods:** Outpatients with IGT (n=60) were randomly divided into two groups: 1) electroacupuncture (EA) (n=30); 2) Auricular Point Sticking (n=30). The electroacupuncture point selection are Shen shu, Pishu, Feishu, Zusanli, Sanyinjiao, electric acupuncture after routine needling with deqi; The auricular point sticking point selection are endocrine, fei, pi, shen, wei. FBG and 2hBG assessed treatment effect at weeks 4, 8, 12 and before treatment. HbA1c assessed treatment effect before and after treatment.

**Results:** The electroacupuncture group scored significantly better on 2hPG, HbA1c after treatment than did before treatment. (P<0.05); there were no statistically significant differences between before treatment and after on FBG. The Auricular Point Sticking group scored significantly better on 2hPG after treatment than did before treatment. (P<0.05); there were no statistically significant differences between before treatment and after on FBG, HbA1c. There was no significant difference in clinical effective rate between electroacupuncture group with 93% and Auricular Point Sticking group with 77%.

**Conclusion:** The electroacupuncture and auricular point sticking have effect in reducing 2hBG. The electroacupuncture has effect in reducing HbA1c. While neither of two methods has effect in decreasing FBG. But the auricular point sticking has a large application range with the superiority of acceptance, simple manipulation and inexpensive way.

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**P02.18**

**Additive Complex Ayurvedic Treatment in Patients with Fibromyalgia-Syndrome Compared to Conventional Standard Care Alone – Results of a Non-Randomized Controlled Clinical Pilot Study**

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**Purpose:** To evaluate the evidence for the effectiveness of bee venom acupuncture (BVA) for CPSP.
Effectiveness of Electro-Acupuncture Therapy in Improving Gait and Balance in People with Parkinson’s Disease

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**Purpose:** Postural instability, gait difficulty, and other facets of mobility are major concerns in people suffering from Parkinson’s disease (PD). Due to the significant limitations of conventional therapy, complementary and alternative therapies are increasingly used in patients with PD and acupuncture is one of the most popular of them. The objective of this study was to assess the effectiveness of a standardized electro-acupuncture (EA) regimen for improving gait and balance in patients with confirmed PD using objective modalities based on innovative body worn sensors technology.

**Methods:** Eleven PD patients were randomly assigned with ratio of 2 to 1, to intervention group (n = 8) and control group (n = 3). The intervention group went through 30-minute EA treatment on weekly basis for three weeks, while the control group received a sham treatment. Outcomes assessed at baseline prior to and at the end of therapy. Measurements included balance (assessed by ratio of mediolateral center of mass sway to anteroposterior sway during eyes open, eyes closed, and eyes open dual task), gait (assessed during habitual speed, dual task, and fast walking), quality of life (SF12), and UPDRS.

**Results:** No between group difference was observed for baseline assessments and demographic information. After treatment, between groups comparison revealed that balance was significantly better in the intervention group compared to control group (p<0.05). The difference was more pronounced during dual task condition, where a between group difference of 60% was observed (p = 0.02). On the same note, gait speed and stride length during all conditions were higher in the intervention group (p = 0.006). Finally, a significant improvement was observed for the intervention group compared to baseline for gait, balance, and quality of life, while no significant change was noticed in the control group.

**Conclusion:** This pilot study demonstrates the proof of concept for EA benefit in gait and balance in PD patients.

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Optical Examination of the Efficacy of Contact Needle Therapy for Chemotherapy-Induced Peripheral Neuropathy: Integration of the Inspection of Kampo Therapy and the Color Spectrum Information

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**Purpose:** Cancer chemotherapy-induced peripheral neuropathy (CIPN) often results in discontinuation of treatment with potentially useful anticancer drugs and may deteriorate the patient’s quality of life. Contact needle therapy (CNT) is one of the traditional Japanese methods of acupuncture. CNT on CIPN has empirically considered being effective, but the objective estimation of its effect has been difficult. Besides the symptom scoring, we have focused on the oxygen saturation. We have already proposed optical path-length matrix method (OPLM) for estimating oxygen saturation of the skin, which may help finding the damage of peripheral tissue including neurons. This study investigated the effect of CNT on CIPN caused by responsible chemotherapeutic agents as taxanes and oxaliplatin with symptom scores and information obtained from skin color spectrum.

**Methods:** Four patients with CIPN were treated with CNT. The severity of CIPN was evaluated using the Common Terminology Criteria for Adverse Events (CTCAE) ver.4 and FACT/GOG-Ntx before and after CNT. We also measured oxygen saturation, hemoglobin concentration at fingertip of the right foot finger. Then, correlations and continuous variables among the values were calculated correlation coefficients.

**Results:** There were significantly better differences in post-CNT than in pre-CNT when comparing in FACT/GOG Ntx and oxygen saturation of the skin (p<0.05). The oxygen saturation showed large correlation (0.5 < |r| < 1) with the score improvements.
**P02.21**

**Patient Centered Outcomes After Receiving Acupuncture for Temporomandibular Joint Disorders**

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**Purpose:** To systematically document patients’ perspective clinical outcomes after receiving acupuncture treatment in a university based orofacial pain clinic, we analyzed Measure Your Medical Outcome Profile (MYMOP) forms collected from TMD patients.

**Methods:** All patients (n = 46) who attended the UNC Orofacial Pain Acupuncture Clinic between October 2011 and July 2013 for TMD-related pain were selected for this retrospective chart review. Acupuncture treatment was provided on a weekly basis at 8 points on average chosen from the cranio-cervical-mandibular area, and distant areas including the extremities. Forty one patients completed the MYMOP, a validated patient-centered outcome measure at each treatment (140 valid forms total) evaluating TMD pain, perceived wellbeing, and MYMOP profile score on a scale of 0 to 6, 0 indicating as good as it could be and 6 indicating as bad as it could be.

**Results:** TMD pain at the initial assessment (3.50±1.55) and after four treatment visits (2.54±1.05) showed statistically significant improvement (p<0.01). Wellbeing and MYMOP profile scores followed the same pattern with wellbeing improving from 2.83±1.43 to 1.64±0.93 (p=0.01) and MYMOP profile scores improving from 3.30±1.16 to 1.28±1.19 (p<0.01). The degrees of change for TMD Pain (1.25±1.25), Wellbeing (1.82±1.75), and MYMOP profile score (1.28±1.19) between the initial assessment and fourth follow-up were all higher than the clinically meaningful minimal difference (0.5–1.0).

**Conclusion:** It is justifiable to develop a hypothesis that acupuncture significantly improves a TMD patient’s pain and wellbeing after four weeks of treatment. Further research is needed to test this hypothesis, and to investigate the mechanism of action behind acupuncture as a therapeutic modality for chronic pain of TMD and other musculoskeletal conditions, for which acupuncture is proven effective.

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**P02.22**

**Acupuncture for Schizophrenia: What Patients Want, What Patients Get**

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**Purpose:** An exploratory case study approach was used to investigate the impact and acceptability of providing acupuncture as adjunct to conventional medications to people with schizophrenia who had incomplete remission. Data was analyzed to compare the outcomes of the study with participants originally prioritizations when initially assessed by the acupuncturists.

**Methods:** Acupuncture was provided pragmatically to 11 people according to TCM acupuncture practice. Outcome measures included the positive and negative symptom scale, the Schizophrenia Quality of Life Scale, and the Pittsburgh sleep quality index. Acupuncture consultations were observed, semi-structured interviews carried out with patients, and clinical case notes were examined retrospectively. A modified version of the Standards for Reporting Interventions in Controlled Clinical Trials (STRICTA) was employed.

**Results:** Eleven participants were recruited to the study. All reported benefits from acupuncture. In order of importance, priorities for treatment with acupuncture were poor sleep/over sleep, poor energy/tiredness, muscular pain, side-effects of antipsychotics, weight gain, anxiety, and voices. Participant outcomes in order of importance were increased engagement with/ demand for support from mental health services, reduced hallucinations, paranoia, tiredness, anxiety, and side effects of antipsychotics, improved confidence, energy, exercise, and a renewed motivation to return to work and develop a romantic relationship. Two participants, who made quite radical improvements, suffered a severe relapse.

**Conclusion:** The priorities of people with schizophrenia seem to be more related to the side-effects of their antipsychotic medicines, aches and pains and weight gain. They were also keen that acupuncture might help their symptoms of schizophrenia. The most striking outcomes for these participants was the extent to which symptoms of schizophrenia improved and the resulting motivation it gave them to engage with services in order to gain support to return to a normal life. Some more vulnerable patients may require more intensive support while they experience recovery.

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6. The WHOQOL-BREF scale on quality of life was given at baseline and week 6. 

Results: There were no differences among the three groups at baseline (p > 0.05). In the two acupuncture plus paroxetine groups, HAMD scores were significantly lower than those in the paroxetine group (p < 0.05); no significant difference was found between the two acupuncture groups (p > 0.05). SERS scores in the acupuncture groups were significantly lower than those for paroxetine alone at weeks 2, 4, and 6 (p < 0.05). WHOQOL-BREF scores for total subjective feelings regarding quality of life and health were significantly higher in the two acupuncture groups than those in the paroxetine only group (p < 0.05). 

Conclusion: Acupuncture plus paroxetine was more effective for patients with depression than was paroxetine alone. Acupuncture can improve patients' life quality, psychological and physical conditions. Acupuncture can eliminate the side effects of medicine and detoxify the medicinal treatment for the depression patients. 

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P02.25 Kampo Traditional Pattern Diagnosis and the Clustering Analysis of Patients with Insomnia 

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Purpose: Insomnia is a very common problem all over the world. In Kampo medicine, Japanese traditional medicine, treatment is based on the pattern diagnosis of patients which is decided by characteristics of patients' profile. In the modern technology, this empirical pattern diagnosis may be reproduced by clustering analysis. In this study, we got clusters of insomnia patients and investigated the relationship with traditional Kampo pattern diagnosis. 

Methods: We analyzed 1017 new patients of Kampo Clinic in Keio University hospital between March 2008 and May 2013. Subjective complaints of patients were collected on the browser-based questionnaire system and also physical findings, Kampo pattern diagnosis and prescription are provided by Kampo experts. We created clusters by applying a principal component analysis and k-means cluster analysis. We analyzed the relationship between each cluster and Kampo pattern diagnosis. 

Results: Four clusters of patients were obtained. The first one was reproductive female group accompanied with menstrual pain, dizziness, periorbital dark circle and vaginal discharge. The second one was menopausal female group, accompanied with hot flush, sweating, palpitation and sluggishness. The third one was aged group accompanied with muscle spasm, numbness, stagger and pain of legs. The fourth one was skin problem group accompanied with skin itchness, dry skin, urticaria and dandruff. In each group, typical Kampo pattern diagnosis were made by experts, which were "blood stasis", "qi depression", "lower abdominal deficiency" and "blood deficiency" patterns respectively, and Kampo prescription were characteristic in each group. 

Conclusion: Cold sensation contains diverse conditions. Kampo physicians consider the holistic symptoms and empirically divide patients based on pattern diagnosis, and then choose an appropriate Kampo formula and treat cold sensation and other symptoms simultaneously. This study showed that the empirical Kampo pattern diagnosis could be reproduced by modern clustering analysis. 

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P02.24 Kampo Traditional Pattern Diagnosis and the Clustering Analysis of Patients with Cold Sensation 

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Purpose: When a patient complains of cold sensation, sometimes it is a substantial cause or the aggravation factor of diseases. In Kampo medicine, Japanese traditional medicine, cold sensation is a very important target of treatment and patient's problems are solved as a result. In Kampo medicine, treatment is based on the pattern diagnosis of patients which is decided by characteristics of patients' profile. In the modern technology, this empirical pattern diagnosis may be reproduced by clustering analysis. In this study, we got clusters of patients with cold sensation and investigated the relationship with traditional Kampo pattern diagnosis. 

Methods: We analyzed 2344 new patients with cold sensation who visited Kampo Clinic in Keio University hospital between 2008 and 2013. Subjective complaints of patients were collected on the browser-based questionnaire system and also physical findings, Kampo pattern diagnosis and prescription are provided by Kampo experts. We applied principal component analysis and k-means cluster analysis to these data and made clusters based on mainly patient's subjective complaints. 

Results: We obtained 4 specific clusters of patients. The first one was aged group, accompanied with hearing loss, urine leakage, extremities’ spasms, pain, numbness and weakness. The second one was gastrointestinal abnormality group, accompanied with abdominal fullness, pain, heartburn and diarrhea. Young females or hot flashes with sweating characterized the other groups. For each group, a typical Kampo pattern is interpreted, which is “lower abdominal deficiency pattern”, “qi stagnation pattern”, “blood stasis pattern” and “qi counterflow pattern” respectively, and Kampo prescription were characteristic in each group. 

Conclusion: In Western medicine, physicians give hypnotics and sedatives to all patients without consideration of accompanying symptoms. In contrast, Kampo physicians consider the holistic symptoms and empirically divide patients based on pattern diagnosis, and then choose an appropriate Kampo formula and treat insomnia and other symptoms simultaneously. This study showed that the empirical Kampo pattern diagnosis can be reproduced by modern clustering analysis. 

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P02.26 Impact on Rehabilitation Effect of Post-Stroke Abnormal Movement Pattern Prevented and Treated with Multi-Needle Puncture of Scalp-Points 

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P02.27 Effects of Home-Based Neck Care Treatment and Eccentric Resistance Combined with Massage Programs on Pain and Function in Office Workers

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Purpose: Objective: Office workers frequently experience non-specific neck and upper shoulder pain due to prolonged forward head posture while working. The purpose of this study was to determine the effects of: 1) Active Muscle Therapy (AMT)-eccentric resistance combined with stripping massage treatments, 2) a home-based neck care program, and 3) both interventions combined on neck pain and function in office workers.

Methods: Sixty office workers with chronic non-specific neck/shoulder pain and stiffness, recruited from the Silicon Valley region of California, were assigned to one of three groups. At baseline, neck flexibility, forward head posture, headache frequency/severity, neck disability index (NDI) and visual analog pain scale (VAS) were measured. Data for compliance with the home-based program were recorded. For six weeks: Group 1 received the massage intervention (30 min, 1 d/wk); Group 2 performed the home-based program (20 min, 3 d/wk); and Group 3 served as a control group. After 6 wk, measures were repeated. Group 3 then became Group 4 and received the massage (30 min, 1 d/wk) and home-based program (20 min, 3 d/wk) interventions for 6 wk. After the second 6-wk period Group 4 was tested again. 40 participants completed the study.

Results: All interventions improved (p<0.05) head posture and neck flexibility, decreased headache frequency/severity, improved NDI scores, and decreased VAS scores compared to control. Groups 1 and 4 reported lower VAS scores after each AMT treatment. Compliance in the home treatment-program was 59% for group 2 and 76% for group 4.

Conclusion: AMT and a home neck care program can reduce neck pain and improve function in office workers. Combining both programs was no more effective than either intervention alone. Combining eccentric resistance with stripping massage shows great potential for helping office workers reduce pain and headache frequency/severity, and improve neck range of motion and forward head posture.

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P02.28 Doctors of Chiropractic Proficiency in Delivering Prescribed Traction Forces During Manual Cervical Distraction of Neck Pain Patients

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Purpose: Neck pain is a common musculoskeletal complaint responsive to manual therapies. Doctors of chiropractic (DCs) may use manual cervical distraction (MCD), a mobilization procedure used to treat neck pain patients. However, it is unknown if clinicians can consistently apply standardized cervical traction forces, a critical step toward identifying an optimal therapeutic dose and determining treatment safety for MCD. The purpose of this study was to assess clinicians’ proficiency in delivering prescribed traction forces in a randomized clinical trial of neck pain patients.

Methods: We randomized 48 participants with neck pain of at least four weeks duration into three treatment groups. Participants received five MCD treatments over two weeks while lying prone on a specially designed treatment table instrumented with force sensors. We trained two DCs to deliver prescribed traction forces in a randomized clinical trial of neck pain patients. Doctors of chiropractic (DCs) were out of range for 25% of the treatments without visual feedback whereas only 3% of the time with visual feedback. Four participants started without visual feedback. Peak traction force data were extracted and descriptively analyzed.

Results: DCs were out of range for 25% of the treatments without visual feedback whereas only 3% of the time with visual feedback. Mean (SD) of traction forces for Group 2 (Medium) by DC1 (n=28) and DC2 (n=46) were 17.6N (1.2N) and 18.6N (1.0N), respectively. Mean traction forces for Group 2 (Medium) by DC1 (n=28) and DC2 (n=46) were 40.9N (8.0N) and 45.9N (2.5N), respectively. Mean traction forces for Group 3 (Heavy) by DC1 (n=32) and DC2 (n=34) were 70.9N (10.6N) and 86.5N (4.1N), respectively.
Conclusion: This study demonstrates that with visual feedback DCs can successfully deliver prescribed traction forces while treating neck pain patients enabling the capability to conduct force-based dose-response clinical studies.

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P02.29
Massage Effectiveness for Primary Care Patients with Chronic Low Back Pain and Below Normal SF-36v2 Mental Health Scores: Secondary Analysis

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Purpose: The challenging condition of chronic low back pain (CLBP) is often complicated by negative mental health factors. Non-pharmacological approaches to address CLBP alone and in combination with mental health issues are needed. A recently completed NIH funded study examined the effectiveness of clinical massage therapy (CMT) on functional health outcomes for CLBP patients referred to CMT by their PCP regardless of mental health status save psychosis. CMT was found to have significant and clinically meaningful effectiveness for patients (N=85) in the primary outcomes: Oswestry Disability Index, SF-36v2 mental and physical components and pain domain (in review). The purpose this study’s secondary analysis is to determine the extent to which participants that began the study below normal in the SF-36v2 mental health component had clinically meaningful change.

Methods: CLBP patients referred by their PCP were assigned to community massage practitioners (CMPs) to receive up to ten, 1-hour CMT sessions over 12-weeks. Individual treatment plans were formulated by study CMPs. Secondary data analyses were conducted examining a subpopulation (n=41) of those beginning the study at below normal (<45) for the SF-36v2 mental health component score.

Results: Mean change for those <norMHC was 8.4 (±7.6) vs. −1.9 (±6.9) for the SF-36v2 mental health component score (p<0.001). 70% (vs. 19%) achieved clinically meaningful improvement (≥4.6 change) in the SF-36v2 mental health component score (p<0.001). Furthermore, 48% of <norMHC, transitioned from below to at or above normal post-intervention. The relationship of mental health scores with other outcomes will be discussed.

Conclusion: While primary study results indicate significant and clinically meaningful outcome for CMT, these secondary analyses suggest striking CMT effectiveness for CLBP patients with below normal mental health component assessments, particularly in regards to their mental health. Stakeholders should consider/ utilize CMT as an effective intervention for CLBP patients, particularly those with below normal mental health assessments.

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P02.30
Development and Validation of Instruments to Evaluate Adverse Events After Spinal Manipulation Therapy

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Purpose: Although spinal manipulation therapy (SMT) is used throughout the world, there are no systematic data collection mechanisms in place to monitor and assess adverse events (AE) after SMT. SafetyNet, a multidisciplinary research team, has established a reporting and learning system to fill this void.

Methods: Development and validation occurred in a step-wise fashion: 1) definition of relevant terms (adverse event, seriousness, causality/relatedness, preventability, patient disposition); 2) identification and development of key domains, items, and sub-items (to assess the relationship between exposure and outcome and to be feasible to complete); and 3) assessment of relevant measurement properties (content validity, hypotheses testing, internal consistency, structural validity, cross-cultural validity, criterion validity, responsiveness).

Results: Two provider short forms, a provider long form, and a patient comment form were developed, refined, and pilot tested with 12 providers and 300 patients. Given that terminology differs amongst SMT professions, two provider forms were designed to be profession-specific. The provider long form is designed to be completed for all moderate, serious, or severe patient reported AEs. These forms contain mostly text boxes to allow for narrative descriptions. The patient comment form is two-sided and designed to collect information on satisfaction and potential AEs after the SMT visit from the patient perspective. Pilot testing refined the forms to versions which providers and patients found reasonable to complete, as well as collected necessary information to assess AEs according to the relevant terms.

Conclusion: The development and validation of instruments to evaluate SMT AEs may benefit the SMT research community as well as clinicians and their patients by providing the opportunity for rigorous prospective assessment of potential SMT-related AEs and their risk factors, thus enhancing patient safety and promotion of a safety culture. Placing the instruments in providers’ offices for use on consecutive patients is next on the SafetyNet research agenda.

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P02.31
Influence of the Amount and Duration of Therapeutic Massage for Chronic Neck Pain on 12 and 26 Week Outcomes of Pain and Function

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Purpose: Determine optimal dose (number, frequency, and duration of sessions) of massage for persons with chronic neck pain for use in future effectiveness trials.

Methods: Two-phase randomized trial for persons with chronic non-specific neck pain. Primary randomization of 191 participants to one of 5 groups receiving 4 weeks of massage (30 minutes 2×/ or 3×/week or 60 minutes 1×, 2×, or 3×/week). Secondary randomization occurred 5 weeks after ini-
tial randomization of the 179 participants who agreed to be re-randomized and completed 5-week assessment. These Phase 2 participants received an additional 6 weeks of weekly 60 minutes massages (Booster) or no additional massage. Neck-related dysfunction (Neck Disability Index, NDI) and pain (0–10 pain numerical rating scale) were assessed at baseline, 12, and 26 weeks. Clinically meaningful improvement from baseline was defined as >5 point decrease in the NDI and >30% decrease in pain. Primary and booster treatment assignment effects were evaluated using modified Poisson generalized estimating equation regression adjusting for baseline outcomes, age, neck pain >5 years, medication, race and each treatment assignment in a single model.

**Results:** There were no observed differences by primary treatment assignment at 12 or 26 weeks. Those receiving booster dose had clinically meaningful improvements in both dysfunction and pain at 12 weeks (NDI: RR = 1.56, 1.06–2.25, p = 0.018; pain: RR = 1.25, 0.98–1.61; p = 0.077), but both were non-significant at 26 weeks (NDI: RR = 1.22, 0.85–1.74, p = 0.277; pain: RR = 1.09 0.82–1.43, p = 0.558). Further analyses looking at subgroup differences by primary and booster treatments found the booster dose only effective at 12 weeks amongst those that initially randomized to one of the 60 minutes massage groups (Booster Effect: 60 minute RR = 1.92 (1.22, 3.04) versus 30 minute RR = 1.07 (0.54, 2.13)).

**Conclusion:** “Booster” doses for those initially receiving 60 minutes of massage should be incorporated into future trials of massage for chronic neck pain.

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**P02.32**

**Complementary and Alternative Medicine (CAM) Therapies as a Means of Advancing Patient-Centered Care for Veterans Receiving Palliative Care**

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**Purpose:** Chronic and life threatening illnesses are influenced by the psychological state of the individuals. In veteran populations, where rates of psychological disorders, debilitating injuries and lack of social support are higher than civilian populations, allopathic medicine is often insufficient to treat these illnesses and resulting symptoms. The objective of this study was to evaluate potential efficacy of massage therapy for palliative care veterans as well as to conduct qualitative surveys to explore the feasibility of expanding Complementary and Alternative (CAM) therapies within VA settings.

**Methods:** A mixed method study design was used. Patients were recruited based on receiving a massage consultation from a provider or by recommendation of the massage therapist. Patients answered many measures of wellness (0–10 numeric rating scales) pre and post-massage. Medical records were extracted for patients’ demographics, histories, social status and support. Semi-structured Interviews were conducted with VA patients, providers and administrators.

**Results:** Data collection will be ongoing through April 2014. Currently, 95.2% of the population is male with an average age of 67 years and 81% are Caucasian. Two-thirds have a primary diagnosis of cancer. From pre- to post-massage: pain decreased 33%, anxiety decreased 44%, nausea decreased 79%, shortness of breath decreased 61%, stress decreased 42%, relaxation increased 42%, and peacefulness increased 30%. Interviews indicate that staff and administrators perceived hesitance to CAM use among some veterans and providers and obstacles to hiring CAM therapists within the VA system as barriers to expansion.

**Conclusion:** Results from current data and data obtained from a civilian population at the collaborating Abbott Northwestern Hospital (Minneapolis) all suggest positive results for the efficacy of massage therapy. This study could assist VA hospitals with expanding their CAM therapy programs for pain and symptom management. Findings may also establish the feasibility of offering CAM therapies to veterans and the impact on patient outcomes.

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**P02.33**

**Observed Changes in Quality of Life Measures and Cerebrospinal Fluid Flow Parameters in Migraine Subjects Receiving Chiropractic Care**

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**Purpose:** This observational case series followed eleven migraine subjects investigating consistency and sustainability of previously observed changes in cerebrospinal and venous outflow parameters. Using Phase Contrast MRI (PC-MRI) imaging, craniospinal flow changes were measured before-after subjects received a National Upper Cervical Chiropractic Association (NUCCA) atlas correction.

**Methods:** After screening by a neurologist, potential subjects signed a consent form, completed baseline migraine-specific measures, and returned in 30-days with a headache diary. Determination in need for NUCCA indicated inclusion, permitting subjects to obtain baseline PC-MRI measures. Subjects received NUCCA care for eight weeks. Follow-up imaging occurred at week four and eight. Adverse reactions were surveyed one week after intervention. Headache diaries were maintained throughout the study. Neurologist end-of-study exit interviews allowed for final outcomes collection.

**Results:** Of eighteen initially screened candidates, eight females, and three males, average age 41 years, met inclusion criteria. Headache days/month decreased from a baseline mean of 14.5 (SD = 5.7) by a mean, 5.7 days, 95% CI [2.0, 9.4] at week eight. Migraine Specific Quality of Life-Preventive scores increased a mean of 32.7, 95% CI [21.0, 44.5] at week eight from a baseline mean, 54.1. Ten subjects reported mild neck pain occurring 24 hours after intervention. Four subjects with secondary paravertebral venous outflow, showed an increase of intracranial compliance, from 7.96 (SD = 4.82), 6.81 (SD = 2.3) at week four, to 9.82 (SD = 4.64) at week eight. Seven subjects exhibiting jugular venous outflow patterns, showed unchanged intracranial compliance from 5.50 (SD = 1.52), 5.94 (SD = 1.49) at week four, to 5.88 (SD = 2.05) at week eight.

**Conclusion:** All patients reported a clinically relevant improvement in headaches as revealed by the MSQ-L Preventive scores, and on at least one of five migraine-specific outcomes.
P02.34  
Effects of Early Adversity and Stress Vulnerability on Treatment Response to Mindfulness-Based Stress Reduction  
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Purpose: Early adversity may contribute to the development of a stress-vulnerable endophenotype – i.e., a tendency to experience more intense negative affect in response to daily stressors, attribute stressful events to personal short-comings (internalizing), and have poorer affective recovery. However, little research has explored whether early adversity and associated stress vulnerability makes individuals more or less likely to benefit from stress-reduction interventions. Objectives: 1) To evaluate the association between early adversity and response to Mindfulness intervention for parenting stress (HEART – Health Enhancement And Resiliency Training), and 2) To investigate whether endorsing a stress-vulnerable endophenotype may explain this relationship.  

Methods: 25 premenopausal women with a range of chronic stress participated in the intervention, including four 6-hour workshops and weekly 1-hour calls over 12 weeks. The Childhood Trauma Questionnaire (CTQ) was used to assess early adversity. Negative affective reactivity, recovery, and attributions in response to daily stressors were assessed using averages across a 7-day nightly diary. The primary outcome was perceived stress over the last month.  

Results: Women endorsing higher CTQ scores experienced significantly greater decreases in stress from pre to post HEART (r=−.52, p=.008). Higher CTQ was also associated with greater negative affective reactivity to daily stressors (r=.45, p=.03), greater internalizing (r=.58, p=.003), and poorer recovery from feelings of shame (r=−.42, p=.04), but not negative affectivity in general (r=−.31, p=.14). In turn, women who endorsed more internalizing and slower recovery from feelings of shame had greater HEART-related reductions in stress (respectively: r=−.44, p=.027; r=.46, p=.02).  

Conclusion: Women exposed to early adversity may benefit more from mindfulness interventions than those who were not. Heightened stress sensitivity may be a mechanism that helps explain this enhanced treatment response.  

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P02.35  
A Pilot Study of Integral Yoga for Menopausal Hot Flashes  
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Purpose: Hot flashes and/or night sweats are the most common and troubling symptoms associated with menopause, experienced by 64% to 80% of women undergoing natural menopause and almost all women who undergo surgical menopause. Hormone therapy is currently the gold standard for treatment, but many women have sought alternative treatments including other pharmaceutical agents, herbal or dietary remedies, and behavioral therapies. These treatments show mixed results. The purpose of this study was to obtain preliminary data on the efficacy of yoga for reducing self-reported menopausal hot flashes in a randomized study including an attention control group.  

Methods: We randomized 54 late perimenopausal and postmenopausal women, aged 45–58 years, with at least 4 hot flashes per day to one of three groups: yoga, health and wellness education (HW), and a wait list (WL) control group. Yoga and HW classes consisted of weekly 90-minute classes for 10 weeks. All women completed daily hot flash diaries throughout the 10 week trial.  

Results: Hot flash frequency declined significantly over time for all three groups with the strongest decline during the first week. There was no overall significant difference in hot flash frequency decrease over time by treatment groups, but the yoga and HW groups followed similar patterns and both showed greater decreases than the WL group. By week 10, women reported a decrease of approximately 66% in hot flash frequency in the yoga group, 63% in HW, and 36% in the WL group corresponding to a decrease in means of 6.5 hot flashes/day in the yoga group, 5.9 in the HW group, and 4.2 in the WL.  

Conclusion: Results suggest that yoga can serve as a behavioral option for reducing hot flashes, but yoga may not offer an advantage over some other types of interventions. Results also highlight the importance of including attention control groups in RCTs.  

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P02.36  
Pilot Study Intra-Dialysis Yoga and Educational Comparison Group for Patients with End-Stage Renal Disease  
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Purpose: Patients with end-stage renal disease on maintenance hemodialysis have high morbidity and mortality due to cardiovascular disease and poor physical functioning. Novel behavioral and exercise programs are necessary to improve outcomes in this chronic disease population.  

Methods: We conducted a prospective pilot study to assess the feasibility and safety of a 12-week intra-dialysis yoga program among 15 patients with end-stage renal disease. In addition, we assessed the feasibility of a 12-week intra-dialysis educational program among 8 patients to inform development of a control group for future studies. Subjects were randomized by dialysis shift to receive either intervention. The pilot study was also used...
Qigong Versus Exercise Therapy for Chronic Low Back Pain in Adults - A Randomized Controlled Non-Inferiority Trial

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Purpose: Physical activity is considered as standard care for chronic low back pain, whereas the value of qigong in the treatment of chronic low back pain is unclear. In a randomized controlled trial we evaluated whether qigong is non-inferior (5 mm non-inferiority margin on the visual analogue scale, VAS) to exercise therapy in the treatment of chronic low back pain.

Methods: German outpatients (aged 46.7 ± 10.4) with chronic low back pain (average pain intensity VAS ≥ 40mm in the last seven days) were enrolled and randomly allocated in a 1:1 ratio to receive either qigong (64 patients, 12 sessions with 1x90 min a week over 3 months) or exercise therapy (63 patients, 12 sessions 1x60 min a week). The primary outcome was a non-inferiority comparison between qigong and exercise of the average pain intensity after three months (VAS 0–100) after three months. Secondary outcomes included Roland-Morris disability, health related quality of life, self-efficacy, sleep quality, suspected adverse reactions and serious adverse events. Follow-up was measured after 6 and 12 months. The primary analysis was by intention to treat using a generalized estimation equation regression model with baseline values, time point and patient’s baseline expectations for treatment success as covariates.

Results: For the primary outcome, the mean change in pain intensity after three months measured on the VAS between qigong and exercise, no relevant differences were observed (qigong: 34.8 95% CI 29.5–40.2; exercise 33.1 CI 27.7–38.4). The non-inferiority (margin of 5mm) of qigong compared to exercise could not be proven (group difference – 1.8 mm 95% CI: -9.4 to 5.8, one-sided non-inferiority=0.204). For the secondary parameters we didn’t find any difference.

Conclusion: Qigong was not proven to be non-inferior to exercise therapy for the treatment of low back pain.

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Tibetan Yoga Can Help People with Lung Cancer and Their Caregivers

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Purpose: Although lung cancer leads to more debilitating physical and psychological sequelae than other cancer sites, evidence for effective behavioral interventions targeting quality of life (QOL) is limited. Moreover, in the context of patient care, the needs of caregivers are rarely addressed. The purpose of this study was to establish feasibility and preliminary efficacy of a mind-body intervention in lung cancer patients and caregivers.

Methods: Patients with stage I-III non-small cell lung cancer undergoing radiotherapy and their family caregiver participated in a 15-session Tibetan Yoga (TY) program that included breathing exercises, guided visualizations, and gentle movements. This single-arm trial assessed pre/post intervention levels of mental health (CESD; BSI), fatigue (BFI), sleep disturbances (PSQI), spiritual well-being (FACT-SP) and overall QOL (SF-36). Feasibility data (e.g., accrual, retention, etc.) were also collected. Fourteen of the 19 couples approached consented (74%) and 10 (71%) completed the program (1 became ineligible; 3 withdrew). Patients (mean age: 73 yrs., 62% male, 85% stage III) and caregivers (mean age: 65 yrs., 73% female, 85% spouses) completed a mean of 12 TY sessions (range: 6–15).

Results: Paired t-tests revealed a significant increase in spiritual well-being (P = .03; d = 1.12) for patients and decrease in fatigue (P = .03; d = .87) and anxiety (P = .04; d = .91) for caregivers. Although not statistically significant, effect sizes for change scores were large for sleep disturbances (d = .60 and .72; patients and caregivers, respectively) and medium for depressive symptoms (d = .48; patients). Ninety-five percent of the participants (patients and caregivers) rated the program as useful or very useful.

Conclusion: This first couple-based mind-body program appears to be a safe, feasible, acceptable and subjectively useful supportive care strategy for patients and their caregivers. Based on these promising preliminary findings regarding treatment gains, the next step is to conduct a randomized controlled pilot trial.

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Hatha Yoga for Patients with Colorectal Cancer: A Randomized Controlled Mixed-Methods Study

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**Purpose:** While studies have demonstrated benefits of hatha yoga for patients with breast cancer, no studies on patients with colorectal cancer are available yet. The purpose of this study was to investigate the effect of hatha yoga in patients with colorectal cancer.

**Methods:** This study was part of a larger multicentre trial. Thirty-six patients with colorectal cancer (68.5 ± 9.4 years, 38.9% female, UICC stage I-III, 2–48 months post-surgery) were randomized to yoga (n = 17) or usual care (n = 19). Patients in the yoga group participated in a 10-week traditional hatha yoga program, 90 minutes once weekly, and additional home practice. The program encompassed yoga postures, breathing exercises, and meditation. Outcomes were assessed at 10 and 22 weeks post-randomization and included disease-specific quality of life (FACT-C), spiritual well-being (FACT-Sp), fatigue (FACT-F), depression (HADS-D), and anxiety (HADS-A).

**Results:** Generally, baseline values for quality of life were high; baseline values for depression and anxiety were low. Significant group differences were found for depression at 10 weeks only (p = 0.046). In qualitative interviews, patients reported good overall health that was not improved much further by the yoga program. The program was perceived as helpful; it improved back pain, body awareness, and flexibility. However, little benefit was perceived for cancer-related symptoms. Patients valued the esteem-ing and non-striving attitude during classes; practicing together with other patients reduced fear and shame about their physical deficiencies.

**Conclusion:** A 10-week hatha yoga program did not improve quality of life in patients with colorectal cancer. While patients that were up to 4 years post-surgery had little health limitations, they perceived the yoga program as helpful. Hatha yoga might be a valuable adjunct intervention during earlier phases of anticancer treatment. Specific yoga programs should be designed for patients with comparable conditions.

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**P02.40**

**Effects of a Mindfulness-Based Day-Care Clinic in Cancer Survivors**

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**Purpose:** Physical and mental symptoms are common consequences of cancer diagnosis and treatment. The aim of this study was to investigate the effect of a mindfulness-based day-care clinic group program on quality of life, cancer-related symptoms, mental health, mindfulness, and interpretation of their illness in cancer patients.

**Methods:** 117 cancer survivors (91.3% female; mean age 45.1 ± 10.5 years; 65% breast cancer; mean time since diagnosis 27.3 ± 46.5 months) participated in an 11-week mindfulness-based day-care clinic group program, 6 hours per week. The intervention incorporated mindfulness-based meditation, yoga, cognitive-behavioral techniques, diet, and lifestyle modification. Outcome measures included quality of life (EORTC QLQ-C30), life satisfaction (BMLSS), depression and anxiety (HADS), mindfulness (FMI), and interpretation of illness (IIQ) were assessed before, immediately after, and at 3 months after the intervention.

**Results:** Using repeated-measures analyses of variance, improvements in global health status (p < 0.001), physical functioning (p < 0.001), role functioning (p < 0.001), social functioning (p < 0.001), and life satisfaction (p < 0.001) were found. Cancer-related symptoms, including fatigue (p = 0.002), insomnia (p = 0.024), and constipation (p = 0.008) also improved. Anxiety (p < 0.001) and depression (p < 0.001) decreased; mindfulness (p < 0.001) increased. Patients interpreted their disease less as a punishment (p = 0.03) but more as something of value (p = 0.002). In adjusted post-hoc analyses, all effects were found immediately after the interventions; and all effects except those on cognitive functioning, constipation, and interpretation of illness as punishment were preserved at 3-month follow-up.

**Conclusion:** An 11-week mindfulness-based day-care clinic group program improved quality of life, cancer-related symptoms, and mental health in cancer survivors at the short- and medium-term. Patients’ mindfulness was increased, and patients interpreted their illness more positively and less guilt-associated negative. Supportive mindfulness-based interventions can be considered as an effective means to improve cancer patients’ physical and mental health.

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**P02.41**

**Feasibility of Yoga Skills Training for Improving Outcomes of Gynecologic Surgery**

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**Purpose:** Women undergoing surgical procedures for suspected gynecologic malignancies frequently experience pain and psychological distress following surgery. Yoga may reduce these negative surgical outcomes. The primary objective of this pilot study was to assess the feasibility of implementing and evaluating a perioperative brief Yoga Skills Training (YST) in this population.

**Methods:** We recruited adult women who were scheduled to undergo an exploratory laparotomy for suspected gynecologic malignancy. The YST consisted of three 30-minute sessions, one before and two after surgery held in the patient’s hospital room. Feasibility (e.g., rate of accrual, adherence, retention) and acute effect of the YST on symptoms (i.e., ratings of pain and distress immediately before and after each YST) were assessed.
Results: Of 19 women approached, 10 enrolled in the study (age M = 54.7 years; 90% White). The most common reason for declining was not interested (n = 7). Three women discontinued the study for different reasons: one did not have surgery, one due to scheduling, and one withdrew after one YST session. Of the 8 participants who received the YST (24 possible sessions), three sessions prior to surgery were missed because of scheduling and the only post-surgical YST sessions missed were by the participant who withdrew. Acute pain and psychological stress decreased from before to immediately after the YST session with moderate to large effects: pain, d’s = -0.67 to -0.95; distress, d’s = -0.66 to -1.08. In addition, participants qualitatively reported that they valued learning how to relax.

Conclusion: These data demonstrated reasonable rates of recruitment, retention and adherence to YST sessions post-surgery. In addition, patients were able to relax and experience short-term reductions in pain and distress in the inpatient setting. Thus, results support the feasibility of investigating the YST in this population. Next steps include evaluating the efficacy of the YST implemented post-surgery for reducing post-operative pain and distress.

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P02.43
Clinical and Genomic Effects of a Relaxation Response-Based Mind-Body Intervention in Stage I Hypertension

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Purpose: Essential hypertension, which has serious long-term cardiovascular consequences, affects approximately 35% of the adult US population. Mind-body approaches that elicit the relaxation response (RR) may be an alternative or adjunct to antihypertensive drug therapy. The current study evaluates the clinical and genomic effects of RR in stage I hypertensive patients.

Methods: 24 patients with stage I hypertension off antihypertensives participated in an 8-week RR-based mind-body intervention. Blood pressure, flow-mediated dilation (FMD, a measure of endothelial function), and transcriptional profiles (on Affymetrix HT HG-U133+ PM arrays containing >47,000 transcripts) were measured pre/post intervention.

Results: Patients had a mean drop of 12 mm Hg (p < .001) in systolic blood pressure (SBP) and 10 mm Hg (p < .001) in diastolic blood pressure (DBP) following the intervention. 13 patients (54%) were responders (SBP < 140 and DBP < 90). No significant changes were observed in FMD for either responders or non-responders. Transcriptome analysis identified 1821 and 1280 differentially expressed genes for responders and non-responders, respectively (p < 0.05). Interactive network analysis of RR-affected genes in responders identified cell cycle, connective tissue, cardiovascular system and metabolism, carbohydrate and lipid metabolism, and immune system networks. The focus molecules for these networks (e.g., NF-kB) overlap with RR-related systems biology modules described previously in healthy subjects. Many genes upstream and downstream of NF-kB complex may be important in mediating the effects of RR on hypertension.

Conclusion: In this prospective, open trial of an 8-week RR-based mind-body intervention for stage I hypertension, 54% became normotensive; however, changes in endothelial function did not appear to mediate this effect. Genomic profiling gives molecular insight into the beneficial effects of RR in hypertensive patients, indicates that NF-kB may be a key focus molecule, and suggests a framework for individualized treatment in the future.

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P02.44
The Effectiveness of a Community-Based Mind Body Group Intervention for Depression & Anxiety: A Pilot Study

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Purpose: This study examined the effects of an 8-week community-based mind-body intervention (MBI) in patients being treated for depression and/or anxiety.

Methods: Retrospective open-label study of 124 depressed and/or anxious patients enrolled in a group MBI at their community health centers. Self-report clinical measures of depression (Center for Epidemiologic Studies Depression Scale – 10 items, CES-D 10), anxiety (State Trait Anxiety Inventory – State Subscale, STAI-State – 20 items), and perceived stress (Perceived Stress Scale – 10 items, PSS-10) were administered pre- and post-intervention. The MBI was created to be accessible to patients receiving care at a community health center. The MBI was billed through behavioral health and accessible to all levels of education. The core of the MBI for depression and anxiety is teaching techniques that elicit the relaxation response (RR), combined with additional resiliency-enhancing components.

Results: Approximately half (52.4%) of the patients completed at least 75% (6 or more) of the 8 sessions, with the average attending 5 sessions. The intervention resulted in a significant decrease in depressive symptoms (change in CES-D 10= −4.3, 95% CI −2.5 to −6.0, p < .0001), anxiety (change in STAI-State= −7.4, 95% CI −2.2 to −12.6, p < .01), and perceived stress (change in PSS-10= −4.8, 95% CI −2.0 to −7.6, p < .01).

Conclusion: Participation in this MBI is associated with an improvement in depression and anxiety symptoms as well as decreases in perceived stress among community health center patients.

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P02.45
Impact of Yoga on Depression and Anxiety

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Purpose: Back to Health is a comparative effectiveness RCT (n=320) addressing non-specific chronic low back pain (cLBP) in low-income minority populations. We wanted to determine whether depression and anxiety were correlated with cLBP in this population, and whether a 12 week yoga intervention impacted depression and anxiety.

Methods: Participants were 18–64 years old with self-reported pain ≥4 on a 0–10 scale. Participants completed questionnaires at baseline measuring pain intensity (0–10), depression (PHQ-8), and anxiety (GAD-7). Participants randomized into yoga received weekly standardized classes supplemented by home practice for 12 weeks. Participants then repeated the PHQ-8 and GAD-7. To determine if depression was independently associated with low back pain intensity at baseline, we performed a linear regression controlling for age, sex, race, and education. The relationship between anxiety and pain intensity was similarly assessed. To evaluate for change in depression and anxiety associated with yoga, we analyzed only participants with at least mild depression (PHQ-8 ≥ 5) and anxiety (GAD-7 ≥ 5). Change scores were calculated by subtracting participants’ baseline PHQ-8 and GAD-7 scores from their 12 week values. Student’s t-test assessed whether mean change scores for PHQ-8 and GAD-7 were statistically different from zero.

Results: Our sample consisted of 163 currently enrolled participants. Baseline cLBP intensity was weakly correlated with depression (r=.27, p=.01) and minimally correlated with anxiety (r=.13, p=.09). 106 (66%) participants had at least mild depression (mean PHQ-8=11.0, sd 5.2) and 93 (57%) had at least mild anxiety (mean GAD-7=10.8, sd 4.9). For yoga participants with at least mild depression (n=36) and/or anxiety (n=33), mean PHQ-8 and GAD-7 change scores reflected statistically significant improvement: −2.4 (sd 5.6, p<.01) and −2.0 (sd 4.6, p=.02), respectively.

Conclusion: Low back pain is weakly correlated with depression at baseline. Yoga may be useful for reducing depression and anxiety in persons with cLBP.

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P02.46
Qualitative Evaluation of an Integrative Medicine Group Visits Program for Patients with Chronic Pain and Associated Comorbidities

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Purpose: The integrative medicine group visits program (IMGV) is a novel 8-week intensive outpatient medical group visit program combining principles of mindfulness-based stress reduction (MBSR) with patient self-care education and yoga, massage, acupuncture, and nutrition. We conducted a qualitative study of participants with chronic pain and comorbidities in an IMGV program in order to better understand the participants’ experiences and interpretations of the program and its effects.

Methods: The IMGV prospective observational cohort study enrolled 65 participants from April 2012–2013. All participants received their primary care in a large urban hospital; most are low-income minorities. We conducted individual semi-structured interviews with a convenience sample (n=19) of participants. The interview guide elicited perceptions of the program and motivation for attending; lessons learned or lifestyle changes made; physical, mental, or behavioral effects attributed to the program; and opinions about group versus individual care. Interviews were audio-taped, transcribed, and analyzed preliminarily. Transcripts will be further analyzed using grounded thematic analysis techniques.

Results: Emerging themes include the significance of the group in providing social support and expanding perspectives on personal health; participants’ willingness to incorporate IMGV lessons into daily life; and the variation in integrative medicine modalities to which participants attribute greatest benefit. We examine the contrast between patient-centered outcomes (e.g., improved mood, confidence in pain self-management) and minimal change in certain biomedical outcomes (e.g., diastolic blood pressure). We explore the multiple meanings of efficacy in an integrative group care delivery model.
Conclusion: IMGV is a multi-faceted intervention teaching health management tools in an environment that builds social connection and rapport. Patients cite nutrition, stress management, and social support as important outcomes.
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P02.47
Predictors of Adherence to Treatment for Chronic Low Back Pain in a 12-week RCT Comparing Yoga, Physical Therapy, and Education
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Purpose: To examine whether sociodemographic, health, and recruitment-related characteristics predict adherence to yoga, physical therapy (PT), and education in a RCT for chronic low back pain (cLBP).

Methods: Back to Health is a 12-week comparative effectiveness RCT for cLBP. We are recruiting 320 adults with cLBP from community health centers in racially diverse neighborhoods of Boston, MA. They are randomized in a 2:2:1 ratio to yoga, PT, and education. During the 12-week intervention period, participants engage in a standardized once-weekly hatha yoga protocol delivered in a class format supplemented by home practice; one-on-one sessions with a physical therapist supplemented by home practice; or are instructed to read a self-care book on back pain. Activities to enhance attendance to yoga classes and PT sessions include weekly reminder phone calls, assistance with child care or transportation, attendance-based raffles, staggered distribution of honoraria, and take home practice supplies. Education participants receive regular phone call check-ins. Attendance rates were calculated for yoga and PT sessions. Adherence was defined a priori as attending >75% of yoga sessions, >11 of 15 (>71%) PT sessions, or having read >75% of the book. Attendance and adherence rates were compared between groups using chi-square. Chi-square and t-tests were used to assess for any associations between adherence and sociodemographic and health-related characteristics.

Results: 163 participants have been analyzed to date. Attendance rates were good: 65% (yoga) and 57% (PT) (p=0.01). However, adherence rates for yoga and PT were suboptimal (47% and 35%, respectively) compared to education (64%) (p=0.08). Preliminary analyses show female gender (p=0.04), pain medication use (p=0.01), and white race (p=0.01) to be associated with greater adherence.

Conclusion: Adherence rates are lower than expected. Further analyses of predictors for poor and good adherence are needed to better understand and address this problem.
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P02.48
A Comparison of Mindfulness-Based Stress Reduction and Cognitive Behavioral Therapy for Improving Sleep and Mood Outcomes in Cancer Patients with Insomnia
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Purpose: Patients who are diagnosed and treated for cancer are three times more likely than the general population to experience disturbed sleep and insomnia. The presence of persistent insomnia places patients at a higher risk for psychological and physical morbidity and reduced quality of life. We compared Mindfulness-Based Stress Reduction (MBSR) to Cognitive-Behavioral Therapy for insomnia (CBT-I) to evaluate their relative effectiveness for improving sleep, mood and stress symptoms.

Methods: The I-CAN SLEEP study was a partially blinded, randomized trial involving a heterogeneous sample of post-treatment cancer patients with insomnia (N=111). Participants were kept blind to both interventions until baseline assessments were conducted, at which point they were informed only about the program they were assigned to. Assessments were conducted at baseline, post-program and three month follow-up. Questionnaires measured sleep quality, mood and stress symptoms. Sleep diaries measured sleep onset latency (SOL), wake after sleep onset (WASO), total sleep time (TST) and sleep efficiency.

Results: Group equivalence via randomization was achieved despite a greater attrition rate in the MBSR group. MBSR was able to produce significant improvement in sleep quality; however, the change in the CBT-I group exceeded MBSR at both time points (p<.001). Both groups experienced significant reductions in mood disturbance (p<.001) and symptoms of stress (p<.001). Sleep diary measured SOL was reduced by 22 min in CBT-I and 14 min in MBSR at follow-up. Similar reductions in WASO were observed for both groups. TST increased by 0.60 hrs for CBT-I and 0.75 hrs for MBSR.

Conclusion: While both CBT-I and MBSR produced significant improvement in sleep and psychological outcomes, a more rapid change occurred in CBT-I. The potential impact of blinding is discussed when patient preference for treatment is likely to play a significant role in retention and adherence.
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P02.49
Mindfulness Training for People with Chronic Insomnia: Focus Group Results
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Purpose: Chronic insomnia affects about 1 in 10 adults. Mindfulness training may be an effective approach to treat chronic insomnia, with sleep outcomes comparable to nightly use of prescription sedatives, but more durable and without troublesome side effects. The purpose of this study was to better understand mindfulness training as experienced by patients with chronic insomnia, and suggest procedures for optimizing sleep benefits.

Methods: Adults (N=18) who had completed an 8-week mindfulness-based stress reduction (MBSR) program as part of a randomized controlled trial to evaluate MBSR as a treatment for chronic insomnia were invited to participate in focus groups. Participants (N=9) described how their sleep routine, thoughts and emotions were affected by MBSR and utility of mindfulness techniques. Groups were recorded, transcribed and content-analyzed.

Results: Four themes were identified: impact of mindfulness on sleep and motivation to adopt a healthy sleep lifestyle; benefits of mindfulness on life beyond sleep; challenges and successes in
adopting mindfulness-based practices; and the importance of group sharing and support. Participants said they were not sleeping more, but sleeping better, waking more refreshed, feeling less distressed and better able to cope with insomnia. Some experienced a call to action, prioritizing meditation practice and following sleep hygiene guidelines. Motivation to sustain behavioral changes was reinforced by feeling better and witnessing improvements in others. The body scan was identified as an effective tool to enable falling asleep faster, and maintaining practice to sustain benefits was important.

Conclusion: First-person accounts are consistent with trial results of positive impacts of MBSR on sleep measured by sleep diary, actigraphy, and self-report sleep scales. Findings indicate that mindfulness training in a group format, combined with sleep hygiene education, is important for effective application of MBSR as a treatment for chronic insomnia. Funded by UMN Academic Health Center Faculty Research Development Grant FRD 06–27.

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P02.50
Effect of Tai Chi as Therapeutic Exercise on Blood Pressure: Rapid Systematic Review
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Purpose: The purpose of this study is to systematically analyze the effect of Tai Chi as therapeutic exercise on depressing blood pressure.

Methods: We reviewed articles published in the PubMed, Chinese Academic Journals (CAJ) and five Korean databases. The searching keywords were “Tai chi AND blood pressure” and “Tai chi AND hypertension”. We evaluated the quality with Cochrane risk of bias tool.

Results: In the 114 articles searched, 7 randomized controlled clinical trials were selected. Yang (으) style Tai chi, exercising over 30 minutes a time and over three times a week, had an effect on decreasing blood pressure. However, Wu (오) style Tai chi was not effective in decreasing blood pressure.

Conclusion: Usual exercises for hypertension patients should be performed in the form of moderate exercises intensity for 10–26 weeks by 30–60 minute a time, over 3 times a week. The study of Tai Chi on blood pressure needs to consider the following criteria in the future.

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P02.52
Patient Perspective on Using Alternative Cancer Treatments (PPACT) Study
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Purpose: Some cancer patients forego recommended proven conventional treatments for cancer, instead using unproven alternative treatments. Studies and cases show this decision may lead to increased morbidity and mortality. The aims of this study are to explore, using semi-structured interviews, patient perspectives on 1) the decision to use alternative cancer treatments (ACTs), 2) expectations, 3) experiences, and 4) self-reported outcomes.

Methods: We conducted a longitudinal study among patients who decided to postpone or forego one or more conventional cancer treatments and who used ACTs instead. Baseline interviews were conducted with follow-ups scheduled at 4 months. We report here on results of baseline interviews, which were
semi-structured qualitative interviews lasting approximately 90 minutes. Interviews were transcribed verbatim, then coded for major themes by at least two investigators using principles of qualitative content analysis. Variations were reconciled through refined definitions and recoding.

**Results:** Seven participants have been interviewed and enrollment is ongoing. All seven participants enrolled to date are female (average age, 56). Six participants had been diagnosed with breast cancer and the seventh with glioblastoma multiforme. Four themes were identified that reflect characteristics of patients who pursued ACTs: 1) philosophical orientation towards natural healing that preceded cancer diagnosis; 2) skepticism towards the conventional medical system that arose either before or during cancer treatment; 3) desire for control in treatment decisions; and 4) serious concerns about side effects of conventional cancer treatments. All participants actively sought providers who discussed alternative treatments non-judgmentally. Four participants experienced progression or recurrence, which led them to reconsider conventional treatments they had previously rejected.

**Conclusion:** Multiple factors including personal beliefs and prior experiences with illness and the medical system influenced decisions to use ACTs. Initial findings suggest progression or recurrence might cause patients to reconsider using conventional treatments, underscoring the importance of following these patients and maintaining open communication.

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**P02.53**

**A Non-Invasive Treatment for Critical Self-Talk and Its Negative Emotional Effect**

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**Purpose:** To evaluate effects of specific sequential acupressure procedure on the qualities and emotional effects of negative self-talk (i.e., cursing at one’s self, calling one’s self insulting names, and thinking negative comments), a component of the thinking process.

**Methods:** This was a randomized single-blind study of 68 participants, ages 18–62, who reported negative self-talk. The treatment, Sequential Acupressure Technique for Listening enhancement (SAT(L)), uses acupuncture points on the head recognized as points related to the endocrine system and the brain to enhance homeostasis. The sham treatment used non-acupuncture points on the arm. SAT(L) and the sham procedure were identified as points related to the endocrine system and the brain to enhance homeostasis. The sham treatment used non-acupuncture points on the arm. SAT(L) and the sham procedure were identified as points related to the endocrine system and the brain to enhance homeostasis. The sham treatment used non-acupuncture points on the arm.

**Results:** Data was categorized and analyzed by whether the ratings were worse, stayed the same or improved for the four qualities of negative self-talk elicited: content, volume, tone, and negative emotional effect (or “negative intensity”). A statistically significant improvement was found in the SAT(L) group. Groups were analyzed via Chi-square test. 40% of the SAT(L) group showed improvement for content while only 12.1% of the sham group showed improvement. 71.4% of the SAT(L) group showed improvement in tonality while only 36.4% of the sham group showed improvement. Using the scale scores in a repeated measures analysis of variance, negative intensity and volume were not significantly different at baseline (p = 0.8032 & 0.3823, respectively) yet were after treatments were administered (p<0.0001 & p = 0.0135, respectively).

**Conclusion:** The data indicated that the SAT(L) can alter the qualities of negative self-talk in a beneficial direction and reduce an individual’s negative emotional response to the negative self-talk. The implications of this research have significance in the areas of psychotherapy, communication, learning and performance.

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**P02.54**

**Improving Mental Health and Diabetes Management with Mindfulness-Based Stress Reduction**

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**Purpose:** Adapting to a new diagnosis of diabetes can be stressful and emotionally challenging. Current diabetes self-management and education programs help patients manage their diabetes through improving skills such as self-efficacy and knowledge. These skills have shown mixed success in helping people manage their diabetes. Addressing the ongoing stress and psychosocial issues that underlie having a long-term chronic health condition such as diabetes could help improve diabetes self-management skills and adaptation to the changes in lifestyle required for successful diabetes management. This purpose of this pilot study was to evaluate the acceptability and feasibility of Mindfulness-Based Stress Reduction (MBSR) for newly diagnosed people with diabetes and to evaluate outcomes on standardized self-report measures and HbA1c values.

**Methods:** 38 people with diabetes and 2 HbA1c values > 8 in the prior 18 months were recruited to complete a community-based MBSR course. Participants attended eight-weekly sessions and participated in home-based practice. Surveys measuring anxiety, depression, mental health and diabetes self-management and HbA1c lab values were obtained at pre and post-intervention. Cohen’s-d statistic was estimated for survey outcomes. Pre-post change was evaluated using paired t-test.

**Results:** Participants were 31- to 78-years-old (M=57), the majority were female (68 %), white (70%), employed, with some college education. Mean HbA1c pre-intervention was 9.18. Participants showed significant improvement in pre-post measures of HbA1c (change .73%, p = .000), overall mental health (Cohen’s-d .69, p = .001), stress (Cohen’s-d .76, p = .001), depression (Cohen’s-d .62, p = .001), and anxiety (Cohen’s-d .66, p = .001). There was also improvement in diabetes management: Problem Area in Diabetes Questionnaire (Cohen’s-d −.71, p = .002) and the Diabetes Empowerment Scale (Cohen’s-d .80, p = .000).

**Conclusion:** These results suggest that MBSR may offer a safe and effective method for helping people better manage diabetes and improve their mental health. Effect sizes were large and significant pre-post differences were found indicating that a larger clinical trial is warranted.

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P02.55
Efficacy of Alexander Technique in the Treatment of Chronic Non-Specific Neck Pain: A Randomized Controlled Trial

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Purpose: Alexander Technique (AT) is an educational method aiming at increased sensory awareness and kinesthetic control to modify postural and movement patterns which might be associated with musculoskeletal disorders. It has been proven effective for chronic low back pain; however no study has yet determined its effects on chronic non-specific neck pain.

Methods: A randomized controlled trial with 3 parallel groups was conducted. Patients were randomly allocated to either 5 weekly sessions of AT, heat pack application (HEAT) or guided imagery (GI) each. The primary outcome measure at week 5 was the neck pain intensity on a 100-mm visual analogue scale; secondary outcomes included neck disability, quality of life, satisfaction and safety. Analyses of covariance were applied on an intention-to-treat population testing ordered hypotheses AT vs. HEAT and AT vs. GI.

Results: 72 patients were included (65 females, 40.7 ± 7.9 years), 52 of them received all 5 interventions. No significant group difference was found for neck pain intensity when AT was compared to HEAT (Difference 4.5; 95% CI: -8.1, 17.1; p = 0.48), but exploratory analysis revealed superiority of AT over GI (Difference -12.9; 95% CI: -22.6, -3.1, p = 0.01). Significant group differences were also found for physical quality of life in favor of AT vs. HEAT or GI (p < 0.05). Adverse events mainly included slightly increased pain and muscle soreness. Besides high levels of benefit from AT, patients also reported increased body awareness and control over the body, relaxing or stimulating effects and mood changes after the sessions.

Conclusion: Five sessions of AT were no better than a heat pack application for relieving chronic non-specific neck pain. Therefore it cannot be recommended as routine intervention at this time. Since exploratory analysis revealed some improvements of AT further trials are warranted for conclusive judgment.

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P02.56
Qualitative Study in a Randomized Trial Comparing Yoga, Physical Therapy, and Education for Low Back Pain in a Predominantly Minority Population

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Purpose: Explore perceived effects of treatments and compare responses between yoga, physical therapy (PT), and education participants in a RCT for chronic low back pain (cLBP) with a predominantly low-income minority population.

Methods: This qualitative study was embedded in a parent RCT for adults with moderate to severe cLBP who spoke English. Participants were randomized to yoga, PT, or education arms for a 12-week treatment phase. Ninety participants who agreed to be contacted for additional research opportunities were asked to take part in individual semi-structured interviews. The protocol included open-ended questions about motivation for participation, experience with treatment, and perceived effects associated with participation. Interviews were audio-taped, transcribed, uploaded into Atlas.ti software and analyzed using a thematic analysis approach.

Results: To date, 18 yoga, 13 PT, and 8 education participants have been interviewed post-intervention. They were predominantly female (77%), black (77%), mean age 50 years (SD 7.8), earned ≤ $30,000 annually (56%), and had moderate-severe pain (mean 7.3, SD 1.3). Major themes from preliminary transcript analysis included: similar expectations for the specific treatments; mental and physical effects of each treatment; and increased knowledge and self-efficacy from all treatments. Most interviewees mentioned both decreased pain and psychological effects (improved mood, decreased anxiety, and/or improved self-efficacy) that they attributed to their intervention. Regarding most valued effects, a majority of education participants felt emotional effects were more important than physical effects while only one PT participant expressed this sentiment. In contrast to PT and education, yoga participants more often discussed “relaxation” and feelings of “peace” from their intervention while describing mental effects.

Conclusion: While perceived physical and psychological effects were reported by participants in all arms, differences in the way participants regard and convey their experiences with the study have emerged.

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P02.57
Randomized Controlled Trial of “The Work” Meditation-Based Intervention for BRCA1/2 Mutation Carriers

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Purpose: Female BRCA1/2 mutation carriers have a substantially increased risk for developing breast and ovarian cancer. Such risks may be associated with emotional distress, sleeping disorders and fatigue. Although body-mind techniques are practiced by BRCA1/2 mutation carriers, the effect of meditation interventions in this population has not been reported. Objective the effectiveness of “The Work” technique, a meditation-based intervention, on quality of life and psychological stress parameters among BRCA1/2 mutation carriers.

Methods: 67 Jewish Israeli women carriers of one of the predominant Jewish mutations in BRCA1/2 genes, who were
followed-up at the high-risk clinic at Sheba Medical Center between January 1, 2000 and December 31, 2010 participated in the study. They were randomly assigned to intervention or control groups. The intervention program included 12 weekly group meetings and an individual weekly practice of “The Work” technique. Outcomes: Sleep quality, Clinical distress, Cancer-related worries and perceived family support were assessed at the beginning and completion of the intervention.

Results: Of the 67 recruited women (mean age 49 ± 8.3 years), 41 were BRCA1 carriers and 26 were BRCA2 carriers. Thirty-three women were assigned to the intervention group and 34 served as controls. Fifty-six women completed the study. There was a significant improvement in perceived family support after the intervention compared with controls (F(1,54) = 5.04 (P = 0.029). Sleep quality improved by 30% and Cancer-Related Worries improved by 6% in the intervention group, but these differences were not significant. Levels of clinical distress levels were similar for all women.

Conclusion: “The Work” intervention improved BRCA1/2 mutation carriers’ perception of their family support. Further controlled studies should evaluate the clinical implementation of “The Work” meditation among women who carry the mutation in BRCA1/2 genes.

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P02.58
Alexander Technique and Supervised Physiotherapy Exercises in Back Pain (ASPEN) Feasibility Trial
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Purpose: To undertake a feasibility trial and perform exploratory biomechanical marker analyses. Our previous large study on Alexander Technique (AT) suggested that it helps back pain but what mechanisms might be involved.

Methods: Feasibility RCT Participants. Patients with chronic or recurrent back pain (> = 3 weeks duration) Interventions. Participants were allocated by an external randomization line to four groups: 1) Normal care; 2) 10 weekly AT lessons; 3) 12 weekly EC; 4) 10 AT lessons + 12 EC. Main outcome. Roland-Morris Disability questionnaire (Primary). Days in pain, Von Korff scale; Overall improvement (Health transition); Fear of activity; Enablement; Oswestry Index; Aberdeen scale.

Results: 83 patients consented, 69 were randomized and 56 (81%) followed-up at 6 months. RMDQ and other instruments were sensitive to change, and the preliminary evidence suggests the Aberdeen scale could be a useful additional measure. Study procedures were feasible, and three methods of recruitment were successfully piloted. Exploratory analysis of most clinical outcomes did not reach significance at the 5% level although some reached a 10% level by 3 and 6 months, particularly in the combined group. The improvement following each session suggested ongoing benefit until the last class or lesson, and the overall improvement was clinically important, comparable to previous more intensive interventions. Novel biomechanical variables strongly associated with RMDQ score at 6 months were muscle tone (beta-coefficient 0.94, 95% confidence intervals 0.48 to 1.40; p < 0.0001), proprioception (1.48, 0.83 to 2.12; p < 0.0001) and muscle elasticity (−4.86, −0.01 to −9.72, p < 0.05). AT improved proprioception at 3 months and elasticity at 6 months, and physiotherapy also affected elasticity – providing important mechanistic links between intervention, proprioception, muscle elasticity, and outcome.

Conclusion: The trial is feasible, and the interventions may provide clinically important benefits. Muscle tone, elasticity and proprioception are strongly associated with outcome, and are likely to be modified by the interventions.

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P02.59
Mindfulness for the Fatigue, Anxiety and Depression in Women with Metastatic Breast Cancer: A Mixed Method Feasibility Study
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Purpose: The impact of living with metastatic breast cancer (MBC) is considerable and psychosocial support is beneficial. Mindfulness-based stress reduction (MBSR) helps the self-management of anxiety, depression, quality of life (QoL) and fatigue and has been evaluated in early stage breast cancer but not MBC. This study investigated the acceptability and feasibility of providing MBSR for women with MBC and of MBSR within the National Health Service (NHS) setting.

Methods: A mixed method concurrent design. Eligible women with MBC, an ECOG score of 0–2; stable disease and life expectancy of 6 months were invited by their oncologist to attend an 8 week MBSR course. Qualitative interviews with patients and a focus group with NHS staff were held to explore acceptability and feasibility of MBSR and of MBSR within the NHS. Questionnaires measuring fatigue, anxiety and depression, mindfulness, disease specific QoL and generic QoL were assessed at baseline, during and after the course.

Results: Nineteen women took part in 3 groups. Commitment to 8 weeks was a reason for non-participation and proved challenging. Participants reported the course as acceptable with many benefits. There was high attendance, completion of course sessions, adherence to home practice, excellent follow-up rates and questionnaire return rates. Questionnaire data showed statistically significant and clinically meaningful improvements in fatigue (3.63, CI: 2.04, 5.22), QoL (−32.81, CI: 4.00), cognitive functioning (−18.42, CI: 4.03), physical functioning (−5.96, CI: −11.52, −0.41) and insomnia (24.56, CI: 7.76, 41.36) when comparing initial baseline measures to those at 24 weeks.

Conclusion: MBSR is acceptable to patients with MBC and effective in managing anxiety and improving QoL; but requires a high commitment of time. There is scope to tailor the intervention so it is less intensive.

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P02.60
Managing Distress in Prostate Cancer: A Feasibility Study into the Design and Evaluation of a Novel Psychological Support Intervention for Managing Distress in Prostate Cancer

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Purpose: The prevalence of anxiety and depression in prostate cancer patients (PCa) being managed with active surveillance (AS) is estimated to be as high as 22% and 13% respectively. Psychological distress currently sits as a significant predictor of men on AS transferring to radical treatment. Such men experience various physical side effects and a reduced quality of life for no additional increase in survival. To prevent this, support interventions are required that will help AS patients better cope and manage their psychological distress. We currently have very little understanding of what kind of support AS patients require.

Methods: We undertook a series of in-depth qualitative interviews in a sample of 20 AS patients. The interviews were designed to elicit a greater understanding of the psychological and emotional distress in AS, what causes it and how best it may be able to manage it in terms of the design, content and delivery of a AS specific support intervention. The interviews were analyzed thematically.

Results: AS patients articulated a need for more information about their PCa and its management with AS. They acknowledged a degree of emotional distress (anxiety and depression) and stated that they would like guidance on self-care approaches that they could use to alleviate these conditions. The participants were positive about the concept of group based support, especially if run by a clinical PCa nurse. Likewise, they were open and positive towards the concept of an AS specific informational support website. These data have been utilised to develop a psycho-educational support intervention for AS patients.

Conclusion: Our results suggest that men being managed with AS articulated a need for additional psycho-educational support to help them better cope and manage with the burden of living with an untreated cancer.

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P02.62
Chinese Herbal Medicine and Polycystic Ovary Syndrome: A Randomized Feasibility and Pilot Study in the United Kingdom

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Purpose: Polycystic ovary syndrome (PCOS) is the most common female endocrine disorder, affecting 6–18% of women of reproductive age. Though anecdotal evidence exists supporting the use of Chinese herbal medicine (CHM) for PCOS, this requires rigorous investigation. This study aims to explore the feasibility of conducting a randomized clinical study involving CHM for PCOS in the United Kingdom (UK) and to pilot and evaluate study procedures.

Methods: This is a prospective, practitioner and patient-blinded study, randomizing 40 PCOS patients aged 18–44 with oligo- or amenorrhoea into 2 parallel groups – standardized or individualised CHM formulations. Both groups will be prescribed granulated formulations at a dose of 8g twice daily (16g per day) for 6 months. The primary outcome measure is menstrual regularity; Secondary measures are body mass index, waist hip ratio, hirsutism and quality of life measures such as Polycystic Ovary Syndrome Questionnaire and Measure Yourself Medical Outcome Profile. Other data include liver and kidney function, compliance and practitioner-blinding. Feasibility outcomes include suitability of primary outcome measure for main study, recruitment rate and acceptability of interventions. Study procedures will be piloted such as randomization, data collection and double-blinding.

Results: Of 245 enquiries, 40 patients with PCOS (16.3%) were recruited between January 2013 and August 2013 with a mean age of 29.4 years (range 19–44). Presently, 10 (25%) have completed the study and 7 withdrawn (17.5%) due to: pregnancy (n = 2), taste (n = 3) and adverse events (n = 2). As the last
participant visit is expected in February 2014, pilot and process evaluation data will be presented.

**Conclusion:** At the end of this study, the potential for both standardized and individualised CHM will be explored. The feasibility and pilot data will help determine whether further research by progressing to an adequately powered definitive RCT is warranted.

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**P02.63**

**Clinical Research Evidence of Tai Chi: A Systematic Literature Review**

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**Purpose:** To systematically review clinical research evidence of Tai Chi for different diseases/conditions.

**Methods:** We searched for all clinical studies on Tai chi in PubMed, the Cochrane Library and four major Chinese electronic databases from their inception to September 2013. Two authors extracted data independently. We performed data analysis using SPSS17.0.

**Results:** 524 clinical studies were identified published between 1958 and 2013, including 44 (8.4%) systematic reviews, 269 (51.3%) randomized controlled trials, 91 (17.4%) non-randomized clinical controlled trials, 116 (22.1%) case series and 4 (0.8%) case reports. Among the 524 studies, 250 (47.7%) were published in English, 268 (51.1%) in Chinese, and 6 (1.1%) in Korean. The studies were conducted in 21 different countries, and the majority of studies (61.3%) were conducted in China, followed by the USA (21.2%). The publications of studies on Tai Chi increased with years, especially after the year 2000. The diseases/conditions in which Tai Chi was commonly employed included neurological, rheumatological, orthopedic, cardiovascular, pulmonary disease and cancer. Many healthy participants played Tai Chi for the purpose of health promotion or wellness. The specified styles of Tai Chi included Yang, Chen, Sun and Wu style, and Simplified 24-form Yang-style Tai Chi was the most popular one (51.3%). Participants learned Tai Chi from Tai Chi instructors in 285 (54.4%) trials, and 49 studies reported the Tai Chi experience of the instructors. Tai Chi intervention was used alone in 231 (44.1%) studies, while in most studies (55.9%) Tai Chi was combined with other therapies including medications, education and other physical therapies. None adverse events were reported.

**Conclusion:** The quantity and evidence level of clinical studies on Tai Chi appears to be improved during the past 55 years, and the evidence suggested that Tai Chi has beneficial effects on health promotion, treatment and rehabilitation for various diseases/conditions.

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**P02.64**

**Impact of Chinese Herbal Medicine on Survival, Relapse and Metastasis in Women with Breast Cancer: A Systematic Review of Randomized Controlled Trial**

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**Purpose:** Chinese herbal medicine (CHM) is widely applied in China for breast cancer, while survival, relapse and metastasis are important direct outcomes. We aim to evaluate the impact of Chinese herbal medicine (CHM) in survival, survival, relapse and metastasis in female breast cancer patients.

**Methods:** We conducted literature searching in Chinese and English databases from the inception to November 2012, randomized controlled trials (RCTs) were selected and data extracted by two authors independently. Papers were reviewed systematically and data were analyzed using Cochrane software Revman 5.1.7.

**Results:** A total of 19 RCTs (involving 2473 women) were included (all in Chinese). The methodological quality resulted in a high risk of bias. All the RCTs involved different Chinese herbal formulas, and we were only able to explore the tendency to effectiveness by pooling similar studies using integrated Chinese and Western medicine treatments. Two studies of CHM + chemoradiotherapy vs chemoradiotherapy showed advantage in the 5-year survival rate of the patients receiving CHM (RR = 1.23, 95% CI:1.02–1.48), while other studies (CHM + chemotherapy vs chemotherapy, 2 trials; CHM + chemoradiotherapy vs chemoradiotherapy, 3 trials; CHM + chemoradiotherapy + endocrine vs chemoradiotherapy + endocrine, 2 trials; CHM vs chemotherapy, 2 trials) did not show significant difference in 3/4/5 year survival rates. Seven studies reported lower recurrence/metastases rates in the CHM treatment groups although the time measured to outcome varied from 1 to 5 years. Only one study reported there were no adverse events, while the rest did not report this information.

**Conclusion:** The benefit of adding CHM to conventional treatments for improving survival, relapse and metastases in women with breast cancer remains unclear, and due to the limited number and methodological quality of studies, more rigorous RCTs are warranted.

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**P02.65**

**Chinese Herbal Medicine for Idiopathic Sudden Sensorineural Hearing Loss: A Systematic Review of Randomized Controlled Trials**

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**Purpose:** Chinese herbal medicine (CHM) is widely applied for idiopathic sudden sensorineural hearing loss.

**Methods:** We conducted a comprehensive search of seven electronic databases and two trial registries to identify
randomized clinical trials of Chinese herbal medicine for idiopathic sudden sensorineural hearing loss through January 2013 with no language limitation. Two authors independently selected trials and extracted data. The Cochrane risk of bias tool was utilized to assess the methodological quality of the included trials. RevMan 5.2 software was applied for data analysis with effect estimate presented as risk ratio and mean difference with its 95% confidence interval.

**Results:** Forty-one randomized clinical trials involving 3560 participants were included. Generally, the methodological quality of the trials was of high risk of bias. Forty-four different herbal medicines were tested in these 41 trials. No sufficient evidence showed Chinese herbal medicine was more effective in average change of pure-tone audiometric threshold than conventional therapy. Twenty trials (20/41) demonstrated significant increase in the proportion of participants with pure-tone audiometric threshold change by using Chinese herbal medicine compared to conventional therapy. Data from six trials (50.0%) showed beneficial effect in improvement of tinnitus from Chinese herbal medicine. There was no significant difference between Chinese herbal medicine and conventional therapy in improvement of dizziness, anxiety and depression. Two trials reported adverse effects and no severe adverse effects were reported in Chinese herbal medicine groups.

**Conclusion:** There appears a limited role for Chinese herbal medicine to significantly contribute to improving hearing in people with idiopathic sudden sensorineural hearing loss. The existing evidence from methodologically poor studies is insufficient to support their clinical use. Therefore, further rigorous trials are needed.

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**P02.66**

**Chinese Herbal Medicine for Cancer-Related Fatigue: A Systematic Review of Randomized Clinical Trials**

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**Purpose:** To assess the effectiveness and safety of Chinese herbal medicine for the treatment of cancer-related fatigue.

**Methods:** We systematically searched seven electronic databases and two trial registries from their inception to February 2013 for randomized clinical trials of Chinese herbal medicine for the treatment of cancer-related fatigue. Two authors independently extracted data and assessed the methodological quality of the included trials using the Cochrane risk of bias tool. Data were synthesized using RevMan 5.2 software.

**Results:** Fourteen trials involving 1076 participants with cancer-related fatigue were identified and the methodological quality of the included trials was generally poor. Eleven different herbal medicines were tested in the 14 trials. Spore powder of ganoderma lucidum, American ginseng, Kangai injection and Jiunqi Yiqi decoction showed significant relief in fatigue severity compared to placebo or chemotherapy. Kangai injection, Aidi injection, Fufang Eijiao jiang and Buzhong Qi pill were significantly superior to chemotherapy or supportive therapy in increasing proportion of participants with fatigue relief based on single trials and meta-analysis of two trials (risk ratio 1.67, 95% confidence interval 1.17 to 2.40). American ginseng, Kangai injection, Renshen Yangrong decoction, Buzhong Qi decoction, Fufang Eijiao jiang exerted a greater beneficial effect on improving quality of life over placebo, chemotherapy or supportive therapy. Ten trials reported adverse events and no severe adverse effects were found in Chinese herbal medicine groups.

**Conclusion:** Current evidence suggests that Chinese herbal medicine may be effective and safe in the treatment of cancer-related fatigue. However, owing to poor methodological quality of these trials, potential promising findings must be interpreted with caution. It’s recommended to employ further rigorous randomized clinical trials that overcome the limitations of current trials to increase the strength of evidence.

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**P02.67**

**Body Awareness and the Practice of Yoga or Meditation in 435 Primary Care Patients with Past or Current Low Back Pain**

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**Purpose:** Low back pain (LBP) is the most common reason for patients to seek integrative medicine care. Neurologically, perceived pain is an element of interoceptive body awareness (BA), which describes how we attend to our body and to pain. It has been hypothesized that yoga and meditation may help pain patients through improved BA, but BA has rarely been assessed in this population. We provide the first quantitative data on BA in primary care patients with past or current LBP, comparing those who practiced yoga and/or meditation with those who did not.

**Methods:** Two-year observational cohort study in a large health care system in California: we applied the Multidimensional Assessment of Interoceptive Awareness (MAIA) questionnaire that assesses 8 dimensions of BA (noticing, distracting, worrying, attention regulation, emotional awareness, self-regulation, body-listening, and trusting) in 435 primary care patients, who had acute LBP at inception. At follow-up we compared rates of non-recovery (chronic pain) and MAIA scores between those who practiced a form of mind-body therapy and those who did not.

**Results:** 172 patients (40%) had persistent/recurrent LBP. 80 practiced yoga, 144 reported experience with meditation; both scored significantly higher on 6 of 8 MAIA scales [Range 0–5] than mind-body inexperienced patients (largest difference for self-regulation: 3.60 vs. 2.80; p < .001). Higher levels of yoga and meditation experience [4 levels] were associated with higher BA scores. Those who reported more than “a taste of” meditation experience had a 38% reduced risk of chronic pain (p = .041); those reporting that level of any type of mind-body therapy experience had a 24% reduced risk (p = .047).

**Conclusion:** In a cohort of primary care patients with acute LBP at inception, those who practiced yoga or reported some
experience with meditation reported higher levels of BA compared to those who did not. Mind-body therapies were associated with better recovery from pain.

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P02.68
Effects of Mindfulness Meditation on Self-Rated Stress-related Measures: Improvements in Neuroticism and Ecological Momentary Assessment of Stress
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Purpose: Mindfulness meditation (MM) may positively impact factors that are prevalent among persons with severe speech and physical impairments (SSPI), including stress, depression, chronic pain, and sleep quality. The aims of this pilot study are twofold: (1) describe the development, implementation, and feasibility of a MM intervention for use by clinicians treating clients with SSPI; and (2) evaluate the feasibility of administering appropriate outcome measures.

Methods: Participants with SSPI are defined by having speech that is understood less than 25% of the time and/or severely reduced hand function for writing/typing. They were recruited from an ongoing brain-computer interface communication study. The MM intervention was based on a previously reported adaptation of MBCT (Wahbeh et al., 2012) and then modified to accommodate SSPI. The six weekly MM trainings were conducted in a one-on-one format at participant residences. They were 90 minutes in length, and suggested home practice was 30–45 minutes per day using audio recordings.

Results: Seven participants were studied (5 men; mean age 47 years; diagnoses included cerebral palsy, amyotrophic lateral sclerosis, and brainstem hemorrhage). Participants meditated an average of 10 minutes per day. Qualitative reports were overall very positive; participants reported enhanced coping skills regarding pain, negative emotions, family stressors, boredom, and frustration with ventilation. While administration of the secondary measures was feasible, there were no significant pre-post results in this small sample size.

Conclusion: MM trainings and home practice are feasible and potentially beneficial for people with SSPI. Obstacles to teaching MM to this population are reported, and future solutions are proposed.

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P02.69
Teaching Mindfulness Meditation to Adults with Severe Speech and Physical Impairments: An Exploratory Study
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Purpose: Mindfulness meditation (MM) may positively impact factors that are prevalent among persons with severe speech and physical impairments (SSPI), including stress, depression, chronic pain, and sleep quality. The aims of this pilot study are twofold: (1) describe the development, implementation, and feasibility of a MM intervention for use by clinicians treating clients with SSPI; and (2) evaluate the feasibility of administering appropriate outcome measures.

Methods: Participants with SSPI are defined by having speech that is understood less than 25% of the time and/or severely reduced hand function for writing/typing. They were recruited from an ongoing brain-computer interface communication study. The MM intervention was based on a previously reported adaptation of MBCT (Wahbeh et al., 2012) and then modified to accommodate SSPI. The six weekly MM trainings were conducted in a one-on-one format at participant residences. They were 90 minutes in length, and suggested home practice was 30–45 minutes per day using audio recordings.

Results: More participants in the mindfulness groups reported minimally and much improved PTSD symptoms (MM 85%, MM+SB 78%, SB 44%, SQ 60%). The SQ and SB groups
reported no change (MM 11%, MM+SB 17%, SB 52%, SQ 40%) more often than MM groups. Most participants endorsed receiving benefit from the study (MM 94%, MM+SB 75%, SB 92%, SQ 92%). Also, more participants in the active training groups endorsed their PTSD symptoms improving from the study (MM 70%, MM+SB 69%, SB 69%, SQ 42%).

Conclusion: Mostly positive benefit was perceived from mindfulness meditation in combat veterans with PTSD. While suggestive, further qualitative and quantitative research is necessary to explore the efficacy of mindfulness meditation in this population.

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P02.71
Effects of Stress-Reducing Aromatherapy on Go-nogo Task Following Acute Stress: An Evoked Related Potentials Study
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Purpose: Lavender aromatherapy is often used for stress reduction, however the evidence for its effects and mechanism is ambiguous. Systematic reviews of aromatherapy research indicated the need for more rigorously designed studies assessing aromatherapy efficacy and mechanism. This study explored aromatherapy effects on the go-nogo (GNG) task performance and ERP components related to response inhibition after stress induction. The roles of aroma- and verbally-mediated expectations were also assessed.

Methods: 81 healthy adults (Mean age = 58.2, 79 % females) were randomized to 3 groups based on aroma (experimental, detectable placebo, and undetectable placebo) and 2 subgroups based on prime (half receiving a suggestion about inhaling a powerful stress-reducing aroma to alter expectancy). Performance on GNG task was evaluated at baseline and post-stress after exposure to a stress battery. Measures of expected aroma effects, subjective stress, affect, and anxiety were also obtained.

Results: Trends for interactions involving prime effects were observed on GNG task performance. Specifically, people receiving a prime displayed faster median reaction times and less response variability after stress than those receiving no prime. Beneficial effects of prime were also noted on ERP N200 and P300 latency and amplitude. Receiving a prime was associated with shorter nogo N200 and P300 latencies post-stress compared with increases in these latencies when no prime was received. Additionally, those in the prime group displayed little change in nogo N200 amplitude post-stress contrasted with a decrease in nogo N200 amplitude in no prime group. Furthermore, lavender aroma was associated with general preservation of the ERP waveform post-stress while exposure to placebo aromas led to some changes in nogo N200 and nogo P300 components.

Conclusion: Based on our ERP results, lavender might buffer some effects of acute stress on cognitive function. Additionally, aromatherapy effects on response inhibition and attention are affected by verbally-mediated expectancy.

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P02.72
Systematic Review of Mind-Body Interventions on Sleep
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Purpose: Mind-body interventions have increasing evidence of benefit for multiple health conditions. Many mind-body studies have included sleep as a primary or secondary outcome measure. The purpose of this study was to formally evaluate the effect of mind-body interventions on sleep.

Methods: We reviewed randomized controlled mind-body intervention trials on adults (prior to 1/1/13) with at least one sleep outcome measure. We searched 11 electronic databases and hand searched the reference lists of included studies and relevant review articles using relevant search terms. We excluded papers: not considered mind-body medicine; not having a proper control group, and, consisting of multi-component interventions. Two reviewers independently reviewed abstracts for inclusion and extracted data. Studies were categorized by type of mind-body intervention, whether sleep was primary or secondary outcome measure, and type of outcome measure.

Results: 1051 non-duplicate abstracts were screened, and 74 out of the 82 reviewed papers were included for analysis. Overall, 61 (82.4%) of studies with a variety of mind-body interventions reported a beneficial effect on at least one sleep outcome measure. Of the most common interventions, 17/17 studies using meditation and 17/21 using relaxation and imagery reported improvements in sleep. 12/74 studies used physiological and the rest used self-rated sleep measures. There was not a remarkable discrepancy between conclusions based on physiologic and self-rated outcomes. There were clear risks of bias for many studies reviewed, especially when sleep was not the main focus of the study.

Conclusion: Many studies using mind-body interventions had sleep as an outcome measure and the majority reported improvements in some aspect of sleep. It is reasonable to include some sleep outcome measure in most mind-body intervention trials since there is evidence that mind-body interventions have a positive effect and quality of sleep is a vital sign has a direct impact on many other health outcomes.

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P02.73
Practitioners’ Perceptions of Yoga’s Impact and Positive and Negative Effects: Results of a National Survey
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Purpose: Yoga is becoming increasingly popular in the US, yet little information is available regarding practitioners’ perceptions of changes they experience through yoga and the positive and negative effects of their practice. This study aimed to characterize yoga practitioners’ perceptions of life changes and effects of yoga practice.

Methods: Yoga practitioners (N = 542, including 162 yoga teachers) were recruited via email and flyers to yoga studios across the U.S. to complete an Internet-based survey. Participants ranged in age from 18 to 85 years (M = 44), were predominantly female (84.4%), married (54.8%), and educated (74.9% had Bachelor’s degree or higher). Participants rated the extent to which they experienced each of 24 benefits (from not at all (0) to very much (6)). They then listed (brief open text) up to three primary positive and negative effects of their yoga
How Effective Is Tai Chi Mind-Body Therapy for Fibromyalgia: A Systematic Review and Meta-Analysis

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Purpose: Tai Chi mind-body practice may alleviate fibromyalgia symptoms. We conducted a systematic review and meta-analysis examining the effectiveness of Tai Chi mind-body therapy in patients with fibromyalgia.

Methods: Medline, Cochrane Central databases, and review of references were searched through July 31, 2013. English-language studies of all designs evaluating Tai Chi in patients with fibromyalgia were included. Data were extracted and verified by 2 reviewers. Extracted information included study and population characteristics, type and duration of interventions, outcomes, risk of bias, and main results. Random effects meta-analysis was used to assess the magnitude of treatment effect when at least 3 trials reported the same outcome.

Results: Seven studies (4 randomized controlled trials [RCTs] and 3 uncontrolled studies) published between 2003 and 2012 met eligibility criteria. All 4 RCTs with a total of 391 participants (90% women) reported data on fibromyalgia symptoms using Fibromyalgia Impact Questionnaire (FIQ). The onset of fibromyalgia symptoms ranged between 2.8 to 24 years. In meta-analysis of RCTs, Tai Chi practice for 1.5 to 3 hour each week for a duration of 6 to 12 weeks statistically significantly improved fibromyalgia symptoms (Effect size [ES] = 0.50, 95% CI 0.19, 0.81), pain (ES = 0.45, 95% CI 0.24, 0.66), and sleep quality (ES = 0.48, 95% CI 0.14, 0.81), compared with a variety of controls. However, meta-analysis found no statistically significant effect during 24 to 32 weeks of follow-up. Of the 3 single-group uncontrolled studies of Tai Chi, fibromyalgia symptoms significantly improved in 2 single-group uncontrolled studies that included a total of 71 women undergoing Tai Chi mind-body therapy, while 1 study conducted exclusively among men found no improvement.

Conclusion: In reviewed studies, Tai Chi practice improves symptoms associated with fibromyalgia at short-term. Further studies of Tai Chi are warranted to understand its sustained long-term effects among patients with fibromyalgia.

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Tai Chi and Sleep Quality in Adults: A Systematic Review and Meta-Analysis

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Purpose: Physical activity and exercise appear to improve sleep quality. However, the quantitative effects of Tai Chi on sleep quality in adult population have rarely been examined. We conducted a systematic review and meta-analysis evaluating the effects of Tai Chi on sleep quality in healthy adults and disease populations.

Methods: Medline, Cochrane Central databases, and review of references were searched through July 31, 2013. English-language studies of all designs evaluating Tai Chi in adults reporting sleep outcomes were examined. Data were extracted and verified by 2 reviewers. Extracted information included study setting and design, population characteristics, type and duration of interventions, outcomes, risk of bias and main results. Random effect models meta-analysis was used to assess the magnitude of treatment effect when at least 3 trials reported the same sleep outcomes.

Results: Eleven studies (9 randomized and 2 non-randomized trials) totaling 994 subjects published between 2004 and 2012 were identified. All studies except one reported Pittsburg Sleep Quality Index. 9 randomized trials reported that Tai Chi practice of 1.5 to 3 hour each week for a duration of 6 to 24 weeks significantly improved sleep quality (Effect Size, 0.89; 95% confidence interval, 0.28 to 1.50), in community-dwelling healthy participants and in patients with chronic conditions. Improvement in health outcomes including physical performance, pain reduction, and psychological well-being occurred in Tai Chi compared with a variety of controls.

Conclusion: Reviewed studies examining effects of Tai Chi on sleep quality were heterogeneous and some trials lacked methodological rigor. Tai Chi significantly improved sleep quality in both healthy adults and patients with chronic health conditions. This suggests that Tai Chi may be considered as an alternative behavioral therapy in the treatment of insomnia. High-quality, well-controlled randomized trials are needed to better inform clinical decisions.

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P02.76
The Use of Guided Mental Imagery for Patients Receiving Knee or Hip Replacement Surgery
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Purpose: The study was aimed to find out whether the use of guided imagery reduces the operating time and length of stay in inpatient care for the patients undergoing knee or hip replacement surgery.

Methods: A de-identified data was collected from patients who had undergone surgical procedure for knee or hip replacement performed at Aurora Sinai Medical Center from 2009 through 2011. The guided imagery (GI) group comprised of 614 patients opted to use guided imagery before, during, and after the surgery, in addition to the standard of care. The GI intervention included the use of earphones and one of the several ways – either by CD, skylight interactive TV system, or by the download from the website. The second group of 809 patients, who did not opt for the use of guided imagery, received only standard of care. Data collected included: age, race, length of stay, type of surgery, discharge outcome (home care, home health, skilled nursing home, and rehab facility), and ASA physical status level.

Results: There were 924 (62.31%) female and 559 (37.69%) male patients who had undergone either hip (n=559, 38.37%) or knee surgery (n=914, 61.63%). Out of the 1483 patients, only 614 (41.40%) opted for the use of GI techniques along with the standard of care. The proportion of patients opting for the use of GI was higher among females (0.44) compared to male patients (0.37, p=0.015). Mean number of days for the GI group were lower compared to the control group (2.40 vs. 2.48 hours with p=0.047). Mean operating time was lower for GI group than the control group (3.21 vs. 3.36 days with p=0.015). After controlling for confounders, mindfulness accounted for 11% of the variation in pain scores (ΔR2, p<.0001).

Conclusion: The study shows that the use of guided imagery as a complimentary therapeutic tool is associated with lower operating room time and with the speedy recovery.

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P02.77
The Relationship Between Mindfulness and Pain in Multiple Sclerosis
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Purpose: Pain is reported in up to 86% of people with MS and as many as half say that it interferes with their daily activities and/or sleep. Pharmaceutical pain-management therapies have limitations due to side effects, and identifying non-pharmacological therapies that can reduce pain and improve quality of life is warranted. Mindfulness, the ability to be wholly present with one’s experience, has been shown to alter the impact of pain in other conditions, but no study has specifically addressed mindfulness and pain in MS. The purpose of this study was to examine the relationship between pain interference, mindfulness, and quality of life in people with MS.

Methods: Cross-sectional survey (n=139). Subjects met the following: 18 – 90 years, definite diagnosis of MS (McDonald criteria), no relapse within 3 months prior to study visit. Outcome measures included: PROMIS Pain Interference survey, SF-36, and the Five-Facet Mindfulness Questionnaire. Bivariate correlations examine the associations between pain, mindfulness, and quality of life; the influence of potential confounders was assessed with linear regression.

Results: Participants who reported greater pain interference experienced lower physical and mental health-related quality of life (r = -0.63, p < .0001; r = -0.33, p < .0001; respectively). Those who reported being more mindful in their daily lives experienced lower levels of pain interference (r = -0.37, p < .0001) and better mental health-related quality of life (r = 0.56, p < .0001). After controlling for confounders, mindfulness accounted for 11% of the variation in pain scores (ΔR2, p<.0001).

Conclusion: As a safe, non-pharmacological intervention, mindfulness may be a good adjunct therapy for MS patients who often require multiple pharmaceuticals for disease management. Results support further investigation of mindfulness training as way to minimize the impact of pain and enhance quality of life in MS.

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P02.78
Integrative Medicine Group Visits and Emergency Department Utilization
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Purpose: Emergency department (ED) use for non-urgent needs contributes to increased cost of health care, strain on ED resources, and decreased continuity of care. Integrative Medicine Group Visits (IMGV) is a novel eight-week outpatient program for patients with chronic health conditions. Our objective was to determine whether IMGV was associated with changes in ED utilization.

Methods: IMGV combines the principles of Mindfulness-Based Stress Reduction, a group medical visit, and exposure to evidence-based CAM, while enhancing self-efficacy and support. Between April 2012 and September 2013, IMGV was offered through a family medicine clinic at a large urban hospital serving a predominantly low-income minority population. ED utilization in the 6 months prior to, during, and 6 months following IMGV was collected through chart review. Secondary outcomes included primary diagnosis, chief complaint, and resultant admissions. Primary analysis compared ED utilization rate before, during, and after IMGV.

Results: Eighty-four patients enrolled in IMGV. Preliminary results show 46 patients visited the ED at least once with a range of 0–7 ED visits per patient, resulting in 99 total ED visits and 24 subsequent admissions. Thirty-one patients had 48 ED visits in the 6 months prior to IMGV; 8 patients made 9 ED visits during the two-month IMGV; and 22 patients made 42 visits in the six months after IMGV. The corresponding ED visit rates per month prior, during, and after IMGV were 8.0, 4.5, and 7.0, respec-
P02.79 Search for Meaning Influences Willingness to Participate in Mindfulness-Based Stress Reduction

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Purpose: Mindfulness-Based Stress Reduction (MBSR) is an evidence-based intervention for managing psychosocial distress associated with cancer. Little is known about the demographic and psychosocial factors influencing one’s decision to participate in MBSR. We evaluated whether meaning in life is associated with willingness to participate in MBSR.

Methods: We conducted a cross-sectional survey study among radiation therapy patients at an urban academic cancer center. Patients were asked to indicate whether they would be willing to participate in a MBSR program if offered. Predictors included demographic and clinical variables as well as a validated measure of the search for, and presence of, meaning in life. Multivariate logistic regression was used to evaluate predictors of willingness to participate in MBSR.

Results: In a heterogenous cancer population (N = 300), 80 patients (26.7%) indicated willingness to participate in MBSR. Search for meaning was the only variable found to be significantly associated with a willingness to participate in MBSR (p < .001) in multivariate logistic regression analysis. When examined individually, non-white race was associated with greater willingness to participate in MBSR (p = .02). Participants who were older than 65 (p = .01) or who already reported the presence of meaning (p = .04) were significantly less likely to be willing to participate in MBSR. Education level, sex, cancer type, and cancer stage were not significant predictors.

Conclusion: Search for meaning was a significant determinant of whether an individual would choose to participate in a MBSR program. In contrast with previous studies suggesting that MBSR participants tend to be well-educated, white females, non-white race was associated with openness to MBSR. This suggests a demographic disconnect between interest and actual MBSR participation. Future research is required to examine potential barriers to participation in MBSR. Understanding characteristics that influence utilization has important consequences for efficient referral, programming and integration of MBSR into cancer care.

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P02.80 Yoga for Patients with Epilepsy: A Pilot Study

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Purpose: Primary Aim: To assess the safety and feasibility of yoga in adults with poorly controlled epilepsy. Secondary Aim: To conduct a pilot study evaluating the impact of yoga on seizure frequency, quality of life, and perceived stress.

Methods: Women ages 18–64 with poorly controlled simple partial and complex partial seizures on antiepileptic medications were recruited for a six-week yoga intervention including in-person instruction and home practice. Seizure frequency was assessed during a six-week baseline period, immediately after, and six weeks after the yoga intervention using seizure calendars. Perceived stress and quality of life were assessed using the Perceived Stress Scale (PSS) and the Quality of Life in Epilepsy Inventory (QOLIE-31) before and after the intervention.

Results: Five women completed the study. No participants reported seizures or adverse events during the six-week intervention phase of the study. Scores on the QOLIE-31 demonstrated an average improvement of 11.7 points (t = 2.591, p = .0606). Additional significant improvements were found on several of the QOLIE Subscales, including Seizure Worry (t = 2.929, p = .0428) and Energy/Fatigue (t = 3.309, p = .0297). A marginal improvement was illustrated on the Perceived Stress Scale (PSS) (t = 2.138, p = .0993).

Conclusion: Results of this small pilot study were compelling on several levels. First, despite longstanding clinical concerns regarding exercise for epilepsy, patients self-reported reduced seizure frequency during the 6 week intervention and no adverse events were reported during the yoga intervention or follow-up period. Second, participants reported significant decreases in seizure worry and increases in energy on the gold standard for epilepsy quality of life (QOLIE-31). Finally, there were modest decreases in perceived stress. These results suggest that yoga is a feasible and safe intervention and should be considered as an adjunctive treatment in individuals with poorly controlled epilepsy on anticonvulsant medications. Follow-up research studies with larger sample sizes are warranted.

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P02.81 Intervention Effect of Baduanjin Exercise on the Fatigue State in People with Fatigue-Predominant Sub-Health: A Cohort Study

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Purpose: To observe the intervention effect of Baduanjin exercise, which is a type of traditional health Qigong exercise and consists of eight sections, on the fatigue state in people with fatigue-predominant sub-health.

Methods: The cohort study method was used and the subjects were divided into Baduanjin cohort and control cohort according to whether they exercise Baduanjin or not. The subjects in the Baduanjin cohort exercised two times a day for six weeks. The fatigue state of all the subjects in both cohort was evaluated with
the fatigue Self-assessment Scale at baseline and the end of sixth week and the changes of fatigue state between two cohorts were compared. The scale consists of the following factors of physical fatigue (PF), mental fatigue (MF), consequence of fatigue (CF), situation of fatigue (SF) and response of fatigue to sleep and rest (RFTAR).

Results: There were 62 subjects in the Baduanjin cohort and 67 subjects in the control cohort. Compared with the baseline, the scores of all of the factors in the Baduanjin cohort are significantly low (P<0.05) with the exception of the factor of SF and no marked changes (P>0.05) in the control cohort. Compared with the control cohort at the end of sixth week, the scores of all of the factors in the Baduanjin cohort are significantly low (P<0.05) with the exception of the factor of SF.

Conclusion: Baduanjin exercise has certain effect on relieving fatigue in people with fatigue-predominant sub-health. (The paper was supported by the 111 Project of China Ministry of Education (B07007). "Innovative Team Project of Beijing University of Chinese Medicine (2011-CXTD-08) and Eleventh Five-year Plan of China State Science & Technology Ministry (2006-BA113B05).

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P02.82
What Do We Really Know About the Safety of Tai Chi?: A Systematic Review of Adverse Event Reporting in Randomized Clinical Trials

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Purpose: The purported safety of tai chi (TC), along with growing evidence of its efficacy in multiple age-related health conditions, is often used to recommend TC as an exercise for older and deconditioned adults. However, to date, there have been no systematic reviews of TC’s safety. We conducted a systematic review of adverse event (AE) reporting in randomized clinical trials (RCTs) of TC.

Methods: Electronic searches were conducted using PubMed/MEDLINE and two additional databases from inception through March 2013. Search terms were tai chi, taiji, tai chi chuan; randomized clinical trials (RCTs) of TC.

Results: 158 eligible RCTs were identified. The majority focused on older adults (median age = 69 y). 99 trials (63%) reported neither AE protocols nor occurrences of AEs; 37 trials (23%) reported AE protocols or AEs, but not both. Only 22 trials (14%) reported both AE protocols and AEs. In the later group, protocols varied with respect to rigor of systematically monitoring AEs, and level of monitoring in comparison groups. Reported AE’s were typically minor and expected, and primarily musculoskeletal related (e.g., knee and back pain, general fatigue); no intervention-related serious adverse events were reported.

Conclusion: Poor and inconsistent reporting of AEs greatly limits the conclusions that can be drawn regarding the safety of TC, and suggests the need for improved guidelines for AE reporting in trials of non-pharmacological interventions like TC. Based on RCTs providing both evaluable AE protocols and AE reports, TC appears to be safe for older and deconditioned adults.

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P02.83
Diabetes Empowerment Council (DEC): Development and Pilot Testing of an Innovative Mind-Body Group Intervention for Young Adults with Type 1 Diabetes

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Purpose: Mind-body stress reduction modalities have reduced stress and improved blood glucose control in type 2 diabetes, but no data exist for type 1 diabetes (T1D). Our objective was to develop and pilot test a theory-based, mind-body group intervention for young adults with T1D grounded in the underlying principles of Self-Determination Theory (SDT).

Methods: Participants (n = 27, age 19.5 ± 8) in our Let’s Empower and Prepare (“LEAP”) diabetes transition program were offered participation in the DEC, meeting every ~3 weeks for 1.5 hrs, 12 sessions. DEC utilized the facilitated group process of “Council”, based on Native American/indigenous practices, to promote trust, relatedness, and depth of communication. Process elements included stress-reduction guided imagery, narrative storytelling, and simple rituals. Post-intervention focus group transcripts were inductively analyzed to derive themes and develop a theoretical model of DEC process and outcomes. Intervention changes in perceived stress and hemoglobin A1C were assessed.

Results: 12 participants (P) attended ≥1 DEC session (mean 6.7 ± 3.7, range 1–11), and 15 never participated (NP) in DEC due to no childcare (n = 2), schedule/travel conflicts (n = 5), or unknown reasons (n = 8). Post-intervention focus groups suggested 1) very high program acceptability; 2) increased relatedness among participants; 3) a theoretical model of program action based on stress-reduction, promotion of autonomy, and interpersonal connectedness. Post-intervention perceived stress decreased in P vs NP (−9.0 ± 8.5 vs −1.0 ± 5.3, p < .02; very large Effect Size [ES]=1.2). A1C decreased modestly but not significantly in P vs NP (−5.1 ± 4 vs −2.2 ± 2.8, ES 0.3, p = .6). Decreased perceived stress predicted decreased A1C across the intervention (linear regression, βstd = .56; R2 = .19; p = .05).

Conclusion: While feasibility issues must be overcome, DEC was well-accepted, increased participant relatedness, and markedly reduced stress, which may improve glycemic control. A larger scale randomized trial is needed to fully determine effects on glycemia and other health outcomes, and to test the theoretical model of program action.

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P02.84
The Impact of a Tai Chi Exercise Program on Patients with Chronic Heart Failure: Qualitative Analysis from a Randomized Controlled Trial

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Purpose: The impact of Tai Chi exercise (TC) on patients with chronic heart failure (CHF) has been explored, but no data exist on intervention acceptability. This study assessed intervention acceptability and qualitative feedback from a randomized controlled trial comparing Tai Chi to a control condition (CT).

Methods: Thirty adult patients with CHF (age 62 ± 11) were randomized to Tai Chi or CT and attended 24 weekly 1.5 hr. sessions (n = 15). Qualitative feedback was collected through in-person focus groups at post-intervention. Focus group transcripts were inductively analyzed to derive themes and develop a theoretical model of program action.

Results: Participants reported 1) very high program acceptability; 2) increased relatedness among participants; 3) a theoretical model of program action based on stress-reduction, promotion of autonomy, and interpersonal connectedness. Post-intervention perceived stress decreased in P vs NP (−9.0 ± 8.5 vs −1.0 ± 5.3, p < .02; very large Effect Size [ES]=1.2). A1C decreased modestly but not significantly in P vs NP (−5.1 ± 4 vs −2.2 ± 2.8, ES 0.3, p = .6). Decreased perceived stress predicted decreased A1C across the intervention (linear regression, βstd = .56; R2 = .19; p = .05).

Conclusion: While feasibility issues must be overcome, DEC was well-accepted, increased participant relatedness, and markedly reduced stress, which may improve glycemic control. A larger scale randomized trial is needed to fully determine effects on glycemia and other health outcomes, and to test the theoretical model of program action.

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P02.86 Feasibility and Preliminary Effects of Centering for Chronic Pelvic Pain: Integrative Group Visits for Medically Underserved Women

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Purpose: The Centering model is an innovative approach to group-based healthcare across the lifespan that integrates healthcare assessment, education, and social support. We adapted the Centering model to provide comprehensive care for women with chronic pelvic pain (CPP) using an integrative health approach and piloted the program to assess feasibility, acceptability, and preliminary outcomes.

Methods: We developed curriculum for ten sessions of Centering CPP focused on improving quality of life and managing symptoms through integrative approaches, such as mind-body strategies, yoga, and nutrition. We pilot tested the curriculum with three groups of CPP patients from a university-affiliated and public hospital-affiliated clinic. We collected qualitative and quantitative data at baseline and three follow-up time points.

Results: Centering CPP participants (n=26) were on average 40 years of age; 76% women of color; 39% attended some college; and 68% had incomes of less than $35,000. Analyses including all participants showed trends toward improvement in quality of life, functional limitations, social and emotional
well-being, and sexual functioning. As-treated analyses including women who attended 4 or more sessions (n=16) demonstrated that average unhealthy days in the past month decreased from 24 at baseline to 18 at ten-month follow-up (p<0.05). Depression scores decreased from 12.1 to 9.0, a clinically relevant difference from minor depression to minimal symptoms (p<0.05). Patient-centered measures of symptom severity using the MYMOP scale decreased from 4.2 to 3.1 (p<0.01). No improvements were observed for pain catastrophizing or healthcare empowerment scales.

Conclusion: An integrative health approach implemented through group medical visits may address a range of physical and psychosocial patient-centered outcomes among patients with CPP. To advance the evidence base for programs such as Centering CPP, additional research is needed comparing this approach with usual care and on targeted efforts to enhance patient engagement and participation.

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P02.87
Impact of Sociodemographic Factors on Attitudes and Beliefs Towards CAM Use Among Cancer Patients
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Purpose: Sociodemographic factors have been associated with the use of CAM among cancer patients, yet little is known about how these factors impact attitudes and beliefs towards CAM use.

Methods: We conducted a cross-sectional survey study at an urban, academic cancer center among adult patients with a primary diagnosis of cancer. Sociodemographic variables were collected by self-report and attitudes and beliefs were measured using the validated Attitudes and Beliefs about CAM (ABCAM) instrument. ABCAM is based on the Theory of Planned Behavior and measures three major components of CAM use: expected benefits, perceived barriers, and subjective norms.

Results: Among the 969 participants (response rate 82.7%), the mean age was 59.1 (SD 12.1) and 63% were female. Seventy-nine percent identified themselves as White, 16% as Black, 3% as Asian, and 2% as other. A majority (74.4%) reported an education level of some college or above. Cancer diagnoses included: breast (315), gastrointestinal (308), lung (297), and other cancer types (48). Younger patients (≤55 years) had greater expected benefits (p<0.001) and subjective norms (p<0.001) than older patients (>65 years), but their perceived barriers to CAM use did not differ. Compared to male patients, females had higher expected benefits (p<0.001) and less perceived barriers (p=0.009). Non-whites and white patients only differed in perceived barriers: non-whites reported more perceived barriers than their white counterparts (p<0.001). Furthermore, patients with higher education had greater expected benefits (p<0.001) and less perceived barriers (p<0.001).

Conclusion: Sociodemographic factors have a substantial impact on the attitudes and beliefs about CAM use among cancer patients. Understanding and addressing these variations have important implications in designing patient-centered integrative cancer care for a diverse group of cancer patients.

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P02.88
Effect of Far Infrared Emitted by Bioceramics on Clinical Measures of Physical Fitness
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Purpose: To evaluate the effect of Far Infrared therapy emitted by bioceramics on flexibility, grip strength and respiratory capacity in a randomized double blind placebo controlled trial involving 9–12 Basketball Players of the Florida Atlantic University (ages 18–22).

Methods: Each participant was randomized to wear either a BioPowerTM bioceramics shirt (bioceramics silkscreened shirt) or a Sham shirt (without bioceramics). Baseline evaluations were conducted on week 1. On weeks 2 and 3 the players wore the shirts for three hours three times a week during practice (short-term use). On weeks 4 and 5 the players wore the shirts 7 days a week throughout the day (extended use). Flexibility was measured with the sit-and-reach test; the grip strength of the dominant hand with a hand dynamometer and respiratory capacity with a spirometer (Forced Vital Capacity - FVC, Forced Expiratory Volume in one second - FEV1 and Peak expiratory flow - PEF).

Results: Short-term use of BioPowerTM bioceramics shirts did not affect flexibility whereas extended use increased it in 5.5% and 14.1% (weeks 4 and 5). In comparison to baseline levels, short-term and extended use of BioPowerTM bioceramics shirts increased grip strength (5.6% - week 3), 10.8% and 10.9% (weeks 4 and 5). Lastly, short-term use of BioPowerTM bioceramics shirts increased FVC (5.8% - week 3) and FEV1 (5.9% - week 3) but did not affect PEF, whereas long-term use increased FVC (5.8% - week 4); FEV1 (15% and 10% - week 4 and 5) and PEF (52.77% and 50.9% week 4 and 5).

Conclusion: Far Infrared therapy emitted by BioPowerTM Bioceramics Shirts increased flexibility, grip strength and respiratory capacity in Basketball Players of the Florida Atlantic University. Extended use induced more significant results than short-term use.

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P02.89
Integrative Care Therapies and Pain in Hospitalized Children and Adolescents: A Retrospective Database Review
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Purpose: Pain is a common problem for pediatric inpatients. Integrative care therapies have demonstrated efficacy as adjunctive approaches to pain management among adult inpatients. However, little research exists on the efficacy of integrative care therapies for pain in pediatric inpatients. The purpose of this study was to examine associations between integrative care therapies and pain and relaxation outcomes in hospitalized children/adolescents at a large Midwestern pediatric hospital.
Methods: We conducted a retrospective database review of an inpatient clinical database using a practice-based naturalistic design. Therapists delivered integrative care therapies (primarily massage therapy and healing touch) to hospitalized children/adolescents over a one-year period, and obtained pre-post ratings of pain and relaxation. We used paired-samples t-tests to examine the extent to which changes in pain and relaxation were associated with the delivery of integrative care therapies. Consistent with standard clinical practice, we examined pain outcomes separately for distinct clinical and demographic groups. No control group was available.

Results: Five-hundred nineteen hospitalized children/adolescents were treated by integrative care therapists for primarily pain or anxiety and had pre-post outcomes data available. Patients had a mean age of 10.2 years (SD = 7.0), 224 were female (43%), and 383 were Caucasian (74%). Mean pain scores decreased significantly from pre- to post-therapy across all subgroups (t = 8.1 to 12.0, p < .001). Up to 77% of patients showed greater than a 50% reduction in pain. Across all subgroups, patients reported significantly greater relaxation following integrative care therapies (t = 16.4, p < .001).

Conclusion: Integrative care therapies were associated with significant improvements in pain and relaxation among a large, inpatient pediatric population. Results indicate a need for rigorous, controlled studies of integrative care therapies for pediatric inpatient pain. Future studies with control groups should examine whether integrative care reduces both pain and cost in inpatient pediatric settings.

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P02.90
Exploring the Utility of Psidium Guajava Leaf Extract as an Adequate Treatment for Giardia Lamblia
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Purpose: Giardia lamblia is one of the most common intestinal parasites worldwide. Psidium guajava (guava) leaf and bark extracts are common folk remedies used to treat Giardia. This prospective cohort study assessed the clinical utility of a standardized guava extract compared to standard treatment, tinidazole, and no treatment given at a natural medicine clinic in Ometepe, Nicaragua.

Methods: The utility of the guava treatment was assessed by stool microscopical examination three, five, seven, and ten days following treatment completion. The primary outcome measure was change in Giardia cysts or trophozoites seen on at least three consecutive stool tests. Patients receiving standard doses of tinidazole and patients not receiving treatment were also followed for two weeks.

Results: 664 individuals submitted stool for examination; 87 of these individuals tested positive for Giardia and 79 enrolled in the study. Of those enrolled in the study, 39 individuals were prescribed the guava extract and returned for re-examination. Of these 39 assessed, 11 tested negative for Giardia cysts and trophozoites on all stool tests, 16 persons tested positive for Giardia cysts and trophozoites on all stool tests, and the remaining 12 tested positive for Giardia cysts and trophozoites on one or more of the stool tests. Seven persons were prescribed tinidazole. All tested negative for Giardia cysts or trophozoites on all stool tests. Eight persons remained untreated throughout the study period; none of the patients tested negative for Giardia cysts and trophozoites on all stool tests. Patients treated with guava and those who did not receive treatment had no adverse effects. Reported adverse effects of the tinidazole included dizziness, and nausea.

Conclusion: Though the guava tincture was more favorably received and had fewer side effects than tinidazole, it appears ineffective in clearing Giardia cysts and trophozoites from the stool.

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P02.91
A Prospective Clinical Study of a Whole Systems Ayurvedic Intervention for Breast Cancer Survivorship
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Purpose: Cancer associated symptoms and impairments in quality of life remain significant problems for patients despite advances in treatment. An Ayurvedic medicine approach has anecdotal evidence of benefit for cancer symptom management but poses research challenges if a whole systems approach is to be used while standardizing intervention elements. We sought to test the feasibility of a manualized whole systems Ayurvedic medicine intervention for breast cancer survivors, and test whether it provides clinically meaningful benefits in symptom management and quality of life.

Methods: We performed extensive work to manualize a whole systems Ayurvedic medicine intervention and are testing it in a single arm study of breast cancer survivors who have completed primary curative therapy (surgery, radiation therapy, and chemotherapy). Based on Ayurvedic diagnoses participants receive an individualized 4 month intervention that includes nutrition, lifestyle, yoga, and marma (similar to acupressure) components, conducted by Ayurvedic practitioners. In addition to feasibility, study outcomes include quality of life (QOL) (EORTC QLQ C30), fatigue, sleep disturbance, spiritual wellbeing, and depressive and anxiety symptoms.

Results: We have enrolled 22 female breast cancer survivors to date, and 16 have completed the intervention with data available for analysis. Participants attended 99% of their visits with study practitioners. Analysis of key quantitative outcomes revealed very large effect sizes for improvements in global health (QOL) (1.0), fatigue (1.0), and depression (0.9); and moderate effect sizes for improvements in sleep disturbance (0.7), anxiety (0.5), and spiritual wellbeing (0.5). There were no significant adverse effects.

Conclusion: Implementing a manualized whole systems modality Ayurvedic intervention based on Ayurvedic diagnoses among breast cancer survivors was feasible and provides a potential model for future studies. Initial results in QOL and symptoms, such as fatigue, suggest potential benefit, but require cautious interpretation until enrollment is complete and the intervention is ultimately tested in a randomized, controlled design.

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P02.92
Development of a Hand Massage Service for Cancer Patients Undergoing Chemotherapy
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Purpose: Patients with cancer endure many difficult symptoms during and after treatment. A 2005 study reported that >20% of cancer patients use massage therapy to manage symptoms like anxiety, pain, & fatigue. Incorporating massage into the comprehensive care for an oncology patient undergoing chemotherapy may help ease the burden of these symptoms and improve the patient’s hospital visit. Yet the cost can sometimes prohibit access to the service. We’ll describe the development of a volunteer hand massage program, discuss its impact, and how it is replicable.

Methods: Clinical standards, feasibility, and benchmarking assessments were performed. Procedures for training, orientation, documentation, infection control, referrals, and communication were developed. Clinical statistics and staff opinions were recorded. A retrospective review of data from a participant survey was done.

Results: In just over three years, 1076 hand massages were performed on patients during chemotherapy visits. Hand massages were 15 minutes in length and performed with patients in an infusion chair. Volunteers reported using hand massage for many symptoms, but mostly for relaxation and stress reduction. 95% of nursing staff respondents reported this new service was very beneficial for their patients. All believed it had an important impact on their patients’ quality of care or hospital stay. 90% reported a “large impact.” All nurse respondents reported being satisfied with it, 90% “extremely satisfied.” Patients have expressed great appreciation for this new service and volunteers have been very pleased with their experience.

Conclusion: Development of this hand massage service for patients undergoing chemotherapy was successful and proved replicable. Analysis revealed that it may improve the comprehensive care offered to patients with cancer and have a significant impact on their hospital visit. Training, documentation, and communication are essential components of fully incorporating this beneficial service for patients. Partnering with our volunteer department was an important strategy in the success of this program.

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P02.93
Yoga Breathing During Cancer Chemotherapy: Qualitative Analysis from a Pilot Randomized Controlled Trial
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Purpose: Patients receiving chemotherapy experience significant morbidity related to treatment. A randomized study of yoga breathing suggested that it may improve chemotherapy associated symptoms such as sleep disturbance and anxiety. The aims of this qualitative study were to evaluate for emergent effects of yoga breathing, to assess the link between yoga breathing and study outcomes, and to examine mechanisms of the effect of yoga breathing.

Methods: Patients receiving chemotherapy with baseline fatigue were randomized to yoga breathing during 2 successive cycles of chemotherapy or wait-list control. Patients (n=16) attended weekly yoga breathing classes and were instructed to use the breathing practices at home. Patients kept daily journals over the course of the intervention and the yoga instructors recorded their impressions of patients from week to week. Textual data were coded using qualitative thematic analysis by at least two investigators.

Results: We identified five themes: (1) Yoga breathing was easy to incorporate into patients’ lives including during daily activities and while receiving chemotherapy. (2) Patients noticed increased energy, stamina, and less need for daytime sleep. (3) Patients noted increased awareness of the mind-body connection; and as a result, felt they were more mindful of the limits of their energy reserves. (4) Patients noted greater peace, calm, and emotional resiliency. (5) Barriers to performing yoga breathing included lack of energy, not knowing proper breathing technique, nasal congestion and severe illness. Some of these barriers were overcome through modifications to the yoga breathing techniques.

Conclusion: Emergent effects detected through qualitative analysis include that yoga breathing may improve emotional resiliency and mind-body awareness. The results support the favorable effects of yoga breathing in improving sleep disturbance and anxiety among chemotherapy patients. The role of mindfulness in mediating the effects of yoga breathing suggested by these findings will be explored in future study.

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P02.94
Far Infrared Therapy Emitted by Bioceramics Improves Postural Sway in Young Brazilian University Judokas
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Purpose: The objective of the present study was to evaluate the effect of Far Infrared therapy emitted by bioceramics on the orthostatic balance of Judo practitioners (Judokas) of a Brazilian University Team in a double blind controlled trial.

Methods: A total of 17 athletes (7 women and 10 men; 23 ± 4.75 of age) of the University of South of Santa Catarina (UNISUL) wore either a BioPowerTM bioceramics shirt (bioceramics silkscreened shirt) or a Sham shirt (without bioceramics) during practice (for two hours, five times a week for a period of five months). The Judokas were of seven different weight categories and were evenly divided in the two experimental groups (BioPowerTM or Sham shirt) in such a way that each group had approximately the same amount of athletes of each weight category. Center of pressure (CoP) parameters (length, sway area, velocity in anteroposterior and mediolateral direction) were measured in three 30 sec duration static bipedal standing tasks - the athletes were asked to maintain their eyes opened and stand in a narrow stance on a Balance Platform (T-Plate Balance Platform, Medicapteurs, France). Evaluations were conducted
often unavailable with standard clinical outcomes. The purpose of this study was to explore the experience of licensed massage therapists participating as practitioners in a randomized controlled trial using a standardized massage protocol and sham-massage control.

Methods: In-depth interviews were conducted with seven massage therapists, focusing on challenges, experiences, and expectations of working in a randomized controlled trial. Interviews were conducted via telephone or in-person and electronically recorded. Transcribed interviews were coded and analyzed for common themes.

Results: Six major themes emerged focusing on 1) expectations of participating in a research study, 2) challenges of protocol adherence, 3) misgivings about sham treatment, 4) scheduling and compensation, 5) promotion of the profession of massage therapy and 6) collaboration as part of a research team. Participants reported overall positive experiences with open-mindedness toward functioning as a research massage therapist, appreciation for the group effort required for study success, and contributing to the advancement of the science of massage therapy. Challenges were noted in lack of freedom to adjust treatment per massage training, exclusion of healing intention in sham treatment, and need for adjustment in compensation and scheduling procedures.

Conclusion: Understanding the experience of CAM providers participating in clinical trials can provide insight into more effective study design and have important clinical implications. The apparent conflict between the individualized nature of massage therapy and the necessary standardization of clinical trial interventions was made more discernable through interviewing massage therapists. While largely positive about the experience, the massage therapists highlighted the need in the future for closer attention to aspects unique to CAM practice and clinical trials.

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P02.95 Micronutrient Levels in Adults with Autism Spectrum Disorders

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Purpose: Autism Spectrum Disorders (ASD) are a group of neurodevelopmental disorders that affect 1 in 88 children. Children with ASD often have abnormal micronutrient levels. Vitamin and mineral supplements have been found to improve micronutrient levels in patients with ASD; however, little research has specifically examined the micronutrient levels in adults with ASD.

Methods: This cross-sectional study examined the micronutrient levels in adults with ASD compared to neurotypical controls. Participants are aged 19 and older and have not been taking vitamin or mineral supplements in the past 2 months. Participants completed the Autism Diagnostic Interview-Revised (ADI-R), filled out a 3-day food diary, and completed an intracellular comprehensive micronutrient panel.

Results: Data was collected on a total of 12 participants. Data analysis was completed using an independent-samples-t-test to compare micronutrient levels. Wilcoxon rank-sum test was used to determine differences between the food diary scores. Briefly, we determined whether autism severity is associated with differences in micronutrient levels using a multi-linear regression analysis. Data analysis is ongoing and will be presented at the conference.

Conclusion: Micronutrient deficiencies may impact adults with autism, both behavioral and physiological outcomes. This cross-sectional pilot study provides a foundation for future interventional studies with different micronutrients.

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P02.96 Perceptions of Massage Therapists Serving in a Randomized Controlled Trial

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Purpose: Research focused on investigating the perceptions and experience of CAM practitioners in clinical research is uncommon. Rigorous qualitative methods can provide rich data that is often unavailable with standard clinical outcomes. The purpose of this study was to explore the experience of licensed massage therapists participating as practitioners in a randomized controlled trial where massage therapy was a part of a research team.

Results: The results obtained demonstrated statistically significant decreases (p<0.05) in all CoP parameters evaluated (length, sway area, velocity in anteroposterior and mediolateral direction) in BioPowerTM bioceramics shirt group athletes when compared with Sham shirt group.

Conclusion: Far Infrared therapy emitted by BioPowerTM Bioceramics Shirts positively affected the orthostatic balance of Judo practitioners of a Brazilian University Team.

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P02.97 Reliability and Validity of the Algometer as a Diagnostic Method of Korean Abdominal Examination

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Purpose: Abdominal examination (AE) is an examination of the status of illness by making observation on phrenic area in Korean medicine (KM). Although AE is currently considered an important diagnostic method in KM due to its clinical usage, no study for its objectification and standardization has been conducted. Algometer has been widely used for evaluating myofascial pain and no study investigated the application of algometer to AE. This study aimed to find a surrogate method to quantify AE and to verify its diagnostic value through reliability and validity assessment of algometer.

Methods: Twelve normal subjects and 21 patients with functional dyspepsia have participated this study. The patients were classified into epigastric discomfort group (ED, n=11) and epigastric pain group (EP, n=10) according to consensus of clinicians by actual abdominal examination. After checking subjective epigastric discomfort in all subjects, 2 independent clinicians measured pain pressure threshold (PPT) 2 times on 3 acupuncture points (CV14 and both SP9) using algometer. Then, we
P02.98 Qualitative Analyses from a Prospective Clinical Study of a Whole Systems Ayurvedic Intervention for Breast Cancer Survivorship

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Purpose: The transition from cancer patient to survivor can be difficult because patients experience less medical contact but still suffer physically and psychologically. We developed a Whole Systems Ayurvedic intervention to address this problem and are testing it in a clinical study. We performed qualitative analysis to capture emergent effects of the intervention, inform the link between the intervention and study outcomes, and explore mechanisms.

Methods: Female breast cancer patients who had undergone chemotherapy and had completed primary curative treatment 1–12 months earlier were eligible for the four month individualized intervention that included diet, lifestyle, yoga, and marma (similar to acupressure). Every other participant was selected for semi-structured interviews at baseline and completion. Two investigators coded the data independently using qualitative thematic analysis. Discrepancies were discussed and resolved by refining codes and themes.

Results: Nine out of nine who were selected completed both interviews. We identified four major themes: (1) Participants reported a sense of empowerment from discovering a new awareness of their body cues leading to a deeper understanding of how to implement personalized self-care using natural methods. (2) A greater integration of mind-body led to a sense of strength and resilience, which was attributed to the intervention. (3) Participants appreciated that the intervention was aligned with their health beliefs. (4) Participants reported some challenges in adhering to the intervention.

Conclusion: The Whole Systems Ayurvedic intervention appeared to lead to an enhanced awareness of the body’s innate healing mechanisms and a strong motivation to use them for self-care. The holistic nature of the intervention facilitated integration of mind-body resulting in a sense of increased vitality. These findings correlated with quantitative quality of life measurements indicating improved global health. We hypothesize that the empowerment and sense of wholeness and integration instilled by the Ayurvedic intervention are important mechanistic steps leading to improved health outcomes.

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P02.99 Reiki Improves Health of Oncology Patients: In and Out of the Hospital

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Purpose: The primary purpose of this study was to evaluate the effect of Reiki on perceived stress, happiness and pain for patients at an outpatient cancer center and for inpatient oncology patients.

Methods: This is a repeated measures longitudinal study. Subjects were recruited from the Patrick Dempsey Center for Cancer Hope & Healing (Dempsey Center) and the inpatient Oncology floor at Central Maine Medical Center (CMMC) in Lewiston, Maine between July 9, 2010 and December 31, 2013. The Institutional Review Board at CMMC approved the study. The Reiki Client Quality Monitoring Tool was given to patients before and after a Reiki session. The tool quantified a patient’s experience regarding pain, stress an happiness using a likert scale from 0 to 10.

Results: Inpatient and outpatient oncology patients in Lewiston, Maine reported decreases in pain and stress, and increased happiness after Reiki. Investigators gathered data on subjects’ self-perceptions of pain, stress, and happiness before and after Reiki sessions at an outpatient cancer center. Data were collected on over 600 sessions during 4 years (July 2009–July 2013). Perceived pain decreased 40%, stress decreased 60%, and 15% increase in happiness. Current data trends suggest a significant post-session decreases in pain and stress, and increased happiness for both inpatients and outpatients, yet the improvement is more dramatic for inpatients.

Conclusion: Subjects reported significantly decreased pain and stress, and increased happiness after their Reiki sessions. Our study identified similar results that other early pilots found, that Reiki decreases stress and pain for conventional oncology patients (Lee, Miles 2003; Olsen 2; Tsang, Carlson, & Olson, 2007). Reiki is relatively easy and inexpensive to perform, does not require special equipment, and is non-invasive. It offers an additional nonpharmacological method to improve pain for patients whether they are in the hospital or receiving treatment as an outpatient.

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P02.100 Comparative Effectiveness Research on Different Treatment Options for Rheumatoid Arthritis in Ayurveda

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Purpose: This study aims to compare the outcomes of systematic reviews, clinical trials and reports from actual point of care in real life situations with a view to identify the contradictions in
the findings from these varying sources with reference to Rheumatoid arthritis (RA). Additionally it aims to identify implications of the results for research and clinical practice of Ayurveda.

Methods: Four systematic reviews including one Cochrane review on efficacy of Ayurvedic interventions in management of Rheumatoid arthritis was (RA) reviewed to compare the findings. Rigorous clinical trials evaluating Ayurvedic interventions in RA published in high impact journals that were not included in the systematic reviews were analyzed independently. Outcomes of Ayurvedic treatments in real life clinical practice (20 doctors) were also carefully documented for comparison.

Results: There is a discrepancy between the conclusions of systematic reviews, independent clinical trials and reports from actual point of care. Systematic reviews unanimously agree that there is no evidence indicating efficacy of Ayurvedic treatments in RA. On the other hand, the independent high quality clinical trials, one of which won an award for excellence in methodology contradict one another with respect to the reported clinical outcomes. The findings from real life clinical practice indicate not only strikingly different outcomes, but also treatment methods that have not been adequately studied before.

Conclusion: There is a gap between research and clinical practice in Ayurveda, which is clearly demonstrated by this study on Rheumatoid arthritis. An over reliance on reductionistic methods of research leads to piece meal evaluation of Ayurveda ignoring its complex whole system approach in actual clinical practice. Variations in traditional diagnosis, the choice of treatments and the methodology of research are responsible for the contradictions in the research findings. Best clinical practices at the point of actual care should be identified and studied using appropriate research methodologies.

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P02.101
Complementary and Alternative Medicine for Post-Traumatic Stress Disorder Symptoms: A Systematic Review
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Purpose: To characterize complementary and alternative medicine (CAM) studies for posttraumatic stress disorder (PTSD), evaluate the quality of these studies, and systematically grade the scientific evidence for individual CAM modalities for PTSD.

Methods: Systematic Review. Data sources included MEDLINE, PsyclnFO, CINAHL, Alt HealthWatch, Allied and Complementary Medicine Database, Cochrane Library, Database of Abstracts of Reviews of Effects, Health Technology Assessment Database. Methodological quality was assessed using the Reisch Quality Assessment Tool and Cochrane Risk of Bias. Selection criteria included any study design assessing PTSD outcomes and any CAM intervention. The body of evidence for each modality was assessed with the Natural Standard evidence-based, validated grading rationale. TM

Results: Thirty-two studies with 1289 participants were reviewed, 16 of which were randomized controlled trials. The mean Reisch quality score for all included studies was 78 ± 10 (median 80, range 54–95) out of 100. Most studies used mind-body therapies, including biofeedback (4 studies), hypnosis (3), meditation (9), relaxation (4), Emotional Freedom and Thought Field therapies (2), visualization (1), and yoga (1). Other modalities represented were repetitive transcranial magnetic stimulation (5), acupuncture (2), and Inositol (1), a natural product. Scientific evidence of benefit for PTSD was Strong for repetitive transcranial stimulation and Good for acupuncture, hypnotherapy, meditation, and visualization. Evidence was Unclear or Conflicting for biofeedback, relaxation, Emotional Freedom and Thought Field therapies, yoga, and inositol.

Conclusion: Several CAM modalities may be helpful for improving PTSD symptoms. TMS has the strongest evidence for benefit followed by acupuncture, hypnotherapy, meditation, and visualization. There is insufficient evidence to recommend biofeedback, Emotional Freedom and Thought Field Therapies, relaxation, yoga, and inositol at this time. Considerations for clinical applications and future research recommendations are discussed. Future research should include larger, properly randomized, controlled trials with appropriately selected control groups and rigorous methodology.

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P02.102
Effects of Flower Essences in Individuals with Anxiety
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Purpose: Increasingly, anxiety comes in relation to psychosomatic diseases. The mechanisms of early identification and treatment for this behavior may be useful in the management of daily stress. Floral therapy is part of an emerging field of vibrational, non-invasive therapies. Floral essences, made from savage plants, flowers and field trees, treat personality disorders, instead of disorders in physical conditions. They intend to harmonize the ethereal, emotional and mental body. This study aimed to observe the effects of these flowers, Impatients, Cherry Plum, White Chestnut and Beech in people with anxiety.

Methods: This was a randomized, triple blind study. Data were collected between May and August 2010 with 34 employees of the Center for Improvement in Health Sciences of the Zerbini Foundation, São Paulo - Brazil. Anxiety was assessed using the Inventory for Diagnosis of Anxiety Traits - performed on two different occasions, at the beginning and end of the intervention.

Results: As a result of this study it could be observed that in both groups, anxiety increased, but the difference between the initial and the final mean State-STAI score corresponded to 16.2 in the experimental group and 3.2 in the control group. To ascertain the statistical significance of this difference, the t-test was applied, which indicated a significant difference (p = 0.001).

Conclusion: After an intervention using floral essences and the analysis of the anxiety measurement instrument’s results, a greater drop in anxiety scores was ascertained in the experimental group when compared with the control group, confirming that the Bach floral remedies chosen in this study positively affected the anxiety decrease. The statistical tests demonstrated a statistically significant difference between the two groups.

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P02.103
“I Hope to Find …”: What We Can Learn From Analyzing Patients’ Goals in Integrative Medicine
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Purpose: This study describes patients’ most commonly stated goals for initiating Integrative Medicine (IM) treatment with accompanying information about their current health status, IM practices, and overall self-rated health.

Methods: 202 patients completed an intake questionnaire at the University of California, San Diego Center for Integrative Medicine. Before initiating the first physician visit, patients were asked: “What are your goals for, or what do you hope to accomplish from this visit?” Patients’ responses were qualitatively analyzed to determine the most common emergent themes. These themes were contextualized using additional data gathered in the intake questionnaire, such as patient demographics, most common symptoms, most common IM modalities currently used, and overall self-rated health.

Results: Qualitative analyses of the patients’ goals of care revealed three primary themes. First, patients were interested in finding different treatments for known medical conditions (51%): “I know what’s wrong with me, but I want a different treatment.” Secondly, patients expressed a desire for optimal health (32%): “Make me a better person.” Finally, 12% of patients visited their IM physician in order to find answers to their “mystery” symptoms: “What’s wrong with me?” Patients in each of the three groups utilized very distinct language to describe their aims. However, patients in all categories were similar demographically, and nearly all reported multiple symptoms. Although patients across all categories reported high self-ratings of overall health, less than half of patients (45%) reported current usage of any of the 30 listed IM modalities.

Conclusion: Although differing with respect to primary goals of care, patients demonstrated similarities in most other areas of interest to clinicians: symptoms, self-rated health, and overall use of IM therapies. This suggests that although patients may present with similar medical profiles, goals of care differ appreciably and may in fact be a key difference when determining personalized treatment plans.

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P02.104
Medical Students Familiarity, Experience and Attitudes Towards Complementary and Alternative Medicine
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Purpose: The present study aims to assess familiarity, experience and attitude towards Complementary and Alternative Medicine (CAM) of students entering Mayo Medical School (MMS).


Results: There were 42 students entering in 2011, 48 in 2012 and 2013. Age and sex distribution were similar (45 females, median age 22 years). Response rates 2011-57%, 2012-60%, and 2013-81%. Questions addressing familiarity and personal experience with 7 treatments/techniques (acupuncture, Ayurveda, biofeedback, chiropractic, homeopathy, massage, mindfulness techniques) revealed that students entering in 2013 had similar understanding of these treatments compared to the 2011/2012 students. The best understood treatment in all years was massage with 97% of students indicating they are familiar (96%-2011; 93%-2012, 100%-2013) and 68% having personally used it (71%-2011, 83%-2012, 56%-2013). Questions regarding familiarity with 8 herbs (echinacea, feverfew, garlic, ginger, ginkgo biloba, ginseng, kava, and St. John’s wort) indicated that students entering in 2013 had similar understanding of these herbs compared to the 2011/2012 students. The herb students were most familiar with was garlic with 68% of students indicating their familiarity with this herb (71%-2011, 72%-2012 and 64%-2013). Questions regarding 9 factors on students’ attitude towards CAM showed that “evidence demonstrating the treatments/herbs physiologic mechanism” was the most convincing tool. There was no change over the 3 years.

Conclusion: This study shows that students entering MMS have a basic understanding of CAM, which however has not changed during a 3 year period. The same survey has and will be sent at 2 additional career time points during the 3rd year and at exit from MMS to follow the development of attitude and knowledge.

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P02.105
Effect of Electromagnetic Fields on Highly Diluted Remedies Measured by Ultraviolet Spectroscopy
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Purpose: In homeopathy or anthroposophically extended medicine high dilutions are used. They showed significant differences in ultraviolet light (UV) transmission between controls and different dilution levels. Exposing such dilutions to physical factors such as UV light or elevated temperature (37°C) yielded significantly different UV transmissions values compared to unexposed dilutions. The aim was to test whether electromagnetic fields (EMF) of a mobile phone affect the UV absorbance of dilutions of Atropa belladonna (Ab) and quartz.

Methods: Commercially available dilutions of Ab 4×, 6×, 12×, 15×, 30× and of quartz 6×, 12×, 15×, 30× were investigated. On 5 days, 4 samples of each dilution were exposed to the EMF by a mobile phone at 900 MHz (GSM) with an output power of 2 W for 3h. Control samples were kept in a separate room. UV-absorbance of the samples in the range from 190 to 340 nm was measured in randomized order. The average absorbance from 200 to 340 nm and from 200 to 240 nm was compared between exposed and unexposed samples by a dependent t-test.

Results: Between unexposed and exposed dilutions of Ab and quartz no significant differences were detected, except for quartz 12× over the range from 200 to 340 nm.
Conclusion: Exposure of high dilutions of Ab and quartz to GSM EMF of a mobile phone did not alter UV absorbance of these dilutions.

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P02.106
The Influence of Inner and Heard Speech in Arts Speech Therapy on Brain Oxygenation and Hemodynamics
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Purpose: Artistic speech therapy is applied in anthroposophically extended medicine to treat several diseases. The aim is to understand the physiology by investigating the effect of inner and heard speech on brain hemodynamics and oxygenation and analyzing whether these changes were affected by changes in arterial carbon dioxide pressure.

Methods: In 29 healthy adult volunteers changes in cerebral absolute oxygenhemoglobin ([O2Hb]), deoxynhemoglobin ([HHb]), total hemoglobin ([tHb]) concentrations and tissue oxygen saturation (StO2) were measured by functional near-infrared spectroscopy (fNIRS). End-tidal CO2 (PETCO2) was assessed by capnography. Each subject performed six tasks: inner speech, heard speech from a person and heard speech from a record with each two different recitation texts: hexameter and alliteration and analyzing whether these changes were affected by changes in arterial carbon dioxide pressure.

Results: Significant changes during tasks: A decrease in StO2, [O2Hb], [tHb] and PETCO2 (only for inner speech); an increase in [HHb]. There was a significant difference between hexameter and alliteration. Particularly, changes in [tHb] at the left prefrontal cortex during tasks and after them were statistically different. Furthermore we found significant relations between changes in [O2Hb], [HHb], [tHb] or StO2 and the participants’ age, the baseline PETCO2, or certain speech tasks.

Conclusion: During the inner speech, hyperventilation led to a decrease in StO2, [O2Hb], [tHb] and PETCO2 (only for inner speech); an increase in [HHb]. There was a significant difference between hexameter and alliteration. Particularly, changes in [tHb] at the left prefrontal cortex during tasks and after them were statistically different. Furthermore we found significant relations between changes in [O2Hb], [HHb], [tHb] or StO2 and the participants’ age, the baseline PETCO2, or certain speech tasks.

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P02.108
Mixed Carotenoids Alter Lipid-Related Risk Factors In Vivo
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Purpose: To compare the in vivo effects of food- and dietary supplement-based mixed carotenoids on lipid-related risk factors and biomarkers of antioxidant status, oxidative stress, and inflammation.

Methods: A single masked, randomized, placebo-controlled clinical trial was performed in 60 healthy adults who consumed less than 3.5 servings of fruits and vegetables per day. Participants were allocated to one of four groups: placebo, carotenoid meals, or one of two commercial mixed carotenoid dietary supplements (DS#1 and DS#2) for 30 days. The following parameters were measured in the fasting state at baseline and after 30-days of supplementation: serum carotenoid concentration, c-reactive protein (CRP), total cholesterol (TC), LDL-C, oxidized LDL, oxygen radical absorbance capacity (ORAC), f2-isoprostanes, and gamma-glutamyltransferase (GGT). Parameters were compared to placebo by unpaired, t-tests and between all groups by ANOVA. Pairwise testing with Tukey’s test was performed for
parameters in which $p < 0.05$ by ANOVA. Serial 24-hour diet recalls were performed to ensure dietary consistency.  

**Results:** Total serum carotenoids increased in all groups except placebo. Reductions in total cholesterol and LDL cholesterol differed by group ($p < 0.05$ ANOVA), with DS#1 and DS#2 showing greater reductions than food-based carotenoids; TC: $-4.8$ mg/dl and $-11.2$ mg/dl vs. $+5.8$ mg/dl, $p = 0.04$ ANOVA; LDL: $-7.3$ mg/dl and $-10.2$ mg/dl vs. $+4.6$ mg/dl, $p = 0.002$ ANOVA. oxLDL also reduced in all three carotenoid groups, without significant differences between groups ($p = 0.58$ ANOVA). CRP, ORAC, I2-isoprostanes and GGT did not change within or between randomization groups.  

**Conclusion:** Increasing serum carotenoid fractions in people who do not consume recommended intakes of fruits and vegetables modifies cardiovascular risk factors, including lipid-related risk, without altering antioxidant or inflammatory status. Dietary supplementation is an efficacious way to increase serum carotenoid status in healthy humans. 

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**P02.109**  
Cardiac Medications and Dietary Supplement Interactions in a Low Income Hospitalized Patient Population  
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**Purpose:** To identify patient characteristics associated with the use of dangerous combinations of dietary supplements and cardiac prescription medications in an urban underserved patient population. 

**Methods:** Prescriptions medication users were identified from the RED-lit trials in order to assess the prevalence and risk factors of dangerous supplement-drug interactions, as identified by the Natural Medicines Comprehensive Database (NMCD). Diuretics, ACE inhibitors, ARBs, antiarrhythmics, anticoagulants, cholesterol-lowering medications were included. Supplements with the potential to interact with the above medications included vitamins C and D, multivitamins, calcium, magnesium, fish oil/omega fatty acids, cranberry, garlic, ginseng, ginger, ginkgo biloba, and St. John’s Wort. We defined a participant as having a dangerous interaction (DI) if at index admission he or she had at least one supplement-drug combination with a moderate or high level of severity according to the NMCD. We examined sociodemographic and clinical characteristics for crude ($\chi^2$ or t-tests) and adjusted (multivariable logistic regression) association with the DI outcome.  

**Results:** Of 558 prescription medication users, there were 121 taking at least one cardiac drug and at least one dietary supplement simultaneously. Out of the 121, 110 (90.1%) had at least one DI, which indicates that patients with concomitant use of cardiac drugs and common dietary supplements are at high risk of DIs. A multivariable logistic regression model (adjusted for gender, age, insurance, income and illegal drug use), shows that every additional product taken significantly increases the odds of having a dangerous cardiac supplement-drug interaction [OR:1.064, 95% CI(1.023,1.107)], and that those with a high school education are significantly less likely to have a DI than those with a college education [OR:0.530, 95%CI(0.310, 0.897)].  

**Conclusion:** Patients taking a combination of cardiac prescription medications and dietary supplements are at a high risk of dangerous supplement-drug interaction. 

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**P02.110**  
Comparison of Polyethylene Glycol 3350 and Product Made from Saccharum Officinarum L. for Treatment of Chronic Constipation; A Double-Blind Clinical Trial  
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(2) Tehran University of Medical Science, Iran  
(3) Department of Pediatric Gastroenterology, Children’s Hospital Medical Center, Iran  
(4) Department of Traditional Medicine of Shahid Beheshti, University of Medical Science, Iran  

**Purpose:** Studies have shown that functional constipation is the most common problem among children and current treatments of chronic functional constipation are effective only for half of children. In fact, recurrence is common. Based on recent medicine books, although there is no effective treatment with low-level side-effects for constipation, considering traditional practices might leads to increase the probability of detection of new treatments, reduction of side effects and medical costs as well. Therefore, conducting new medical researches and experiments in order to find effective treatments is an important issue.  

**Methods:** This study includes children who were less than 10 years old and had constipation with defined criteria. Among 60 participants, half of them were treated with new product from Saccharum officinarum L(SOL), while others were treated with Polyethylene Glycol (PEG) as a control. Before treatment careful physical examination was applied to all the patients in order to exclude other types of pediatric constipation. Based on patient’s weight, proper dose of SOL pill and PEG were prescribed for a period of three weeks. After completion of medication period, medical conditions of patients in order to compare with medical conditions of the patients before the treatment.  

**Results:** After one week 96.3 percent of the patient’s appetite grew significantly. After three weeks, defecation of 59.3 percent of patients dramatically increased from the average of one time per a week to everyday. In patients who did not achieve acceptable results after a period of three weeks, treatment continued for one week more. After the end of this period, no recurrence was found. Compared to treatment with PEG, 70 percent of patient’s appetite remained unchanged and 86.7 percent of disease recurrence observed.  

**Conclusion:** Saccharum officinarum L is effective and cost benefit treatment for pediatric constipation. 

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**P02.111**  
Natural Medicines in Schizophrenia: A Systematic Review  
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**Contact:**
Conclusion:

In our study, we assessed the evidence for natural medicines with and without antipsychotics in treating symptoms or reducing side effects of antipsychotics in schizophrenia. Despite progress in treatment options in the last century, the results of pharmacological treatment of schizophrenia are frequently unsatisfactory. Therefore some patients use natural medicines although it is unclear whether natural medicines are effective and safe. We assessed the evidence for natural medicines with and without antipsychotics in treating symptoms or reducing side effects of antipsychotics in schizophrenia.

Methods:

A systematic review until April 2013. Only RCTs with a Jadad score of 3 or higher, were included.

Results:

105 RCTs were identified. Evidence was found for glycine, sarcosine, NAC, some Chinese and ayurvedic herbs, ginkgo biloba, estradiol and vitamin B6 for improving symptoms of schizophrenia when added to antipsychotics (glycine not when added to clozapine). Inconclusive or no evidence was found for omega-3, D-serine, D-alanine, D-cycloserine, B vitamins, vitamin C, dehydroepiandrosteron (DHEA), pregnenolone (PREG), inositol, gamma-hydroxybutyrate (GHB) and des-tyr-gamma-endorphin when added to antipsychotics. Omega-3 without antipsychotics might be beneficial in the prevention of schizophrenia. In one large study, ayurvedic herbs seemed effective without antipsychotics. Other agents without antipsychotics (vitamin B3, vitamin C, sarcosine, glycine, Protolin) were not effective or had only been tested in single or small trials. Ginkgo and vitamin B6 seemed to be effective in reducing side effects of antipsychotics (tardive dyskinesia and akathisia). The evidence for reducing side effects of antipsychotics by omega-3, melatonin and DHEA appeared to be inconclusive. All natural agents produced only mild or no side effects.

Conclusion:

High quality research on natural medicines for schizophrenia is scarce. However, there is emerging evidence for improved outcome for glycine, sarcosine, NAC, some Chinese and ayurvedic herbs, ginkgo biloba, estradiol and vitamin B6, all with only mild or no side effects. Most study samples are small, the study periods are generally short, the studies only cover a modest part of the world’s population and most results need replication.

Contact:

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Purpose:

Laminaria japonica (L. japonica) and lactic acid bacteria (LAB) are main components of traditional fermented Korean food ‘Kimchi’, which has been widely consumed in Korea. There have been studies which investigated that each L. japonica and LAB may alter human intestinal microbiota composition and has a positive effect on various digestive problems. However, few clinical trials have reported the benefits of L. japonica when combined with LAB for human intestinal microbiota. Therefore, this study was designed to evaluate the effects of L. japonica with representative LAB on the human intestine.

Methods:

Forty participants with no known digestive diseases were randomly assigned to 1 of 2 combination groups: (1) L. japonica with LAB and (2) L. japonica with placebo LAB. The study agents were administered for 4 weeks, and the follow-up period was 2 weeks. The primary outcome measure was the number of each of the 7 LAB species (Bifidobacterium brevis, Bifidobacterium lactis, Bifidobacterium longum, Lactobacillus acidophilus, Lactobacillus plantarum, Lactobacillus rhamnosus, and Streptococcus thermophilus) in the human intestine, and the secondary outcome measures included the Korean version of the Gastrointestinal Symptom Rating Scale, the World Health Organization Quality of Life, and bowel functions. The primary outcome was evaluated before and after administration of the study agents (0 and 4 weeks), and the secondary outcomes were evaluated at 0, 4, and 6 weeks.

Results:

The number of 4 of 7 LAB species was found to be significantly increased in the L. japonica with LAB group (2 species; P<0.05, other 2 species; P<0.001) and 5 species were significantly different from those of the placebo group (2 species; P<0.05, 1 species; P<0.01, another 2 species P<0.001). The secondary outcome measures did not change significantly.

Conclusion:

L. japonica with LAB facilitated the proliferation of beneficial human intestinal microbiota.

Contact:

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Purpose:

Eleutherococcus senticosus root in hypertensive patients: an unjustified contraindication unmasked?

Karina Kraft (1), Olaf Kelber (2), Mathias Schmidt (3)

Methods:

A systematic database search was conducted in Embase and Medline. Key words were ((Eleutherococcus) or (Acanthopanax)) and its contraindication,

Results:

A large number of clinical and preclinical studies as well as reviews and monographs was identified and evaluated systematically. Two original publications could be found, which have been presented in a review from 1985. This was directly or indirectly referenced to in all subsequent monographs and
This study aimed to assess the effect of Chilgi-Tang on arterial hypertension.

**Purpose:**

Korea University, Pusan National University, Yangsan, Kyeongnam, South Jung Nam Kwon (1), Hye-Yoon Lee (1), Hyun-Ju Choi (1), Young-Ju Yun (1)

**Purpose:** This study aimed to assess the effect of Chilgi-Tang on arterial hypertension.

**Methods:** This is a retrospective study of two cases of complete AV block treated with Chilgi-Tang, conducted with institutional review boards (IRB) approval. These two patients refused pacemaker-insertion, and they voluntarily visited traditional Korean medicine (TKM) treatment. For patient 1 (P1), she experienced usually scotodinia, palpitation, stuffiness and sometimes syncope. Complete AV-block was diagnosed by 24 hours holter monitoring. Mokhyangsunki-San was given three times a day for 7 days, and then Chilgi-Tang for next 31 days. For patient 2 (P2), she was diagnosed as complete AV-block by electrocardiogram (EKG) and had been suffered from exertional dyspnea. Bunsinkleum was given three times for 5 days, and then Chilgi-Tang for last 83 days.

**Results:** For P1, clinical symptoms maintained during taking Mokhyangsunki-San. After the prescription change, these symptoms started to be alleviated and nearly disappeared. Syncope did not reoccur during 2 years follow-up. For P2, resting time during walking certain distance was shortened consistently. Resting time was 15 minutes at the first assessment and 22 minutes at the third, that is the longest. It decreased to 2 minutes and 56 second at the last. The average of radial pulse rate of 6am, 12pm and 8pm was 33.3 bpm at the first and it increased to 35.7 bpm at the last.

**Conclusion:** Chilgi-Tang could be an alternative medication to treat clinical symptoms caused by complete AV block. Subjective symptoms can be improved with Chilgi-Tang, but change in objective measurement such as EKG or pulse rate is circumscribed. Reduction in resting time and increase in average pulse rate suggest possibility of Chilgi-Tang to treat complete AV block and its symptoms. Therefore, further studies with larger number of subjects and appropriate outcome measurement are needed.

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**P02.115**

Efficacy and Safety of Ayurvedic Herbs in Diarrhea-Predominant Irritable Bowel Syndrome – A Randomized Controlled Cross-Over Trial

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**Purpose:** The irritable bowel syndrome (IBS) is one of the most common gastrointestinal disorders with prevalence up to 45%. Patients with IBS are regularly using phytotherapy; however clinical evidence for their efficacy is lacking. This study aimed to test the efficacy of an Ayurvedic herbal preparation in the treatment of IBS.

**Methods:** This was a randomized double-blind placebo-controlled cross-over trial with two treatments administered in 3 treatment periods each. The verum preparation of curry, pomegranate and turmeric (ratio 6:3:1) as well as the placebo were delivered as grinded powder in sealed opaque containers, and in each period patients were advised to prepare a decoction from the powder twice daily for 4 weeks, followed by one week wash-out phase. The primary outcome measure was symptom severity (IBS Symptom Severity Score); secondary outcomes included quality of life, psychological distress, and safety.

**Results:** 32 patients were included in the trial (19 females, 50.3 ± 11.9 years). 9 patients dropped out at various phases during the trial. Compliance was moderate with 2/3 of the patients being highly compliant. No differences between verum and placebo were found for symptom severity (Difference 24.10; 95% CI: –17.12; 65.32), responder rates were not different with 18.9% and 31.1% for verum and placebo respectively. Moreover, no statistically significant differences were found for secondary outcomes. Altogether 9 (0) and 4 (2) minor adverse events (serious adverse events) were recorded in verum and placebo periods respectively.

**Conclusion:** An Ayurvedic herbal preparation from curry, pomegranate and turmeric seems to be no more effective in improving irritable bowel symptoms than placebo. The preparation appeared to be safe.

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**P02.116**

Efficacy of Caraway Oil Poultices in Treating Irritable Bowel Syndrome: A Randomized Controlled Cross-Over Trial

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**Purpose:** Irritable bowel syndrome (IBS) is a common gastrointestinal disorder, with a prevalence approaching 45%. Poultices are frequently used for self-management, but no evidence exists to support such use. This study tested the efficacy of a caraway oil poultice for treating IBS.
**P02.117**

**Effects of a Dermatological Formulation Containing Mesembryanthemum Crystallinum Extracts on Skin Hydration Levels**

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**Purpose:** Mesembryanthemum crystallinum also known as ice plant is a succulent plant native in the Mediterranean region of Europe and Africa. Covered with glistening bladder cells its leaves are able to store huge capacities of water. Thus dermatological formulations containing the pressed juice of Mesembryanthemum crystallinum are traditionally expected to have an impact on human skin hydration levels. To investigate this effect we conducted a three-armed controlled pilot study.

**Methods:** In 6 skin healthy female subjects (mean age: 49 +/- 11 years) with dry (n = 1) or very dry skin (n = 5) either the cream containing Mesembryanthemum crystallinum or only the basic cream was applied to the right or left volar forearm. A third region on the left volar forearm without any applications served as a control group. To evaluate hydration effects corneometer measurement was used before and after two days of application of the product. Corneometer units below 30 indicate very dry skin, while normal skin is defined by values above 40 arbitrary Corneometer units.

**Results:** Dermatological formulations containing pressed juice of Mesembryanthemum crystallinum show significant effects (p = 0.011) on skin hydration (25.8 +/- 5.8 pre vs. 46.6 +/- 9.2 post treatment) compared to untreated skin (26.3 +/- 6.0 pre vs. 33.8 +/- 6.0 post treatment) and a statistical trend (p = 0.11) compared to skin treated with the basic cream formulation only (25.1 +/- 4.7 pre vs. 41.9 +/- 7.3 post treatment). During the test no adverse events were recognized which points towards a good safety profile of the formulation.

**Conclusion:** This pilot study on the traditional medical plant Mesembryanthemum crystallinum has shown promising skin hydrating effects. Further studies should explore the underlying mechanisms in more detail and should reveal more information on safety issues. In addition studies on patients with skin irritations should be conducted to obtain more information on the impact of Mesembryanthemum crystallinum cream on patients’ skin quality of life.

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**P02.118**

**Effect of the Probiotic Saccharomyces Boulardii on Cholesterol Levels and Additional Cardiovascular Biomarkers in Hypercholesterolemic Adults**

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**Purpose:** The majority of probiotic research has focused on the gastrointestinal tract and the microbiome. However, emerging research indicates that probiotics may also have clinical applications in the cardiovascular system, including the reduction of blood cholesterol levels. Several bacterial probiotic strains have been shown to lower cholesterol in human subjects. Saccharomyces boulardii, a probiotic yeast that has demonstrated efficacy in the treatment of certain gastrointestinal illnesses, may also affect cholesterol levels. If probiotic S. boulardii does lower cholesterol levels, it may provide an alternative or adjunctive therapy to standard lipid-lowering medications. This study aimed to examine the effect of S. boulardii on standard blood cholesterol levels, as well as lipoprotein particles and additional cardiovascular biomarkers.

**Methods:** Twelve hypercholesterolemic participants were recruited into a single-arm, open-label pilot study. Participants took encapsulated S. boulardii daily over an 8-week period. Outcome measures included cholesterol levels (total cholesterol, LDL-C, HDL-C, triglycerides), lipoprotein particles (VLDL-P, remnant lipoprotein (RLP-P), total LDL-P, LDL III-P, LDL IV-P, total HDL-P, HDL 2b-P), and additional cardiovascular biomarkers (apo B-100, lipoprotein (a), high-sensitivity C-reactive protein, homocysteine, fibrinogen, and insulin).

**Results:** Eight weeks of daily supplementation with S. boulardii resulted in non-significant decreases in total cholesterol, LDL-C, HDL-C, and triglycerides. There was a 15.46% reduction in remnant lipoprotein particles (RLP-P), which was statistically significant (p = 0.01). Levels of additional lipoprotein particles and cardiovascular biomarkers were not significantly altered.

**Conclusion:** Saccharomyces boulardii supplementation lowers remnant lipoprotein, a highly atherogenic lipoprotein particle, in hypercholesterolemic adults. Although the reductions in standard cholesterol levels were not significant in this pilot study, they were similar to changes reported in previous studies.
P02.119

Willow Bark Extract STW 33-I is Safe and Effective in the Long-Term Treatment of Outpatients with Chronic Musculoskeletal Pain

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Purpose: To examine the effectiveness of a recently developed special extract from willow bark with an enhanced content of polyphenols under pragmatic conditions.

Methods: Open observational trial with patients suffering from chronic musculoskeletal pain of different etiology (fibromyalgia, chronic back pain, osteoarthritis) in a multi-centre outpatient setting (university outpatient pain centre, pain centres, practices with family medicine). Duration 24 weeks, primary endpoint overall pain (VAS) measured at 6 visits, secondary endpoint pain as registered in diaries, and physicians’ judgement on tolerability. Pre-existing pain medication could be continued (esp. NSAID and opioids).

Results: 436 patients (ITT) from 74 study centres were included. Mean age was 59.3±12.1 y, 108 (24.5%) male, leading etiologies (multiplicity possible): low back pain 61 (59.4%), osteoarthritis 245 (56.2%), fibromyalgia 67 (15.4%), others 77 (17.7%), 258 (59.2%) with more than 5 y duration. 277 (63.5%) patients (PP) completed the study after 24 weeks, 159 (36.5%) terminated the study prematurely mainly due to lack of efficacy. Mean VAS (0–100) dropped continuously from baseline 58±4 to 22.6 to 31.8±22.5 after 24 weeks, reaching significance (p<0.05, WILCOXON test for related samples) at visit 2 after 3 weeks and any time thereafter. There was no significant difference between ITT and PP populations in VAS outcome. Decrease of pain by diaries followed a similar pattern to VAS at the 6 visits. Adverse events were reported more often at 3 weeks (4.8%) than at 24 weeks (0.3%). By using the conservative LOCF method, as well as a linear model fitted in the transformed domain to regress the wavelet coefficients to a set of interesting frequencies, significant influences of the variables age, BMI, and concomitant treatment could be identified as predictors.

Conclusion: Phytotherapy with STW 33-I might be effective in long-term pain therapy of musculoskeletal etiologies. It seems appealing, to do further studies of this type with consumption of NSAID and opioids as primary parameters.

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P02.120

Comparing the Effect of Ozonated Olive Oil and Clotrimazole Cream for the Treatment of Vulvovaginal Candidiasis

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Purpose: Vulvovaginal candidiasis is the most common infection of vulvovagina which manifests with itching, burning sensation and leucorrhoea. Conventional treatments are azoles to them tolerance have been reported especially in immunosuppressed patients. New studies suggested the antifungal effects of ozone which is the allotropic form of oxygen. This study compares the effect of ozononated olive oil with clotrimazole in the treatment of vulvovaginal candidiasis.

Methods: One hundred patients with confirmed vulvovaginal candidiasis were randomly classified to two groups and treated by ozonated olive oil or clotrimazole for 7 days. The study outcomes were changes in itching, burning, leucorrhoea and culture before and after the treatment; which were evaluated by an interview and paraclinical examination. Statistical analysis was done by SPSS software, version 17. The significance level stood at 0.05.

Results: Ozone and clotrimazole both reduced the symptoms significantly and led to negative specimen culture (P<0.05). There was no significant difference between two groups in their effect on itching, leucorrhoea and culture (P>0.05). However, ozone decreased burning sensation significantly better than clotrimazole (P<0.05).

Conclusion: Considering the potential efficacy of ozonated olive oil in the improvement of clinical and paraclinical aspects in patients with vulvovaginal candidiasis, it could be suggested as an effective topical treatment in these patients.

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P02.121 LB

Effect of Acupuncture on Heart Rate Variability: A Systematic Review

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Purpose: To summarize all relevant trials and critically evaluate the effect of acupuncture on heart rate variability (HRV).

Methods: This was a systematic review with meta-analysis. Keyword search was conducted in 7 databases for randomized controlled trials (RCTs) on this topic. Data extraction and risk of bias were done.

Results: Fourteen studies were included. Results showed a decreasing modulating effect of acupuncture on low frequency (LF) and low frequency to high frequency ratio (LF/HF ratio) of HRV for non-healthy subjects and on normalized low frequency (LF norm) in healthy subjects. Significant decreasing effect on HF component and LF/HF ratio of HRV when acupuncture was performed on ST36 among healthy subjects and PC6 among both healthy and non-healthy subjects respectively.

Conclusion: This study partially supports the possible effect of acupuncture in modulating the LF of HRV in both healthy and non-healthy subjects, which is contradictory to Lee and colleagues’ (2010) review. They reported that acupuncture did not have any convincing effect on HRV in healthy subjects. More published work is needed in this area to determine if HRV can be an indicator for the therapeutic effect of acupuncture because the
P02.122 LB
Acupuncture for the Treatment of Insomnia—A Pilot Study
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Purpose: Insomnia is a common problem with significant psychological and general health comorbidities and is often resistant to treatment. Specific aims included: 1. To determine the efficacy of acupuncture on self-report and objective measures of sleep. 2. To determine the impact of acupuncture on daytime manifestations of insomnia. 3. To explore the impact of acupuncture on physiologic measures of hyperarousal.

Methods: 47 subjects were randomized to receive verum-vs-sham acupuncture in a protocol based on TCM principles. Verum treatment involved 15 needles with mild manual stimulation over 30 minutes. Park Sham Needles were used for the sham protocol. Subjects were seen twice weekly for 4 weeks then weekly for 4 weeks. Self-report measures included sleep quality, fatigue, anxiety, and depression. Objective outcomes included polysomnography, wrist-actigraphy, and psychophysiologic testing of HRV. Assessments were obtained at baseline, end-of-intervention, and 3-months post-treatment. Intention-to-treat analysis was used.

Results: Four subjects dropped out. Significant improvement was seen in both groups over time on self-report measures of insomnia and secondary symptoms, but there was no between group difference. The key objective measure, sleep-efficiency on polysomnography, did not improve in either group. Physiologic measures of hyperarousal, including EEG delta power on polysomnography, and HRV, improved over time, but there were no significant group differences. On secondary analysis there was no correlation between primary sleep measures and physiologic measures of hyperarousal. Nor was there a difference in physiologic measures of hyperarousal between responders and non-responders to the intervention, independent of group assignment.

Conclusion: Based on TCM literature, acupuncture shows promise for insomnia. In this trial, acupuncture was no more effective than placebo. Subjects in both groups showed improvement in self-report measures of insomnia as well as secondary symptoms. The primary weakness of this study was small sample size. While this trial is considered negative, acupuncture for insomnia merits further study.

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P02.123 LB
Effects of Acupuncture on Pain and Inflammation in Pediatric Emergency Department Patients with Acute Appendicitis
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Purpose: Pain associated with pediatric appendicitis is often treated with narcotics. Acupuncture has been shown to treat various medical conditions, including acute and chronic pain, and there is speculation that it has anti-inflammatory effects. The current pilot study, conducted in a Pediatric Emergency Department (PED), sought to treat acute pain in pediatric patients diagnosed with appendicitis, using acupuncture. The study was designed to examine the impact of acupuncture on patients’ subjective pain ratings and inflammatory bio-markers.

Methods: PED patients (7–17 years) conventionally evaluated for appendicitis were recruited. After diagnosis, consented patients reported their pain using 3 tools: Visual Analogue Scale (VAS), Colored Analogue Scale (CAS) and Faces Pain Scale-Revised (FPS-R). As a measure of inflammation, routine White Blood Count (WBC) and C-reactive protein (CRP) values were obtained. A licensed acupuncturist performed Japanese acupuncture after initial evaluations. Two minutes prior to removing the needles and 30 minutes post-needleling, WBC/CRP tests were again obtained. Twenty minutes after acupuncture was completed, the patient’s self-reported pain was reassessed.

Results: Six Latino patients (4M, 2F), 10–17 years (M = 15 years) and with no previous acupuncture experience, were recruited. Pre/post-acupuncture pain scores (medians) were: VAS 46 vs. 32; CAS 6.1 vs. 4.8; FPS-R 5 vs. 4. Acupuncture lasted 22–32 minutes (median = 28.5 minutes). At Time 1, 2 and 3, respectively (medians): WBC 13.2, 11.8, 11.4; and CRP 4.5, 4.9, 5.1. No complications occurred.

Conclusion: These pilot data suggest that acupuncture may be a feasible and effective treatment modality for decreasing self-reported pain and inflammation as measured by WBC. Acupuncture may prove to be an effective non-pharmacological intervention for treating PED patients with acute appendicitis pain.

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P02.124 LB
Effect of Acupuncture on Expression of CREB and p-CREB in Hippocampus and Prefrontal Cortex of Depression Rats
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Purpose: To explore effects of acupuncture on expression of CREB and p-CREB in hippocampus and prefrontal cortex of chronic stress rats.

Methods: Rats were randomly divided into six groups (n = 10 each): normal, normal + manual acupuncture (MA), model + Electric Acupuncture (EA), model + MA and model + paroxetine. Chronic stress model was induced by alternations of the following methods: water deprivation (24h), day-night inversion (12h), cold water swimming (4°C, 5min), cage shaking on a rocking bed (30min), and restraint (3h), inductions were performed every day for four weeks. For acupuncture treatment, Baihui (GV 20), Yintang (GV 29) and Neiguan (PC6) were selected; stimulation parameters were 2/100 Hz, 0.2mA for 10min, every 2 days for four weeks. 10 mg/day of paroxetine was given for the model + paroxetine group. The rats were decapitated and hippocampus and prefrontal cortex were harvested after four-week intervention. Western-blot was applied to detect the expression of CREB and p-CREB in hippocampus and prefrontal cortex.

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Results: After four-week intervention, CREB expression in hippocampus of model group decreased remarkably compared with those in normal group (P<0.05). The expression of CREB in model +EA group increased obviously compared to those in model +MA group (P<0.05). p-CREB level in hippocampus and prefrontal cortex of model group reduced significantly in contrast with those in normal group (P<0.01). Hippocampal p-CREB level in model +MA group, model +EA group and model +paroxetine group increased substantially compared with those in model group (P<0.01). In comparison with model +MA group, model +EA(P<0.05) and model +paroxetine group(P<0.01) exhibited higher p-CREB level with significant differences. Differences between normal group and normal +MA were not statistically significant.

Conclusion: Acupuncture might reverse chronic stress through an underlying mechanism of CREB and P-CREB expression regulation.

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P02.125 LB
Using NIH PROMIS Computer Adaptive Tests in a Prospective, Longitudinal Pragmatic Trial of Acupuncture Therapy for People with Cancer and Other Medical Conditions

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Purpose: To examine prospective, longitudinal patient reported outcomes of symptom status, quality of life and treatment expectations in an acupuncture program at a comprehensive cancer and integrative medicine clinic.

Methods: Following IRB approval, a research coordinator consented eligible patients. Using Assessment Center (www.assessmentcenter.net), patients completed demographic & clinical forms and PROMIS computer adaptive tests of health related quality of life for up to 20 acupuncture sessions. Data were analyzed using SAS.

Results: We enrolled 81 patients in total. The majority were female (77%), Caucasian (82%) and in their early 50’s. The median number of items delivered via CAT was 4 per domain. Compared to acupuncture naive participants, those who received prior acupuncture treatment reported significantly higher anxiety, fatigue, sleep disturbance, cancer symptoms and lower positive affect at baseline. By the second assessment however, these differences became nonexistent. Participants who held greater baseline acupuncture expectations (e.g., their situation would improve a lot, they’d be able to cope better, their symptoms would disappear, their energy would increase) reported significantly higher fatigue, pain interference, cancer symptoms and problems with physical functioning. We speculate that those with higher expectations invest more in its potential to help them due to greater symptom severity, and/or those with lower expectations invest less in its ability to help because they have less severe symptoms. Between time 1 and time 2, participants reported significant improvements in anxiety, depression and fatigue. Longitudinal models demonstrated significant linear improvements over time in anxiety, depression, pain interference, and sleep disturbance.

Conclusion: This study pragmatically examined longitudinal changes in QOL in a medical patient sample following acupuncture using CATs from the NIH PROMIS initiative. Although pretreatment acupuncture expectations highlighted sub-group differences in outcomes at baseline, linear growth models demonstrated the positive effects of acupuncture over time on anxiety, depression, pain interference, and sleep disturbance.

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P02.126 LB
Massage Satisfaction in Children and Adolescents with Chronic Pain

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Purpose: We examined patient satisfaction of massage provided for children and adolescents with cancer during or prior to their first treatment at a pediatric pain management clinic.

Methods: A sample of 45 children and adolescents receiving massage for the first time participated. Participants completed a brief survey before and after each massage. Participants rated their pain, calmness, comfort, relaxation, and anxiety with 10-cm Visual Analog Scales (VAS) ranging from 0 indicated “strongly disagree” to 10 indicated “strong agree.” The FACES Pain Scale Revised (FPS-R) was also used to assess pain intensity.

Results: There were significant decreases in pain measured by the VAS (t(44)=2.50, p=.02) and pain measured by the FPS-R (t(41)=−4.50, p=.00) after the first massage treatment. There were also significant increases in calmness (t(42)=−4.97, p=.00) and relaxation (t(44)=−3.32, p=.00). There were no significant changes in anxiety from pre- to post-treatment.

Conclusion: Overall, patients’ first massage treatment was effective in reducing pain and increasing calmness, comfort, and relaxation. Findings demonstrate the efficacy of massage for children and adolescents with various types of chronic pain.

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P02.127 LB
Optimal Timing of Mindfulness-Based Stress Reduction in Cancer: Research Synthesis and State of the Science

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Purpose: Mindfulness-based stress reduction (MBSR) has been evaluated for the management of symptoms in cancer survivors mainly in the post-treatment period. However, patients experience symptom distress before the completion of treatment, and MBSR may be most beneficial for patients if offered earlier. The purpose of this review is to explore the efficacy of the timing of MBSR during the cancer trajectory on psychosocial outcomes in patients with cancer.

Methods: Articles were retrieved from Pubmed and Science Direct using MBSR, cancer, symptoms, chemotherapy, and radiation as key search terms. Inclusion criteria: 1) quantitative articles published during or prior to 2013; 2) adult patients with cancer; 3) MBSR as the main intervention; and 4) psychosocial variables as measurable outcomes. Exclusion criteria: 1) qualitative studies; 2) reviews or meta-analysis; and 3) dissertations.
Results: From the 14 eligible articles, 9 were conducted in patients with breast cancer and 5 in patients with heterogeneous types of cancer. Two studies enrolled patients receiving treatment, and the remaining 12 studies were with patients who had completed treatment. Five studies were randomized controlled trials (RCTs), and the remaining 9 studies were interventional. Patients receiving treatment while participating in MBSR experienced significant improvements in quality of life (QOL), depression, anxiety, and mood (chemotherapy and/or radiation); psychosocial coping, helplessness, hostility, and emotional control (radiation only). These two studies demonstrated the feasibility of further testing MBSR as an adjunct therapy to improve QOL in patients receiving treatment. Post-treatment RCTs showed a positive effect on psychosocial variables at the immediate post-intervention, 3 or 4 months follow-ups. However, the effects of the intervention were not sustained at 12 or 24 months.

Conclusion: Timing of the MBSR intervention in the cancer experience may be an important variable to consider. MBSR during treatment is a viable intervention to test.

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P02.128 LB
Diet-Gene Interactions May Impact Inflammation Status in Patients with Chronic Venous Leg Ulcers
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Purpose: Chronic venous leg ulcers (CVLUs) are serious conditions costing the U.S. healthcare system ~$3.5 billion annually. CVLU pathobiology involves persistent systemic inflammation. Inflammation mediators (eicosanoids) are generated from n-6 and n-3 polyunsaturated fatty acids (PUFAs) contained in plasma and cell membranes. Eicosanoids generated from n-6 arachidonic acid (AA) generally have much stronger proinflammatory actions than those from n-3 eicosapentaenoic acid (EPA). Thus, higher AA/EPA ratios indicate more inflammation than balanced ratios. Diet (AA) generally have much stronger proinflammatory actions than balanced ratios. Diet (AA)

Methods: Blood samples were collected from all participants during the onetime study visit to determine average plasma AA/EPA ratios and genotype for rs174537. Questionnaires elicited participants’ opinions about dietary supplements.

Results: On average, the AA/EPA ratio for this sample of CVLU patients was 21.7 (SD = 7.87) and the genotype distribution of rs174537 was 17% GG (high converters to AA) and 67% TT (modest converters to AA) with 17% undetermined.

Conclusion: CVLU patients in this study had high AA/EPA ratios indicating high-level inflammation. The frequency distribution of rs174537 genotypes suggests that diet-gene interactions may be affecting AA/EPA ratios and thus, inflammatory status. EPA supplementation that considers genotype may be an effective strategy to reduce AA/EPA ratios (and thus, inflammation) and improve healing outcomes for patients with these recalcitrant wounds.

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P02.129 LB
An Analysis of Meditation Consultations in an Integrative Oncology Outpatient Clinic
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Purpose: The majority of cancer patients use some complementary medicine modality. Mind-body practices, and especially meditation, are amongst the most utilized. Research shows that they help cancer patients manage psychological distress and control symptoms such as pain, nausea, and sleep disturbances. However, the effects of a single meditation session on self-reported symptoms, including physical, psychological and symptom distress in an outpatient setting, are largely unknown. After more than 10 years of conducting group meditation classes for our patients and caregivers, in 2011 we started an outpatient meditation consultation in our Integrative Medicine Center.

Methods: All patients receiving an individual meditation consultation (60 minute initial visits, and 30 minute follow-up visits) at our Integrative Medicine Center outpatient clinic from May 2011 through December 2013, were asked to complete a modified Edmonton Symptom Assessment Scale (ESAS; scale from 0–10, where 10 is most severe). Data were analyzed examining the pre- and post-meditation scores using paired t-tests.

Results: Our analysis included 81 meditation visits for 121 participants (mean 1.2 visits/person) over 32 months. The ESAS revealed a significant reduction from pre- to post-meditation session in physical, psychological, and symptom distress component scores (−7.85; −4.6; and −12.4, respectively; all p < 0.0001). The greatest mean reductions for individual symptoms were for: Anxiety [-1.9], Fatigue [-1.9], Distress [-1.8], Well Being [-1.6]; Sleep [-1.5]; and Pain [-1.0]; all changes reaching statistically (all p < 0.0001) and clinically significant thresholds (decrease in symptom score ≥ 1).

Conclusion: A single meditation session resulted in acute relief in multiple self-reported symptoms, with the greatest reduction in Anxiety, Fatigue and Distress symptom scores. Further research with a larger sample size is needed to better understand the symptoms that meditation can help control and the frequency of self-practice outside of the clinic to help maintain the long-term benefits.

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P02.130 LB
Mindfulness-Based Cognitive Therapy for Youth with Anxiety Disorders at Risk for Bipolar Disorder: A Pilot Trial
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Purpose: Children of parents with bipolar disorder are at an increased risk of developing mood disorders compared to children without bipolar parents. Early signs of bipolar disorder include symptoms of anxiety, depression, and inattention. Pharmacological interventions for treating these symptoms are
often poorly tolerated and may accelerate the onset of manic symptoms. Mindfulness-Based Cognitive Therapy-Child (MBCT-C), an evidence-based manualized 12-week group intervention, has been shown to effectively treat mood and anxiety disorders in children/adolescents. However, there has been no examination of MBCT-C for youth at high risk for bipolar disorder. We examined the effects of MBCT-C on outcomes among youth with anxiety disorders and a familial risk for bipolar disorder.

Methods: Participants were 10 children/adolescents (Mage = 13.17, SD = 1.93; 80% girls; 40% White/African-American) who met DSM-IV criteria for an anxiety disorder (i.e., generalized anxiety disorder, separation anxiety disorder, panic disorder or social phobia) and had at least one parent with bipolar I disorder. A within-subjects, pre-post design was used to examine changes in anxiety, mindfulness, and emotion regulation associated with participation in MBCT-C.

Results: Significant decreases were seen in both child-rated (Mpre = 18.5 vs. Mpost = 4.7, t = 10.8, p < .01) and clinician-rated anxiety symptoms (Mpre = 11.1 vs. Mpost = 4.3, t = 6.1, p < .01). Additionally, reductions in clinician-rated anxiety symptoms were significantly correlated with improvements in mindfulness (r = -.69, p < .05) and emotion regulation (r = -.82, p < .05). No significant changes were seen pre-post intervention in depressive symptoms, mania symptoms, mindfulness, or emotion regulation - though all changes were in the expected direction.

Conclusion: Findings support the preliminary efficacy of MBCT-C in reducing anxiety among youth at risk for bipolar disorder, and suggest that changes in anxiety symptoms may be associated with changes in mindfulness and emotion regulation processes. Further research utilizing an active control group, larger sample size, and objective markers is warranted.

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P02.132 LB

Acupuncture and Mindfulness-Based Stress Reduction Among Female Child Abuse Survivors: A Randomized Waitlist-Controlled Pilot Study

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Purpose: Adult survivors of childhood sexual abuse can suffer psychological consequences, including Post Traumatic Stress Disorder (PTSD), depression, and pain throughout their lifetime. The present study examined the efficacy of MBSR and Acupuncture (AT) compared to Wait-List Control (WLC) among female child abuse survivors to reduce psychological distress.

Methods: Eighty-three (N = 83) adult survivors were randomized to either MBSR, AT, or a WLC. Self-report assessments, including the PTSD Checklist (PCL), the Beck Depression Inventory (BDI), the Pittsburgh Sleep Quality Inventory (PSQI) and the Mindfulness Attention Awareness Scale (MAAS), were conducted at baseline, 4, 8 and 12 weeks. MBSR and AT treatments occurred between baseline and 8 weeks. The SAS PROC MIXED procedure for repeated measures was used to compute fixed effects.

Results: The participants ranged from 21 to 72 years (mean = 45.8 years); 56% (N = 47) had a Bachelor’s or graduate degree; 47% married (N = 39); 50% were European American, 29% were African American; and household income $20k 28% (N = 23%); $20–49k 24% (N = 20); $50–99k 33% (N = 27). Analyses indicate a significant interaction of time and groups. MBSR and AT significantly improved mindfulness (F = 5.85; p = .00101). AT significantly improved PTSD symptoms (F = 3.37; p = .0052) and Sleep Quality (F = 3.74; p = .0076). MBSR and AT significantly improved depressive symptoms (F = 2.78; p = .0165), but this effect was not sustained at 8 or 12 weeks.

Conclusion: Particularly interesting is the effectiveness of AT for mindfulness, as well as PTSD symptoms and sleep quality. The results warrant further investigation of AT for mindfulness, and perhaps studies of the combination of these two approaches for this important patient population.

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P02.131 LB

An On-the-Job Mindfulness-Based Intervention for Pediatric ICU Nurses: A Pilot Study

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Purpose: Studies have demonstrated the prevalence of nurse stress and burnout (Aiken et al., 2002; Huffman & Rittenmeyer, 2012). Mindfulness interventions provide aspects of social support, stress reduction and the promotion of self-efficacy (Chiesa & Serretti, 2009). However, there are few mindfulness interventions for nurses (Cohen-Katz et al., 2005; Mackenzie et al. 2006; Pipe et al., 2009) and none for nurses on the pediatric intensive care unit (PICU). We assessed the feasibility of a 5-minute mindfulness meditation for nurses on the PICU before each work-shift to investigate change in nursing stress, burnout, self-compassion, mindfulness and job satisfaction.

Methods: Using a pre-post-test design we studied 38 predominately White female nurses under 40 years of age with less than 5 years of nursing experience at an urban academic pediatric hospital. The Nursing Stress Scale, the Mindfulness Attention Awareness Scale and the Self-Compassion Scale were administered at baseline, post-intervention and one month following.

Results: The intervention was found to be feasible for nurses on the PICU. A repeated measures ANOVA demonstrated significant decreases in stress from baseline to post intervention and maintained one month following the intervention. There was also a significant decline in nurse burnout. Additionally, there were no significant differences in nurses that had previous meditation experience and those that did not have meditation experiences in decreases in stress.

Conclusion: Findings highlight the feasibility and efficacy of a short intervention conducted on the job. Additional research, such as randomized control trials, are needed to further establish the effectiveness of the intervention.

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The relaxation-focussed yoga programme was developed in accordance with Delphi recommendations for the design and reporting of yoga interventions for musculoskeletal conditions.

Methods: Participants were recruited via a hospital database, and randomized to either an 8-week yoga programme (one 75-minute group practice and three 20-minute home practice sessions per week), or a usual care control. Feasibility outcomes included recruitment rates, retention, adherence, participant satisfaction, and adverse events. Additionally, secondary outcomes of RA-related pain, sleep quality, functional disability, disease activity, quality of life, mood, and fatigue were measured at baseline (week 0), week 9 (primary time point), and week 12 (follow-up).

Results: Of 103 patients identified from the database, 26 met eligibility criteria (25% recruitment; 96% female; mean age 54 years). Thirteen yoga participants (100%) and 12 usual care participants satisfied eligibility criteria (25% recruitment; 96% female; mean age 54 years). Thirteen yoga participants (100%) and 12 usual care participants completed both the Week 9 and Week 12 assessments. Yoga participants completed a median of seven of the eight group classes and 14 of the 24 home practice sessions. Eleven yoga participants (85%) reported the study was not bothersome, although several depended on the use of specialized equipment to practice the yoga postures. No serious adverse events were attributed to the study. No group effects of yoga were attributed to the study. No group effects of yoga in treating children aged 7 to 14 with depression and bipolar disorder.

Conclusion: The relaxation-focussed yoga programme was feasible, safe, and highly acceptable to study participants. Adverse events were predominantly mild, and may potentially be reduced through a more conservative introduction of yoga postures over the 8-week intervention. Based on these findings a fully powered trial of yoga for RA is recommended, preceded by focus groups to investigate methods to improve recruitment of males and adherence to home practice.

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P02.135 LB
Characteristics of Families Who Enroll in Non-Pharmacologic Treatment Studies for Childhood Mood Disorders
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Purpose: This report characterizes children enrolled to date (enrollment ends 5/31/14) in two NIH-funded trials examining omega3 fatty acids and psychotherapy in treating children aged 7 to 14 with depression or bipolar disorder—not otherwise specified.

Methods: Half the children were randomized into Individual-Family Psychoeducational Psychotherapy (IF-PEP), which includes several sessions focused on improving healthy habits. Pre-post change in health behaviors was compared for those in IF-PEP (n = 37) vs active monitoring (n = 33).

Results: At baseline, parents’ top choice/s of a behavior to change was: 42% eat more fruits/vegetables; 28% play outside more often; 24.3% reduce screen time; 22.9% drink more water; 11.4% drink less sugared beverages; 8.6% eat less fast food; 5.7% remove TV from bedroom; and 0% switch to low-fat milk. In terms of baseline healthy habits, children ate 2.2 servings of fruit or vegetables daily, breakfast 5.5 (±2.2) times weekly, and fast food 2.0 (±1.1) times weekly. Beverage consumption included the following daily: water 3.2 (±2.5); fruit/sports drinks 1.7 (±4.8); juice 1.1 (±1.4); reduced fat milk/soy milk/ahmld milk 1.6 (±1.4); soda 1.3 (±2.0); and whole milk 0.6 (±0.9). Families had 4.3 (±2.3) dinners together weekly. Children had 3.0 (±2.6) hours/day of screen-time and 1.6 (±1.3) hours/day of active play. 47.1% of children had a TV and 12.9% had a computer or tablet in their bedroom. Participation in IF-PEP was associated with small to medium effect sizes for increased water (Cohen’s d = .40) and whole milk consumption (Cohen’s d = .32), and decreased soda (Cohen’s d = .39), and fast food consumption (Cohen’s d = .27). Overall, there was a small effect size for decreased soda consumption for all participants (Cohen’s d = .23).

Conclusion: IF-PEP contributed to improved health habits.

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Few studies have investigated the effectiveness of integrative medicine (IM) therapies on pain and anxiety among cardiology inpatients. Nonpharmacologic intervention was of interest to a wide range of families.

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P02.136 LB
Effects of Inpatient Integrative Medicine on Cardiovascular Patients
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Purpose: Few studies have investigated the effectiveness of integrative medicine (IM) therapies on pain and anxiety among cardiology inpatients.

Methods: Retrospective data obtained from electronic medical records (EMR) identified patients with a cardiology ICD-9 code who were admitted to a large Midwestern hospital between July 1, 2009 and December 31, 2012. Outcomes were change in patient-reported pain and anxiety, rated before and after IM treatments using a numeric scale (0–10).

Results: Of 57,295 hospital admissions over the study period, 6,589 (11.5%) included IM therapy. Older patients had reduced odds of receiving any IM therapy (OR: 0.98, (0.97–0.99)) and females had 96% (OR: 1.96, (1.84–2.09)) higher odds of receiving any IM therapy compared to males. Compared to other diseases of the circulatory system, admissions from hypertensive diseases and IM therapy for pain control.

Conclusions: Traditional Chinese medicine accounted for the majority of IM sessions. As a whole, IM therapies resulted in significant reductions in pain and anxiety in hospitalized patients after joint replacement surgery.

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P02.137 LB
Inpatient Integrative Medicine for Pain and Anxiety After Joint Replacement Surgery
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Purpose: To investigate the effectiveness of integrative medicine (IM) therapies on pain and anxiety after knee and hip joint replacement surgery.

Methods: Retrospective data obtained from electronic medical records identified inpatients who underwent knee and hip joint replacement surgery at a large Midwestern hospital between July 1, 2009 and December 31, 2012. Primary outcomes were change in patient-reported pain and anxiety, rated before and after IM treatments using a numeric scale (0–10).

Results: There were 3,834 hospital admissions for joint replacement surgery over the study period, of which 1,648 (43.0%) included IM therapy. Of 2,482 total IM sessions administered during these admissions, 116 (4.7%) were bodywork, 88 (3.6%) were mind-body and energy therapies, 2,063 (83.1%) were traditional Chinese medicine therapies, and 215 (8.7%) were a combination of these three categories. Each additional year of age was associated with a 2% reduction in the odds of receiving any IM therapy (OR: 0.98, (0.97–0.99)) and females had 34% higher odds of receiving any IM therapy compared to males (OR: 1.34, (1.08–1.68)). Females were twice as likely to receive IM therapy after knee replacement surgery as compared to hip replacement surgery (OR: 2.01, (1.49–2.21)), while males had 48% higher odds of receiving any IM therapy after knee replacement surgery as compared to hip replacement surgery (OR: 1.48, (1.19–1.84)). After receiving IM therapy, patients averaged a 41.3% (38.9–43.6%) reduction in pain. Males receiving hip replacement surgery had a greater pain reduction compared to males receiving knee replacement surgery (48.6% versus 36.1%, p-value=0.003), while women’s pain reduction did not significantly differ by surgery type (43.5% versus 41.1%, p-value=0.479). IM therapy patients averaged a 6.7% (5.6–7.9%) reduction in anxiety.

Conclusions: Traditional Chinese medicine accounted for the majority of IM sessions. As a whole, IM therapies resulted in significant reductions in pain and anxiety in hospitalized patients after joint replacement surgery.

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P02.138 LB
Information Medicine as Delivered by Intention Host Devices: A Case Report
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**Purpose:** Physics research has conclusively shown that 1) directed human intention can be implanted into a device, 2) the resulting “intention host” device (IHD) can subsequently change living systems in a specific and individual direction, 3) an IHD can be implanted with intention or information highly specific for a patient. In conjunction with the division of rheumatology of a tertiary hospital, we present the first case utilizing an IHD for treatment of refractory arthritis. This novel approach is termed “Information Medicine” (INFOMED) as distinct from pharmaceutical and energy medicine.

**Methods:** The patient, a 58-year-old Caucasian male with a 6-year history of refractory pain secondary to seronegative spondyloarthropathy (HLA B 27 positive), had failed aggressive conventional care including biologics. The patient and the imprinting team cooperated to determine physical, emotional, and mental goals of the 18-month INFOMED program. Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) outcome scores and qualitative measures were obtained every 3 months. Sequential MRI of the left elbow was obtained every 6 months. The IHD was re-imprinted every 3 months. During the INFOMED program, no conventional DMARDs were prescribed.

**Results:** Compared with baseline, the emotional and mental health improved progressively with each 3-month cycle of INFOMED. Baseline BASDAI score of 5 (active; range, 0–10) was unchanged at each time point indicating stable joint function and pain level. MRI of the left elbow demonstrated minimal enthesal enhancement without synovitis at the 12-month point.

**Conclusion:** INFOMED is personalized health-care. No direct physical contact is necessary between the physicist and the patient, with the implanted-IHD carrying the information to the recipient. There is an “inside-out” sequence of health-gain, that is, mental and emotional functioning improved significantly ahead of any impact on physical pain. INFOMED may be a future frontier for cost effective, highly personalized medical interventions.

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**P02.139 LB**

**Potential Effect of Saffron as an Antiplatelet Drug in Patients with Autoimmune Diseases**

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**Purpose:** The risk for thrombosis is significantly increased in chronic autoimmune diseases, affecting both venous and arterial vessels. Activated platelets are known to participate in thrombus formation and growth. Platelet factor 4 (PF-4) and beta-thromboglobulin (b-TG) are known to be platelet activation markers. Saffron (Crocus sativus L.) is classified as a beneficial herb in the treatment of “Oketsu,” eliminating blood stagnation in Japanese Traditional Medicine. The clinical symptoms of “Oketsu” include feeling cold and arthralgia. The pathological condition of “Oketsu” is considered to be increased blood viscosity and microvascular disorders. Here, we investigated the clinical effect of saffron on the symptoms of “Oketsu” in patients with autoimmune diseases. At the same time, we measured the plasma levels of PF-4 and b-TG for evaluation of the treatment with Saffron.

**Methods:** 69 patients (63 women and 6 men, mean age 55.3 ± 16.1, Systemic Lupus Erythematosus: 24, Rheumatoid Arthritis: 8, Polymyalgia Rheumatica: 7, Mixed Connective Tissue Disease: 5, Sjögren’s Syndrome: 4, Antiphospholipid Syndrome: 2, other diseases: 19) were studied. They were administered saffron (300 mg ~ 900 mg/day) with traditional Kampo medicine for a month. We measured PF-4 and b-TG in pre- and post-saffron treatment periods. Moreover we evaluated the clinical symptoms of “Oketsu” in pre- and post-saffron treatment periods.

**Results:** The plasma levels of PF-4 and b-TG significantly decreased after saffron therapy (PF-4: before 49.6 ± 29.8, after 24.0 ± 19.6 ng/ml, b-TG: before 117.5 ± 64.0, after 64.6 ± 47.1 ng/ml; paired t-test, p < 0.0001, respectively ). The clinical symptoms of “Oketsu” improved (78.7%, n = 37/47). No patients experienced side effects to saffron’s medication.

**Conclusion:** These results suggest that saffron had a dose-dependent effect in chronic autoimmune disease patients with activated platelets.

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**P02.140 LB**

**Vitamin D Sufficiency Status May Effect Circulating Levels of the Anti-Aging Protein Klotho**

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**Purpose:** Vitamin D insufficiency, serum 25(OH)D ≤ 33 ng/mL, is associated with increased disease risk and all-cause mortality in population-based studies. The study aim is to determine if correcting 25(OH)D insufficiency results in increased circulating levels of Klotho protein, an anti-aging biomarker, which is tightly involved in vitamin D homeostasis, and could potentially contribute to the health benefits of 25(OH)D sufficient status.

**Methods:** This is an ancillary study to a 12-week clinical trial (N = 66), in which 10,000 IU/day of oral vitD3 was administered (drop, capsule or tablet) to adults (18–65 years) diagnosed with 25(OH)D insufficiency, in Seattle, WA and Kailua Kona, HI. In the Seattle cohort, 25(OH)D sufficient controls (n = 35) were matched to the treatment group (n = 40) by age, gender, BMI, and baseline vitD intake and sun exposure, using Mahalanobis metric matching. Mean (SE) changes in 25(OH)D (ng/dL) and Klotho (pg/mL) levels from treatment, compared to matched control, were assessed using ANOVA and adjusted for multiple comparisons using Tukey’s test.

**Results:** ANOVA of matched pairs (n = 29) showed significant (p < 0.0001) between-group differences in 25(OH)D levels post treatment 69.3 (33.0), compared to insufficient levels at baseline 20.9 (12.2) and to sufficient controls 42.0 (10.6). The results for Klotho showed a mean increase of 75.3 (33.0) circulating Klotho levels in the treatment group (p = 0.03), which approached significance (p = 0.07) after adjustment for multiple comparisons with Tukey’s test, between-group differences all p > 0.05. Non-significant changes in levels of 1,25(OH) 23, Ca, Pi, PTH and FGF23 were also observed.

**Conclusion:** These results suggest a significant increase in 25(OH)D and an increase in circulating Klotho approaching significance, after 12 weeks of vitD3 supplementation and repletion of 25(OH)D. Interpretation of the results is limited because post-hoc analysis showed insufficient power to measure the observed effect. These findings represent the first evidence
that correction of 25(OH)D insufficiency may effect the circulating levels of the anti-aging protein Klotho in humans.

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**P02.141 LB**  
**Comparative Analysis of Radioimmunoassay and LC/MS/MS for the Determination of Serum Vitamin D Levels**

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**Purpose:** Vitamin D insufficiency, serum 25(OH)D ≤ 30 ng/mL, is becoming a more commonly ordered preventative screening measure in medical care. The study is a comparative analysis of two analytical methods for the analysis of serum 25(OH)D: 1) DiaSorin radioimmunoassay (RIA), and 2) tandem mass spectrometry (LC-MS/MS). The aim of this study is to determine the correlation of the results from the two methods and to report the proportion of reclassification of 25(OH)D insufficiency status.

**Methods:** Serum 25(OH)D was measured in blood samples from study subjects (N=109) participating in a comparative effectiveness trial of vitamin D supplementation to correct vitamin D insufficiency. Serum 25(OH)D was measured using both the RIA and tandem mass spectrometry (LC-MS/MS). The 25(OH)D (ng/mL) levels are reported as mean (SD) and paired t-test was used to assess between group differences in 25(OH)D. Correlation is reported as Pearson’s correlation coefficient. Fisher’s exact test was used to determine the odds ratio (OR) of reclassification.

**Results:** The data showed mean 25(OH)D levels 43.0 (24.3) using RIA, and 41.3 (17.9) using LC-MS/MS, which were not significantly different between groups, p > 0.05. From the analyses, 35% were 25(OH)D sufficient using RIA and 27.5% using LC-MS/MS. With 2.8% being reclassified as sufficient and 10.1% as insufficient, the likelihood of reclassification of 25(OH)D status was OR 67.1, 95%CI 17.6 to 256.2, p < 0.001, comparing RIA to LC-MS/MS. A strong correlation was observed between the results using RIA to LC-MS/MS analytical methods (Pearson’s r = 0.78, 95%CI 0.70 to 0.85, p < 0.0001).

**Conclusion:** These results show a significant correlation between the RIA and LC-MS/MS methods, suggesting that the LC-MS/MS and RIA analytical methods are comparable. However, there is a high likelihood of reclassification of vitamin D status between methods. Care should be taken in interpreting clinical and study results using different analytical methodologies for the determination of serum 25(OH)D.

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**P02.143 LB**  
**An Evidence Map of the Effects of Acupuncture**

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**Purpose:** The Yo-Yin concept is integral to making a diagnosis using the techniques of Kampo (Sho). Unfortunately, there is little objective data to confirm the validity of these concepts. This study was done, using Holter ECG to determine heart rate variability (HRV), to investigate possible differences in the autonomic nervous function of patients taking Yo and Yin medicines.

**Methods:** Twenty men and 67 women (mean age 52.4 years) who were prescribed a Kampo medicine after diagnosis using Kampo techniques and for whom the medication was effective were enrolled. Assessment of autonomic function was made by HRV obtained with the MemCalc/Chiram software after Holter ECG. The patients were divided into Yo- (n=49) and Yin-sho groups (n=38) according to the prescribed Kampo.

**Results:** BMI was significantly higher in the Yo-sho than the Yin-sho group (P=0.015), but no significant differences were found in the other baseline characteristics or in the daytime HRV of the Yo-sho and Yin-sho groups. However, nocturnal ultra-low frequency (ULF1, 0.0001–0.003Hz) and ULF2 (0.0003–0.003Hz) were significantly higher in Yin-sho group than in the Yo-sho group (P=0.030, 0.016) suggesting higher variation of autonomic nervous function according to the stage of sleep. Multivariate analysis extracted BMI (23.0 ± kg/m2) and ULF-1 (≥ 1150) as independent factors associated with a differential diagnosis of Yo-sho or Yin-sho (Odds ratio (OR) 11.63, P=0.002, OR 0.30, P=0.038 respectively). Furthermore, when the sleep period was divided into the early and late stages, ULF1 was significantly higher in the Yin-sho than in the Yo-sho group in the latter phase of sleep (P=0.023).

**Conclusion:** A difference related to the sleep phase was found in the autonomic nervous function of patients treated with Yo and Yin-sho Kampo medicines.

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**P02.142 LB**  
**Nocturnal Difference in Ultra-Low Frequency Band of the Heart Rate Variability of Patients Stratified by Kampo Medicine Prescription**

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**Purpose:** The Yo-Yin concept is integral to making a diagnosis using the techniques of Kampo (Sho). Unfortunately, there is little objective data to confirm the validity of these concepts. This study was done, using Holter ECG to determine heart rate variability (HRV), to investigate possible differences in the autonomic nervous function of patients taking Yo and Yin medicines.

**Methods:** Twenty men and 67 women (mean age 52.4 years) who were prescribed a Kampo medicine after diagnosis using Kampo techniques and for whom the medication was effective were enrolled. Assessment of autonomic function was made by HRV obtained with the MemCalc/Chiram software after Holter ECG. The patients were divided into Yo- (n=49) and Yin-sho groups (n=38) according to the prescribed Kampo.

**Results:** BMI was significantly higher in the Yo-sho than the Yin-sho group (P=0.015), but no significant differences were found in the other baseline characteristics or in the daytime HRV of the Yo-sho and Yin-sho groups. However, nocturnal ultra-low frequency (ULF1, 0.0001–0.003Hz) and ULF2 (0.0003–0.003Hz) were significantly higher in Yin-sho group than in the Yo-sho group (P=0.030, 0.016) suggesting higher variation of autonomic nervous function according to the stage of sleep. Multivariate analysis extracted BMI (23.0 ± kg/m2) and ULF-1 (≥ 1150) as independent factors associated with a differential diagnosis of Yo-sho or Yin-sho (Odds ratio (OR) 11.63, P=0.002, OR 0.30, P=0.038 respectively). Furthermore, when the sleep period was divided into the early and late stages, ULF1 was significantly higher in the Yin-sho than in the Yo-sho group in the latter phase of sleep (P=0.023).

**Conclusion:** A difference related to the sleep phase was found in the autonomic nervous function of patients treated with Yo and Yin-sho Kampo medicines.

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**P02.143 LB**  
**An Evidence Map of the Effects of Acupuncture**

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**Purpose:** The available published literature on acupuncture is extensive, including many systematic reviews and meta-analyses summarizing individual studies on the effectiveness of acupuncture. The project objective was to produce an evidence map that provides a visual overview of the distribution of evidence (both what is known and where there is little or no evidence).

**Methods:** We conducted a review of systematic reviews of acupuncture published from 2005 to 2013. The evidence was distilled into bubble plots representing the distribution of evidence for acupuncture on three dimensions: the estimated literature size, the estimated treatment effect and the confidence in the identified effect. We examined indications of pain (59 reviews, 20 conditions); mental health (17 reviews, 9 conditions); wellness (43 reviews, 21 conditions); or other indications (48 views, 20 conditions); mental health (17 reviews, 9 conditions); wellness (43 reviews, 21 conditions); or other indications (48 reviews, 48 reviews). We rated the evidence as showing no effect, unclear effect, potentially positive effect, or positive effect.
Results: The evidence reflected acupuncture as having a positive effect for chronic pain, headache, and migraine, while the evidence reflected a potential positive effect for a number of other indications including dysmenorrhea, cancer pain, insomnia, smoking cessation, postoperative nausea and vomiting, depression, and schizophrenia treatment. Despite a substantial number of research studies, judging from published systematic reviews there is unclear evidence for acupuncture’s effectiveness on back and neck pain, postoperative pain, fibromyalgia, cancer-treatment associated adverse events, irritable bowel syndrome, rhinitis, blood pressure, menopausal symptoms, and opiate addiction.

Conclusion: This effort provides only a broad overview of the existing evidence base. More detailed, definitive answers can be obtained only by conducting individual systematic reviews for each clinical indication. The therapeutic effectiveness of acupuncture is unclear and further research is needed regarding a substantial number of specific clinical indications related to wellness and mental health indications.

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P02.144 LB
A Randomized Trial Comparing a Brief Meditation Retreat to a Vacation: Effects on Daily Well-Being
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Purpose: Research on brief meditation retreats shows psychological benefits. Most studies utilize at-home control groups, immersed in work and life. A major criticism is the extent to which the benefits result from meditation or from being away from their typical lives and relaxing elsewhere - “the vacation effect”. Here, we examined changes in daily wellbeing and stressful experiences during a 5-day resort stay in a group of non-meditators randomized to attend meditation and yoga training or to relax at the resort.

Methods: We randomized 66 eligible women, aged 31 to 60, with no meditation experience into a resort control or a meditation retreat group (The Chopra Center), staying at the same location, given the same diet, had blood draws on Day 1 and 5 of the study, and had lectures on health (resort) or meditation, yoga, awareness and self-reflection (retreat). Nightly, end-of-day diaries were completed and assessed affect, stressful event occurrence and reactivity. Stressful events were objectively rated for severity. Paired t-tests comparing day 1 to 5 within groups were calculated to examine the differences in changes between the first and last day for positive and negative affect, stressor severity appraisal, control, and rumination.

Results: Positive affect significantly increased and negative affect decreased the first to last day of the study in the retreat group, but not in the control group. Both groups felt less ‘stressed’ by the day’s most significant stressor at the end (p < .001), and this is despite no change in rater-coded severity. Only retreat women reported significantly greater control over the stressor (p = .01), and all participants reported decreased rumination from first to last day, with more pronounced changes in retreatants (p < .001).

Conclusion: These findings suggest benefits to retreat over vacation in promoting a more resilient response to daily stressors and positive affect.

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P02.145 LB
The Effectiveness of an Energy-Based Healing Modality to Improve Medical, Psychosocial, and Spiritual Outcomes: Survey Development and Pilot-testing
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Purpose: This project develops and pilot-tests a survey using practitioners of an energy-healing modality, Brennan Healing Science (BHS; Brennan, 1993), to determine which medical, psychosocial, and spiritual outcomes are beneficially impacted. This survey was sent to 40 BHS faculty/practitioners (9.9 ± 6.3 years of experience), and will be administered to hundreds of others worldwide, as a preliminary step to determine which conditions may be amenable to energy-healing and to investigation via controlled experiments.

Methods: This self-report survey comprises symptom checklists and free-response prompts for qualitative case study descriptions. Widely-used physical symptom checklists (Brim et al., 2004; Pennebaker, 1982) were adapted to measure 39 physical symptoms. Checklists of 43 psychosocial symptoms/stressors, and 17 spiritual/other experiences (e.g. improved relationships, self-esteem, and spiritual awareness) were developed through consultation with BHS faculty and a psychiatrist. A 4-point Likert scale measured changes in medical, psychosocial, and spiritual/other outcomes. Checklists assessed which BHS techniques were utilized by healers. Free-response prompts assessed noteworthy aspects of each case. Survey refinement followed two interactive pilot-tests with BHS faculty/practitioners.

Results: Results represent 48 clients treated for 17 (± 15) sessions by 17 healers (44% response rate). Healers reported that an average of 25.4% of physical symptoms improved completely; 13% did not improve. Arthritis/back/neck pain, thyroid conditions, and insomnia improved at least somewhat; BHS did not impact stroke, ulcers, or varicose veins. An average of 27.8% of psychosocial symptoms/stressors improved completely; 3.5% did not improve. In all cases, anxiety/stress, guilt, and anger improved at least somewhat; disordered eating was modestly impacted. An average of 35.2% of spiritual/other outcomes improved completely; 6.8% did not improve. In all cases, peacefulness, self-awareness/acceptance, and insight/perspective improved at least somewhat.

Conclusion: Spiritual factors improved most in response to BHS, followed by psychosocial symptoms/stressors (e.g. anxiety/stress), and physical symptoms (e.g. pain). Online survey administration will be used to extend these preliminary results.

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P02.146 LB
Pilot Study of the Efficacy of Pulse Stimulation Treatment (PSTIM™) for Chemotherapy-Induced Peripheral Neuropathy: A Retrospective Chart Review
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Purpose: Peripheral neuropathy is a common problem that can occur during chemotherapy treatment, resulting in pain, numbness, and reduced function. One promising yet understudied integrative care therapy that may offer pain relief for patients is
PSTIM™, a percutaneously placed microchip-controlled pulsed neurotransmitter that provides electrical pulses to specific peripheral nerves in the ear. The purpose of this study was to examine the efficacy of PSTIM™ in reducing pain and improving function in patients with chemotherapy-induced peripheral neuropathy (CIPN).

**Methods:** We conducted a mixed-method retrospective chart review of patients receiving PSTIM™ for CIPN by an integrative oncologist. Charts between Jan/2012 and Nov/2013 were reviewed for a) demographic/clinical variables (e.g., number of PSTIM™ treatments); b) patient pain ratings pre-post PSTIM™ (0–10 scale); and c) functional outcomes (e.g., gait/balance). We used a paired-samples t-test to examine pain scores pre-post PSTIM™ treatment. A qualitative content analysis was used to examine pain and functional outcomes associated with PSTIM™ in those charts that did not have quantitative pain scores documented.

**Results:** Fifty-eight charts were reviewed. Eighteen patients had pre-post pain scores available for quantitative analyses (Mage = 63 years; 67% female). Pain scores significantly decreased after PSTIM™ (Mpre = 8.11 vs. Mpost = 3.17; t = 13.52, p < .001), regardless of number of PSTIM™ treatments (M = 4.5; SD = 2.5). Content analysis was conducted on the additional 40 charts, 8 of which were drop-outs (i.e., PSTIM™ device placed but no follow-up). Fifty-nine percent of patients with qualitative data (n = 19) reported significant improvements and 25% (n = 8) reported minimal improvements in pain following PSTIM™. Functional improvements, including improved gait, balance, and activities of daily living were reported often.

**Conclusion:** PSTIM™ was associated with significant improvements in pain, and significant functional improvements in patients with CIPN. Preliminary results suggest that PSTIM™ may be a useful non-pharmacologic treatment for patients with CIPN. Further controlled studies using prospective research designs and active control groups are warranted.

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**P02.148 LB**

**A Pilot Study Examining the Feasibility of the MBSR(BC) Home-Based Approach via an iPad**

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**Purpose:** The purpose of this pilot study was to test the feasibility of Mindfulness-Based Stress Reduction for Breast Cancer (MBSR(BC)) Home-based approach through smart technology platform using an iPad.

**Methods:** A single group, pre-post design was implemented among female breast cancer (BC) patients (stages 0-III) who completed treatment. Data were collected at baseline and at week 6 on self-reported measures of psychological and physical symptoms and quality of life (QOL). The MBSR(BC) is a standardized stress-reducing intervention that combines sitting and walking meditation, body scan, and yoga adapted for BC survivors. The Home-based program was designed to deliver the weekly 2-hour sessions for 6 weeks on an iPad decreasing subject burden and allowing completion of the intervention at home. Participants received an orientation on use of the iPad, and recorded practice time in a daily diary.

**Results:** Of the 15 enrolled, the mean age was 58 and one participant was Black Non-Hispanic with the other 14 being White Non-Hispanic. Of the 13 who completed the study, there were significant differences and improvements from pre-MBSR(BC) to 6 weeks (post MBSR(BC)) in psychological and physical symptoms of depression, state anxiety, stress, fear of recurrence, sleep quality, fatigue and quality of life (p < .05).

**Conclusion:** These results provide preliminary support that the Home-based MBSR(BC) program is feasible and acceptable, and had a clinical impact on decreasing psychological and physical symptoms. This program offered an alternative to the standard 6 week intervention by allowing for delivery flexibility at home while receiving the benefits of the MBSR(BC) program.

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P02.149 LB
Responding to Device-Guided Breathing: A Mixed Methods Analysis

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Purpose: The use of device-guided breathing for blood pressure (BP) reduction allows recording of the dosage of the intervention, unlike other mind-body-intervention. Patient-specific details might predict outcomes. While completing a large RCT, we looked for predictors of BP response.

Methods: We studied a subgroup of subjects (n=50) participating in a randomized clinical trial of testing the RESPeRate device for the treatment of hypertension, in the device-guided treatment arm. Subjects with good adherence to the intervention (>20 practice sessions total), were included, 5 low users (<20 sessions total) were excluded from the analysis. We examined downloaded device data and ambulatory BP monitoring data before and after the 8 or 16 week intervention. We tested psychosocial variables as predictors of BP change. We performed a qualitative data analysis of their exit interviews.

Results: The number of practice sessions did not change systolic (r = -.05) or diastolic (r = -.07) BP. No differences in demographics were found. Patients with higher levels of brooding had better responses (−7.3mmHg vs. −8.4mm Hg, p = .05). Nonresponders had larger white coat effects (6.7mmHg vs. 0.4mmHg, p = .05). Qualitative analysis showed responders and nonresponders endorsed relaxation effects during the practice. Responders voiced more enjoyment of using the device, endorsed learning an ability to utilize learned skills outside of formal practice, and less reactivity to life events after completing the intervention. Nonresponders enjoyed the practice less and were less likely to utilize learned skills outside formal practice.

Conclusion: BP lowering by using the RESPeRATE biofeedback device does not depend on demographics including gender, age, or race. Some psychological characteristics predict better response to this intervention. Responders share some characteristics of enjoyment of the practice and an ability to transfer learned skills. White coat hypertension might be a negative predictor to BP reduction using this feedback device.

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P02.150 LB
Mind-Body Medicine and Irritable Bowel Syndrome: A Randomized Control Trial Using Stress Reduction and Resiliency Training

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Purpose: Irritable Bowel Syndrome (IBS) is a functional bowel disorder characterized by symptoms of abdominal discomfort and alterations in bowel habits. The pathophysiology of IBS is not well understood, though it is believed that stress may play a role in the disease. Diet, lifestyle changes, and pharmacological treatments are partially effective therapies for IBS. Several psychological and mind-body therapies have demonstrated promise in the treatment of some patients. This study seeks to test the effectiveness of a mind-body therapy, Stress Manage-
P02.152 LB
Developing the Evidence for Kinesiology-Style Manual Muscle Testing: A Series of Diagnostic Test Accuracy Studies
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Purpose: Kinesiology-style Manual Muscle Testing (kMMT) is estimated to be practiced by over 1 million people worldwide. Despite its widespread use, the clinical validity of kMMT has never been rigorously assessed and its true usefulness is frequently questioned [1-4]. This paper describes a series of diagnostic test accuracy studies aimed at developing evidence for one application of kMMT: distinguishing true from false spoken statements. The main objectives of this series was to estimate the accuracy of this application of kMMT under varying conditions.

Methods: Six prospective studies of diagnostic test accuracy were carried out where kMMT practitioners were paired with kMMT-naïve test patients (TPs). TPs were instructed to make true/false statements, after which the kMMT was performed. The paradigm under investigation is that a muscle will weaken after speaking a lie and stay strong after speaking a truth. The reference standard was the statements’ actual verity and the index test was kMMT.

Results: Consistently through this series of studies kMMT practitioners correctly distinguished lies from truth using kMMT more often than by chance alone or guessing (p < 0.01). In Study 3 there was no significant difference between dynamometer-measured grip strength for true versus false statements (p = 0.94). Testing for various factors that may have influenced kMMT accuracy failed to detect any correlations.

Conclusion: Significant differences were found between accuracy in identifying verity of spoken statements using kMMT compared to both chance and guessing. Furthermore, the practitioner appears to be an integral part of the kMMT dynamic because when removed, no significance is achieved (Study 3). The main limitation of these studies is its lack of generalizability to other applications of kMMT.

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P02.153 LB
Concentrations of Chromium, Selenium, and Copper in the Hair of Visceral-Obese Adults Are Associated with Insulin Resistance
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Purpose: Visceral adiposity is linked to the development of insulin resistance, which is a condition that may contribute to metabolic abnormalities and cardiovascular disease. Various minerals play essential roles in different metabolic functions in the body. Thus, the relationships between mineral concentrations in hair and insulin resistance were analyzed in 144 Korean adults (71 visceral-obese subjects and 73 normal control subjects) in this cross-sectional study.

Methods: Visceral obesity was measured using a bioelectrical impedance analysis (BIA) and insulin resistance levels were assessed using the homeostasis model assessment insulin resistance (HOMA-IR) index.

Results: The visceral-obese group exhibited significantly higher levels of serum glucose (96.5 versus 91.0 mg/dL, P = 0.023), insulin concentration (4.78 versus 2.98 μU/mL, P = 0.003), and the HOMA-IR index (1.18 versus 0.64, P = 0.003) compared with the normal control group. After adjusting for age and sex, there was a positive correlation between copper levels in hair and the HOMA-IR index in the visceral-obese group (r = 0.241, P = 0.046) whereas chromium and selenium levels in hair were negatively correlated with the HOMA-IR index (r = -0.256, P = 0.034, and r = -0.251, P = 0.038, respectively).

Conclusion: Chromium and selenium levels in the hair of visceral-obese adults were inversely associated with insulin resistance, whereas copper levels in the hair were positively associated with insulin resistance. This suggests that the mineral status of visceral-obese adults might play a role in the development of insulin resistance.

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P02.154 LB
Minimum Inhibitory and Bactericidal Concentrations of Different Hones and Bee Propolis Against Multidrug Resistant Staphylococcus Sp. from Mastitis

Abstract Withdrawn
Abstract Withdrawn
(continued)

P02.155 LB
Anti-Atherosclerotic Effects of Polygonum Aviculare L. Ethanol Extract in ApoE Knock-Out Mice Fed a Western Diet Mediated via the MAPK Pathway
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Purpose: Polygonum aviculare L. has been used in traditional Korean medicine to treat obesity and symptoms associated with hypertension. The effectiveness or mechanism of Polygonum aviculare L. ethanol extract (PAE) on atherosclerosis disease has not been examined experimentally. This study investigated the protective effect of PAE in atherosclerotic mice.

Methods: ApoE KO mice were fed a Western diet (WD) alone or with PAE or a statin for 12 weeks, followed by analysis of bodyweight, serum lipid levels, and blood pressure. Staining of the aorta and adipose tissue, expression levels of adhesion molecules, and the MAPK pathway were also examined. Cell viability, NF-xB activity, and protein levels of adhesion molecules were assessed in vitro.

Results: ApoE KO mice fed PAE (50 and 100 mg/kg) or statin (10 mg/kg) gained less body weight, and has less adipose tissue and lower serum lipid levels and blood pressures than the WD group. Aorta ICAM-1, VCAM-1, and NF-xB levels were decreased by PAE in a dose-dependent manner, consistent with the in vitro observations. PAE and statin decreased atherosclerotic plaque and adipocyte size versus the WD group. Furthermore, PAE decreased phosphorylation of MAPK pathway components in the aorta of PAE-treated mice, suggesting that PAE’s anti-atherosclerotic effects are mediated via a MAPK pathway-dependent mechanism.

Conclusion: PAE may protect against the development of atherosclerotic disease. The beneficial effects are associated with lowering bodyweight, serum lipids, blood pressure, adhesion molecular protein levels, atherosclerotic plaque, and adipocyte size, involving the MAPK pathway.

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P02.156 LB
The Effectiveness of Early Intervention for Undergraduate Depressive State
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Purpose: Apply early intervention to depressed undergraduates, compare acupuncture, psychology and combined method (acupuncture combined psychology) on improvement of depressive state and life quality.

Methods: 1270 undergraduates were investigated during the period from Apr. 2009 to Sep. 2010. All undergraduates were assessed through the WHOQOL-BREF (World Health Organization Quality of Life-BREF), CES-D (Center for Epidemiologic Studies Depression Scale) and HAMD (Hamilton Depression Rating Scale). Undergraduates (n = 50) with CES-D scores ≥ 16, HAMD scores ≥ 7 and ≤ 17 were selected for early intervention. According to volunteers’ own will, undergraduates were divided into control group (n = 10), acupuncture group (n = 16), psychology group (n = 9) and combined group (n = 15) to receive an 8-week period treatment to evaluate the efficacy of these methods in improving the depressive state and quality of life.

Results: 1. ITT and PP analysis showed, there were significant differences in CES-D scores between pre-intervention and post-intervention (P<0.05); There is no significant difference in CES-D scores reduction between groups in post-intervention (P>0.05); The control group showed no significant difference between pre-intervention and post-intervention, 2. The control group have significant difference between pre-intervention and post-intervention in physiology score (P<0.05), while acupuncture group, psychology group and the combined group showed no significant difference (P>0.05); There is no significant difference between pre-intervention and post-intervention in psychology score (P<0.05); The control group, acupuncture group and combined group have significant difference between pre-intervention and post-intervention in environment score (P<0.05); The acupuncture group have significant difference between pre-intervention and post-intervention in social relationship score (P<0.05), while the control group, psychology group and combined group showed no significant difference (P>0.05).

Conclusion: Early intervention of acupuncture, psychology and combined method could improve undergraduates’ depressive state, but the three intervention method has no difference; early intervention of acupuncture could significantly improve undergraduates’ life quality, health evaluation, environment satisfaction and social relationship.

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P02.157 LB
A Survey on Motivation and Satisfaction of Subjects in Acupuncture & Moxibustion Clinical Trial
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Purpose: This study was aimed to find the motivation and satisfaction of subjects who participated in acupuncture and moxibustion clinical trials and to suggest ways to improve clinical trial management.

Methods: We conducted a survey and collected the data of 233 subjects of acupuncture and moxibustion clinical trials from 6 university hospitals.

Results: For all 233 subjects, the mean of the total satisfaction score was 4.07 (perfect score 5.0), and the score was particularly
high in aspects of the investigator and clinical research coordinator, but low in the site and sponsor aspects. There were no differences in the satisfaction degree with general characteristics. The satisfaction degree of the acupuncture and moxibustion clinical trials was strong positive correlated with participation benefits (r = 0.595) and easy contact with the research team (r = 0.500).

**Conclusion:** Most subjects showed positive perception and interest in the clinical trials. Future studies should investigate how personal factors influence the satisfaction of subjects, should identify a specific classification criterion, and create a standardized protocol for the clinical trials.

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**EDUCATION RESEARCH**

**P03.02**

**Predictors of Knowledge and Use of Research Literacy Skills Among Students of Acupuncture and Chiropractic Programs**

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**Purpose:** There is a general indifference among CAM students towards the research methods courses developed to teach research literacy. This general apathy calls for constant evaluation of the pedagogy adopted to teach this course. “Research Debates” were adopted at a CAM school with an intention to encourage students’ participation in this course as well to help them retain the research literacy skills. We previously assessed and reported the self-perception of students who participated in the research debates as part of this course. The purpose of this paper is: To Identify the predictors of Knowledge and Use of Research Literacy Skills among students of Acupuncture and Chiropractic Programs.

**Methods:** Sample: All currently enrolled students who passed the Research Methods course and participated in the research debates. Design: Cross-Sectional Study (Survey Design). A questionnaire developed exclusively for this study was administered both in-person and online to collect the data. The survey was anonymous and voluntary in nature.

**Results:** A total of 171 students responded to the survey. The respondents were predominantly males, chiropractic students, and reported having a bachelor’s degree as the highest level of education prior to entering the CAM programs. The results indicated that a majority of students rated that their research literacy skills, which included familiarity with databases and critical appraisal skills, as either outstanding, above average or average. Most respondents also reported that they used these skills at least 1–5 times in clinical internship in the past week. The pedagogy adopted to teach these skills, research debates were also rated either very useful or useful by a majority of these respondents. However, there was no association between the age, gender, program or highest level of education to knowledge of databases or critical appraisal skills.

**Conclusion:** CAM students perceive their research literacy skills high, but there are no predictors for these perceptions.

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**P03.03**

**Core Competencies for Integrative Medicine Fellowship Training Programs**

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Purpose: Integrative Medicine Fellowships are becoming well established in academic health centers. In 2010 the Consortium of Academic Health Centers for Integrative Medicine (CAHCIM) convened a 2-year Task Force to study the characteristics and curricula of existing Fellowships and draft Integrative Medicine Fellowship core competencies.

Methods: The Task Force convened by CAHCIM reviewed the learning objectives and curricula of the 13 existing Integrative Medicine clinical Fellowships. All Fellowship Directors were contacted by email or phone to complete a template of questions regarding program design, curriculum, financial information, educational methods, and required competencies. Through regular conference calls, Task Force members used this survey information, the existing scientific literature, and their own expertise to draft an initial set of competencies using the ACGME categories. Task Force and other CAHCIM members revised the competencies through several monthly conference calls and through email. Oral presentations at professional conferences provided opportunities for public commentary and discussion. The Task Force additionally solicited constructive feedback from Integrative Medicine Fellowship Directors of all existing programs.

Results: Differentiation of competencies for Integrative Medicine Fellows from customary care as described by other medical specialties was most notable in four areas of Medical Knowledge and Patient Care: 1) Pain Management, 2) Nutritional Science, 3) Mind-Body Medicine, and 4) Lifestyle Medicine. Additional Integrative Medicine competencies include characteristics of commonly used evidence-based CAM practices, demographic and epidemiologic patterns of Integrative Medicine use, and relevant legal and ethical issues.

Conclusion: Developing uniform minimum standards for Integrative Medicine clinical Fellowship graduates are necessary to ensure quality training for future leaders in the field. Mastery of these competencies may be fostered by Fellowship programs through innovative training strategies, validated assessment methods, and continued faculty development tailored to the unique strengths and characteristics of each site.

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P03.04
Surveys of Cancer Patients and Cancer Care Providers Regarding Complementary Therapy Use, Communication and Information Needs

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Purpose: In previous surveys, approximately 45% of cancer patients have reported the use of various Complementary Therapies (CTs). The high prevalence of use creates a need for a closer examination of patient and health care practitioner (HCP) CT use, knowledge, communication, opinions, and beliefs. We sought to compare statistics from the Tom Baker Cancer Centre (TBCC) in Alberta, Canada, with other published surveys worldwide.

Methods: 481 cancer patients and 100 HCPs were surveyed at the TBCC. Patients were surveyed on their use of CTs, their motivations and barriers to use, patient-practitioner interactions, and their interest in CT resources. HCPs were asked about patient-practitioner interactions, their CAM knowledge and skills, their CAM opinions and beliefs, and their CAM training.

Results: 47% (n = 227) of patients had used CTs since their diagnosis. Patients’ top reason for CT use was to improve quality of life (65%). The largest barrier to use was uncertainty of the evidence supporting CTs (35.9%). 80% of patients had not had a HCP speak to them about CTs and few felt they had received enough CT information (16%) or support (14%). 73% of patients indicated they would utilize a CT education program. 71% of HCPs had patients report their CAM use. 62.5% reported asking patients about using CAM. Few practitioners reported being knowledgeable about CAM (18%) or prepared to address CAM (13%). HCPs endorsed positive views of CAM, with 66% believing CAM can benefit conventional medicine. Though only 31% of practitioners had received any CAM training, 90% reported interest in receiving CAM education.

Conclusion: CT use is similar at our centre to other surveys worldwide. There is a strong need for patient and practitioner educational resources, enhanced communication about CTs, support for decision making and greater integration of CTs into conventional medicine.

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P03.05
A Barrier Opener for Personal Insights: Nursing and Medical Students Experiences of Participating in an Experiential Mind-Body Skills Program

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Purpose: This study aimed to obtain an in-depth understanding on how nursing- and medical students participating in a Mind-Body Medicine Skills program experienced participation and what the program has meant to them on a personal and a professional level.

Methods: Based on a qualitative approach, first and second year students were interviewed 3 months after completion of the program. Interviews were analyzed with a qualitative content analysis. As part of a larger study evaluating the effects on stress, empathy and self-reflection, this qualitative sub-study included 10 nursing students from Mid Sweden University, Sweden, and 10 medical students from University of Utrecht, The Netherlands. The Mind-Body Medicine Skills program was adapted from the program developed at Georgetown University School of Medicine, Washington DC, and included 11 experiential sessions were the students were introduced to different mind-body techniques (mindfulness meditation, guided imagery, bio-feedback etc).

Results: Data analysis is ongoing and more complete analysis will be presented at the conference. In preliminary analysis an
P03.06
Perceived Effects on Health Professionals of a Mind-Body Medicine Program: Exploratory Study with Physicians
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Purpose: Developed in Europe in the 1980s, Awakening the “Sensible” Being (ASB) is a formative practice that examines how use and movement of the body allow for the development of one’s awareness, sense of self and of others, which are desirable qualities for healthcare professionals. Our goal was to explore if and how ASB training followed by healthcare practitioners modifies the quality of their self-awareness, their presence to others, as well as their relationship with respect to health and their medical practice.
Methods: Based on two types of semi-structured interviews (comprehensive and elicitation) the project was conducted in two phases. Phase 1: exploratory interviews with three nurses trained or presently being trained in ASB. Phase 2: interviews with six physicians having completed their ASB training (500 hours over 4 years). The content of the interviews was first analyzed thematically then grouped by categories. Results of Phase 2 are presented here.
Results: ASB training seems to enable participants to gradually ground their presence through a bodily experience. Results suggest a difference between participants who were in harmony with themselves prior to training and those who weren’t. For the latter, the training process enabled the emergence of awareness and a movement towards self-reconciliation with individuals learning to make choices based on their needs (both personal and professional). Overall, participants reported having transformed their listening skills and their relationship with therapeutic touch - actions that transformed them personally and professionally. Participants in general were increasingly in line with their vocational identity and, for many, the concept of health broadened.
Conclusion: Participants report transformations in their relationship with their bodies, themselves, their health, their relationship with others, and in their healthcare practice. ASB training allowed them to refocus on themselves, thereby bringing about changes in their personal and professional life.
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P03.07
Effects of a Mind-Body Medicine Skills Program on Perceived Stress, Empathy and Self-Reflection Among Medicine and Nursing Students: A Quantitative Study
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Purpose: This study aimed to implement and quantitatively evaluate the Mind-Body Medicine (MBM) Skills program among Dutch medical and Swedish nursing students.
Methods: The MBM Skills program was piloted among second year medical students at Utrecht University and first year nursing students at Mid Sweden University in the period 2011–2013. During the course, the participating students learned and practiced Mind-Body techniques such as relaxation, meditation, guided imagery, biofeedback, physical exercise, art, music and movement. The effects of the MBM skills program on perceived stress, empathy, and self-reflection were evaluated by the following validated scales: Perceived Stress Scale, Interpersonal Reactivity Index, and Groningen Reflection Ability Scale. Participants and controls answered different questionnaires at baseline, at the end of the course, and 6 and 12 months later.
Results: In total, 55 medical students and 49 nursing students have participated in the MBM skills program. Baseline analysis showed that participants were significantly older (p<0.001), and had higher scores for empathetic concern (p<0.001) and self-reflection (p<0.001) than participating medical students. Further, baseline analysis showed no significant differences in baseline characteristics between intervention and control group for medical students, except from significantly higher levels of perceived stress among controls (p=0.008). Regarding nursing students, no differences were found between intervention and control group, except from significantly higher scores for empathetic concern among participants (p=0.023).
Conclusion: We have successfully implemented the MBM Skills program for medical and nursing students. Baseline analysis showed that participants of the course were not a selected group, except from perceived stress among medical students and empathetic concern among nursing students. Data on the effects of the MBM skills program on perceived stress, empathetic concern and self-reflection are currently being evaluated and will be presented at the conference.
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P03.08
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Purpose: The evaluation of an integrated medical program aimed at educating students in patient-centered integrative care through anthroposophic medicine.
Methods: In 2003, the Witten/Herdecke University in Germany piloted the Integrated Curriculum for Anthroposophic Medicine (ICURAM), a new integrative medical program which is integrated into the full 6 years of the university’s regular medical curriculum. The main goal of the program is to emphasize a broader, multifaceted and holistic view of human being and to prepare its participants for a patient-centered integrative and anthroposophic healthcare. A qualitative study with in-depth field manual based interviews with alumni of the ICURAM program was conducted. Inclusion criteria were full participation at the ICURAM program and at least twelve months of clinical experience as a resident. The qualitative analysis of the material is being conducted by means of the framework analysis.

Results: Of the 164 medical students of the years in question, 27 (16%) were full-time ICURAM participants, of which 13 fulfilled the residency time criterion, ten of which could be interviewed. Preliminary results indicate a positive impact of the ICURAM participation for the alumni concerning their conventional medical training (e.g. higher interest and motivation to study with scientific details put into a more holistic and meaningful context and a more multifaceted medical training through ICURAM), their professional development (e.g. improved self confidence and ability to understand and deal with difficult situations/patients, improved ability for empathy, more appreciation for interdisciplinary teamwork through positive teamwork experiences during ICURAM training) and not the least personal development (improved self-management and self reflection, being enabled to implement own ideals into practice).

Conclusion: An integrative medical program like the ICURAM program with a student centered educational approach can contribute to a positive and sustainable experience of the students’ medical training and can have a positive impact on their professional and personal development as doctors-to-be.

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P03.09
Does Complementary and Alternative Medicine Exist in Australian Nursing and Midwifery Courses?
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Purpose: An increasing number of Nurses and Midwives have described positivity towards or an affinity for complementary and alternative medicine (CAM), yet many receive little formal training regarding this highly accessed form of care during their education. Use of CAM is increasing among patients and pregnant women and there is concern Nurses and Midwives are not able to fully meet this trend. It is suggested that Nurses and Midwives are positioned in a crucial nexus between conventional and complementary medicine and require CAM education if they are to practice efficaciously and in line with demand while maintaining patient and women’s safety. The aim of this study is to examine whether CAM education is present in Nursing and Midwifery courses and what factors contribute to its inclusion or exclusion.

Methods: Coordinators of Nurse and Midwifery courses in Australia (n=102) were invited to complete a survey which included their course characteristics, CAM course characteristics and factors that could influence CAMs inclusion. These included an examination of department focus, resource allocation, political support and philosophical concerns. Analysis of survey data includes descriptive statistics, chi squared test and logistical regression.

Results: The amount of CAM learning included in Nursing and Midwifery courses is variable, but preliminary results indicate midwifery courses may include CAM education more than nursing courses. Factors which may influence the inclusion of CAM could be lack of political support for CAM inclusion, despite some reporting of student and patient interest and institutional pressure after initial analysis. This suggests there could be a trend for patients and women to possibly be the initiators of the push for CAM knowledge amongst Nurses and Midwives, rather than the education community itself.

Conclusion: Further analysis needs to explore CAM education delivery quality and the statistical significance of the attitudes and perceptions of decision makers. A trend towards lack of professional resources and impetus is expected to be the outcome.

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P03.10
Classifying the Use of Integrative Medicine on an Undergraduate Campus
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Purpose: The purpose of this study was to determine factors associated with the use of CAM amongst undergraduate students at University of California Irvine. This data could be used in order to gauge the exposure of undergraduate students to CAM particularly those that self-identify as pre-healthcare students. The ultimate goal would be to guide further CAM educational opportunities for undergraduate students.

Methods: This is a cross-sectional study using an electronic questionnaire conducted among a convenient sample of undergraduate students at University of California, Irvine from Fall 2010 to Spring 2011. We conducted descriptive statistics, univariate and multivariable analyses using STATA statistical software.

Results: Of the 21,976 UC Irvine undergraduates enrolled during that time, 2,839 (13%) responded to the survey. One third of the participants reported that they have used CAM in the past 12 months. In our multivariable model, participants’ perceived familiarity with CAM and effectiveness with CAM were significantly associated with use of CAM in the past 12 months. In our multivariable model, participants’ perceived familiarity and effectiveness with IM were independently associated with reported CAM use. Gender was also found to be an independent correlate of CAM use.

Conclusion: To date, this study has the largest sample of undergraduates in investigating their use of CAM. This study reveals a high proportion of recent CAM use among undergraduate participants. Evidence-based CAM education programs may help undergraduate CAM users to make better-informed decisions on their use of CAM.

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P03.11 Evaluating Students’ Attitudes Participating in Integrative Medicine (IM) Undergraduate Courses
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Purpose: The objective of this study was to determine the changes in perceptions on Integrative Medicine (IM) before and after taking IM related courses at University of California, Irvine. We hypothesized that student’s familiarity, confidence in assessing treatments, and willingness to take more college courses would increase after taking these IM courses.

Methods: This was a time series, cross sectional questionnaire-based study conducted on the undergraduates enrolled in IM related classes offered at UCI. This study was conducted on 5 different classes over 2 and half year (at least 2 terms for each). The classes ranged from curricula based in biology, pharmaceutical sciences, public health and sociology. An IRB approved survey was administered to students before and after they had taken the course.

Results: There were a total of 443 participants before the class and 371 participants after classes. There was a significant increase in student’s confidence in assessing the effectiveness of individual IM treatments, from 3.79 to 4.89, on a Likert scale from “Strongly Agree” to “Strongly Disagree” (p<.001). There was also a significant increase in the mean of students’ understanding of the definition of IM from 3.35 to 6.07 on a scale from “Not Familiar” to “Very Familiar” (p<.000). Students expressed high interest at the end of the class in learning more about therapies such as Acupuncture, Oriental Medicine, Massage, Meditation and Body Movement (all over 4.0 from “Not Interested” to “Very Interested”). Also the mean score of IM’s effectiveness after the class was perceived at 5.33 (+/-1.336) on a scale from “Not Effective” to “Very Effective”.

Conclusion: In general, it was found that the classes had a positive effect on students’ perception, and desire for further education in IM. Next to be determined are, the most contributing factors to the increased positive perception of IM over time.
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P03.12 Integration of A Stress Management and Resiliency Training (SMART) Program in a Nurse Residency Program: A Feasibility Study
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Purpose: The purpose of this study was to assess the feasibility of integrating a Stress Management and Resiliency Training (SMART) program within a nurse residency program, and assess the effects of the program on participants’ stress, anxiety, mindfulness and resilience.

Methods: A convenience sample was employed for this quasi-experimental study (intervention group, n = 23; control group, n = 28). Focus group interviews were conducted with the intervention group (n = 27) to assess the impact of the program. Quantitative outcome measures were assessed at baseline, and 1 month, 3 months, 9 months, and 1 year after the initial intervention and included: Perceived Stress Scale (PSS), Generalized Anxiety Disorder (GAD-7), Mindful Attention Awareness Scale (MAAS), and Connor-Davidson Resilience Scale (CD-RISC). Scores were compared across time after adjusting for age with linear regression models using generalized estimating equations to account for the repeated data.

Results: The intervention group exhibited compliance with the SMART program; however, they were not adherent to the intervention according to the pre-determined parameters. Statistically significant improvements were observed for all scales within the intervention group (p<0.0001), but scores remained relatively steady over time within the control group with the exception of GAD-7. Scores changed similarly for GAD-7 within each of the study groups. The intervention and control groups differed significantly from each other with respect to the degree of change over time on the remaining 3 measures (p<0.001). Themes that emerged from the focus group interviews include: 1) Enhanced Personal and Professional Development, 2) Sensitivity to Learner Needs, and 3) Fostering the Principles of Mindfulness.

Conclusion: The outcomes provide support of integration of the SMART program within a nurse residency program. Future studies are indicated with larger numbers to further explore the efficacy of the SMART program and to determine an adequate level of adherence to the intervention.
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P03.13 Evidence Informed Practice and Culture Change: The CAM Practitioner Research Education Partnership Project
Mary Jo Kreitzer (1), Louise Delagran (1), Barry Taylor (2), Michele Maiers (2), Corrie Vihstadt (2), Roni Evans (2)
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Purpose: Evidence-informed practice (EIP) requires academic and clinical cultures that encourage associated behaviors. This presentation will describe the outcomes of the CAM Practitioner Research Education Partnership Project (NCCAM, R-25AT003582), a multi-faceted educational program, implemented at one CAM institution. The aims of the program are to establish sustainable EIP-focused faculty, student, and postgraduate programs to enhance participants’ ability to use research information and participate in research.

Methods: The ADDIE instructional model provided the framework for developing multi-faceted, competency-based EIP educational programs designed to meet participants’ needs. Focusing on analysis, design, development, implementation and evaluation, this iterative model is consistent with models of behavioral change emphasizing routine monitoring. Program evaluation is done at several levels and includes a range of data collection including formative and summative assessments, surveys, focus groups, and other methods.

Results: Approximately 90% of faculty (n = approx.140) participated in online EIP programs, 33% have taken part in comprehensive Research Scholars seminars, and nearly 20% take part in twice monthly practice workshops. Annual surveys of faculty self-reported EIP skills continue to demonstrate improvement from 2008 data (ranging from 8–20% depending on...
specific skill) with the greatest improvement among Scholars participants. Over 1000 students have participated in foundational EIP courses with gains in self-reported EIP skills of 20–50%. Thirty percent of students express an interest in additional research related coursework. Over 500 CAM practitioners will have been reached through post-graduate programs. The majority of participants are highly satisfied with the new EIP curricula.

Conclusion: The implementation of EIP at this institution has been broad and comprehensive. Faculty and student engagement in the EIP programs has been high, and post-graduate participation is increasing. EIP has become part of the institutional fabric, playing a pivotal piece in the institution’s mission, values and strategic plans suggesting that CAM can be evidence-based.

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P03.14

Comparison of Residents and Medical Students on Measures of Well-Being and Lifestyle

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Purpose: To examine differences between residents and medical students on measures of well-being and lifestyle.

Methods: A sample of 149 family medicine residents and 127 senior medical students (n=276) completed measures of perceived stress, burnout, depression, life satisfaction, mindfulness, and lifestyle behaviors (health status, work, sleep, nutrition, exercise, mind-body, spirituality/religion, family/social, hobbies, and time outdoors).

Results: Residents reported lower perceived stress, greater emotional exhaustion, lower life satisfaction, and less mindfulness than medical students. Residents worked more hours, reported more days feeling overwhelmed at work, and fewer days enjoying work. For health status, residents reported more days of physical pain and were less likely to have a normal BMI (62% vs. 79%). Residents reported fewer days waking feeling rested; however students were more likely to use an herbal product for physical pain and were less likely to have a normal BMI (62% vs. 79%). Residents reported better nutritional habits than students, including more days eating plant-based protein, eating breakfast, less eating out, more high fiber servings, and consuming fewer sugary drinks, caffeinated sodas, and energy drinks. While residents were more likely to report more days of healthy touch and time outdoors; students reported greater use of social media, belonging to more social groups, and more time engaging in hobbies. Students were more likely to report no alcohol use (32.4% vs. 50.6%), greater journaling, praying, and church attendance.

Conclusion: Residents reported greater emotional exhaustion and lower life satisfaction which may be due to working more, greater work stress, poorer sleep quality, and less social activity. Less mindfulness in residents may be due to engaging in fewer activities that allow mental disengagement, e.g., spiritual/religious activities. However, students reported greater stress and poorer nutritional habits suggesting that stress begins early in medical education. Therefore, efforts at teaching students and residents about self-care are vital. This is in keeping with the new ACGME milestones expectations for physician well-being.

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P03.15

Promoting Resiliency Among Palliative Care Clinicians: A Pilot Intervention

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Purpose: Amongst healthcare providers, palliative care (PC) professionals face unique challenges of working with seriously ill patients and their families, and are prone to personal vulnerabilities. No intervention has been reported in looking at resilience with an interdisciplinary group of palliative care team members. We aimed to examine the feasibility of a pilot group intervention based upon the Relaxation Response Resiliency Program (3RP), targeted for a PC team.

Methods: Our pilot study intervened with a PC team at a major academic medical center using a 12 hour intervention. The goals of the program included: 1) relaxation response elicitation, 2) stress reactivity reduction, and 3) increased connectedness. The intervention incorporated a multimodal approach to introduce and reinforce new skills, including didactics, in-session activities, discussions, and weekly practice assignments. Preliminary intervention efficacy was assessed as pre/post-intervention changes in sum scores on proposed outcomes which reflected core intervention goals: perceived stress, positive and negative affect, perspective-taking, optimism, satisfaction with life, and self-efficacy.

Results: Participants showed a reduction in perceived stress (p=.03; Cohen’s d=.65) and increase in perspective-taking (p=.10; Cohen’s d=.67), with a medium effect size for change in each factor. Effect sizes for improvements in positive affect (p=.17; Cohen’s d=.42), optimism (p=.15; Cohen’s d=.36), satisfaction with life (p=.24; Cohen’s d=.29), and self-efficacy (p=.38; Cohen’s d=.30) were small. Among 16 PC providers, 15 enrolled in the study. There was no study attrition among enrollees.

Conclusion: Findings from this study demonstrate the feasibility of a pilot intervention targeted for the PC team, with significant decrease in perceived stress. Other outcomes were not significant; however, they did demonstrate a small to moderate effect size. Future studies should further examine further effects of these multimodal skill-building interventions delivered during work hours.

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P03.16

Self-Directed Online Solution-Focused Coaching Used to Reduce Occupational Stress

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Purpose: This study intended to measure the effectiveness of a web-based, self-directed, solution-focused coaching designed to help healthcare professionals investigate to self-identified problems in their lives. This pilot online therapy (www.baconng.org) consisted of four sessions and was derived from the best available evidence in promoting positive life style changes for health care workers who exhibit risk of work-related burnout.
P03.17 Integrative Treatment Modalities for Stroke Victims in Korea
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(2) Department of Meridian and Acupoint, College of Korean Medicine, Kyung Hee University, Seoul, South Korea
(3) Physical Medicine and Rehabilitation University of Medicine and Dentistry of New Jersey, Newark, NJ, USA
(4) Asian Medicine & Acupuncture Research, Department of Physical Medicine and Rehabilitation, School of Medicine, University of North Carolina at Chapel Hill, NC, USA

Purpose: The use and interest in complementary and alternative medicine (CAM) is increasing among stroke patients and more hospitals are expanding their offerings in favor of CAM in response to patient demand. However, it is challenging to organize and incorporate CAM services into mainstream medical settings and develop an effective integrative medicine model. To suggest and discuss an integrative medicine model for stroke patients, we introduce our experience in Korea, describe treatment modalities used for stroke in Korean medicine, and present safety data on integrative care.

Results: The Stroke and Neurological Disorders Center in Kyung Hee University Hospital at Gangdong consists of four departments: Korean medicine, Neurology, Neurosurgery, and Physical Medicine & Rehabilitation. For inpatients, integrative management is applied at the request of the primary physician with the consent of patients or their families. In the acute stage, neurologists or neurosurgeons take charge as the primary physicians. Korean medicine doctors cooperate as secondary physicians to the neurologists and neurosurgeons. After the acute stage, responsibilities are exchanged. The rehabilitation program is conducted under the supervision of rehabilitation medicine doctors. The most frequently used complementary and alternative medicine modalities are acupuncture (including manual acupuncture, electroacupuncture and intradermal acupuncture), moxibustion, herbal prescriptions, and acupuncture point injection.

Conclusion: Despite multiple difficulties in the process of integrating CAM and Western medicine, the integration could expand available treatment options, improve patient and provider satisfaction, better balance the deficiencies in each system, and lead to improved therapeutic outcomes. Based on our field experiences, we believe it is worthwhile to continue efforts to integrate complementary and alternative medicine and Western medicine.

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P03.18 Attitudes, Personal Uses and Perceptions Regarding CAM and Traditional Medicines (TM) Amongst Medical Doctors in Argentina and Latin American Countries
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Purpose: To estimate the attitudes, personal uses and perceptions regarding CAM and traditional medicines (TM) therapies amongst physicians in Argentina and Latin American countries.

Methods: A pilot survey was done using an interviewer-administered questionnaire to medical doctors contacted by postgraduate students at Argentina and Latin America between May 2004–April 2011.

Results: 1003 medical doctors from Latin America, 75% of them from Argentina and 25% from 15 other countries were interviewed for this survey. Among different types of CAM/TM, only acupuncture and homeopathy are considered effective for over 50% of the respondents. A large majority of respondents felt that they hadn’t sufficient information on Ayurveda (70%), Phyto-medicine (55%), Anthroposophical Medicine (76%), Traditional Chinese Medicine (56%) and osteopathy (65%). 51% of the doctors had used some form of CAM/TM for themselves. At the same time, 50% of the doctors had referred some of their patients to some kind of CAM care. 80% of the doctors considered they support the decision of their patients when they are using some type of complementary medicine but only 67% of the doctors think they receive this information from their patients. 73% encourages their patients the practice of yoga, 67% the use of massages and 64% body relaxation techniques. Of all surveyed physicians, 93% considered it is necessary for the doctors to know which CAM/TM are used by their patients; 89% considered that the knowledge of CAM/TM is almost nonexistent in the formation of medical doctors; 88% judge that most physicians inquire little about the subject; and 86% think that most physicians approach the issue through toxicology. There is a favorable opinion to have training of CAM/TM at postgraduate level.

Conclusion: There is a correlation of the personal use of CAM/TM by medical doctors and the referral of their patients for this kind of medical care.

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P03.19 The Next Generation of Dietitians: Implementing Dietetics Education and Practice in Integrative Medicine
Leigh Wagner (1), Randall Evans (1), Diana Noland (1), Rachel Barkley (1), Debra Sullivan (1), Jeanne Drisko (1)

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Purpose: Integrative Medicine is an expanding field of healthcare that emphasizes nutrition as a key component. Dietitians and nutritionists have an opportunity to meet workforce demands by practicing Dietetics and Integrative Medicine (DIM). We report the results of an interprofessional nutrition education and practicum program developed at the University of Kansas Medical Center (KUMC) Department of Dietetics and Nutrition and KU Integrative Medicine.

Methods: KU Dietetics and Nutrition and KU Integrative Medicine implemented a feasibility study conducted between October 2010 and February 2011. Results of the feasibility report advised team members to proceed to Phase II to develop curriculum for online and classroom content, the dietetic internship and practicum schedules.

Results: The benchmarks were successfully completed by the end of 2011 and a Master of Science degree was developed for the Graduate Certificate in DIM. KU Integrative Medicine clinic was chosen as a supervised practice experience site for dietetic interns because of the inter disciplinary practice environment. Phase III was implemented in January of 2012 with a beta-test of the DIM internship curriculum. There was a subsequent announcement in early 2012 that invited interested prospective students to apply as fellows for the program with official start date in August 2012. The first group has successfully completed the program.

Conclusion: The demand for education in Dietetics and Integrative Medicine to address chronic health problems necessitates the identification of required core competencies, learning objectives and activities to guide the development of curriculum for dietetic internship. This process requires interprofessional education and teamwork. We propose that the KUMC Dietetics and Nutrition and KU Integrative Medicine collaboration is a model for the development of innovative educational programs. The result of this collaboration provides tools for solving chronic complex disease with patient focused biochemically-based nutritional interventions and models a method to train future practitioners.

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P03.21
Examining the Impact of a Week-Long National Training Program to Enhance Well-Being in Medical Students: Leadership and Education in Integrative Medicine Program (LEAPS)

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Purpose: Concern has been mounting over the increase in depression and hardening of empathy occurring during medical school. Training on health promotion through integrative medicine treatment and prevention which may counteract this trend is still absent from most medical school curricula. In response, the CAHCIM in collaboration with two national organizations has implemented a week-long summer intensive residential program (LEAPS) to foster leadership in integrative medicine and enhance medical student well-being. The aim of this study is to present effects of this curriculum innovation and explore mechanisms for observed outcomes.

Methods: Participants included two cohorts of medical students (N = 60) who participated in the LEAPS program during the summer of 2012 and 2013. Each cohort represented a range of allopathic and osteopathic schools in North America and spanned the M1 through M3 training years. The residential curriculum included didactic training in integrative medicine, with experiential learning in self-care practices and small group work focused on cultivating personal awareness, leadership and community. Participants completed a pre-post survey protocol of several validated measures related to mental health and well-being. Thematic content of student’s responses to open-ended survey questions were content analyzed.

Results: Paired sample T-tests revealed significant decreases on anxiety and depression scales pre-post training for both cohorts. Moreover, all students presenting with elevated referral risk for...
clinical depression (n=13) fell below these risk levels post-training. Students described the holistic immersion as a transformative experience increasing their felt sense of community and support.

**Conclusion:** A one-week intensive learning experience that emphasizes holistic self-care and belongingness in a community of like-minded peers and faculty appears to be effective in reducing negative affective states related to anxiety and depression which may be exacerbated by medical school training. The sustained impact of this effect was replicated in two cohorts and is currently being explored through follow-up data analysis.

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**P03.22 LB**

**Upper Respiratory Tract Infection (URTI) Among Children in Eastern Province of Sri Lanka**

Thoufeek Rifka Jesmin (1)

**Purpose:** This study was conducted on Upper Respiratory Tract Infections among School children at a moderately remote village Kinniya which falls in the Eastern province of Sri Lanka to find out the prevalence about grade 5 to 10 students and to derive possible interventions on how they have influenced due to lack of knowledge regarding hygiene.

**Methods:** The descriptive study on 9 to 15 age group of school children in 2 rural schools in Eastern province was done using a number of 222 conveniently selected sample. Data was collected using an interviewer administered questionnaire and the data were analyzed using “descriptive statistics”.

**Results:** Out of 222 students, only 48 students (21%) were washing hand more than 3 times at school. Out of 116 students 69 students (59%) are sharing water bottles at school. Findings clearly indicate that one sixth of the children (15%) among the candidates refrained from using the elbow to cover and wipe the nose during sneezing. However 77% of students were aware of the proper manners of preventing contamination with sputum. When questioned about the risk activities for spreading respiratory infections 113 (50%) identified by touching an infected person, 116 (52%) identified as by water; 100 (45%) as through personal contact, 122 (54.9%) identified as by food.

**Conclusion:** This study demonstrates how poor hygienic factors contribute to Upper Respiratory Tract Infections among school Children. Never the less most of the students were aware of spreading of infections though they were not aware of preventive hygienic factors.

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**P03.23 LB**

**Screening of Antioxidant Activity of Methanolic Extract of Citrullus Colocynthis Seeds**

Gurpreet Singh Bal (1)

**Purpose:** To assess the antioxidant property of Citrullus colocynthis seed extract by DPPH free radical scavenging and hydrogen peroxide method.

**Methods:** Citrullus colocynthis seed extract was prepared by cold maceration method with methanol for 6 hours. The extraction process was repeated for 3 times. The concentrated extract was investigated for phytochemical screening followed by antioxidant activity using 1, 1-diphenyl-1-picrylhydrazyl (DPPH) free radical scavenging and Hydrogen peroxide method.

**Results:** The IC50 (inhibition concentration 50) of methanolic seed extract of Citrullus colocynthis using DPPH and H2O2 at 300 μg/ml was found to be 70.3% and 72.4% respectively as compared to standard ascorbic acid.

**Conclusion:** This study provides scientific insight in the use of Citrullus colocynthis seeds as a potent source of antioxidant and can be used in the treatment of various health ailments and against oxidative stress.

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**P03.24 LB**

**Improving Chinese Medicine (CM) Knowledge Base for Non-CM Community Health Practitioners: A Description of Shanghai-Based Community Health Education Program**

Weijun Zhang (1), Wenjian Wang (2), Ka-Kit Hui (1)

**Purpose:** Since its launch in 2009, China’s healthcare reform has anchored in primary care and prevention mainly through development of community health. Chinese medicine (CM) is expected to play a substantial role in the treatment of common diseases as well as in public health services. Service networks in community health centers have been building up in the last four years. Realizing that the capacity to deliver services and the quality of services should be improving further, the Shanghai Bureau of Public Health decided to develop a key project to enhance the knowledge and skills of Chinese medicine for Non-CM practitioners in Shanghai community health program. The non-CM community health practitioners include three groups: (1) 8043 western medicine physicians; (2) 1826 public health workers; and (3) 1746 rural health workers. The goal is to better equip these community health practitioners with skills in addressing common diseases and general health management utilizing appropriate techniques based on the principles of integrative medicine. The program started its implementation phase in the February of 2014.

**Methods:** This study describes the program including the historical context, structure, content, and activities of the program, as well as selected program outcome measures and demographic characteristics. The study also explores the challenges of the implementation and maintenance of the project.

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**P03.25 LB**

**Listening to Oneself: A Description of Resiliency Practices of First-Year Medical Students**

Nicole A. Steckler (1), Ayla D. Ervin (1), Michael Latteri (1), Tamera Wilkins (1), Lauretta Young (1)

**Purpose:** A one-week intensive learning experience that emphasizes holistic self-care and belongingness in a community of like-minded peers and faculty appears to be effective in reducing negative affective states related to anxiety and depression which may be exacerbated by medical school training. The sustained impact of this effect was replicated in two cohorts and is currently being explored through follow-up data analysis.

**Contact:** Rita Benn, ritabenn@umich.edu
Purpose: Resiliency is critically important for medical students and health professionals. This qualitative inquiry illuminates practices that medical students reported using to bounce back from stressful experiences during their first year.

Methods: Semi-structured interviews were conducted with 16 students at the end of first year, including students who had and had not taken a resiliency-skills elective the prior year. Questions focused on students’ perceptions of practices that helped them bounce back from stress, including probes about specific practices they had found helpful before, during, and after an event they identified as stressful. Thematic analysis was conducted by four coders.

Results: Most notable was the wide range of both sources of stress and specific recovery practices. Medical school itself was named as a source of both chronic and episodic stress. It was a significant finding that students demonstrated exceptional resiliency in the face of a diverse set of negative life events including illness, loss, romantic relationship distress, and major social, cultural and geographic dislocations. An overarching theme highlighted the importance of listening to one’s own inner compass, learning what works for oneself (which might be different than others’ advice) and being intentional about engaging those practices. The specific practices named included a wide range of formal and informal methods for self-awareness, self-regulation and intentional positivity practices, including seeking perspective, resetting, anticipating stress and practicing self-care. An additional important theme was the “normalizing” impacts of planned and spontaneous contexts for community and interpersonal connection. We were surprised at how rich, nuanced and diverse the stories were that would otherwise be encapsulated in the phrase “social support.”

Conclusion: This research has practical implications for orientation and support at each stage of medical education. These preliminary findings suggest curricular and advising strategies that support self-efficacy and trusting one’s own judgment rather than external sources of information and advice.

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P03.26 LB
Effect of CAM Course Title and Definition on Medical Students’ Attitudes About CAM in Saudi Arabia

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Purpose: To compare the effect changing the course title and definitions, (Traditional versus complementary medicine), on the attitudes about complementary and alternative medicine (CAM) of undergraduate medical students from one medical school in Saudi Arabia.

Methods: Self-administered survey study including 128 students from Al Majmaa medical school in the central region of Saudi Arabia. Students were given randomly the questionnaire but using different course title and definition to describe the same CAM course. Using “Traditional medicine” as defined by WHO or “complementary medicine” as defined by the NCCAM/NIH. We use the attitudes questionnaire developed by Furnham et al., and each item was judged on an 8 points agree-disagree scale. The study was conducted before attending the CAM course.

Results: For both course titles, all students strongly agreed that “medical students know too little about the specialty” and “doctors should take the specialty to complement the efficacy of orthodox medicine”. Using the “traditional medicine” title instead of “complementary medicine”, students more statistically significantly agreed that “the specialty has low status compared to medicine” (p = 0.004), “the students who express an interest in the specialty as seen as completely mad” (p = 0.04). While using “complementary medicine as a title, students more statistically significantly agreed that “only doctors should be allowed to practice the specialty” and strongly disagreed that “you need to be gifted to carry out the specialty” (p = 0.009).

Conclusion: Introducing the same CAM course under different titles and definitions may affect the attitude of the undergraduate medical students towards CAM.

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P03.27 LB
A Pilot Study Using Traditional Chinese Medicine Providers to Promote Colorectal Cancer Screening in the Chinese American Community

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Purpose: There is limited research on the use of traditional healers in community-based public health promotion in the United States. Given the high use of traditional Chinese medicine (TCM) among Chinese Americans a pilot study was conducted to explore the feasibility of a novel approach—incorporating TCM providers to promote colorectal cancer (CRC) screening in the Chinese American community.

Methods: A CRC education program was developed for TCM providers using formative qualitative research, including community stakeholder input. The program consisted of a 38-page educational flipchart, which presented an integrative TCM and biomedical model of cancer prevention, and a 4-hour training curriculum. 4 TCM providers (two acupuncturists and two herbalists) were recruited and trained. Each TCM provider then recruited 15 participants and conducted a single education session for each participant in small groups on CRC prevention. Eligible participants were Chinese Americans aged 50–75. Survey data on demographics, CRC knowledge, and behaviors, was collected at pre- and three-months post-intervention. McNemar’s tests were used to evaluate pre-post changes.

Results: Study participants (N = 60) included 62% females, mean age of 62.4 years, and 97% born in China. Nearly half (41.7%) had received an herbal prescription from a TCM provider and 23.3% at least one acupuncture treatment in the past year. At 3-months, participants’ knowledge of CRC screening recommendations increased significantly. Rates of having heard of a fecal occult blood test (FOBT), sigmoidoscopy, or colonoscopy increased from 82% to 93% (p = 0.008). Ever receipt of any one of those tests increased from 70% to 83% (p = 0.01). The rate of being up-to-date with CRC screening increased from 68% to 79% (p = 0.03).

Conclusion: It is feasible to use TCM providers in community-based CRC prevention outreach and education. This pilot study
A community health center clinic specializing in acupuncture in a managed care setting is acceptable and desirable by patients and physicians. Favorable clinical and cost-of-care outcomes support the continued integration of acupuncture services into medical care.

Methods: Data for this observational assessment were collected on patient demographics, health history, clinical outcomes, satisfaction, and associated costs. All patients received individualized acupuncture treatments provided by licensed acupuncturists according to standards of care.

Results: Data were collected on 560 individuals. Seventy-eight percent were female, 47% were Hispanic/Latino, 18% were African-American, 30% were white. Mean age was 38 years. 73% were referred for pain and 21% were referred for headache. Mean reduction in pain level based on a 10-point Likert scale was 2.2 (p < 0.0001). Duration of painful episodes decreased (p < 0.0001) as did frequency of pain episodes (p < 0.0001). Activities of daily living also showed improvement: ability to move or work, sleep quality, ability to enjoy recreation and life (all p < 0.0001). Quality of life based on SF1 improved (p = 0.0004). Headache intensity levels were significantly reduced by 2.4 points (p < 0.0001). Headache-related fatigue, sleep quality, and mood improved (p = 0.004, p = 0.09, p = 0.001, respectively) as did Quality of life (p = 0.03). Preliminary cost estimates suggest a decrease in other healthcare costs ($40/member/month) and increased likelihood that individuals who received acupuncture continued their membership in the managed care plan.

Conclusion: Preliminary results indicate that offering acupuncture in a community health setting is acceptable and desirable by patients and physicians. Favorable clinical and cost-of-care outcomes support the continued integration of acupuncture services into medical care.

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P04.02
Acupuncture in a Managed Care Setting: Clinical Outcomes, Patient Satisfaction, Cost Considerations
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Purpose: A community health center clinic specializing in acupuncture partnered with a large managed care organization to determine whether acupuncture treatment might influence clinical outcomes, patient satisfaction and costs of care. Members of the managed care organization were referred through their physicians to receive up to 20 treatments. Results of the first 6 years will be presented.

Methods: Data for this observational assessment were collected on patient demographics, health history, clinical outcomes, satisfaction, and associated costs. All patients received individualized acupuncture treatments provided by licensed acupuncturists according to standards of care.

Results: Data were collected on 560 individuals. Seventy-eight percent were female, 47% were Hispanic/Latino, 18% were African-American, 30% were white. Mean age was 38 years. 73% were referred for pain and 21% were referred for headache. Mean reduction in pain level based on a 10-point Likert scale was 2.2 (p < 0.0001). Duration of painful episodes decreased (p < 0.0001) as did frequency of pain episodes (p < 0.0001). Activities of daily living also showed improvement: ability to move or work, sleep quality, ability to enjoy recreation and life (all p < 0.0001). Quality of life based on SF1 improved (p = 0.0004). Headache intensity levels were significantly reduced by 2.4 points (p < 0.0001). Headache-related fatigue, sleep quality, and mood improved (p = 0.004, p = 0.09, p = 0.001, respectively) as did Quality of life (p = 0.03). Preliminary cost estimates suggest a decrease in other healthcare costs ($40/member/month) and increased likelihood that individuals who received acupuncture continued their membership in the managed care plan.

Conclusion: Preliminary results indicate that offering acupuncture in a community health setting is acceptable and desirable by patients and physicians. Favorable clinical and cost-of-care outcomes support the continued integration of acupuncture services into medical care.

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interdependent relationship in the changing lifestyle as a whole, might support the reduction of risk behavior prevalence and its effect on non-communicable diseases.

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P04.04
Identifying Complementary and Substitute Relationships Between Korean Medicine and Western Medicine in Korea

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Purpose: The aim of this study is to identify complementary and substitute relationships between Korean Medicine (KM) and Western Medicine (WM) in Korea.

Methods: The data of 19,413 respondents was collected from the data of 2009 Korea Health Panel. The correlation between KM and WM was identified by examining the choice of Korean people between Korean Medicine institutions and Western Medicine institutions, the frequency of visits to two medical areas, and the amounts of health care expenditures from it. For statistical analysis, Logistic Regression Analysis, Poisson Regression Analysis, and Multiple Linear Regression Analysis were used according to the properties of dependent variables. The data were analyzed by the 7 disease groups; diseases of nervous system, diseases of the digestive system, diseases of the skin and subcutaneous tissue, diseases of the musculoskeletal system and connective tissue, injury, poisoning and others.

Results: The result of analysis has shown that Korean people use KM and WM complementarily in general. However, according to the analysis of choices of medical institutions, non-pharmacological KM treatment and WM has been used as a substitute for another in the diseases of the skin and subcutaneous tissue, diseases of the musculoskeletal system and connective tissue, injury, poisoning and others. And according to the analyses of frequency of visits and the health care expenditure, Korean people use one medical service as a complementarity for another in all treatment areas and disease groups.

Conclusion: The correlation between KM and WM for the Korean people was investigated by using Korean National Survey. Also, it should be valued that this research analyzed the data both in terms of diseases and the forms of services for the first time. This study can be the base line data for the future policies development for KM service delivery.

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P04.05
The Study on Factors Related to the Use of the Korean Medical Service by the Korea National Survey

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Purpose: The purpose of this study is to identify which factors affect the use of the Korean medical (KM) service rather than the Western medical (WM) service upon the use of outpatient medical service in Korea.

Methods: This study analyzed 2009 annual data in Korea Health Panel data which is Korea national survey data based on Korea Population Census. Subjects were 10,144 adults at the age of 18 or higher who had ever used the outpatient KM or WM services in 2009. Since we adopted Andersen behavioral model as the theoretical model for use of medical service, dependent variables were composed of predisposing characteristics, enabling resources, needs. The variables were set after reviewing the factors affecting the use of KM service from previous studies, followed by descriptive analysis, chi-square test, and logistic regression analysis.

Results: In conclusion, when all other variables were controlled, women, several particular area residents, 45–64 years old, the dropped out of middle school and high school graduate, family with one generation, people with more than two chronic disease, people with pain or discomfort, people with arthritis, people without hypertension, people with 28 million won or higher to people with household normalized annual income showed higher probability of using KM service rather than WM service than any other group. However the married state, occupation, exercise ability, anxiety or depression, diabetes, metabolic disease, nasal disease, urban or rural residents showed no statistical significance.

Conclusion: Demographic and social structure factors related to culture and health beliefs affected the use of the KM service rather than the WM service in Korea. Under needs factor, diseases or discomfort related to pain affect using the KM service. Access to health insurance and distance access to medical institution were not affected, while economic access affected the use of the KM service.

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P04.06
Risk in Homeopathy: Classification of Adverse Effects and Homeopathic Aggravations - A Cross Sectional Study Among Norwegian Homeopath Patients

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Purpose: Risk to the patients can be divided into direct and indirect risk. Direct risk is related to the intervention while indirect risk is related to the treatment setting, rather than the medication. Homeopathic aggravation has been defined as a temporary worsening of existing symptoms following the administration of a homeopathic remedy, which was subsequently followed by an improvement. However, this concept may impose a particular risk, as it is tolerant towards a worsening of the patients’ symptoms. The aim of this study was to investigate direct and indirect risk to patients from homeopathic treatment.
Methods: In a cross sectional survey, the study participants were questioned about possible reactions 14 days after an initial homeopathic consultation. The participants’ initial complaints were categorized according to the International Classification of Primary Care. All adverse effects reported by the patients [AE(all)] were scrutinized by two Medical Doctors, who independently graded them for severity, according to the Common Terminology Criteria for Adverse Events and reached consensus. The patient reported adverse effects were then evaluated independently by two homeopaths and classified either as “Homeopathic Aggravations” (HA) or Adverse Effects [AE(select)] according to the definition by Stub et al.

Results: Approximately half of the study participants (53%, n = 154) reported no reactions after treatment, 21% (n = 60) reported improvement and 26% (n = 74) reported worsening of the symptoms (adverse effects). All adverse events were rated as being mild to moderate. Of the 74 adverse effects, 49 (66%, 17% of the study participants) were classified as “homeopathic aggravations”.

Conclusion: This study was the first attempt to test criteria to distinguish “homeopathic aggravations” from adverse effects. It was found that two out of three adverse events reported by patients after taking a homeopathic remedy could be classified as “homeopathic aggravations”, which indicates an improved health status after an initial aggravation.

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P04.08
Attitudes Towards Heart Disease Among Chinese Elders Living in the North West of the UK
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Purpose: The aim of these two studies was to investigate the understanding of Coronary Heart Disease (CHD) among Chinese Elders in the North West of the United Kingdom (UK).

Methods: Study 1 included 33 self identified “healthy” Chinese Elders from the North West of the UK in an inductive grounded theory (Glaser and Strauss 1967) qualitative study using in depth interviews and systematic coding of the data using grounded theory methods. Study 2 involved focus groups (N=6) involving 26 Elders and followed the same analytic process of constant comparison and inductive analysis as study 1.

Results: Chinese Elders have a limited understanding of CHD and where there is knowledge it is usually related to a serious or catastrophic perception of the illness. Their understanding of CHD is that it is largely preventable, unexpected and that there is nothing that can be done to stop the progress of CHD. Elders relate the idea of CHD to death and dying and are reluctant to engage in conversation about the issue of CHD with health professionals. Rather than seeking help for CHD related symptoms (for example chest pain) the Elders will minimise their symptoms and look for alternative explanations or traditional Chinese medicine approaches which feel less threatening and evoke less anxiety.

Conclusion: A combined lack of knowledge and the minimisation of their symptoms means that Chinese Elders will invariably present late at health care services. This means that often their treatment is more intensive, at the last minute and variably present late at health care services. This means that Chinese Elders relate the idea of CHD to death and dying and are reluctant to engage in conversation about the issue of CHD with health professionals. Rather than seeking help for CHD related symptoms (for example chest pain) the Elders will minimise their symptoms and look for alternative explanations or traditional Chinese medicine approaches which feel less threatening and evoke less anxiety.

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P04.09
American Adult Acupuncture Use: Preliminary Findings from NHIS 2012 Data
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Purpose: Acupuncture has become popular since it was introduced to the US in the 1970s. The National Health Interview Survey (NHIS) showed that the ever acupuncture users increased...
from 4.2% of to 6.3% of US adult population, representing 8.19 million and 14.01 million in 2002 and 2007 respectively. This study examined the most recent NHIS 2012 data and described preliminary findings on American adult acupuncture use.

**Methods:** All individual completed 2012 NHIS adults core interviews (n = 34,525) were included. Analyses were performed in STATA including examination of the weighted distribution and prevalence of variables among subset samples of acupuncture ever users and recent users (i.e. used acupuncture in the past 12 months). Main variables assessed include number of adults using acupuncture, number of visit, cost, conditions, reasons, communication and etc.

**Results:** The findings revealed that 6.2% (14.48 million) of adults ever used acupuncture and 1.6% (3.66 million) used it in the past 12 month. Average number of recent acupuncture visits is 6.81 ± 0.52 (95% CI 5.79–7.84). Average cost per visit is $92.69 ± 39.27 (95% CI 12.38–173.00). About 2.2% (1.52 million) of adults CAM users ranked acupuncture as the first of top three important ones of all CAM therapies inquired. They reported using acupuncture for general wellness or disease prevention (45.2%), improving energy (31.6%) and immune function (25.6%), or specific health problems (72.1%). Acupuncture was mostly reportedly used for pain related conditions. One third (33.7%) of the recent users told their personal health care provider about acupuncture use.

**Conclusion:** Although the proportion of recent acupuncture user appeared increased at a steady pace (1.6% in 2012 vs. 1.4% in 2007), the proportion of ever acupuncture users decreased 0.1% from 2007. In addition to the differences of population size (223,200,000 in 2007 vs. 234,960,000 in 2012) and NHIS question format, the findings may indicate potential acupuncture user saturation with more return users.

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**P04.11**

**Dietary Supplement Medical Reconciliation in the Inpatient Setting**

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**Purpose:** To explore medical reconciliation of dietary supplements (DS) in an urban hospitalized population and to determine characteristics associated with appropriate medical documentation of DS.

**Methods:** We analyzed DS use reported among 558 prescription medication users from inpatients recruited as part of the Re-Engineered Discharge clinical trial to identify: 1) if patients self-reported DS to physicians or nurses, and 2) if DS use was documented in the admission note. We examined socio-demographic and clinical characteristics for association with DS documentation. Crude associations were assessed using chi square tests for dichotomous and categorical variables and t-tests for continuous variables. A multivariable logistic regression analysis was performed to assess adjusted associations with DS documentation.

**Results:** Sixty percent reported DS use (n = 333). Among these users, 36% had DS documentation in the admission note, 20% were asked about supplement use by a physician or nurse at admission, 18% said they would disclose use if asked, and 48% reported that they would continue to use DS after discharge. Of those reporting the use of at least one DS, only 21 (6%) were both asked about and had documentation of DS use. A multivariable logistic regression revealed that every additional year of age is associated with significantly lower odds of having documentation of supplements [OR: 0.979, 95% CI: (0.962, 0.997)]. Identifying as Hispanic or other also reduces the odds of having supplement documentation compared to those who identify as white [OR: 0.424, 95% CI: (0.185, 0.936)].

**Conclusion:** Six percent of participants were asked, disclosed and had documentation of DS, thus meeting Joint Commission standards. While more than half of hospitalized patients used DS, most were not asked about this use. The odds of documentation of supplements decrease with age of the patient, and are generally lower among those who identify as Hispanic or of other race.

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**P04.12**

**Health-Related Self-Perceptions Over Time and Provider-Based Complementary and Alternative Medicine (CAM) Use in People with Arthritis or Inflammatory Bowel Disease**

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**Purpose:** For people with chronic inflammatory disease, maintaining a healthy lifestyle and managing stress are an important part of disease management. Previous research suggests that
CAM use may promote engaging in health behaviors, and that people may use CAM because it fits with their self-image of being a person with a healthy lifestyle. However, little of this research has been conducted with chronic illness samples. The aim of this study was to prospectively investigate how health-related self-perceptions are associated with the use of provider-based CAM in two chronic inflammatory diseases, arthritis and inflammatory bowel disease (IBD).

Methods: A prospective online survey was administered to convenience samples of individuals with arthritis or inflammatory bowel disease, and a follow-up survey completed 6 months later. Surveys included measures of provider-delivered CAM use, disease-related factors, health-related self-perceptions, and trait resilience.

Results: 325 people (170 with arthritis and 155 with IBD) completed the initial and follow-up surveys. Rates of CAM use were 43.2% and 45.9% for the arthritis and IBD groups, respectively. T-tests revealed significant differences on healthy lifestyle self-perceptions and trait resilience for both illness groups. Differences in self-perceptions about handling stress were only significant in the IBD group. Multivariate logistic regression controlling for demographics and health-related variables revealed that seeing oneself as having a healthy lifestyle predicted CAM use in both illness groups (arthritis OR = 1.29; IBD OR = 1.24). Being resilient predicted CAM use only in the IBD group (OR = 2.09), and self-perceptions about handling stress predicted CAM use only in the arthritis group (OR = 1.20).

Conclusion: These findings suggest that that people with arthritis and IBD who perceive themselves to have a healthy lifestyle, handle stress well, and are resilient are more likely to use provider-based CAM. Such information has implications for maximizing the health-promoting aspects of CAM use.

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P04.13
Missed Opportunities: A Descriptive Analysis of CAM Discussions and Practices in the Management of Pain in Oncology Patients

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Purpose: To identify patient circumstances in which CAM treatment options may be relevant for symptom control and to describe these opportunities based on clinician response and management approach.

Methods: The first 166 patients enrolled in a parent study on cancer communication who had also completed a 3-month follow-up survey were eligible for analysis. From these, we identified patients with high, self-reported pain symptom ratings (severity and frequency $\geq 5/10$) and reduced quality of life ratings ($\leq 5/10$). For these patients, we further analyzed post-encounter patient and clinician surveys, the medical record, audio recordings in all but 1 case. During follow-up, 65% of patients were receiving traditional pain medications at enrollment or had these therapies added or escalated over the 3 month period. Average patient reported quality of life increased 0.6/10; pain severity and frequency decreased by 1.0 and 1.55/10, respectively.

Conclusion: Discussion of CAM treatment options for cancer-related pain does not often occur, even in contexts where it is most relevant. Despite this, many cancer patients seek out or engage in CAM therapies. Although clinicians appropriately address cancer pain with traditional medications, significant opportunities exist for patient-centered discussions about adjunctive CAM treatment options in this context.

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P04.14
Marginalization and Companionable Silence: CAM Practitioners’ Perspectives of Their Interprofessional Relationships with Maternity Care Providers

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Purpose: Contemporary maternity care is characterised by therapeutic pluralism whereby women engage with multiple care providers from varied professional groups. This includes the concomitant involvement of conventional maternity care providers and complementary and alternative medicine (CAM) practitioners. While there have been some attempts to explore the perspective of conventional care providers towards the involvement and inclusion of CAM in women’s maternity care, the views of CAM practitioners have been overlooked.

Methods: This study draws upon semi-structured interviews with 21 CAM practitioners who provide care to women during pregnancy. The practitioner groups represented within the study were: naturopaths, osteopaths, massage therapists, doulas, acupuncturists, and chiropractors. Based upon a modified grounded theory approach, the interviews were analyzed and common themes across interviews were identified.

Results: The analysis identified 3 major themes associated with the interface between CAM and conventional care providers in maternity care. Through the first theme the CAM practitioners described conventional care providers’ rejection of CAM creating marginalization of doctors. Second, the interface between midwives and CAM practitioners was depicted as an interprofessional ‘companionable silence’. Finally, CAM practitioners describe practicing in isolation even from other CAM practitioners, despite desiring collegial support.

Conclusion: The interprofessional dynamics experienced by CAM practitioner providing maternity care is complex. There is a need to improve the collaboration and communication between all care providers involved in women’s maternity care team. Without addressing these interprofessional issues safe and effective woman-centred care will not be realized.

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P04.15
Changes in the Attitudes of Medical Doctors Toward Traditional Korean Medicine - A Systematic Review in Korean Literature
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Purpose: To find a collaboration strategy between western medicine and traditional Korean medicine (TKM), this study aims to figure out the changes in the attitude of doctors toward TKM through systematic review.

Methods: Systematic literature searches were performed on six databases in Korea. Studies were categorized according to the respondents and question items and analyzed by the context of questions, similarity of respondents and measurement scale. And we analyzed the changes of response regarding to doctors’ and medical students’ perspective and attitude to TKM.

Results: Eighteen survey studies including attitude of doctors and medical students toward TKM were selected, which were conducted between 1993 and 2011. Although the attitudes toward TKM did not show a positive changes, doctors have had more interest in acupuncture than herbal medicine and appreciated TKM’s treatment effect for muscular skeletal disease. In spite of little TKM education experience, they had intentions for acupuncture education at least. Many doctors have listed the unscientific aspect as major reason they cannot trust TKM. Doctors working for cooperative practice showed more positive attitude than other doctors and medical students had more positive attitude in general than doctors.

Conclusion: Though the growth of TKM service and cooperative practice since 1990s, doctors’ attitude toward TKM seem to become more negative in Korea. To improve their attitude, making scientific evidences for TKM are required as well as giving more education and treatment experience.

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P04.16
American Adult Yoga Practice: Preliminary Findings from NHIS 2012 Data
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Purpose: Research examining benefits of Yoga has been growing rapidly in the past decade. The 2007 National Health Interview Survey (NHIS) showed that yoga is one of the top 10 complementary health approaches used among U.S. adults, with about 6% of adults having used yoga for health purposes in the previous 12 months. This study examined the most recent NHIS 2012 data and described preliminary findings on American adult yoga practice.

Methods: All individual completed 2012 NHIS adults core interviews (n=34,525) were included. Analyses were performed in STATA including examination of the weighted distribution and prevalence of variables among subset samples of yoga ever users and recent users (i.e. practiced yoga in the past 12 months). Main variables assessed include number of adults practicing yoga, number of visit, cost, conditions, reasons, communication and etc.

Results: The findings revealed that 13.2% (30.99 million) of US adult ever practiced yoga and 8.9% (20.95 million) practiced it in the past 12 months. Average number of seeing an instructor in the past 12 month is 18.58 ± 18.45 (median = 10.0). Of those who paid for a visit, average cost per visit is $23.16 ± 28.59 (median =15.0). About 13.2 % (9.16 million) of adult CAM users ranked yoga as the first of top three important ones of all CAM therapies inquired. They reported using yoga for general wellness or disease prevention (39.7%), reducing stress (15.4%) and improving overall health (14.6%), or specific health problems (15.3%). The mostly mentioned conditions were pain related such as back pain. Almost half (47.6%) reported that they told their personal health care provider about the yoga practice.

Conclusion: The proportion of adults practicing yoga in the past 12 months increased about 50%, from 6.1% in 2007 to 8.9% in 2012. This increase may be associated the recent research findings on the positive impact of yoga on pain.

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P04.17
Use of Complementary and Alternative Medicine Among Adults with Neck Pain in the 2007 National Health Interview Survey
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Purpose: Estimated 12-month prevalence rates of neck pain among adults range from 30% to 50%. Our objective was to describe correlates of neck pain, predictors of complementary and alternative medicine (CAM) use in adults with and without neck pain, and differences in reasons for CAM use among adults with and without neck pain.

Methods: We compared 23,393 adults with and without self-reported neck pain using the 2007 National Health Interview Survey. Data on CAM use, socio-demographics, health status and healthcare factors were extracted from the Adult Complementary and Alternative Medicine supplement, the Sample Adult core, and the Person core components.

Results: 3105 adults (13.3%), representing an estimated 29 million U.S. adults, reported neck pain within the 3 months prior to the survey. Compared to adults without neck pain, those with neck pain were significantly more likely to be older, non-Hispanic white, and women. Those with neck pain were also more likely to be in fair or poor health, have a history of comorbidities, be a current smoker, and have functional limitations. Past year visits to the emergency room and delayed medical care due to cost were also associated with having neck pain. CAM use was more common among adults with neck pain compared to adults without neck pain (56.3% vs. 32.7%, p < 0.01). The most common modalities were herbal supplements, deep breathing exercises, and chiropractic. Acupuncture was least commonly used. Compared to CAM users without neck pain, those with neck pain were more likely to use CAM because conventional treatment was thought to be too expensive or ineffective and because of recommendations from providers or family/friends.

Conclusion: Adults with neck pain use CAM more often than those without. Given the prevalence of adults with neck pain who use CAM, there is a great need to understand the effectiveness of CAM on neck pain.

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P04.18
Chinese Herbal Medicine Guizhi Fuling Formula for Treatment of Uterine Fibroids: A Systematic Review of Randomized Clinical Trials

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Purpose: Guizhi Fuling Formula is widely applied for treatment of uterine fibroids in China. The formula consists of five herbs: Ramulus Cinnamomi, Poria, Semen Persicae, Radix Paeoniae Rubra or Radix Paeoniae Alba, and Cortex Moutan. Many clinical trials have been published. This review aims at assessing the efficacy and safety of the Guizhi Fuling formula for uterine fibroids.

Methods: PubMed, Cochrane CENTRAL, EMBASE, and four Chinese databases were searched till May 2013. We included randomized trials testing Guizhi Fuling Formula for uterine fibroids, compared with no intervention, placebo, medication, or other Chinese patent medicines approved by the State Food and Drug Administration of China. Authors extracted data and assessed the quality independently. We applied RevMan 5.2.0 software to analyse data of included randomized trials.

Results: A total of 38 randomized trials were identified with involving 3816 participants. The methodological quality of the included trials was generally poor in terms of risk of bias. Meta-analyses demonstrated that Guizhi Fuling formula plus mifepristone was more effective than mifepristone alone in reducing the volume of fibroids (in total volume of multiple fibroids subgroup, mean difference (MD): 1.87, I²=0.76 cm³, 95% CI 1.23 to 0.48; in average volume of maximum fibroids subgroup, MD: 3.35 cm³, 95% CI 2.84 to 3.87, I²=93%, random effects model). Guizhi Fuling Formula significantly improved dysmenorrhoea either used alone (relative risk (RR) 2.27, 95% CI 1.04 to 4.97) or in combination with mifepristone (RR 2.35, 95% CI 1.15 to 4.82). No serious adverse events were reported.

Conclusion: Guizhi Fuling Formula may have additional benefit based on mifepristone in reducing volume of fibroids. However, due to high risk of bias of the trials, we could not draw confirmative conclusions on the benefit. Further well-designed clinical trials are warranted.

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P04.19
Electronic Medical Record Documentation of Practices, Patient Experiences, and Impacts of Integrative Medicine

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Purpose: VA is transforming its healthcare system to be personalized, proactive, patient-driven, and focused on holistic patient-centered care (PCC). One strategy is by providing integrative medicine modalities e.g., complementary and alternative medicine (CAM) and integrative mental health (IMH). However, little is known about how referral to/use of these modalities is documented in patients’ medical records (EMR). We aim to understand documentation of patient interest in, recommendations to, and participation (or not) in CAM and IMH in EMRs at 4 VAs.

Methods: We utilized administrative data to identify patients with CAM (159) or IMH (534) clinic stop-codes. During FY 2012, 292 CAM and 367 IMH visits were recorded, from which we identified a random sample (~10 patients each for CAM and IMH) at each VA.

Results: Most CAM-codes were from one VA (88%). IMH use was seen at all 4 VAs, but 92% were from the 3 facilities with sparse CAM-codes. 69 EMR reviews (29 CAM, 40 IMH) are being conducted that include all encounters in the 6 months prior to EMR review date. CAM users were male-83%, white-74%, married-51%, and average age of 63. IMH users were male-81%, white-53%, unmarried-62%, and average age of 50. Findings show variation in consistency/types of documentation for referrals to/use of CAM/IMH. Documentation often uses standardized templates with limited patient-specific/visit-level detail. Patient preferences for CAM/IMH are not regularly documented.

Conclusion: Documentation of the patient’s experience is critical to providing PCC. Although EMR templates are helpful for streamlining documentation, richer patient-specific information for use of integrative modalities, e.g., CAM/IMH is needed. Documentation should include patient-reported information, e.g., interest in/experience with, these modalities. Finally, documentation on who CAM/IMH is offered to, who is participating, reason for participating or not, and if providers are following-up on non-use, is needed to understand reach, acceptance, impact, and patient-centeredness of these modalities.

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P04.20
Measuring Contextual Factors in the Healthcare Encounter

Abstract Withdrawn
Abstract Withdrawn
(continued)

P04.21
Manipulative Therapies for Infantile Colic
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Purpose: To evaluate the efficacy or effectiveness of manipulative therapies for infantile colic.

Methods: Major databases searched for studies in all languages including Centre Watch, NRR Archive and UKCRN in 2010. Study selection criteria: Randomized trials evaluating the effect of chiropractic, osteopathy or cranial osteopathy alone or in conjunction with other interventions for infantile colic.

Results: We identified 6 studies for inclusion in our review representing 325 infants. No information was found on 3 further studies and there were 3 ongoing studies. Of the 6 included studies, 5 were suggestive of a beneficial effect and one found no evidence of beneficial effects. Combined data shows manipulative therapies had a significant effect - reducing average crying time by 72 minutes per day (mean difference (MD) = 1.20; 95% CI = 1.89 to 0.51). This conclusion is sustained for studies with a low risk of selection bias and attrition bias. When analyzing only those studies with a low risk of performance bias (parental blinding) the improvement in daily crying hours was not statistically significant (MD = 0.57; 95% CI = 2.24 to 1.09). The quality of the studies was variable. There was a generally low risk of selection bias but a high risk of performance bias. One of the studies recorded adverse events and none were encountered.

Conclusion: Parents of infants receiving manipulative therapies reported fewer hours crying per day than parents whose infants did not and this difference was statistically significant. Most studies had a high risk of performance bias due to the fact that the assessors (parents) were not blind to who had received the intervention. When combining only those trials with a low risk of such performance bias the results did not reach statistical significance. Further research is required where those assessing the treatment outcomes do not know whether or not the infant has received manipulative therapy.

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P04.22
When Complex Care Goes Complementary
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Purpose: To assess patterns of complementary and alternative medicine (CAM) use for children with special health care needs (CSHCN) and associations with conventional medical care (CMC) utilization, expenditures, access and quality of care.

Methods: Data from a linked file of the 2007 National Health Interview Survey (NHIS) and 2008 Medical Expenditure Panel Survey and the 2012 NHIS were used. Bivariate and logistic and two-part regression analyses were employed.

Results: CAM use was prevalent among CSHCN (24.7%), children with multiple chronic conditions (2 CC: 24.9%; 3 + CC 37.9%), and more complex CSHCN who meet criteria for the Affordable Care Act Diagnostic Condition List (ACA, 42.2%) or experience difficulties in daily activities/functioning (36.4%). Regardless of co-occurring condition types assessed, CAM use was significantly higher among children who missed two or more weeks of school (Rate Ratio: 1.58–3.26 across diagnosis groups). CSHCN not receiving care within a medical home were more likely to use CAM (27.9% vs. 16.3%, p = 0.04). CSHCN CAM users were less likely to meet criteria across nearly all subdomains of medical home compared to CSHCN non-CAM users (e.g., 66.8% vs. 81.2% on shared decision making). The mean adjusted CMC expenditures for CAM users were significantly higher than for non-CAM users ($2,084 vs. $1,342, p < .0001) and the highest expenditures were reported for CSHCN using CAM who qualify on ACA criteria ($6,462). A significant proportion of children’s CAM use (40%) was not disclosed to CMC providers.

Conclusion: CAM use is associated with the complexity and intensity of children’s health conditions and service needs, difficulties in accessing and poorer quality of CMC. Children with complex health problems receive multiple forms of conventional, complementary and alternative care, emphasizing the need for well integrated and coordinated pediatric care systems within the context of a medical home.

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P04.23
Use of Complementary and Alternative Medicine in Pediatric Cancer Patients: Differences Between Children and Adolescents
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ACM-2014-5000-abstracts-ver9-Poster-Abstract_7P.3d 05/06/14 1:53pm Page 115

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Purpose: Use of complementary and alternative medicine (CAM) in children with cancer is common and probably increasing worldwide. However, data concerning differences between children and Adolescents (> 16 years of age) focusing on prevalence, socio-demographic factors, reasons for use/non-use adverse effects and costs are lacking.

Methods: A population-based questionnaire-survey with 497 participants was conducted in Germany.

Results: Of the 457 respondents (92%) 322 were children and 135 adolescents with malignant diseases. 31% reported CAM use from the time when being diagnosed, compared to an overall lifetime prevalence rate of 41% before cancer diagnosis. CAM use was higher in adolescents than in children after being diagnosed with cancer. There was a significant decrease of CAM use in the children’s subgroup after cancer diagnosis whereas the user rate in the adolescents’ subgroup slightly increased. Among CAM users the most prevalent therapies were homeopathy, massage, anthroposophic medicine, acupuncture, and Bach flowers. Reasons for use were to reduce therapy-related side effects, strengthen the immune system, achieve physical stabilization and increase healing chances. CAM-users had a higher parental education and family income. A total of 68% in children and 55% in adolescents were confident that CAM had beneficial effects. A majority of CAM users (97%) would recommend CAM use to other patients. Most users (78%) informed a physician about CAM use. Side effects were minor and self-limiting and rarely reported (5%).

Conclusion: The high prevalence rates seem to represent the parental or patients needs for additional treatment perceived as successful and devoid of side-effects. Clinical care and the physician-patient relation might profit from an enhanced understanding of CAM and a greater candidness towards the parental needs. Safety and efficacy – especially of CAM with high prevalence rates – should be studied in rigorous basic and clinical research.

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P04.25 Vaccination Attitudes and Education in Naturopathic Medicine Students

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Purpose: Use of CAM providers has been associated with parental refusal of childhood vaccines and increased risk of vaccine preventable diseases, however vaccine attitudes and practices among CAM providers are poorly understood. This study aimed to assess the attitudes, education, and sources of knowledge surrounding childhood vaccinations among students in a complementary medicine program.

Methods: Cross-sectional survey among 560 students at National College of Natural Medicine (Portland, OR) in May 2013 using web-based Qualtrics software. The survey instrument was created using an iterative process combining previous surveys coupled with expert opinion from thought leaders in the field. Students were asked about demographics, sources of information about childhood vaccines, differences between mainstream and CAM education on childhood vaccines, alternative vaccine schedules, adverse effects, perceived efficacy, and credibility of information sources.

Results: 109 students provided responses (19.4% response rate). All students surveyed learned about vaccinations in multiple courses and through independent study; with varying levels of perceived credibility. The majority of students planned on regularly (26%) or occasionally (45%) prescribing or recommending vaccinations for their patients and 82% supported the general concept of vaccinations for prevention of infectious diseases. However, the vast majority (96%) reported that they would recommend a schedule different from the standard CDC-ACIP schedule. Concerns identified by respondents included vaccines being given too early (73%), too many vaccines administered simultaneously (70%), too many vaccines overall (59%), and concerns about preservatives and adjuvants in vaccines (72%).
About 40% reported a healthy diet and lifestyle was more important for prevention of infectious diseases than vaccines. 90% reported that they were more critical of vaccines than mainstream pediatricians, medical doctors, and medical students.

**Conclusion:** Education surrounding childhood vaccinations comes from varied sources in this cohort of CAM students. Attitudes surrounding childhood vaccinations are highly nuanced, with potential public health implications.

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**P04.26**

Use of Complementary and Alternative Medicine by Adults with Gastrointestinal Conditions: Results from a National Survey

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**Purpose:** Evidence suggests that specific complementary and alternative medicine (CAM) modalities may be useful in addressing gastrointestinal (GI) conditions. However, the overall patterns of CAM use for GI conditions remains unknown. We sought to elucidate the prevalence and patterns of CAM use among U.S. adults with GI conditions.

**Methods:** We used the 2012 National Health Interview Survey (n = 34,525), a nationally representative survey of the civilian, non-institutionalized U.S. population, to estimate the prevalence of CAM use among adults with GI conditions (abdominal pain, acid reflux/heartburn, digestive allergy, liver condition, nausea and/or vomiting, stomach or intestinal illness, ulcer). We also examined perceived helpfulness of CAM therapies, disclosure of use to health care providers, and out-of-pocket costs. We weighted prevalence estimates, to reflect the complex sampling design, using SAS. Logistic regression was used to model factors associated with CAM use.

**Results:** Of 13,505 respondents with an acute or chronic GI condition in the past year, 42% (n = 5629) used CAM in the past year and 3% (n = 407) used at least one CAM modality to address a GI condition. The top 3 modalities specifically used to address GI conditions were natural products (80%, most commonly probiotics, fish oil, and digestive enzymes), mind body therapies (50%), and manipulative therapies (41%). Use of CAM modalities to address GI conditions helped “a great deal” (59%) and made it easier to cope with health problems (51%). Respondents told their health care provider about use of these therapies 68% of the time. Additional analyses will report on dollars spent and explore sociodemographic and lifestyle characteristics associated with CAM use for GI conditions.

**Conclusion:** CAM is used by nearly half of the 92 million Americans with GI conditions. The most common therapies used for GI conditions are natural products, mind body, and manipulative therapies. The majority who use CAM for GI conditions find it helpful.

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**P04.27**

Beyond Expectations: Developing a New Questionnaire to Measure Patients’ Beliefs about Conventional and Complementary Therapies for Low Back Pain

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**Purpose:** In low back pain (LBP) clinical guidelines recommend diverse conventional and complementary therapies and suggest clinicians should take into account patients’ treatment preferences. A previous qualitative study showed that patients evaluate LBP treatments along four dimensions: credibility, effectiveness, concerns, and personal suitability. Existing questionnaires typically focus on single therapies (e.g. medication) or one or two dimensions (e.g. expectations). This study aimed to test whether all four dimensions from our qualitative work can be measured reliably using equivalent items for acupuncture, manual therapy, medication, and exercise.

**Methods:** A cross-sectional survey of 439 LBP primary care patients inquired about treatment beliefs using 20 items measuring patients’ perceptions of treatment credibility, effectiveness, risks and personal suitability. We analyzed responses via non-parametric item response theory (Mokken R).

**Results:** Four poorly functioning items were removed from the questionnaire to achieve 4-item sub-scales with two reversed items each; item selection was based on homogeneity and monotonicity at item level and at scale level, for all 4 treatments. The sub-scales had good homogeneity and monotonicity levels and Cronbach’s α values were above the recommended threshold (all < .7). Overall, medication items showed slightly lower homogeneity (H = .42) in comparison to acupuncture, exercise, and manual therapy beliefs (H = .50, .56, and .60).

**Conclusion:** We have developed a 16-item questionnaire with four 4-item uni-dimensional sub-scales that reliably measure patients’ beliefs about treatment credibility, effectiveness, risks, and personal suitability across diverse LBP therapies - acupuncture, manual therapy, medication, and exercise. Our questionnaire appears to be suitable for use in conventional and complementary medicine settings. Future research using our questionnaire could test whether patients’ beliefs about different therapies predict treatment-decision making and patient outcomes. Non-parametric item response theory provides a useful alternative to classical test theory for developing questionnaire measures of patients’ beliefs in integrative medicine.

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**P04.28**

Qualitative and Quantitative Evaluation of the Impact of Peer Wellbeing Group Coaching for Undergraduate Students

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**Purpose:** Given undergraduate college students’ changing needs, higher education professionals are obligated to explore innovative means of supporting students. This study examines the experiences of students who participated in wellbeing-focused peer coaching groups through focus group data, and compares the results of quantitative measures of insight and self-reflection between the treatment and control groups. This study was exploratory in nature and aimed at evaluating the experience
of peer coaching for undergraduate students. The study sought to answer the following research questions: 1. How do students describe the skills they gain as a result of participation in the peer coaching groups? 2. What do students learn about themselves through participation in peer coaching groups, and how does this learning contribute to their overall sense of wellbeing?

Methods: Twenty-nine sophomore students self-selected to participate in the coaching program. Participants took part in a 2-hour training to introduce solution-focused, holistically-oriented coaching skills. The training, based upon the University of Minnesota 4-Pillars of Health Coaching model, covered deep listening, motivational interviewing, and mindful presence. Following the training, the students were expected to meeting weekly for 60-minute coaching sessions in groups of four. These sessions were facilitated by one or two students who had participated in a previous phase of this coaching program. Each group met nine times. A control group of 17 sophomore students did not participate in the coaching program.

Results: Students who participated in the program reported numerous benefits via focus groups, such as increased self-reflection and a greater sense of social support. Quantitative analysis revealed increases in numerous dimensions of Ryff’s (1998) Scales of Psychological Well-being.

Conclusion: This pilot justifies larger studies on the benefits of peer group wellness coaching for college students. Further research should seek to contribute to this conversation with both qualitative and quantitative measures.

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P04.30 CAM in Cancer Care Within the European Partnership Action Against Cancer (EPAAC): Preliminary Data of the European Survey of Integrative Oncology Centres

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Purpose: The Health Department of Tuscany was included as Associated member in WP7 “Healthcare” in the European Partnership for Action Against Cancer initiated by the EU Commission in 2009. The main aim was to assess evidence and use of Complementary Medicine (CM) in cancer care and to map the centers across Europe prioritizing those providing public health services in integrative oncology (IO).

Methods: To carry out the European survey of “integrative oncology” centres/clinics a questionnaire was elaborated to be administered to every centre identified by a search on websites focused on oncology and through the analysis of the official website of every centre to get more information about their integrative oncology activities.

Results: The survey is being evaluated and therefore these results are preliminary. Information returned till September 30th was 107 (45.53%) of 235 centres contacted. 45 out of 85 responding centres included in the survey (52.94%) provided IO treatments, 24 from Italy and 21 from other European countries. The average number of patients seen per year is 283.9. Among centres providing IO services, 32 (71.1%) use fixed protocols and 34 (75.55%) have systems for the evaluation of results. 30 centres (66.66%) had researches in progress or carried out till the deadline of the survey. CM more frequently provided to cancer patients were acupuncture: 27 (60.0%) and homeopathy 19 (42.22%), herbal medicine 18 (40.0%), other techniques of traditional Chinese medicine 16 (35.55%); anthroposophy 7 (15.55%); homotoxicology 6 (13.33%); other therapies 29 (62.22%). Treatments are mainly directed to reduce adverse reactions to chemo-radiotherapy, in particular nausea and vomiting, reduce pain, fatigue, improvement QoL and supportive treatment during chemo-radiotherapy.
PO04.31
Complementary and Alternative Medicine (CAM) Use Among Currently or Recently Pregnant Women
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Purpose: Women of childbearing age are the primary users of CAM. However, little is known about the extent to which CAM is used by women during pregnancy and childbirth. The objective of this study was to document the prevalence of CAM use, types of CAM used, and reasons for CAM use among women of childbearing age.

Methods: We used 2007 National Health Interview Survey data for women ages 18 to 44, (n = 5,764 unweighted) to examine CAM use by pregnancy status (current, recent, neither currently/ recently pregnant). Outcomes were any past year CAM use, reasons for using CAM, and health conditions treated with CAM. Descriptive analyses included cross-tabulations with design-based F-tests. Multiple logistic regression was used to estimate the odds of CAM use by pregnancy status adjusted for demographic, social, and economic factors.

Results: Overall, 67% of women of childbearing age reported using CAM in the past year. This differed by pregnancy status with currently or recently pregnant women having significantly higher prevalence of CAM use than others (78.2% vs. 65.8%; P < 0.001). Back pain (17.1%), neck pain (7.7%), and anxiety (3.7%) were the most common specific conditions treated with CAM among women of childbearing age. However, nearly 12% of currently pregnant women and 28% of recently pregnant women reported using CAM for pregnancy-related reasons (P < 0.001). In adjusted analyses, currently and recently pregnant women had 2.7 times higher odds of past year CAM use compared with other women of childbearing age (95% CI 2.1–3.4; P < 0.001).

Conclusion: CAM use during the childbearing year is prevalent, with over three-quarters of currently/recently pregnant women reporting some CAM use. Of women who reported CAM use during the year in which they were pregnant, 20% reported using CAM specifically for pregnancy-related reasons, making this the most common reason for CAM use among pregnant and postpartum women.

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PO04.33
Health Care Personnel in Relation to Patients Who Integrate Traditional Spiritual Healing and Conventional Medicine in an Ethnically Mixed Context
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Purpose: The purpose is first to provide knowledge on how conventional primary health care providers relate to patients who integrate the traditional spiritual healing “reading” and conventional treatments for their health problems. Second to understand if/how providers’ own ethnic and/or geographical background influences relations to this patient group.

Methods: The study has a qualitative design; semi-structured interviews with 13 conventional primary health providers in one rural municipality of 2000 inhabitants, with a mixed Sami and Norwegian population. Participants were recruited from one mainly Sami and one mainly Norwegian village in the municipality. Among them were 2 doctors, 7 nurses and 4 welfare workers. Interviews were tape-recorded, transcribed, and are being analyzed using content analysis.

PO04.32
District Nurses Experiences of Working with Health Promotion and Lifestyle Interventions Among Patients at Risk of Developing Cardiovascular Disease
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Purpose: In preventive health work it is possible to map risk factors at healthy individuals which include information and advice aiming to decrease the risk of developing cardiovascular disease. This preventive health care is in Sweden carried out primarily by the district nurses and they have a key role in promoting health and prevent cardiovascular disease. The aim of the study was to examine district nurses’ experiences of working with health promotion among patients with risk factors of cardiovascular disease, and to identify possibilities and obstacles for prevention work in the practical reality.

Methods: The study has been carried out with a qualitative approach where narrative interviews were performed with a total of 12 district nurses working at health centers in north Sweden. Data transcripts were analyzed with qualitative content analysis.

Results: The participants express that their work in health promotion is an essence of the job as district nurse. It gives an opportunity to promote healthier lifestyle on an individual level with direct effects on patients’ health. Participants are clear about what should be included in the preventive work and mention the topics of diet, exercise, tobacco, alcohol habits and obesity. The district nurses state that education in Motivational Interviewing, (MI), in Physical Activity on Prescription, (PAP) and the colleagues attitudes are important facilitators for making the health promotive work to function in the practical reality. Lack of knowledge (own and among colleagues) and inadequate organizational structures constitute obstacles.

Conclusion: District nurses are unanimous about what should be included preventive health care. It is experienced as an important part of their duties but has sometimes difficulties to prioritize it. Furthermore, the district nurses consider that knowledge within MI, PAP and the employees’ attitudes constitute possibilities while one sees lack of time, negative attitudes and inadequate structures that obstacles for the preventive work.

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Results: All health professionals express great respect for "reading". They do not experience "reading" as problematic to regular conventional medical treatment; patients combine them, they do not substitute reading for conventional care. Health professionals experience that patients use "reading" for healing of both somatic and psychiatric diseases, from minor to serious and acute illnesses. Health care providers do not follow-up the subject any further, and neither discourage nor recommend "reading". Health care providers do not tie "reading" sharply to the Sami culture, but rather as a Christian practice. They do, however connect the practice more to the semi-religious groups. The interviews show that health professionals' own background influence their understanding of "reading", and of how much patients will tell. The semi-health providers have more detailed knowledge.

Conclusion: Conventional primary health care providers get to know about patients use of "reading", and they handle the information by listening respectfully. They do not, however, follow up this information in their work to help patients. There are differences in their level of knowledge, depending primarily on their ethnic background.

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P04.34
A Literature Study on Usage of and Satisfaction Levels with Combined Treatment Including Oriental and Western Medicine

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Purpose: This study aimed to summarize and analyze the usage of and the satisfaction levels with combined treatment including Oriental and Western medicine.

Methods: We searched studies on the usage of and the satisfaction levels with combined treatment including Oriental and Western medicine over the past 10 years (2001–2011) from 3 Korean databases (National Assembly Library, Research Information Service System, and National Discovery for Science Leaders). The reviewers also conducted a summarizing analysis by sampling the literature according to the type of study, study period, region, study subjects, sample size, type of sampling, research method, data analysis, study instruments, main results, etc.

Results: When the main results of six studies on combined treatment usage and satisfaction levels were considered together, the most important decisive factor in determining the usage of combined treatment was the illness of the patient, followed by the patient's occupation, sex, age, education, marital status, religion, treatment cost, and treatment results. In addition, the most important factor that determined satisfaction levels with combined treatment was age, followed by education, religion, income, health status, treatment procedures, staff attitude, and cleanliness.

Conclusion: Elderly patients with musculoskeletal, cerebrovascular, and circulatory system illnesses are more likely to prefer combined treatment over independent Oriental or Western treatment and are more likely to request specialized, adjusted medical care.

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P04.35
What Gets Said About CAM in Cancer Care: Preliminary Descriptive Data from a Qualitative Content Analysis

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Purpose: Cancer patients frequently seek out but often fail to disclose use of CAM to their treating clinicians. Little is known about the dynamics of clinical deliberations about CAM and factors influencing those deliberations when it is discussed. Purpose: To describe the fundamental dynamics of CAM deliberations that occur between patients and clinicians during routine cancer care consultations.

Methods: We audio-recorded clinical interactions between 23 medical oncology clinicians and a cross-sectional sample of 187 unique medical oncology patients at a NCI-funded comprehensive cancer center. We transcribed and have begun analyzing recordings using qualitative content analysis to identify themes about the circumstances and dynamics surrounding CAM discussions. In addition to audio recordings, we also conducted chart review to analyze how CAM discussions were reported.

Results: We analyzed any conversation including any mention of CAM. We classified conversations into five major categories developed by consensus: who initiated (the clinician, the patient, and the companion), what is discussed (the nature of CAM and its implications), the extent of discussion (briefly mentioned, mentioned and discussed, and extensively discussed), how is it discussed (as general information or treatment plan, the tone of the conversation – dismissive or inviting), and discussed but not mentioned in the chart. Out of 25 CAM discussions, 17 were patient-initiated, 6 were clinician-initiated, and 2 were companion-initiated. Among all these conversations, 13 were briefly mentioned, 10 were mentioned and discussed, and only 2 were extensively discussed. Most of the 'mentioned and discussed' and 'extensively discussed' instances are the clinician-initiated discussions. In 6 of the 25 discussions, CAM discussed but not mentioned in chart reviews. Further preliminary themes exploring how it is discussed will be presented.

Conclusion: 25 of the 187 medical oncology encounters include CAM. Half were mentioned without discussion. Only 2 included extensive conversation.

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P04.36
Delivery of Constraint-Induced Movement Therapy Through a Video Game for Individuals with Hemiparesis Post-Stroke

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P04.37
Pregnant Women’s Use of Complementary & Alternative Medicine in the United States
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Purpose: Pregnancy is a unique time in life where women can be motivated to make healthy lifestyle changes. At the same time, these women and their developing babies may be in a more vulnerable state. Complementary and alternative medicine (CAM) modalities may be particularly attractive to this population due to the perceptions that these therapies are safer due to their natural or holistic origins. Surprisingly, little is known regarding national estimates of CAM use in pregnancy.

Methods: We utilized the 2012 National Health Interview Survey (NHIS), a nationally-representative survey of the U.S. civilian adult population to examine CAM use during pregnancy. Descriptive statistics were used to estimate weighted prevalence and patterns of CAM use among pregnant women, including top modalities, reasons for use, patterns of disclosure to conventional providers, and perceived helpfulness. Comparisons are made with non-pregnant respondents of childbearing age.

Results: Of the 10,002 respondents who were women of childbearing age, 7% (n=727) were currently pregnant or pregnant during the year previous to the survey. 35% of the pregnant women had used one or more CAM therapies in the previous year (compared to 37% in non-pregnant women, p>0.05). The top three most commonly used modalities in pregnancy were non-vitamin/mineral supplements (14%), yoga (13%) and massage (11%). Use of non-vitamin/mineral supplements was significantly less common than in non-pregnant women (p=0.02). 30% of the pregnant CAM users disclosed their use of CAM to their primary providers.

Conclusion: CAM use in pregnancy is common, with a third of the population using one or more therapy, mirroring CAM use in non-pregnant women of childbearing age. Only one third disclosed their use to conventional providers. Given the relative paucity of safety and efficacy data for specific therapies in pregnancy, this study highlights the important need for further research in this area as well as education of patients and providers.

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P04.38
A Whole System Approach to Caring for Chronic Disease Patients in Primary Care: A Six Month Mindfulness-Based Therapeutic Lifestyle Change Program
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Purpose: Chronic disease is steadily escalating and projected to dominate healthcare in the next decade. With the rise in chronic disorders is the concomitant burden on providers who have insufficient time and training to deliver appropriate care to this population.

Methods: The Tallahassee Family Medicine Residency Program (FMRP) has taken an innovative inter-professional, whole systems approach to meeting both patient and provider needs by developing a 24-week group-based Mindfulness-based Therapeutic Lifestyle Change (MBTLC) program for patients with chronic disease. This program is readily exportable to other residencies and community-based organizations. The program addresses evidence-based domains of health and lifestyle that are modifiable by patient choice: nutrition, movement/rest, stress management, and relationships. Weekly 2.5-hour instruction addresses these areas, co-facilitated by a psychologist, dietitian, and yoga instructor). Daily homework as well as participation in bi-weekly individual visits with an acupuncturist are additional program components.

Results: Preliminary data on patient outcomes were collected with 29 enrolled patients. Multiple parameters were assessed at baseline, 3 and 6 months: anthropometrics, inflammatory and metabolic biomarkers and medication use as well as quality-of-life (SF-12) and mindfulness (FFMQ) measurements. Over 75% of patients completed the program. Significant differences were evident from baseline to program completion on the majority of outcomes.

Conclusion: The highly successful pilot project is a living laboratory of patients and primary care physicians, with the goal of effectively managing and preventing chronic disease and training physicians in these approaches. The residents’ curriculum has a physician wellness component in which they learn the knowledge and skills taught in the MBTLC patient education program. Throughout the 3 years, residents learn to maintain
their own health so they can care appropriately for their patients and enjoy a long career in primary care and avoid burn-out. This presentation will address program results, curriculum, lessons learned, and resources needed for implementation in other settings. **Contact:** Cathy Snapp, cathy.snapp@tmh.org

### P04.39
**Use of Meditation and Breathing Exercises in Mind-Body Exercise in the U.S.**

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**Purpose:** In traditional thought, meditation and attention to breathing are inherent and fundamental components of mind-body exercise. However, in the U.S. mind-body practices such as yoga, tai chi, and qigong are particularly heterogeneous and do not uniformly incorporate these practices. The extent to which meditation or breathing exercises are incorporated into mind-body exercise in the U.S. has not been studied.

**Methods:** We examined data from the 2012 National Health Interview Survey (NHIS) (n=34,525), a nationally representative survey of the civilian, non-institutionalized U.S. population, to estimate the prevalence and patterns of use of meditation and breathing exercises as part of 3 mind-body practices: yoga, tai chi, and qigong. We weighted estimates to reflect the complex sampling design using SAS.

**Results:** Approximately 10% of the U.S. population (n=3,205) reported practicing mind-body exercise in the last 12 months. Compared to non-practitioners, practitioners were more likely to be women (72% vs. 50% male), younger (mean age: 40 vs. 47) and have a lower BMI (27 vs. 31). A large proportion of mind-body practitioners reported they do not incorporate meditation (43% of yoga users; 48% of tai chi users; 38% of qigong users) into practice. A smaller proportion reported they do not incorporate breathing exercises (10% of yoga users; 16% of tai chi users; 11% of qigong users).

**Conclusion:** Mind-body exercise practice in the U.S. population differs from traditional teachings that emphasize meditation and breathing. These findings have implications for future research including interpretation and translation of studies of mind-body exercise. In traditional thought, meditation and attention to breathing are inherent and fundamental components of mind-body exercise. However, in the U.S. mind-body practices such as yoga, tai chi, and qigong are particularly heterogeneous and do not uniformly incorporate these practices. The extent to which meditation or breathing exercises are incorporated into mind-body exercise in the U.S. has not been studied.

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### P04.40
**Complementary and Alternative Medicine Practice Patterns for MD and DO, 2006–2010**

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**Purpose:** To characterize practice patterns of MDs and DOs reporting the use of complementary and alternative medicine (CAM) based on the National Ambulatory Health Care Survey (NAMCS) results.

**Methods:** Five years of the NAMCS data were used, 2006–2010. This visit level survey identifies the use of CAM during a visit. From this three groups were created, visits that used CAM, visits to physicians that used CAM on other visits, and visits to physicians that never used CAM. Comparisons were made for demographics, screening exams, health education, diagnoses and conditions, medication use and methods of payment. Analyses were done using the weighted data to represent US population trends.

**Results:** There were 154,421 visit surveys analyzed from the years 2006 to 2010 representing, when weighted, approximately 4.9 billion ambulatory physician visits in the United States. About 63% of the visits included the use of CAM (CC), 4.9% of the visits were to physicians that used CAM on other visits but not the current visit (CNC), and the remaining 94.5% of the visits were to physicians that never used CAM (NC). For the CC group there were more musculoskeletal complaints (33% vs 10% and 8% for CNC and NC), there were about twice as many previous visits in the last 12 compared to the NC group, physicians spent a few more minutes with patients compared to both CNC and NC groups, they had less acute and preventative visits but more chronic, especially chronic flare ups, they gave about twice as much health education as the other two groups, ordered less new medication and had a higher percentage of DOs.

**Conclusion:** Physicians using the CAM during their visits appear to rely less on medication and more on health education and greater visit frequency.

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### P04.41
**Complementary and Alternative Medicine (CAM) Use During Cancer Treatment at a Comprehensive Cancer Center**

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**Purpose:** We sought to define CAM use before and during active cancer treatment and investigate factors that might influence changes in CAM use for cancer patients.

**Methods:** We conducted a cross-sectional survey of adults diagnosed with breast, prostate, lung, or colorectal cancer between 2010–2012 at the UNC Comprehensive Cancer Center. An introductory letter, questionnaire, and return-postage envelope was sent to 1794 patients. Phone calls were made to non-respondents followed by resending the questionnaire. Logistic regression was used to investigate the association between CAM use and discussion of CAM use with an oncologist.

**Results:** We received 397 (33.3%) completed questionnaires. The mean age (SD) was 64 years (±11); 62% were female; 79% were white; and 98% were non-Hispanic. Respondents reported the following cancer types: breast (47%), prostate (27%), colorectal (15%), lung (11%). Ninety-one percent reported any cancer treatment for all categories (MBM-9%, DS-17%, BBT-38% decreases) except energy medicine (8% increase). Specific therapies responsible for the changes in CAM use included: acupuncture or yoga (43% decrease), vitamins (19% decrease),
P04.42 LB
A Retrospective Analysis of Integrative Medicine Consultations at MD Anderson Cancer Center: Reasons for Consultation, Symptom Burden, Quality of Life, and Satisfaction
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Purpose: Many cancer patients use complementary and alternative medicine, but limited data exists regarding the reasons for an integrative medicine consultation among a cancer population and the patient’s symptom burden, quality of life, and satisfaction.

Methods: Beginning in September of 2009, all patients receiving an integrative oncology consultation were asked to complete a modified Measure Yourself Concerns and Wellbeing (MYCaW), a modified Edmonton Symptom Assessment Scale (ESAS, 0–10 scale – 10 worst), and a satisfaction rating (0–10 scale – 10 highly satisfied). Quality of life was measured starting in June of 2010 by the Short Form 12 (SF-12) and later replaced by the Patient Reported Outcomes Measurement Information System Global Health (PROMIS-10).

Results: A total of 2,564 new patient integrative oncology consultations were conducted from 9/2009 to 12/2013, representing 63% of all consultative visits, with most patients (97.5%, n = 2,501) completing at least one assessment. About one-quarter of patients (26.0%) had at least one follow-up visit (average 3.2 ± 1.9). The most common reasons for consultation as reported by the MYCaW were integrative approach (32.3%), herbs/supplements (31.9%), nutrition (20.4%), overall health (13.0%), and pain (12.6%). Overall satisfaction was rated ≥ 8 by 94.6% of patients. The most common symptoms reported by the ESAS (% rating symptom > 0, mean ± SD) were fatigue (85.4%, 4.7 ± 2.5), sleep (85.0%, 4.9 ± 2.5), poor memory (76.8%, 4.1 ± 2.5), distress (71.4%, 4.2 ± 2.5), poor appetite (66.5%, 4.2 ± 2.5), and pain (65.2%, 4.0 ± 2.5). For the SF-12 (n = 1252) and PROMIS-10 (n = 711), the mean standardized T-scores were 35.7 and 43.6 for physical health and 46.7 and 45.8 for mental health (a score of 50 representing healthy population levels), respectively.

Conclusion: Patients at a major cancer center commonly seek an integrative oncology consultation to address issues of integrative approaches, herbs/supplements and nutrition. Patients had a high satisfaction with the clinical service and reported mild-moderate symptom burden and physical health problems.

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P04.43 LB
Integrative Healthcare and Wellness (IHW) Program: Baseline Characteristics of a Veteran Sample
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Purpose: The War Related Illness and Injury Study Center at the Washington DC VA (WRIISC-DC) developed the Integrative Healthcare and Wellness (IHW) Program to provide multiple CIM modalities to veterans in a comprehensive clinic setting. This study aimed to examine baseline physical and mental health characteristics for veterans currently enrolled in the IHW Program.

Methods: Participants consisted of veterans (n = 226; 159 male, 67 female), mean age 49.52 (range 23–86), with a wide range of medical and mental health diagnoses. Veterans enrolled in the IHW Program complete clinical questionnaires and satisfaction surveys to assess symptom improvement and patient satisfaction. The questionnaires include: Measure Yourself Medical Outcome Profile-2 (MYMOP-2), Medical Outcomes Study Short-Form-36 (VR36), Insomnia Severity Index (ISI), DoD/VA Pain Rating Scale (DVPRS), Pain Disability Questionnaire (PDQ), Perceived Stress Scale (PSS), and Beck Depression Inventory-II (BDI-II).

Results: Participants reported clinically significant depressive symptoms (BDI; M = 24.27), anxiety (PSS; M = 22.83) and sleep difficulty (ISI; M = 18.62) as well as significant pain (DVPRS; M = 6.48) that interferes with daily functioning (PDQ; M = 88.16) and negatively impacts mood (PSS item 14; M = 6.14). Additionally, 100% of participants rated pain or psychological distress as most important to address through IHW Program services (MYMOP-2).

Conclusion: Results reveal that veterans referred to a CIM clinic have a high level of psychological distress and pain-related symptoms, regardless of the referral source. Notably, 125 VHA facilities (82%) provide and/or refer patients to CIM providers and 80% cited “patient preference” as the reason they offered these modalities (HAIG, 2011). With many veterans reporting significant emotional distress, pain, and a preference for CIM, it is important for researchers and clinicians to better understand the efficacy, feasibility, and optimal delivery mechanisms of these services.

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P04.44 LB
An Integrative Two-Week Admission Program for Bell’s Palsy in South Korea: A Qualitative Report on Patients’ Experience
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Purpose: Emotional distress caused by irreversible damage to the facial nerves is higher in Bell’s palsy patients than in any other palsy groups. Therefore, Bell’s palsy patients often want more active care such as integrative medicine than just conventional corticosteroid treatment. This study aimed to explore...
Bell’s palsy patients’ experience of admission care and to identify the benefits of the specialized integrative care program. **Methods:** A qualitative study using in-depth, semi-structured interviews were conducted on Bell’s palsy patients. Participants were recruited from diverse backgrounds, and all had experience in both conventional treatment and the admission program. Two analysts independently coded that data. Qualitative study software NVivo10 was used for analysis. **Results:** Dissatisfaction with conventional treatment was the primary reason for admission. Bell’s palsy patients felt helpless due to emotional or mental problems as well as facial disfigurement. On the first few weeks, most of the patients went through fear, self-pity, and embarrassment which soon changed to restlessness, regret, and even social phobia. During the acute stage, many patients withdrew from social activities but didn’t have much treatment options other than medication and waiting. The integrative two-week program with self-management lessons, facial qigong exercises, acupuncture, and moxibustion therapies in addition to conventional treatment gave patients the support necessary for psychological adjustment and active care. Patients believed this approach helped in the overall recovery. **Conclusion:** Bell’s palsy differs from other diseases in that it characteristically disfigures the face making social activity difficult. However, current guidelines are blind to the psychosocial aspects of Bell’s palsy and merely advise prescription therapies. Integrative health programs can provide many physical and psychological benefits for the patients. **Acknowledgment:** This study is supported by the National Research Foundation of Korea (NRF) grant (No. 2011-0028968) and Traditional Korean Medicine R&D Project, Ministry of Health & Welfare, Republic of Korea (H113C0580). **Contact:** Seung Min Lee, jollymin@nate.com

**P04.45 LB**

**Factors Affecting the Definitions and Approaches of Integrative Medicine: A Mixed Qualitative and Quantitative Study from China**

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**Purpose:** In China, integrative medicine (IM) has been meticulously planned and implemented by government in various institutional contexts over last 60 years. Education, clinical practice and research have been taking place in both Chinese medicine (CM) and Western medicine (WM) working environments to develop IM. There have been many ways to define integrative medicine, but as-of-yet no shared definition exists. This study identifies existing definitions and examines the relationships between the definitions and key characteristics of practitioners.

**Methods:** This study used snowball sampling to develop two lists of subjects for semi-structured interviews: 33 pioneers who actively participated in the development of integrative medicine at least early 1960s; and 40 current leaders. Two independent raters analyzed the contents related to subjects’ responses regarding the definition of IM (k = 0.816). Four key factors, including age, education, practice type, and working environment – were chosen. The associations between the IM definition and each factor were evaluated both individually and in combination.

**Results:** Four unique definitions were identified, including IM as a “new medicine” (D1), as a combination of two medicines (D2), as a modernization of Chinese medicine (D3), and as a westernization of Chinese medicine (D4). D4 was only chosen by those working in WM organizations, while D3 was only chosen by those working in CM organizations (p = 0.00004). More than 64% clinicians had D2 while only 1 (5.9%) non-clinicians had D2. Only 1 clinician (1.8%) had D4 while almost 30% non-clinicians had D4 (p = 0.0001). Among non-clinicians working in CM organizations, only 1 had D-2; almost all non-clinicians working in WM organizations (83.3%) had D-4 (p = 0.0001). Clinicians working in CM organizations had more D3 than D1 (p = 0.03).

**Conclusion:** These results suggest that working environment and practice type are keys for understanding how suitable working definitions for IM are developed over time in specific sociocultural contexts.

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**P04.46 LB**

**OEF/OIF/OND Veteran Participation in an Integrative Healthcare and Wellness Program**

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**Purpose:** As the number of Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn (OEF/OIF/OND) Veterans grows, it has become increasingly important to identify and provide services that target their unique physical and mental health needs. This study examines self-reported physical and health symptoms and utilization of complementary and integrative medicine (CIM) interventions among OEF/OIF/OND Veterans.

**Methods:** This study included 226 Veterans enrolled in the Integrative Health and Wellness Program, a comprehensive CIM clinic within the Washington DC VA War Related Illness and Injury Study Center. This study focused on individual acupuncture, group acupuncture, and iRest® yoga nidra utilization in the six months following program enrollment.

**Results:** A series of t-tests indicated that OEF/OIF/OND Veterans reported significantly more depressive symptoms (BDI-II, p = .02) compared to veterans of other war eras, though there were no differences with respect to pain/pain disability, sleep, and anxiety. Analyses focused on individuals who enrolled in at least one service in a six month period (n = 163) indicated that OEF/OIF/OND Veterans attended significantly more individual acupuncture sessions (p < .01), and significantly fewer group acupuncture (p < .01) or iRest yoga nidra (p < .01) sessions. Of the 69 OEF/OIF/OND Veterans, 45 participated in services during the study period. Service users had a higher proportion of females (p = .03). There were no significant differences between service users and non-users on other demographic or symptom severity measures.

**Conclusion:** These findings suggest certain patterns in service utilization among OEF/OIF/OND Veterans, and make an initial attempt to identify correlates of enrollment in CIM services. Findings for outreach and treatment engagement are discussed.

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P04.47 LB
Physical Health, Mental Health, and Utilization of Complementary and Integrative Services Among Gulf War Veterans

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Purpose: Gulf War Veterans have received attention as a population for which there is great need to identify services that positively impact physical and mental health. This study explored differences in physical/mental health and service utilization among Gulf War and non-Gulf War Veterans enrolled in the Integrative Health and Wellness Program, a comprehensive CIM clinic within the Washington DC VA War Related Illness and Injury Study Center.

Methods: This study focused on individual acupuncture, group acupuncture, and iRest® yoga nidra utilization in the six months following program enrollment. Forty-two of the 226 individuals in this study were Gulf War Veterans.

Results: A series of t-tests compared Gulf War and non-Gulf War Veterans on self-reported physical and mental health symptoms. Gulf War Veterans reported more depressive symptoms (BDI-II, p = 0.04), and greater pain and pain-related disability (PDQ, p = 0.04; DVPRS, p = 0.02). A trend toward greater severity of sleep impairment was observed (ISI, p = 0.06). Chi square analyses revealed no differences in each type of service (defined dichotomously). Analyses focused on individuals who enrolled in at least one service type (n = 163) revealed no differences in the symptom severity of Gulf War and non-Gulf War Veterans, and indicated that Gulf War Veterans attended less group acupuncture (p = 0.01). Subsequent analyses compared Gulf War Veterans who attended services (n = 30) with those who did not (n = 12). No significant differences were observed for self-reported physical/mental health symptoms. Point biserial correlations examined the relationship between physical/mental health symptoms and service participation (defined dichotomously). Results demonstrated that those who endorsed higher levels of pain had lower utilization of iRest yoga nidra (r = -0.40, p = 0.01).

Conclusion: These results are an important initial examination of CIM utilization by Gulf War Veterans. Implications for treatment provision are discussed.

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P04.49 LB
Vitamin D Recommended Daily Allowance (RDA) Insufficiency in Female Healthcare Employees of Childbearing Age

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Purpose: The Recommended Dietary Allowance (RDA) to ensure a serum 25-OH-vitamin D level ≥ 20 ng/ml in 97.5% of all healthy individuals was recently re-calculated and increased by 50% to 600 IUs. We sought to assess the accuracy of this calculation in medically literate, fully insured women of childbearing age.

Methods: Observational study of early spring serum levels of 25-OH-vitamin D and self-reported vitamin D intake in female healthcare employees aged 15–49.

Results: Of the 6874 participants, 2809 (40.9%) reported taking iRest yoga nidra (r = 0.30, at least an additional 3000 IUs/day would be needed to achieve the same goal. For any BMI,
reported vitamin D intake >4000 IUs/day did not provide any additional benefit nor result in excessively elevated serum levels.  

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**P04.50 LB**

**Survey of Complementary and Alternative Medicine Services Within the Department of Defense: Prevalence, Attitudes and Beliefs**

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**Purpose:** During the past decade the use of Complementary and Alternative Medicine (CAM) in the United States has changed healthcare. The Department of Defense (DoD) has become increasingly interested to incorporate CAM modalities in the areas of behavioral health, pain management and traumatic brain injury. The purpose of this study was to identify the prevalence of CAM services offered in the Department of Defense: including military treatment facility (MTF), Morale Welfare and Recreation (MWR), and Chaplaincy programs. The objectives: (1) Identify the DoD programs that provide CAM services, (2) Describe the DoD CAM services provided and (3) Describe the attitude and beliefs of the respondents toward CAM modalities.

**Methods:** The main research questions were, (1) What is the prevalence of CAM practices? (2) Are there differences in the prevalence and practices of CAM services provided between the branches of the military? (3) What are the attitudes and beliefs towards CAM amongst the leadership in the different military facilities? (4) What are the obstacles and barriers for the access to CAM services? (5) Is the inclusion of CAM part of the strategic plan for the various agencies? A web-based survey was disseminated via e-mail across leaders in the various DoD MTF, MWR and Chaplaincy.

**Results:** A total of 47 surveys have been completed, most of them (70%) reporting providing CAM as part of their services. The main reasons for CAM use were pain, stress and rehabilitation; and the top 3 practices were acupuncture, chiropractic and breathing exercises.

**Conclusion:** The main challenges to offering CAM services included logistical issues, financial and structural resources, and patient CAM seeking behaviors. Overall the prevalence of CAM services offered in the DOD was higher, and the types of services more varied than anticipated.

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**P04.51 LB**

**Effectiveness of Therapeutic Massage in Conjunction with Aromatherapy for Pain and Anxiety Relief of Hospitalized Patients**

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**Purpose:** To quantify pain and anxiety relief in hospitalized patients from therapeutic massage versus therapeutic massage in conjunction with aromatherapy.

**Methods:** Abbott Northwestern Hospital began charting Integrative Medicine (IM) services in an EPIC-based electronic medical record (EMR) on July 1, 2009. Through December 31, 2012, the hospital recorded 115,457 admissions eligible for retrospective research. Retrospective records included demographics, diagnoses, pre- and post-IM intervention pain and anxiety assessments (0–10 verbal scale). IM services were reviewed for the presence of therapeutic massage and aromatherapy and stratified by pre-intervention pain and anxiety levels (mild: 1–3, moderate: 4–6, severe: 7–10).

**Results:** IM services were provided during 12,465 (10.8%) inpatient admissions during the retrospective review period. Therapeutic massage was provided during 7678 (61.6%) admissions, of which 5436 (71%) were determined by All Patient Refined Diagnosis Related Group codes to be between moderate and major severity. IM practitioners engaged patients multiple times during a hospitalization, accumulating 6,741 therapeutic massage sessions. Average pain reductions were greater during combined aromatherapy and therapeutic massage sessions versus therapeutic massage alone for both mild (69.1% vs 61.0%, p-value <.001) and moderate pre-pain (47.8% vs 44.8%, p-value <.001). Despite large reductions in those categorized as severe pre-intervention pain, reductions were not significantly different (34.1% vs 34.1%, p=94). Similarly, average anxiety reductions were greater when massage was accompanied by aromatherapy in both mild (71.5% vs 63.4%, p-value <.001) and moderate pre-intervention anxiety (52.7 vs 47.8, p-value <.001), but not in severe pre-intervention anxiety (44.4% vs 43.1%, p=.36).

**Conclusion:** Combination therapeutic massage and aromatherapy provides, on average, greater pain and anxiety reductions than therapeutic massage without aromatherapy for hospitalized patients reporting mild to moderate pre-intervention pain or anxiety.

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**P04.52 LB**

**Ensuring Model Validity in a Programme of Research to Develop and Evaluate a Nurse-Delivered Acupuncture Intervention for Patients with Cancer**

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**Purpose:** There is evidence that acupuncture is effective for various symptoms experienced by patients at different stages of cancer treatment; such symptoms often occur in clusters. We are conducting a programme of research culminating in a pragmatic multi-centre randomized controlled trial of nurse-delivered acupuncture in cancer treatment. The first phase of the programme aims to establish the optimal acupuncture treatment to address a cluster of symptoms in cancer patients and produce and evaluate a training programme for the nurses who will deliver the intervention.

**Methods:** To ensure model validity the first phase consists of a systematic review of published research of acupuncture and similar treatments (acupressure, auricular therapy, moxibustion) for cancer; a one day workshop of acupuncturists with expertise in treating cancer; design and piloting of a customised short training course in acupuncture for oncology nurses. A systematic review focusing on the details of the treatments used as opposed to their effectiveness as in previous reviews) has been conducted. Databases searched were: Medline, Embase, CINAHL, Cochrane (all databases), Scopus, and PubMed from the date of
their inception. Clinical trials, observational studies, and case studies were included, no language restrictions. Data recorded included details of treatment; details of the study; and study findings.

Results: We identified over 100 eligible papers. The most frequent primary symptoms were pain, nausea and vomiting, ileus, xerostomia, hot flashes, and fatigue. Sample sizes were 1 to 500. Details of the acupuncture treatments have been recorded. The findings will inform the workshop of acupuncturists with expertise in treating patients with cancer which will agree the course content. The short training course in acupuncture for oncology nurses will be piloted and evaluated.

Conclusion:

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P04.53 LB

Disclosure of Complementary and Alternative Medicine Use Among Diverse Safety Net Patients with Diabetes

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Purpose: Complementary and alternative medicine (CAM) is used by at least 30% of patients with diabetes and is associated with poor glycemic control and greater disease severity. CAM is frequently used alongside prescription medications underscoring the need for patient-provider communication to ensure safety and minimize adverse events from interactions. Disclosure of CAM use to providers is low particularly among racial/ethnic minorities. We sought to identify sociodemographic factors and patient-provider processes of care associated with CAM disclosure among diverse patients with diabetes.

Methods: As part of a regional Medicaid Managed Care program providing language-concordant health coaching to patients with diabetes, the San Francisco Health Plan’s Smart Steps Program enrolled 362 participants. Interviews at 6-month follow-up collected past month CAM use and disclosure to providers. Interviews at 6-month follow-up were collected from 278 participants who completed follow-up interviews. CAM use was assessed among CAM users (n = 133), who were predominantly Asian (54.9%) or Latino (26.3%), and non-English-speaking (66.2%), with a mean age of 56 years and 7.1 years with diabetes. Age, race/ethnicity, sex, birthplace, education and household income were not associated with disclosure of CAM use. Language concordance with primary care providers was associated with disclosure (p = 0.01). No association was found between disclosure and patient ratings of provider bias, trust, or communication clarity. Adjusting for sociodemographics, shared decision-making and goal setting with providers were significantly associated with patients’ disclosure of CAM use.

Conclusion: Use of CAM is common among diverse, safety net patients with diabetes. Prior research suggests overall quality of care is associated with disclosure of CAM use. We identified specific factors, such as patient-provider language concordance and shared decision-making, that may facilitate disclosure and appropriate use of CAM in the context of diabetes management.

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RESEARCH METHODOLOGY

P05.01

Stability Indicating Densitometric HPTLC Method for Quantitative Analysis of Biomarker Naringin in the Leaves and Stems of Rumex Vesicarius L.

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Purpose: Development of a simple, sensitive and stability indicating TLC-densitometric method for quantification of naringin in the methanol extracts of stems and leaves of Rumex vesicarius.

Methods: Chromatography was performed on glass-backed silica gel 60 F254 HPTLC plates with the green solvents Ethyl acetate: GAA: MeOH: H2O in proportion of 30:10:5:1, v/v/v/v as mobile phase. Scanning and quantification of developed plate was done densitometrically at 275 nm. Naringin was subjected to acid and alkali hydrolysis, peroxide treatment, photodegradation, dry heat, moist heat and UV treatment for the stability studies.

Results: The method was found to give compact spot for naringin at RF = 0.46 ± 0.001. The linear regression analysis data for the calibration plots showed good linear relationship with r = 0.9973 with respect to area in the concentration range of 100–1000 ng. The regression equation of standard was found to be Y = 8.448X + 21.395. The method was validated for detection and quantification limits, precision, recovery and robustness. The LOD and LOQ were found to be 8 and 24 ng band-1, respectively. The drug undergoes complete degradation under acidic treatment and mild degradation under basic and H2O2 treatment. The degraded products were well separated from the pure drug. The statistical analysis proves that the developed method for quantification of Naringin is reproducible and selective. The content of Naringin in the stems and leaves of R. vesicarius were found to be 1.35% and 2.73% w/w, respectively.

Conclusion: Due to the ability of this method in separating degraded products from the pure drug (naringin), it can be employed as stability-indicating method for in process as well as finished products in the market.

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P05.02

Temporary Practice Pause Then Resumption Study Design: An Extension of the Withdrawal Study Design to Complementary and Alternative Medicine Mind and Body Interventions

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Purpose: A novel study methodology for complementary and alternative medicine’s mind and body interventions (CAM-MABI) is presented here. CAM-MABI have been hindered not only by the inability to mask participants and their teachers to the study intervention but also by the major practical hurdles of long-term study of practices that can be lifelong. Two other important methodological problems are that study of newly trained practitioners cannot directly address long-term practice and that long-term practitioners likely self-select in ways that
P05.03
Assessment of the Quality of Reporting for Treatment Components in Cochrane Reviews of Acupuncture

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Purpose: High quality reporting of treatment details can aid replication of study results in real-world clinical practice. The Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) is a reporting guideline for key elements of acupuncture interventions in clinical trials. This study used STRICTA to investigate whether Cochrane reviews of acupuncture adequately report important treatment details.

Methods: Cochrane reviews of acupuncture were identified from The Cochrane Library (Issue 7, 2012). Randomized controlled trials (RCTs) included in the reviews and published after 2005 were obtained. Using STRICTA, we extracted acupuncture-related information from both the Cochrane reviews and the RCTs. The characteristics of included studies table was the major source of intervention information from Cochrane reviews. Reporting quality of acupuncture interventions in Cochrane reviews was assessed and compared to the respective RCTs.

Results: In total, 25 Cochrane reviews of acupuncture and 92 RCTs met the selection criteria. Cochrane reviews were 16% less likely to report the acupuncture-related items of STRICTA than RCTs (risk ratio 0.84, 95% confidence interval 0.79 to 0.88, I² = 8%) (Figure 1). Information was significantly better reported for 10 of the 15 treatment-group items of STRICTA in RCTs than in Cochrane reviews (p < 0.05), while four items did so without statistical significance. One item related to practitioner background was significantly better reported in Cochrane reviews.

Conclusion: Reporting quality of treatment details in Cochrane reviews of acupuncture was insufficient with regard to STRICTA, even though such information was readily reported in RCTs. The overall quality of reporting of the RCTs, while better than the reviews, was also often suboptimal. Use of the STRICTA guideline during the review process is recommended to adequately report the key treatment components in Cochrane reviews of acupuncture. The potential impact of STRICTA to the external validity and generalizability of reviews needs to be investigated.

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P05.04
Pitfalls in the Assessment, Analysis, and Interpretation of Routine Outcome Monitoring (ROM) Data; Results from an Outpatient Clinic for Integrative Mental Health

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Purpose: To assess characteristics of patients and the real life effectiveness of their treatments in a center for integrative psychiatry. To discuss whether routine outcome monitoring (ROM) is suitable for this purpose.

Methods: Statistic analysis of ROM data of 376 outpatients.

Results: The sample consisted of 115 men and 261 women. Mean age was 41.3 years (SD = 12.8). Fifty percent had a high educational level. Median illness duration was 11 years (IQR = 15). Median treatment duration was 388 days (IQR = 357). The sample was highly heterogeneous as regards diagnosis. Mood (36%) and anxiety disorders (15%) (axis I of DSM 4) and borderline (8%) and type C personality disorders (18%; axis II) were most prevalent. Patients’ satisfaction with the treatment center was good (median = 8; range 1 to 10). 206 patients (55%) completed one or more follow-up measurements. Drop-out analysis showed that non-completers were younger, had a lower level of education and used less medication than completers. Mixed-model analysis showed significant improvement in symptomatology, quality of life, and autonomy, and differential improvement for different subgroups. Effect sizes were small (0.38) to large (1.42), depending on the outcome measure and subgroup. Subtle variations in analytic strategies influenced effect sizes substantially. We discuss the results in the light of
several pitfalls associated with the assessment, analysis, and interpretation of these data.

**Conclusion:** Patients at this center were mostly female, highly educated, middle aged, with a long illness duration suffering from mood and anxiety disorders and or personality disorders. Statistical analysis showed significant improvements, but problems inherent to design and analysis of ROM data prevent drawing definite conclusions about (comparative) treatment effectiveness.

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**P05.05**

**Assessment of the Quality of Reporting in Randomized Controlled Trials of Acupuncture in the Korean Literature Using the CONSORT and STRICTA Statements**

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**Purpose:** Adequate reporting quality of randomized controlled trials (RCTs) is a prerequisite for comprehensive understanding and optimal utilization of research results. However, the current status is not necessarily satisfactory. This study aimed to assess the reporting quality of RCTs of acupuncture in the Korean literature.

**Methods:** Twelve Korean databases and seven Korean journals were searched to identify eligible RCTs published after 2005. The Consolidated Standards of Reporting Trials (CONSORT) checklist for parallel RCTs was used to assess the quality of reporting in Korean RCTs. The revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) was used to investigate the quality of reporting for intervention-related items.

**Results:** In total, 103 eligible RCTs were identified. Incomplete reporting (reported in less than 50% of RCTs) was found in 50% (11 out of 22) of items that comprise CONSORT. Items related to the risk of bias, including randomization reporting, allocation concealment and outcome assessor blinding, showed especially incomplete quality of reporting (range 5.8% to 20.3%). Although some items of STRICTA for acupuncture rationale (range 47.6% to 97.1%), needling details (range 55.3% to 97.3%) except the item for reporting the response to the needle (32.0%) and treatment regimen (range 77.6% to 88.3%) were relatively well reported, items related to treatment context (range 13.5% to 44.6%) and practitioner background (21.3%) were incompletely reported.

**Conclusion:** The reporting quality of Korean RCTs of acupuncture was suboptimal with regard to the CONSORT and the revised STRICTA statements. Inclusion of the CONSORT and revised STRICTA statements in author instructions and attempts to utilize those statements in the design, implementation, writing and peer-review process of the RCTs are necessary to achieve better quality of reporting in Korean RCTs of acupuncture.

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**P05.06**


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**Purpose:** Chinese patent medicines (CPMs) are thought to be effective for common cold, and dozens have been authorized recommended in the ‘China national essential drug list’ by the Chinese Ministry of Health. However, there is no critically appraised evidence on potential benefits and harms of CPMs for common cold to justify their clinical use and their recommendation.

**Methods:** CENTRAL, MEDLINE, EMBASE, SinoMed, CNKI, VIP, China Important Conference Papers Database, China Dissertation Database, and online clinical trial registry websites were searched for published and unpublished clinical studies of CPMs listed in the ‘China national essential drug list’ for common cold till 31 March 2013.

**Results:** A total of 40 CPMs were listed in ‘China national essential drug list 2012’ for the treatment of common cold. However, only eight have clinical evidence supported. A total of six RCTs and eight CSs were included, no other study design was identified. All studies were conducted in China, and published in Chinese between 1995 and 2013. All the included studies were with flawed study design and poor methodological quality, and were graded as low or very low quality level according to GRADE approach (Grades of Recommendation, Assessment, Development and Evaluation Working Group).

**Conclusion:** Most of the CPMs recommended in the ‘China national essential drug list 2012’ were not supported by clinical evidence, which revealed the lack of evidence for clinical use and health policy in China. To ensure evidence-based clinical practice of Traditional Chinese Medicine, further rigorous placebo-controlled, randomized trials are warranted.

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**P05.07**

**Acupuncture for Treatment of Diabetic Peripheral Neuropathy: A Systematic Review of Randomized Controlled Trials**

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**Purpose:** Acupuncture has commonly been used in China, either alone or in combination with conventional medicine, to treat diabetic peripheral neuropathy (DPN). The objective of this study was to perform a systematic review to evaluate the potential benefits and harms of acupuncture for DPN to justify its clinical use.

**Methods:** We searched for published and unpublished randomized controlled trials of manual acupuncture for DPN till 31
March 2013. Revman 5.2 software was used for data analysis with effect estimate presented as relative risk (RR) and mean difference (MD) with a 95% confidence interval (CI).

**Results:** A total of 38 trials involving 2506 participants were included. The methodological quality of included trials was generally poor. Meta-analysis indicated that manual acupuncture had better effect on motor nerve conduction velocity in common peroneal nerve than electric acupuncture (MD 6.25 95%CI 5.53, 6.97, MD 2.59 95%CI 1.21, 3.96) when compared with mecobalamin. Acupuncture plus moxibustion did not show additional better effect on nerve conduction velocity compared with acupuncture alone. Adverse events were not reported in any trials. The asymmetric funnel plot suggested publication bias.

**Conclusion:** Despite the number of trials of acupuncture for DPN and their uniformly positive results, no clinically relevant conclusions can be drawn from this review due to the trials' high risks of bias and the possibility of publication bias. Clearly defined and internationally acknowledged outcome measures are required for future study. There remains an urgent need for training Chinese researchers in conducting unbiased trials as well as prospectively registering all initiated Chinese trials to avoid publication bias.

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**P05.08 Positive Results in Randomized Controlled Trials on Acupuncture Published in Chinese Journals: A Systematic Literature Review**

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**Purpose:** To systematically identify randomized controlled trials (RCTs) on acupuncture published in Chinese journals, analyze the rate of positive results, and explore possible factors that may influence the reporting of positive results.

**Methods:** We searched four main Chinese databases (CNKI, VIP, CBM, Wanfang) from their inception to January 2013 to identify randomized controlled trials (RCTs) on acupuncture compared with no treatment, sham-acupuncture or conventional treatment. We bibliometrically described the trials and analyzed the rate of positive results from primary outcomes in relation to trial risk of bias, statistical results and author’s conclusions.

**Results:** A total of 840 RCTs with 71,871 participants were identified, including 727 RCTs comparing acupuncture with conventional treatment, 51 RCTs with no treatment, and 62 RCTs with sham-acupuncture. Among them, 838 trials (99.8%) reported positive results from primary outcomes, while only two trials (0.2%) reported negative results, comparing acupuncture with conventional treatment and sham-acupuncture respectively. Among the 726 RCTs comparing acupuncture with conventional treatment, 641 trials (88.3%) favored acupuncture groups; While 85 trials (11.7%) showed no significant difference between acupuncture and conventional treatment groups, the authors concluded positive results based on the findings. For methodological quality, the percentages of reporting ‘random number generation’, ‘concealment of the allocation sequence’, ‘blinding’, ‘information on withdraws or lost of follow-up’, and ‘Sample Size Calculation’ among the 840 RCTs were 43.7%, 5.9%, 4.9%, 9.9%, and 1.7% respectively. In addition, 99.8% of trials reported names of points used, 74.5% of trials reported manipulation methods to gain response sought such as de qi, and 18.2% of trials reported syndrome differentiation.

**Conclusion:** Publication bias might be major issue in RCTs on acupuncture published in Chinese journals reported, which is related to high risk of bias. We suggest that all trials should be prospectively registered in international trial registry in future.

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**P05.09 Chinese Herbal Medicine for Oligomenorrhoea and Amenorrhoea in Polycystic Ovary Syndrome: A Systematic Review and Meta-Analysis**

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**Purpose:** Oligomenorrhoea and amenorrhoea are cardinal symptoms of polycystic ovary syndrome (PCOS), a common female endocrine disorder affecting 6–18% of women of reproductive age. Although randomized controlled trials (RCTs) have explored the use of Chinese herbal medicine (CHM) for PCOS, this requires rigorous investigation. Our aim was to evaluate the evidence on CHM for PCOS-related oligomenorrhoea and amenorrhoea by conducting a systematic review and meta-analysis.

**Methods:** We conducted a comprehensive search using international and Chinese language electronic databases from their date of inception to June 2011 and grey literature search. RCTs were assessed for eligibility and data extracted independently by two reviewers. Study authors were contacted where eligibility remained unclear.

**Results:** 4 RCTs involving 246 participants were eligible. Pooled analysis was not possible for our primary measure of menstrual cyclicity, reported in one study to show a significantly greater number of responders with CHM plus Diane-35 (n = 13), compared with Diane-35 only (n = 5) (RR2.60, 95%CI 1.06 to 6.39, p = 0.04). Pooled analysis showed significant reduction in total testosterone favoring CHM plus Diane-35 over Diane-35 alone (MD −0.69, 95%CI −0.72 to −0.66, p < 0.00001), and in luteinising hormone (LH) (MD −2.54, 95%CI −3.03 to −2.06, p < 0.00001). Compared with conventional medicine alone, CHM alone showed significantly greater reduction in total testosterone (MD −0.45, 95%CI −0.63 to −0.28, p < 0.00001) and no significant between-group difference in LH reduction (MD −0.62, 95%CI −1.80 to −0.55, p = 0.30). Two studies reported fewer adverse events with CHM. One study reported no change in liver function with CHM plus Diane-35 or Diane-35 alone. All studies were rated as being at high risk of bias.

**Conclusion:** Although preliminary evidence suggests CHM may help regulate menses and correct endocrine abnormalities in PCOS, these results should be interpreted with caution owing to the small number of studies and high risk of bias found. Further research with more methodologically robust RCTs is required.

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P05.10
The Fuzzy Edge of CAM Use: Challenges in What Constitutes CAM Use in Self-Administered Questionnaires
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Purpose: Whether certain practices like “prayer,” “supplements,” or “special diet,” constitute CAM is an important debate when measuring CAM use. We sought to determine the degree of variation in self-reported CAM use in self-administered patient questionnaires based on what patients consider CAM.

Methods: We extracted patient-reported CAM use data using a broad and inclusive definition from the first 177 patients enrolled in a cancer communication study that had completed a follow-up survey. We identified those patients that reported any history of CAM across 15 CAM modalities derived from existing NIH definitions. We then calculated self-reported CAM use rates using a narrower definition of CAM. The narrow definition excluded disputable or “fuzzy” categories (“prayer,” “supplements,” “special diet,” and “other practitioner”).

Results: When we used a broader definition of CAM that included the fuzzy categories, 154 patients (63% female with a variety of cancers at various stages) self-reported CAM use at some point in their life (87%). From these patients, CAM category usage rates varied from 2.6% (hypnotherapy) to 79.2% (prayer). Of all CAM-users, 13.6% reported prayer as their only type of CAM. Supplement use, special diet, and other practitioner were the only types of CAM reported in 1.9%, 1.9%, and 0.6% of cases, respectively. One third of all CAM use under this broader definition was attributable to modalities in the fuzzy categories 54/154 (35%). Conversely, when we used a narrower definition of CAM, 100 out of 177 used CAM (56%).

Conclusion: Accepted definitions for what qualifies as “CAM” are not concrete and pose measurement challenges in self-administered questionnaires, even if clear definitions are presented. Exclusion or inclusion of “prayer” alone as a type of CAM will change self-reported CAM use rates by as much as 12%. Excluding or including all types of “fuzzy” CAM categories can affect CAM self-report rates by as much as 31%.

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P05.11
Controlling for Placebo Effects in Clinical Trials of Craniosacral Therapy: Blinding Success and Credibility of a New Sham-Control Protocol
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Purpose: Determining efficacy and controlling for non-specific effects in complementary and alternative medicine (CAM) requires valid placebo or sham control groups that generate similar levels of expectancy, credibility and therapist attention and ensure successful patient blinding. To differentiate specific effects of Craniosacral Therapy (CST) from non-specific, placebo-related mechanisms a new sham-control procedure was developed and tested for its credibility.

Methods: Patients from a randomized controlled trial on chronic neck pain (NCT01526447) completed the Credibility/Expectancy Questionnaire and the Helping Alliance Questionnaire as well as questions about compliance and safety. Patients in the treatment group received 8 individual CST sessions once a week whereas sham group patients received light touch of the same extent. Complete (N = 50) and multiple imputed data (N = 54) were analyzed separately using a logistic regression model with patients’ ratings as independent predictors and group assignment as dependent variable. An additional t-test for analysis of the overall compliance/attendance was computed.

Results: Patients’ ratings of treatment expectancy, treatment credibility and therapeutic alliance were not found to have a significant power for classifying patients into CST or sham group (p ≥ .05). Only satisfaction with treatment revealed a significant adjusted odds ratio (AOR: 6.83; 95% CI: [1.54; 30.24]; p = .011) in the analysis of the complete cases, but was not stable for the imputed dataset (AOR: 4.09; 95% CI: [0.94; 17.76]; p = .060). Compliance of both groups was comparable (p = .054) as were reasons for non-attendance. No serious adverse events were reported.

Conclusion: Study results indicate that blinding patients to treatment allocation was successful; patients’ expectancy, credibility and alliance to the therapist did not appear to affect study outcomes, and sham manipulation was tolerable and safe. The design can therefore be regarded as a credible means to control for placebo effects in future CST clinical trials.

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P05.12
Avoiding Unrealistic Results When Analyzing Influencing Factors Associated with CAM Use: Introducing the Idea of Multilevel Modeling
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Purpose: Many researchers explored the possible influencing factors from individual’s perspective for selecting or rejecting CAM among individuals in different health conditions all over the world. In order to reveal the factor levels (individual or population) and statistical methodologies which were used in the previous studies, we conducted this review.

Methods: MEDLINE, CNKI and VIP electronic databases were searched till Oct. 2013. Surveys which presented evidences on associations between CAM use and various influencing factors were included this review.

Results: 67 articles were identified. After reading titles and abstracts, 29 of these articles were excluded because they were duplicates, reviews, or their objectives different from this review. Data in 31 (81.6%) of surveys had the hierarchical structure, but none of them were analyzed using multilevel models. Of articles demonstrated that many individual level characteristics (such as elder age, female, higher income or education level,
disease status, lifestyle and spiritual change, etc.) were significantly related to CAM use. Meanwhile, 10 (2.6%) of study results found that geographical regions, health services, health providers or families which the individuals belonged to played an important role on predicting CAM use. The statistical techniques currently used in these studies with hierarchal data structure e.g. t-test, univariate or multivariate regression have the risks to exaggerate the standard errors and confidence intervals. So that we may not well conclude that there are real associations.

**Conclusion:** Most of the data from current surveys had hierarchal structures and could not meet the assumption of independently identically distribution (iid). There were notable methodological limitations in the existing studies. Future researches should take account of the clustering structure in their samples, and apply multilevel models to handle the clustered or grouped data to avoid concluding biased results.

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### P05.13

**Decision Analytic Modeling: An Innovative Tool to Explore the Effectiveness of Acupuncture on Patients in the United States with Lower Back Pain (LBP)**

**Abstract Withdrawn**

### P05.14

**Method of Drug Discovery in the Classical Tradition of Ayurveda as a Preliminary Tool for Refinement of Folklore Knowledge of Medicinal Plants**

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**Purpose:** The study aims to understand the methods employed by ancient physicians of Ayurveda to discover the medicinal properties of plants and to formally incorporate them into the Ayurvedic Pharmacopoeia. A little more than 1/10th of nearly 9000 plants used for medicinal purposes in India has been used in Ayurveda suggesting the existence of rigorous criteria and methodology for acceptance of medicinal plants.

**Methods:** Twelve classical text books of Ayurveda representing typical chrono-geographical reference points in the evolutionary history of Ayurveda were selected for analysis. These sources were studied for methodological criteria used for rigorous study and acceptance of plant sources as medicines for use in humans. The texts were carefully studied to determine and classify information available on medicinal plants under specific data heads. The minimum, maximum and average time span for addition of new plants into the Pharmacopoeia was also determined by study of the selected texts.

**Results:** It was found that Ayurveda employs fairly rigorous methods to evaluate and accept plant sources as medicines. Inadequately understood plants are prohibited from being used as medicines. For accepting a plant source as medicine, elaborate information had to be compiled and classified under the data heads of nomenclature, identity, properties and applications of the plant. This includes standardisation of nomenclature, study of varieties, substitutes, pharmacological properties, interactions, safety and specific disease applications. Perhaps Zoopharmacognosy may have been an important method for first clues of medicinal properties of plants. It took anywhere between 30 years to a few centuries before new plants were added to the Pharmacopoeia suggesting that plant sources were studied for long periods before being accepted as medicines.

**Conclusion:** Classical Ayurvedic texts delineate an early systematic attempt of bioprospecting and development of drugs from plant sources that can be developed as a preliminary tool to filter and refine folklore knowledge of medicinal plants.

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### P05.15

**Using the Systematic Review Data Repository for Systematic Reviews of Complementary Medicine**

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**Purpose:** The Systematic Review Data Repository (SRDR) is a Web-based open-access tool that supports electronic data extraction and entry by multiple users, data comparison and exporting, and data archiving and sharing. SRDR has the potential to reduce the burden of conducting systematic reviews (SRs), while improving data quality and transparency of the process. The development of SRDR is funded by AHRQ and is
led by a team at Brown University. The objective of this project was to introduce the audience to SRDR, share user experience, and invite feedback and discussion.

**Methods:** The steps to initiate a SR project in SRDR include creating the project and extraction forms, assigning users, and adding study citations, which may be imported directly from the Complementary Medicine (CAM) registry. The systematic reviewers then extract and enter data directly from study reports into SRDR for seamless data storage and processing. The Data Comparison and Adjudication tool allows identification and adjudication of discrepancies between data extractors. The Summary Table Creation tool can generate reports and descriptive information about data collected in SRDR. The Data Exporting tool enables users to export data from SRDR for importing into meta-analytic software.

**Results:** SRDR was launched in June 2012, and since then over 70 SR projects have been initiated with over 200 users entering over 2,000 study records. The creation of a central database of SR data enables data sharing among organizations and individuals producing SRs worldwide. The system was recently tested by authors based at the Cochrane CAM Field and they will present their experience using SRDR for their review on the topic of yoga and back pain.

**Conclusion:** SRDR can facilitate efficient data collection, adjudication, preparation of a dataset for analysis, and archiving. Future efforts must focus on further testing by multiple user groups conducting SRs in diverse CAM topics.

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**P05.16**

**Consideration of Personal and Environmental Variables in the Measurement of Psychophysiological Stress Response to Different Environmental Settings**

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**Purpose:** To test the design of a pilot study measuring urban environmental effects on psychological and physiological measures of stress.

**Methods:** A four-way crossover design was used. Fifteen participants passively experienced each of 4 outdoor urban settings (i.e., Very Natural (VN), Mostly Natural (MN), Mostly Built (MB), and Very Built (VB)) on separate days in randomized order for 20 minutes each. Pre- and post-exposure data were collected via saliva and self-report questionnaires. Data regarding participants’ pre-existing stress state, environmental self-identity, and perceived restorativeness and aesthetic appreciation of each setting were collected as co-variates. Environmental variables (i.e., ambient light, sound, temperature, humidity) were also included in the study design, and qualitative post-exposure data were collected to inform future study design.

**Results:** Compliance and attendance were very high for this repeat-measures study (59 of 60 visits). ANCOVA revealed near-significant between-setting differences for changes in subjective stress ($F_{3,40.84} = 2.670$, $p = 0.060$), tension-anxiety (T-A: $F_{3,41.21} = 2.986$, $p = 0.043$) and salivary alpha-amylase (sAA: $F_{3,38.3} = 1.69$, $p = 0.186$), but not for salivary cortisol. Post-hoc analyses revealed significant differences, primarily between the VN and MB settings (stress: $p = 0.008$; T-A: $p = 0.007$; sAA: $p = 0.033$). Co-variate measures included in analyses were shown to have important moderating effects. Equipment error prevented the inclusion of environmental data the analyses. However, qualitative data demonstrated that noise, as well as presence of non-study personnel, familiarity with the setting, and presence of odors, influenced participants’ subjective experience of each setting.

**Conclusion:** Measurement of environmental stressors in a field setting is challenging but possible. The need to consider multiple environmental and personal variables necessitates the use of complex, multivariate analysis techniques. Special attention toward the natural/built content of urban environments may be fruitful in understanding how outdoor spaces can be utilized to beneficially modulate the stress response.

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**P05.17**

**Measuring Complexity of Heart Rate Variability in Naïve Yoga Practitioners with Insomnia and PTSD**

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**Purpose:** Insomnia comorbid with posttraumatic stress disorder (PTSD) is a prime example of dysfunction in the linkages between mind and body, thus serving as an ideal disease model to study the mind-body practice of yoga. The overall objective of this research is to evaluate feasibility of yoga as an adjunctive treatment for insomnia related to posttraumatic stress disorder (PTSD). A sub-aim is to develop a novel method for evaluating complexity of heart rate variability in this population. A powerful way to assess the nonlinear behavior of a dynamical system, such as the autonomic nervous system (ANS), is represented by the Lyapunov exponents (LE). When evaluated on heart rate variability (HRV) time series, these nonlinear indices quantify how the cardiovascular control is sensitive to the ANS variations.

**Methods:** This study pertains a single-arm trial of an 8-week, closed-group yoga intervention for patients with insomnia and PTSD who are naïve to yoga ($< 1$ hour/week past 6 months). Continuous EKG data was collected at baseline and end treatment using a paced breathing protocol: 3 minutes regular breathing, 11 minutes audio-guided paced breathing at 15 cycles/minute, 3 minutes regular breathing. We estimated the instantaneous dominant LE (IDLE) through nonlinear point-process modeling of HRV data gathered from 12 study participants before and after yoga training.

**Results:** Between the two sessions, we found a significant decrease in the IDLE median absolute deviation ($p < 0.05$), rather than in IDLE median value.

**Conclusion:** Previously we have shown that patients with severe cardiac health failure are characterized by a significant increase of complexity variability with respect to healthy subjects. The current results suggest that yoga affects ANS dynamics through shifts in sympathetic and parasympathetic activations which go towards a healthy ANS dynamical pattern and can be detected by the IDLE methodology.

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P05.18
An Exploration of the Effects of Tibetan Yoga on Patient’s Quality of Life and Experience of Lymphoma: An Experimental Embedded Mixed Methods Study

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Purpose: To explore the effects of a Tibetan Yoga (TY) intervention on patient’s experience of lymphoma and quality of life (QOL) through a comparative analysis.

Methods: Research Approach: An experimental embedded mixed methods design. Participants: 16 lymphoma patients receiving or having received treatment within the prior 12 months. Methods: Quantitative and qualitative data were collected concurrently from the same participants using various surveys evaluating social, physical, emotional, and spiritual domains and open-ended narrative questions at four time periods: baseline, and 1-week, 1-month and 3-month post intervention. Qualitative data consisted of written responses to 3 open-ended questions focusing on patient’s experiences of cancer. Results of the two data sets were compared to elucidate findings and clarify congruent and divergent patterns in patient profiles. Qualitative findings between participants in the TY and wait-list group were also compared for salient differences.

Results: Convergence, divergence and contradiction were found in the comparison of the two data sets. The qualitative data served to explain, elucidate and expand upon some of the findings and discrepancies between the data sets and captured experiential effects beyond the pre-set measurements of the quantitative instruments. The theme of acceptance was significantly more prominent in participant’s narratives in the TY as opposed to control group.

Conclusion: Comparing and integrating data and findings from quantitative and qualitative methods in a mixed methods study resulted in a more complete understanding of research questions than either approach alone, capturing experiential effects meaningful to patients and recognizing a more comprehensive range of patient outcomes. Incorporating a qualitative component within this RCT grounded experimental research-based results within the real-world context of patient’s lives contributing to research focused on translation, dissemination and implementation.

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P05.19
Psychometric Analyses of the Arizona Lifestyle Inventory: A Multi-Dimensional Integrative Medicine Measure to Assess Wellness Behaviors

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Purpose: A measure of wellness-oriented behaviors reflecting the whole person orientation of Integrative Medicine (IM) was developed. Initial psychometric analyses of the measure are presented.

Methods: Residents and medical students (n=276) completed the Arizona Lifestyle Inventory (ALI). The ALI is a 77-item scale assessing diet/supplements, exercise, mind-body, spirituality, relationships, sleep, social/leisure activities, work, and background health status. Validated measures of well-being: burnout (emotional exhaustion, depersonalization), depression, positive and negative affect, perceived stress, life satisfaction, and multi-dimensional well-being ratings were also completed.

Results: Psychometric analyses using Classical Test Theory techniques confirmed scales for the following domains: diet/supplements, spirituality/mind-body, exercise/time outdoors, relationships, and sleep. Social/leisure activities and work items did not form psychometrically sound scales. Convergent validity and divergent validity was assessed by correlating the ALI scales to the multidimensional well-being scale. The diet and exercise scales were more strongly correlated with physical well-being; while spirituality/mind-body and relationship scales correlated more strongly with spiritual and social well-being respectively. Sleep correlated most strongly with mental well-being. All scales correlated significantly with overall well-being in the past month and at the present moment. Additionally, the sleep, relationship, and exercise scales correlated significantly with the burnout, depression, affect, perceived stress, and life satisfaction measures. The diet and spirituality/mind-body scales were significantly correlated to life satisfaction only. Several items not loading on scales correlated with the well-being measures. Work stress items correlated significantly with the well-being measures; however work hours did not correlate with depersonalization, perceived stress, and physical and social well-being. Two social/leisure items (hobbies, belonging to organized groups) correlated significantly with most of the well-being measures.

Conclusion: Initial psychometric analyses confirmed the primary wellness behavior domains. Future analyses on a larger sample include Item Response Theory analyses to further validate these findings. A psychometrically sound wellness behavior inventory for IM could be important for research and clinical purposes.

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P05.20
Obtaining an Investigational New Drug Number (IND) from the FDA for Research with a Fruit

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Purpose: As part of the research project to investigate the use of Synsepalum Dulcificum (Miracle Fruit) for taste alterations in patients undergoing chemotherapy, we decided, as it is customary in most oncology studies, to pursue an application with the Food and Drug Administration for an Investigational New Drug Number for the use of the whole fruit.

Methods: All application materials and research protocol were submitted to the FDA, explaining the intention to collect the fruit from the Fairchild Botanical Garden and provide it frozen to oncology patients having taste alterations secondary to chemotherapy. Patients were instructed to 10 to 15 minutes prior to meals put the whole fruit in their mouth and gently suck/chew it to remove the flesh from the seed. Then discard the seed.
They used a validated questionnaire to grade taste and quality of life. The study length was 7 weeks from enrollment. **Results:** The FDA required to submit the following aspects regarding the fruit including: type of fertilizer used, pesticides, stage of maturation at which the fruit was collected, how it was washed after collection, if dried or fresh frozen fruit was to be used, how fast it was frozen and at what temperature, how we maintained the cold chain from the garden to the hospital and then to the patients house, results of microbiology studies since there was the potential use by neutropenic patients, and how the study was planning to report the possible adverse events that might occur during the study. **Conclusion:** After complying with all these requirements, we were granted the approval for research with IND number 102148 on April of 2008. The study was completed in November of 2011 after enrolling 48 patients and is in preparation for publication. **Contact:** Mike Cusnir, mike.cusnir@msmc.com

**P05.21**  
Using the Nominal Group Technique to Identify the Key Methodological Issues in Acupuncture Clinical Trials  
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**Purpose:** To identify the key methodological issues that might influence the acupuncture treatment adequacy and introduce bias to the results when designing and implementing acupuncture clinical trials from the views of Chinese acupuncturists and methodologists.  
**Methods:** Nominal group technique (NGT) as a structured group decision-making method was applied. Nine participants from mainland China and Hong Kong were invited, including six acupuncturists, two acupuncture trialists and one methodologist. An introduction to the subjects for discussion was given at the beginning. When all the participants were clear with the subjects, 20 minutes were given to them to write down their own thoughts. Then one by one, the participants presented their opinions. Then all the opinions were discussed until consensus were made by voting.  
**Results:** All participants expressed their opinions. Four key issues on methodology were raised and consensus was achieved after discussion. First, under different acupuncture clinical practice, five aspects were agreed: (1) different expertise and practicing habits of acupuncturists; (2) insufficient training according to the research protocols; (3) insufficient acupuncture treatment details described in the protocols (such as acupoint names and locations, needle insertion methods and direction, manipulation methods, sequence of acupoints stimulated in one treatment, extent to which the treatment could be individualized); (4) deviation from protocols by the acupuncturists; and (5) alternatives of acupuncturists. Second, incompliance of the participants due to lack of confidence to acupuncture therapy and acupuncturists, use of sham acupuncture and inadequate acupuncture treatments. Third, inappropriate set of sham control (lack of theoretical validity and practical validity). Forth, multiple roles of personnel in acupuncture trials.  
**Conclusion:** Methodological issues around acupuncture trials were identified from this study, and future guidelines for designing and managing of acupuncture trials should consider these aspects. We suggest that some of the items of the CONSORT statement and STRICTA could be referred when designing acupuncture trials. **Contact:** Yutong Fei, yutong_fei@163.com

**P05.22**  
Role of TCM for Cancer in China: A Semi-Structured Qualitative Interview of Cancer Patients, Family Members and Oncologists  
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**Purpose:** Traditional Chinese Medicine (TCM) is widely used for cancer in China, and almost all the cancer patients would to some degree receive TCM treatment. The reason and attitude toward TCM in cancer field is unknown. This study aims to identify the role of TCM for cancer treatment.  
**Methods:** Semi-structured qualitative interview was taken in in/out-patient sections of four integrative Chinese and Western medicine hospitals in China and thematic analysis was applied  
**Results:** Totally 35 cancer patients, 9 family members, and 3 TCM oncologists were interviewed. Four themes including 1) aim of TCM application, 2) people’s satisfaction, 3) understanding and attitude and 4) believe and expectation toward TCM arose. TCM is applied in purpose of regulating the body, improving immunity, maintaining physical strength, and controlling the tumor. The satisfaction and compliance is highly coordinated with the clinical effectiveness. TCM is believed to be long-time intervention adjuvant to conventional treatment in holistic and softer way, which must be taken with or after the surgery or chemoradiotherapy. People have deep trust in the effectiveness of TCM for cancer, and its status and importance is irreplaceable. TCM and Western medicine are indispensable for cancer patients. Compared with Western medicine, although slower, TCM has indelible advantages and value, largely bringing hope to patients and their families. The interviewees also had great expectations for the further development and breakthrough in the applications of TCM in improving quality of life and controlling the tumor, the comprehensive inheriting and wider spread of real TCM expertise, as well as hospital administration.  
**Conclusion:** TCM is considered playing the role adjuvant to conventional treatment, but is highly trusted by cancer patients, their family and oncologists as an indispensable part in cancer clinical applications in China. We suggest the effectiveness of TCM be evaluated in further clinical studies. **Contact:** Jianping Liu, jianping_l@163.com

**P05.23**  
Comparison of Integrative Health Therapies as Related to Pain and the Influence of Sleeping Patients as Missing Data  
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Purpose: While disruptions in sleep patterns are common in an inpatient setting, sleeping patients can also provide unique challenges concerning missing data. Our aim is to 1) explore the pattern of sleeping and its relationship to therapeutic intervention, patient characteristics and/or clinical characteristics; and to 2) compare different imputation techniques for handling missing data caused by patients sleeping post therapeutic intervention.

Methods: T-tests and chi-square were utilized for comparison of patients who provided post therapeutic scores versus patients who were sleeping post treatment. Mixed models of complete data were used to create a known biased estimate of self-reported pain changes, future models will include quantile imputation. Logistic regression compares integrative treatments to education and assessment sessions.

Results: During 4958 admissions 8769 sessions of integrative therapies were delivered. Practitioners reported 953 (15.38%) patients who were sleeping at the conclusion of the interventions. When missing data from sleeping patients were ignored, on average patients reported a pain change of -1.67 (95% CI -1.73, -1.62). Sleeping patients were more likely to be younger (p = .04), women (p < .001) and had higher pre scores (p < .001) than those who were able to provide post treatment pain scores. Patients who received bodywork and mind-body combination therapies were 1.94 times more likely to sleep then patients who provided scores during assessment and education sessions.

Conclusion: Waking a patient after an intervention could minimize the influence of missing data; however it is contrary to the intention of the therapists who’s primarily focus on pain and anxiety reduction. Future refinements of this model will include last value carried forward and imputation of a range of quantiles as well as additional examination of the post sleeping population by clinical characteristics. Observing true pain reductions in sleeping patients is not possible, our goal is to understand the influence of missing data and minimize bias by utilizing appropriate imputation methodology.

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P05.25 LB
Which Database Do I Use? A Review of Database Retrieval of Yoga Articles for Musculoskeletal Conditions
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Purpose: Review the comparative effectiveness and efficiency of databases at retrieving articles include in a systematic review of yoga for musculoskeletal conditions.

Methods: Twenty electronic databases previously used in systematic reviews of complementary therapies and musculoskeletal conditions were searched using database-specific search strategies to identify full-text, peer reviewed, randomized controlled trials of yoga interventions for musculoskeletal conditions. Of the 774 articles returned by the 20 databases, 17 met criteria for inclusion in the systematic review. Each database was subsequently analyzed to determine how many of these 17 articles it retrieved (effectiveness), and how many of the total number of articles the database retrieved were included in the review (efficiency).

Results: Fourteen of the 20 databases retrieved at least one of the 17 articles included in the systematic review. Of these 14 databases, effectiveness ranged from 12% (PsycInfo: 2/17 articles) to 88% (PubMed: 15/17 articles); and efficiency ranged from 8% (Google Scholar: 12/143 articles) to 41% (Cochrane Central Register of Controlled Trials: 13/31 articles). There was differential retrieval of the 17 articles across databases, based on country of journal publication. Articles published in journals from India were retrieved from a maximum of five of the 20 databases (range 1–5); in contrast, articles published during a corresponding time period in Western journals were retrieved from 6–12 databases. Results also indicated some databases may take longer to index recently published articles, with only six of the 20 databases retrieving articles published in the three months prior to the review.

Conclusion: Variability in article retrieval suggests a range of databases should be used when designing systematic reviews of complementary therapies. While highly effective databases such
as PubMed are currently regularly used, the addition of less efficient databases such as Google Scholar and Scopus is recommended to reduce retrieval bias based on time or place of publication.

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P05.26 LB
Measuring Botanical Supplement Use among Hispanics/Latinos in the United States: A Comparison of Methods in the Hispanic Community Health Study/Study of Latinos (HCHS/SOL)

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Purpose: Conventional assessment methods may underestimate the use of botanical supplements in ethnic minorities who reportedly consume teas rather than encapsulated forms. The purpose of this study was to examine and compare methodology for botanical and non-vitamin non-mineral (NVNM) dietary supplement measurement in a sample of Hispanics/Latinos in the United States (US).

Methods: At baseline (2008–2011), supplements were assessed with three methods in HCHS/SOL (n = 15,673): 1) past 4-week medication inventory; 2) past 30-day dietary supplement interview (DI); and 3) two 24-hour dietary recalls. Prevalence estimates for medication inventory, DI, and recalls were adjusted with sampling and nonresponse weights and age-standardized to the US 2010 Census. Concordance statistics compared the medication inventory and DI.

Results: Self-reported prevalence of NVNM and botanical supplement use was markedly higher for the DI as compared to the medication interview—for NVNM (including botanical) supplements (24.6 vs. 12.9%) and for botanicals alone (9.4 vs. 4.4%). Concordance between the two measures was fair/moderate (Kappa 0.30–0.57), but negative agreement was high (≥0.88). With the addition of teas and raw botanicals from the dietary recalls, prevalence increased by 34% for NVNM supplements and 127% for botanicals. In the DI data (without recalls), the most common supplement ingredients mirrored those widespread in the general public: omega-3 fatty acids (e.g., fish oil, flax oil) (9.7%), lutein (9.6%), and lycopene (10.5%). Commonly reported botanical ingredients were ginseng (2.6%), ginkgo (2.6%), garlic (1.7%), and extracts of fruits (4.2%) and vegetables (2.3%). In 24-hour recalls, chamomile tea was more often reported (1.9%) than in the DI (0.2%)

Conclusion: Different botanical supplement measurement methodologies yielded different results among Hispanics/Latinos in HCHS/SOL—measurement methodology should be considered when evaluating study results. Among Hispanics/Latinos, comprehensive botanical use ascertainment require multiple assessments, including those that capture raw botanicals. Because botanicals may have adverse effects and interact with medications, accurate measurement is critical.

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P05.27 LB
Acupuncture in the Treatment of Cancer-Related Psychological Symptoms: A Closer Look at Efficacy and Methodology

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Purpose: Cancer patients/survivors are high utilizers of acupuncture. Additionally, they experience a high prevalence of psychological symptoms such as depression, anxiety, sleep disturbance, and impairment in quality of life. Non-pharmacologic interventions for these symptoms are of interest given the high chemical burden resulting from cancer treatments.

Methods: We reviewed studies from 2000–2013 evaluating acupuncture for depression, anxiety, sleep disturbance and quality of life in cancer patients/survivors, with attention to acupuncture efficacy and methodology. Twelve studies met review criteria: 1) original research utilizing acupuncture, and 2) cancer-associated psychological symptoms (as above) as primary or secondary outcomes.

Results: All 12 studies (total participants N = 933) had a positive signal for acupuncture in the treatment of these psychological symptoms. However, only 2 of 12 studies reported all essential aspects of acupuncture methodology as outlined by the 2010 Standards for Reporting Interventions in Controlled Trials of Acupuncture guidelines. The most commonly omitted information in these studies was: 1) details of needle administration (4/12 studies), 2) rationale for acupuncture point selection (6/12 studies), and 3) training level of acupuncture provider (6/12 studies). There was frequent non-reporting of statistical parameters important for evaluating effect sizes and significance.

Conclusion: The regular omission of methodological data suggests that the heterogeneity of acupuncture administration is not being adequately evaluated. We propose a shift in methodology such that study design 1) clarifies the role of Chinese medical theory in designing studies, which involves a holistic accounting of symptoms rather than the single-symptom focus of modern scientific trials, 2) determines the role of needling technique, such as vigorous stimulation of needles to obtain “De Qi” (a specific needling sensation), and 3) evaluates the characteristics of potential responders and non-responders to acupuncture. More research is needed, but acupuncture may provide an effective and well-tolerated alternative to pharmacological interventions for management of psychological symptoms in cancer.

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P05.28 LB
Methodological Considerations in Evidence-Based Indian Systems of Medicine – A Systematic Review of Controlled Trials of Ayurveda and Siddha
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Purpose: With the recent developments in evidence-based complementary medicine, the Indian systems of medicine (ISM) with its multimodal individualized treatment, perceives many challenges in conducting randomized controlled trials (RCTs). A clear understanding of these challenges is a basic step in determining the feasibility of RCTs and development of research methods in this field. The aim of our study was to identify the important methodological considerations specific for ISM (Ayurveda and Siddha) in conducting a RCT and to review systematically all currently undertaken controlled trials of ISM regarding these features.

Methods: We formulated a 18 point checklist in a PICO (Population Intervention Comparison Outcome) format including usage of ISM concepts in diagnosis and outcome assessment, whole treatment package or integrated treatment as intervention, choice of comparison groups, a non-inferiority hypothesis with the benefit of safety, etc. For the systematic review, we identified all controlled trials published between January 2000 and December 2012. Basic and design specific characteristics of the trials were extracted and analyzed.

Results: The searches retrieved 295 articles, of which 70 controlled trials were identified. Only about 20 to 30% of the trials used ISM concept in diagnosis and outcome assessment. About 20% tested integrated interventions. There were 11 different types of comparison groups used. All the trials studied a superiority hypothesis and only 29% involved an active surveillance for safety outcome. However, RCTs adopting ISM principles, using relevant comparison groups, and further high methodological qualities could be found.

Conclusion: Our research showed that there is ample room for improvement of ISM clinical trial designs. The formulated checklist of specific methodological features can help ISM trialists plan better RCTs. Though current RCTs about ISM often show deficiencies in methodological considerations, we could find examples of successful adaptation of RCT methodologies and hence evidence for its feasibility in ISM.

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OTHER

P06.01
The Effectiveness of a Generic Guided Imagery CD Compared with Individualized Complementary Therapies and Standard of Care for Reducing Preoperative Anxiety: Preliminary Results
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Purpose: Preoperative anxiety is associated with a negative surgery experience and increased morbidity. Complementary Medicine (CM) therapies have been shown to reduce preoperative anxiety, however, comparative effectiveness of such therapies has not been conducted. We compared the effectiveness of individualized CM treatments, a generic guided imagery CD, and standard of care on preoperative anxiety.

Methods: Patients undergoing surgery were assessed for anxiety using a VAS questionnaire at entry to the holding room area. Thereafter, patients were randomized into individualized CM treatments (acupuncture, guided imagery, reflexology, combined reflexology and guided imagery) on top of standard of care (SOS anxiolitics), a generic guided imagery CD, and standard of care alone. Prior to transfer to the surgery theater, a repeat evaluation was conducted.

Results: 58 patients received guided imagery, 41 acupuncture, 41 reflexology, 65 combined reflexology and guided imagery, 62 generic guided imagery CD, and 48 patients received standard of care only. Mean VAS scores changes from baseline to post-treatment were: In the standard of care group 4.9 to 5.09 (p = 0.95); In the Guided Imagery group 5.08 to 1.59 (p < 0.0001); In the reflexology group 6.05 to 2.50 (p < 0.0001); In the reflexology combined with guided imagery group 5.84 to 1.51 (p < 0.0001); In the acupuncture group 6.08 to 2.05 (p < 0.0001); in the generic guided imagery CD group 4.86 to 3.41 (p = 0.001). There was no significant difference between the individual CM treatment groups. However, individualized CM treatments were all significantly more effective in reducing anxiety than the generic CD, and standard of care (p < 0.001).

Conclusion: Individualized CM interventions were superior to generic guided imagery CD, and standard of care.

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P06.02
Active, Self-Care Complementary and Integrative Medicine Therapies for the Management of Chronic Pain Symptoms: A Rapid Evidence Assessment of the Literature
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Purpose: Chronic pain management typically consists of prescription medications or provider-based, behavioral or interventional procedures which are often ineffective, may be costly and can be associated with undesirable side effects. Because chronic pain affects the whole person (body, mind and spirit), patient-centered complementary and integrative medicine (CIM) therapies that acknowledge the patients’ roles in their own healing processes have the potential to provide more efficient and comprehensive chronic pain management. Active self-care CIM therapies (ACT-CIM) allow for a more diverse, patient-centered treatment of complex symptoms, promote self-management, and are relatively safe and cost-effective. To date, there are no systematic reviews examining the full range of ACT used for chronic pain symptom management. Thus, a systematic review was conducted, using Samueli Institute’s rapid evidence assessment of the literature (REAL©) methodology, to rigor-
P06.03
Differential Relations Between Mindfulness, Self-compassion, and Eating Behavior

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Purpose: Maladaptive eating behaviors affect weight gain and may exacerbate the obesity epidemic (Koenders & van Strien, 2011). Mindfulness and self-compassion (SC) have been individually linked to healthful eating behaviors in experimental (e.g., Adams & Leary, 2009) and cross-sectional research (e.g., Lavender et al., 2011), representing salient intervention targets. While these variables are conceptualized to interact synergistically and operate mechanistically in contemplative practices, no research has explored the combined associations of mindfulness and SC with dimensions of eating behavior.

Methods: Participants were 283 university undergraduates (152 females; mean age = 19.12 ± 1.63; m. BMI = 23.73 ± 4.29). Multiple regression analyses were performed to assess how mindfulness and SC were associated with Emotional Eating (EE), Uncontrolling Eating (UE), and Restrained Eating (RE), after controlling for associated variables: Gender (EE/RE), distress (EE/UE), and BMI (RE).

Results: For EE, distress (β = .220, p ≤ .001) and gender (β = .248, p ≤ .001) were positive predictors, and mindfulness (β = -.207, p ≤ .001) and SC (β = -.184, p = .006) negatively predicted EE above and beyond distress and gender (R2 = .210, p ≤ .001). For UE, distress (β = .208, p ≤ .001) was a significant predictor, and mindfulness (β = -.265, p ≤ .001), but not SC (β = -.050, p = .450), negatively predicted UE above and beyond distress (R2 = .123, p ≤ .001). For CR, BMI (β = .250, p ≤ .001) and gender (β = .275, p ≤ .001) were positive predictors, and self-compassion (β = -.167, p = .014), but not mindfulness (β = .078, p = .243), negatively predicted CR above and beyond BMI and gender (R2 = .131, p = .048).

Conclusion: In this sample, mindfulness and SC negatively predicted EE, mindfulness negatively predicted UE, and SC negatively predicted CR. These findings suggest that mindfulness and SC may differentially affect motivations to engage in maladaptive eating behavior. Further, because each eating behavior subtype is linked to a greater likelihood of overweight/obesity (e.g., Snoek & Engels et al., 2013), future research should investigate whether mind-body interventions that increase mindfulness/SC regulate eating behavior or body weight through these mechanisms, and whether the latter are differentially moderated by eating behavior subtype.

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P06.04
Effect of Drakshavaleha on Cyclophosphamide Induced Weight Loss and Reduction in Crown-Rump Length in Developing Mice Embryo

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Purpose: Cyclophosphamide (CP) is an anti-mitotic and apoptosis inducing agent causes stunting in size and loss of body weight of the pups when injected intra-peritoneal to pregnant mice. Due to anti-anemic properties and nutritional values, Drakshavaleha has been used to a woman during her pregnancy, expecting a good health of both mother and her offspring. The objective of the study was to investigate a protective effect of Drakshavaleha against CP induced growth retardation in mice pups in terms of body weight and crown-rump length.

Methods: Group I: Mice (n = 10) received 0.2 ml of distilled water (vehicle) intra-peritoneal on day 11 of pregnancy. Group II: Mice (n = 10) received Drakshavaleha 16g/kg orally from day ‘0’ to ‘18’ of pregnancy. Group III: Mice (n = 10) received CP 10mg/kg intra-peritoneal on day 11 of pregnancy. Group IV: Mice (n = 10) received CP 10mg/kg intra-peritoneal on day 11 under the cover of Drakshavaleha 16g/kg orally from day ‘0’ to ‘18’ of pregnancy.

Results: Effects of CP causing growth retardation, decreased fetal weight and digital anomalies in terms of polydactyly or syndactyly were seen when the drug was injected on 11th day of gestation in III group. Amongst litters whose mothers received the drug on same day and dosage under Drakshavaleha cover, the pups were seen with significant (p < .001) weight gain which however was lower as compared to the pups born to mothers with administration of Drakshavaleha alone (group II). CR length and digital anomalies were also of same conclusion in group II and group I respectively.

Conclusion: The above observations suggest that Drakshavaleha fulfills the required nutrition and increases the size and weight of the pups if be given to mother mice during their gestation.

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P06.05
A Program Analysis of the Massage Therapy Foundation’s Community Service Grants Program

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**P06.06**

**International Integrative Medicine Day: An Emerging Opportunity for Inter-Professional Education**

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**Purpose:** In 2002, the National Center for Complementary and Alternative Medicine (NCCAM) developed a strategic plan to eliminate ethnic and racial disparities in health by improving access to complementary and alternative medicine (CAM) therapies for underserved populations via collaborations with traditional healthcare providers. International Integrative Medicine Day (IIM Day) addresses this strategic plan and is maintained by inter-professional volunteers. IIM Day’s mission statement is to inspire worldwide dialog, education, collaboration, research initiatives and programming about medicine that is patient-centered, holistic, economically and environmentally sustainable, and conscious of integrating different global medical systems.

**Methods:** An IRB-exempt quality improvement survey compiled data from 2011, 2012 and 2013 with 196 subjects responding. We used Survey Monkey and teleform as data collection tools.

**Results:** IIM day attendees ranged in age with 16% (31) under 21 years old and 25% (49) between 30–59 years old. 58% (113) of participants were female, with 74% (146) Caucasian and 14% (27) Asian. 27% (52) of the responders were health professionals and 26% (51) were students. 78% (153) attended conferences, 48% (94) ate a healthy meal and 39% (77) reflected on their personal health. 85% (166) agreed or strongly agreed that IIM Day increased knowledge about IM. When asked about the most important thing participants needed to further their education in IM, 48% (94) chose experiential workshops/retreats, 27% (53) were interested in web classes and talks, 23% (45) wished to attend IM rotations and 18% (36) wanted additional training in specific modalities. Qualitative responses suggest that participants found it meaningful to learn about the definition of integrative medicine, appreciated the moment for reflection, and valued interacting with like-minded individuals.

**Conclusion:** Creating structured learning opportunities amongst healthcare providers and community members may allow for more effective utilization of CAM practitioners.

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**P06.07**

**Integrative Approach with Diet and Complementary Medicine in Oncology: The Experience in the Hospital of Lucca (Italy)**

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**Purpose:** In order to tackle side effects of anticancer treatment an “Integrative Oncology Outpatient Clinic” was started in the public hospital of Lucca where a CAM expert and an oncologist provide diet advices, qualified information and evidence-based indications about CAM and their potential interactions with anticancer drugs.

**Methods:** Near all patients are referred by their medical oncologists. All patients were calculated BMI and when needed a diet was prescribed. Also apply pre-defined simple protocols to reduce some of the side effects of cancer therapies, indication of therapeutic sessions of acupuncture/homeopathy to decrease side effects in chemotherapy/radiotherapy and during anti-hormonal treatments such as hot flashes in order to obtain an improvement of the quality of life.

**Results:** From October 2010 till April 2012 and from January to September 2013, 117 patients have been visited (16 male and 91 female); the average age is 56 (32–88) years; 82 patients with breast cancer, 6 gynecologic cancer, 12 gastro-intestinal cancer, 2 head and neck cancer, 4 prostate cancer, 1 brain cancer, 4 NSCLC, 4 hematologic and 3 other cancer; 26 % had already metastasis. 40% of patients asked for information about CAM in oncology. 10% of patients were using CAM for other purposes before cancer diagnosis: most were women with high level of education. 17 % of patients were using “alternative therapy” often instead of anticancer treatment. We observed an improvement in the quality of life with decreased hot flash frequency and severity, fatigue, anxiety and depression; weight loss
with better lipid profile in patients with diet therapy and decrease of NASH.

Conclusion: A clinic of integrative oncology seems to give the possibility to reduce the adverse effects of anticancer therapy; to investigate interactions between CAM and antiblastics and to advise patients about the potential harmful effect of alternative treatment used instead of fully proven anticancer therapy.

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P06.08
Traditional Chinese Medicine for Stroke: An Overview of Systematic Reviews

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Purpose: To overview the clinical research evidence, reflected by systematic reviews, of traditional Chinese medicine (TCM) related interventions for stroke and its complications to inform clinical practice in relevant countries.

Methods: This study was a survey of systematic reviews of TCM for stroke. We searched for all TCM systematic reviews on stroke in PubMed, the Cochrane Library and four major Chinese electronic databases from their inception to September 2013. Two authors extracted data independently. We performed descriptive data analysis using SPSS17.0.

Results: 136 systematic reviews were identified published between 2000 and 2013, including 26 (19.1%) published in English and 110 (80.9%) in Chinese. The number of trials included in reviews varied from 1 to 191 (17.04 ± 20.77) and the number of participants was from 66 to 1938 per review (1499.35 ± 2012.65) with 16 reviews unreported. The interventions applied in the 136 studies included acupuncture (28/136, 20.6%), Cupping (1/136, 0.7%), moxibustion (1/136, 0.7%), integrative medicine (6/136, 4.4%), combination of different TCM therapies (3/136, 2.2%) and Chinese herb medicine (97/136, 71.3%). The individual herbs commonly used in stroke included Radix Notoginseng, Radix Salviae Miltiorrhizae, Herba Erigerontis, Rhizoma Chuanxiong, Radix Astragali, Qingkailing Injection, Angong Niuhuang Pills and so on. The types of stroke included acute ischaemic stroke (42/136, 30.9%), post-stroke rehabilitation (30/136, 22.1%), acute hemorrhagic stroke (14/136, 10.3%), acute stroke (10/136, 7.4%), acute cerebral infarction (10/136, 7.4%) and so on. The quality of all trials included in the 106 (77.9%) reviews was poor. Referring to the effectiveness of TCM for stroke concluded in these included systematic reviews, 86 (63.2%) reviews reported positive results, 43 (31.6%) suggested further evidence were needed and 7 (5.1%) were unreported or uncertain.

Conclusion: Substantial number of systematic reviews of TCM for stroke have been published during the past decade, and the existed evidence suggested that TCM has beneficial effects on stroke while the high-quality trials are needed to test its effectiveness.

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P06.09
Distance Education Online Intervention for Evidence-Based Practice Literacy (DELIVER)

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Purpose: This study was designed for two purposes: 1) To gather information about the barriers to dissemination and implementation of research evidence within the chiropractic profession. 2) To examine the effectiveness and feasibility of using an online educational program to improve the attitudes and skills of chiropractors about research evidence.

Methods: This study employed two methods: 1) An online national survey of the chiropractic profession using a validated instrument called the Evidence-Based Practice Attitude and Utilization Survey (E-BASE). The E-BASE has three subscores: Attitudes, Skills, and Use of evidence in clinical practice. 2) A prospective randomized wait-list controlled trial with two parallel arms. Group 1 was exposed to a series of online educational modules about research and evidence informed practice while Group 2 was placed on a 6-month wait list. Both Groups are being retested with the E-BASE instrument at 6-month for comparison. Feasibility is being assessed by tracking adherence and completion rates of the online educational modules, as well as the technical issues associated with online education.

Results: 1) The online survey was completed by 1,378 chiropractors from around the U.S. with good geographic and demographic diversity. The E-BASE subscores were highest for “attitudes” and lowest for “use” of research evidence in clinical practice. 2) Completion rate for the structured online program with Group 1 was slightly greater than 55%. Technical issues were minimal and feedback from most participants has been positive. The post online-education E-BASE scores for Group 1 will be compared with Group 2 in mid-November 2013.

Conclusion: We have surveyed almost 1400 chiropractors about their attitudes, self-perceived skills and use of research evidence in clinical practice. We are successfully implementing an online educational program about evidence informed practice for chiropractors, which we believe has the potential to be implemented with other CAM professions. NCCAM Grant: 1R21AT007547-01

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P06.10
Informed Consent for Chiropractic Care: The Patient’s Experience

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Purpose: A qualitative investigation of patients’ perspectives of informed consent for chiropractic care has not been conducted. This study explored how patients’ views of informed consent for chiropractic care compare and contrast with the legal definitions and requirements for informed consent.
Methods: Open-ended telephone and in-person interviews were conducted with 26 participants recruited from chiropractic academic teaching clinics and one private clinic. Eligible participants were new patients at the clinics, over 18 years, and not employed as health care professionals. Interview transcripts were analyzed using a constant comparative method of analysis. Results: Participants experienced informed consent as an ongoing process where risk perceptions were influenced during four distinct stages. Stage one was preconceptions of risk: risks were assessed based on information that participants acquired prior to arriving at treatment. This information appeared to have a significant impact on participants’ decisions to receive treatment. Stage two was perceived practitioner competence: this impression was influenced by early interactions. Practitioners who were perceived as competent seemed to engender feelings of safety for participants. Stage 3 was risk disclosure: participants signed the consent form and discussed the disclosed risks with their practitioner. Participants perceived the consent form as a formality intended to protect practitioners from litigation, yet they valued the accompanying discussion. Stage 4 was patient/practitioner feedback loop: during treatment, participants and practitioners communicated about the amount of force being applied and the resulting level of comfort/discomfort. This feedback loop was often believed to mitigate harm, and for some it presented an opportunity to withdraw consent if they felt that they were at risk of being harmed.

Conclusion: Informed consent was perceived as a social process. These findings suggest that it may be possible to educate chiropractic patients about the risks associated with treatment while satisfying the legal requirements of informed consent.

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P06.12 Apoptosis Induction in Osteosarcoma Cells by Cardiac Glycosides

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Purpose: Osteosarcoma is the most common type of malignant bone tumor in children and adolescents. This cancer has a poor prognosis, is highly metastatic and resistance to current therapeutic approaches. In searching of innovative natural anti-cancer components different herbal extracts used in phytotherapy were screened. Therefore, cardiac glycosides and aglyca – cardenolides and bufadienolides – from Digitalis sp., Strophantus sp., Drimia maritima Convallaria majalis and Buto sp. were examined in accordance to their potential of inducing apoptosis in osteosarcoma cell line 143B-HOS.

Methods: 143B-HOS cells cultures were exposed to increasing concentrations of 20 cardiac glycosides and aglyca for 24 h. Morphological changes were examined by phase contrast microscopy. Cell proliferation ability was measured using cell counting method with the CASY Cell Counter®. Early cytotoxicity was examined using LDH-assay. Apoptosis induction was evaluated by annexin V-APC/PI double staining and flow cytometry. In addition, changes in the mitochondrial membrane potential were measured using JC-1, a lipophilic cationic fluorescent marker.

Results: After 24 h treatment of 143B-HOS with cardiac glycosides and aglyca morphological changes were observed. Inhibitory effects on proliferation were detected in a dose dependent manner. Early cytotoxicity after 4 h treatment was not significant. Both, cardiac glycoside and aglyca induced apoptosis in a dose- and time-dependent manner. Here, the bufadienolides Proscillarin A and Arenobufagin and the cardenolides Ewonomosid, Convallatoxol and g-Strophanthin showed the strongest apoptosis induction, associated with a decrease of mitochondrial membrane potential. In contrast, the bufadienolid Bufaregogenin showed the least potential. The bufadienolid Resibufogenin and the cardenolid Uzarin did not show any effect in apoptosis induction or mitochondrial membrane potential.

Conclusion: In conclusion cardiac glycosides induce highly effective apoptosis in osteosarcoma cell line 143B-HOS and decrease mitochondrial membrane potential. Both the cardenolides and bufadienolides – glycosides as well as aglyca – showed apoptosis induction. The bufadienolid Proscillaridin A possessed the strongest potential.

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**P06.13**

Is Satisfaction a Good Outcome? Exploring the Patient Perspective

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**Purpose:** Patients receiving CAM are typically very satisfied with care. While patient satisfaction is a widely advocated means of measuring patients’ preferences and views related to treatment quality, recent studies have questioned the utility of patient satisfaction as an outcome. The purpose of this presentation is to describe satisfaction from the patient vantage point.

**Methods:** This is an embedded mixed method design in which qualitative data was collected concurrently in a randomized clinical trial. Study subjects were a consecutive subset of individuals with chronic neck pain who had completed 12 weeks of exercise with or without spinal manipulation. One-on-one semi-structured interviews were conducted with 208 participants; these were tape-recorded and transcribed. Content analysis was performed with an iterative approach to theme identification that included inductive and deductive perspectives. Theme frequency was calculated and described.

**Results:** We identified 3 broad themes related to satisfaction: process (focused on delivery of care, 81%), outcomes (focused on results of care, 57%), and expectations (14%). Process related themes included provider/staff interaction (62%), specific aspects of treatment (47%), condition related information (11%), and accessibility/organization of care (11%). Outcome related themes were global perceived effect (31%), pain severity (26%), bio-mechanical function (14%), self-efficacy (13%), and activities of daily living (4%).

**Conclusion:** When rating satisfaction, patients placed greater emphasis on the delivery of care than the outcomes. Global measures of satisfaction may mask important information that could have long term consequences on health care utilization and costs; for instance, patients satisfied with process but not outcome may continue to seek treatment over the long term. Consequently, high levels of global patient satisfaction should be interpreted with caution at the societal level. At the individual level, multiple item satisfaction instruments might be better suited for understanding factors unique to individual patients and tailoring care plans to enhance engagement.

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**P06.14**

Systematic Review of Traditional Chinese Medicine, Soy, Black Cohosh & Mind-Body Interventions for Symptom Clusters During Menopausal Transition/Early Postmenopause

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**Purpose:** Most women experience multiple co-occurring symptoms (clusters) during the menopausal transition (MT) and early postmenopause. Clinical trial reports of hot flash (HF) therapies often omit co-occurring symptoms as outcomes. Systematic reviews of therapeutics for symptoms have focused almost exclusively on a single symptom, HF. Although most investigators have focused systematic reviews on hormonal therapy, an increasing number are studying non-hormonal therapies. The purpose of this project is to systematically review clinical trials of Traditional Chinese Medicine, black cohosh, soy/isoflavone preparations and mind-body therapies for managing symptom clusters during the MT and early postmenopause.

**Methods:** To date there are no published reviews of multiple co-occurring symptoms in the MT literature. An experienced librarian searched for randomized controlled trials reported in English between 2004 and 2012. The following databases were searched: PubMED/Medline, CINAHL Plus, PsycInfo, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Web of Science, EMBASE, AMED, and Alt-Health Watch. Reports that met all inclusion criteria and no exclusion criteria were reviewed and data were extracted and summarized.

**Results:** 1193 abstracts were identified and 58 reports of trials examining the effectiveness of therapies on HF and at least one additional symptom including mood, pain, sleep and cognitive concerns were reviewed. Statistically significant between-group change in HF plus one or more symptoms were reported in: 8 of 12 trials of Traditional Chinese Medicine (TCM), 10 of 19 trials of herbal therapies, 8 of 19 trials of soy-isoflavones, and 3 of 8 trials of mind-body therapies.

**Conclusion:** The papers reviewed reported few harms. TCM and herbal therapies show promise. Most investigators didn’t include symptom clusters in the design or use measures with homogeneous scales. Most studies included fewer than 100 participants. Investigators should be encouraged to measure and report treatment effects in ways that allow clinicians to consider symptom clusters when prescribing therapies.

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**P06.15 LB**

Searching Grey Literature for Evidence: Ozone Therapy as a Model

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**Purpose:** Systematic reviews of the studies published in the major medical data bases have not shown solid support for the use of ozone therapy. Unpublished or grey literature, including postgraduate theses, may solve this controversy. Objectives: To assess the clinical safety and effectiveness of ozone therapy in specific medical condition using grey literature.

**Methods:** The databases of the Egyptian Universities’ Library Consortium and the databases of each university were searched for postgraduate theses that evaluated ozone therapy as an intervention for any disease or condition in any age group, compared to any or no other intervention, and published before September 2010.

**Results:** A total of 28 quasi trials were included. The theses did not report any safety issues regarding ozone therapy. Regarding its effectiveness, the studies suggested some benefits of ozone in the treatment of dental infection and recovery,
musculoskeletal disorders, diabetes mellitus, chronic diseases, and obstetrics and gynaecology. However, the number of included studies was small, and they were of limited quality.

**Conclusion:** There is insufficient evidence to recommend the use of ozone in the treatment of dental infections, in speeding dental recovery after extraction or implantation, in diabetes mellitus, musculoskeletal disorders, or obstetrics and gynaecology. Addition of grey literature to published studies may increase the number of available studies to be used in reviews.

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**P06.16 LB**

**Information Medicine: Emergence of a New Medical Paradigm**

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**Purpose:** Information theory shows an increase in information leads to a decrease in disorder (entropy). This is also true of living systems which continually exchange thermodynamic free energy via information at multiple levels of organization in order to maintain themselves. Disease can be considered to emerge from perturbations of the information flow within the body. Our aim is to review clinical studies demonstrating efficacy of human intention and information in improving human health. This innovative whole system healing is termed “information medicine (INFOMED).”

**Methods:** The second law of thermodynamics (TD) is examined to understand Gibbs free energy, ΔG, which drives all processes in nature including chemical potentials. Human intention as a source of information is also shown to be a source of ΔG via a reduction in disorder. Experimental data from pilot studies of INFOMED in depression, autism as well as individual case reports are reviewed. The set of quantifiable conditions wherein the intention effects materialize are described.

**Results:** Diverse concepts of energy and human intention are shown to have inter-relationship and are readily understood under the unifying umbrella of TD. There is increasing ΔG as one ascends from chemical medicine to energy medicine from veritable and putative sources. Compared with chemical and energy medicine, INFOMED has higher ΔG and nourishes all levels of a living system.

**Conclusion:** Information (intention) is a source of free energy and can change whole living systems in a specific and beneficial direction and robustly expands the normal molecular theories of bio-information. Crucially, human consciousness as the source of free energy is capable of driving chemical processes and opens the door to INFOMED. Modern physics concepts of information theory suggest a higher level of therapeutic intervention that go beyond the traditional mental, emotional and physical approaches to treating diseases.

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**P06.17 LB**

**State and Regional Comparisons of the Use of Complementary Health Approaches: National Health Interview Survey, 2012**

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**Purpose:** Based on previous health behavior studies, we expected variation in use of individual complementary health approaches by geographic location. This analysis presents geographic comparisons of use of complementary health approaches among U.S. adults ≥18 years, using data from the 2012 National Health Interview Survey (NHIS).

**Methods:** Data from the Adult Complementary and Alternative Medicine supplement of the 2012 NHIS were examined to compare prevalence estimates of complementary health approaches among 9 geographic regions and the top 10 most populous states in the U.S. Differences between regional/state percentages and national averages were evaluated using two-sided significance tests at the 0.05 level. All analyses were conducted using SUDAAN to account for the complex NHIS sample design.

**Results:** Non-vitamin, non-mineral dietary supplements (NVNMDS) (17.9%), chiropractic and osteopathic manipulation (8.5%), and yoga (8.4%) were the top three approaches used in the U.S. The prevalence of adults who used any of the most popular approaches was consistently higher in the Mountain region and consistently lower in the South Atlantic region when compared to the national average. Adults in Michigan (24.6%) and Ohio (23.3%) were more likely to use NVNMDS. Fewer adults in Florida (6.2%) and Texas (5.9%) saw a practitioner for chiropractic or osteopathic manipulation. A greater proportion of adults in California (11.0%) and Illinois (11.0%) used yoga. Other complementary health approaches commonly used by adults in 2012 included massage (6.8%) and meditation (6.3%).

**Conclusion:** Prevalence of use of complementary health approaches was consistently higher in the Mountain region compared to the national average. States with the lowest prevalence were in the southern regions.

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**P06.18 LB**

**Why Adults Use Complementary Health Approaches: An Analysis of Nationally Representative Data**

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**Purpose:** The use of complementary health approaches such as mind-body therapies and natural products is popular among Americans. We investigated the specific reasons that complementary health approaches are used and individuals’ perceived outcomes of utilizing a particular approach.

**Methods:** Using data from the 2012 National Health Interview Survey Complementary and Alternative Medicine Supplement we examined the reasons for use and reported outcomes of popular complementary health approaches among their individual users aged 18 and over. We report percentages and standard errors for each sub-group in this nationally representative cross-sectional study.

**Results:** Popular therapies used included, but were not limited to non-vitamin non-mineral dietary supplement (NVNMDS) use, chiropractic or osteopathic manipulation, yoga, massage therapy
and meditation. Eighty-three percent of persons who used NVNMDS did so for general wellness or disease prevention while 42% used them to treat a specific condition. Sixty-six percent of persons who used chiropractic and osteopathic manipulation did so to treat a specific health condition, and 67% said it improved their overall health and made them feel better. Individuals using massage therapy reported a number of benefits including reduced stress (76%) and better sleep (54%). More than 80% of individuals using yoga or mindfulness meditation used these approaches for general wellness or disease prevention and said these approaches improved their overall health and made them feel better. Complementary health approaches were also perceived to be beneficial to social wellbeing, improving relationships and attendance at work/school.

**Conclusion:** The reasons Americans use complementary health approaches differ greatly by the approach, with some, such as NVNMDS used primarily for wellness or disease prevention, and others like chiropractic and osteopathic manipulation, used primarily to treat specific health conditions. The perceived outcomes associated with each therapy also varied considerably by approach.

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**P06.20 LB**  
**Changing Dietary Supplement Use Among U.S. Adults: 2000–2012**

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**Purpose:** Non-vitamin, non-mineral dietary supplements (NVNMDS) such as fish oils, melatonin and Echinacea are used by many Americans for improving health and wellbeing. Previous studies indicate a steady increase in overall use of NVNMDS over time, but none have documented changes in individual NVNMDS use.

**Methods:** We used data from the 2000, 2002, 2007 and 2012 National Health Interview Survey (NHIS), which are collected from representative samples of U.S. adults aged 18 and over. Point and standard error estimates of overall and selected NVNMDS use were calculated using SUDAAN, accounting for the complex sample design of the NHIS. For each year, the denominator was the estimated number of adults in the U.S. Data were age-adjusted to the projected 2000 U.S. standard. Estimates of NVNMDS use were compared between years using two-tailed significance tests at the 0.05 level.

**Results:** In 2000, 14% of adults aged 18 years and over used NVNMDS. Overall use has remained stable with an increase of over 3 percentage points between 2000 and 2012, but little change was seen when comparing 2007 to 2012. However, during this same time period, there have been significant changes in the specific NVNMDS used. In 2002, Echinacea, ginseng and ginkgo biloba were the most common supplements used by adults. In 2007 and 2012, the use of these three supplements decreased, and they were no longer among the top 5 NVNMDS used in 2012. In 2007 and 2012 fish oil was the most common NVNMDS used among adults (4.8% and 7.8%, respectively). Between 2007 and 2012 the use of melatonin doubled, while probiotic/prebiotic use quadrupled. Conversely, there was a decrease in glucosamine/chondroitin use between 2007 and 2012.

**Conclusion:** While the overall use of NVNMDS has remained relatively stable over time, large increases and decreases in the use of individual NVNMDS have been noted.

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**P06.21 LB**  
**MBRS, Mindfulness and Genetics: A Review of the Literature**

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**Purpose:** The purpose of this review was to determine the state of the science related to the integrative practices of mindfulness...
meditation, including mindfulness based stress reduction (MBSR), and potential changes in genetic expression.

**Methods:** Through a synthesis of published research the PsycINFO, ScienceDirect, PubMed and Web of Science databases were reviewed through February 2014. Search terms included combinations of: “MBSR, mindfulness, genes, genetics.” Searches were further limited to include only: 1) Original research studies; 2) evaluated mindfulness meditation and/or MBSR; 3) assessed potential genetic factors and 4) Research published in English. Exclusion criteria: 1) Anecdotal notes; 2) Studies published in a language other than English; 3) Reviews; and 4) Dissertations.

**Results:** Analysis of these searches identified 200 potential results, with two of these studies meeting the outlined inclusion criteria. In the first study, the researchers examined whether an 8-week mindfulness based stress reduction program vs. a waitlist control could reduce loneliness and down-regulate loneliness-related pro-inflammatory gene expression in forty lonely older adults. Results found that MBSR reduced loneliness in the intervention group (p = .008) and at baseline, an association between reported loneliness and upregulated pro-inflammatory NF-κB-related gene expression in circulating leukocytes was downregulated at post-treatment in the intervention group. In the second study, the researchers investigated the whole genome expression of the higher state of consciousness compared to an ordinary state of consciousness in meditators’ in a long-term meditator living a normal life and a Buddhist lama and found that although the number of differently expressed genes and high proportion of genes themselves differed between meditators, there were significant biological and molecular processes shared among the meditators’ in a higher state of consciousness.

**Conclusion:** This review of literature suggests a continued need to establish strong research evidence testing the relationship between changes in genetic expression and the integrative mechanisms play a certain role in these interactions. Potential herb-drug interactions should be considered when herbal medicine used to patients with hypertension.

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### P06.23 LB

**Rhodiola Rosea Modulates Apoptosis and Autophagy in Myelodysplastic Syndrome Tumor Xenograft Model**

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**Purpose:** Considering the ineffectiveness of single-target drugs on Myelodysplastic syndrome (MDS), we investigated the effects of the plant Rhodiola rosea extract (RRE) on the apoptosis and autophagy process implicated in the pathophysiology of this disorder.

**Methods:** The human tumor xenograft model of MDS was used. A total of 2 x 10⁶ P39 cells (AML transformed from MDS) were subcutaneously injected in dorsal region of NOD.CB17-Prkdcscid/J mice (n = 6). Tumor volume was measured once every 7 days. Treatment started when tumors reached 100–200 mm³. The dose of 250 mg/kg/day was given orally (gavage). Controls (n = 6) received vehicle only. After 14 days, mice were sacrificed, tumors removed, minced, homogenized in protein extraction buffer or fixed in formalin immediately for the performance of immunohistochemistry and detection of apoptosis and autophagy.

**Results:** In RRE-treated mice, reduction of approximately 30% in tumor volume was observed after 14 days treatment. Increased expression of beclin-1, STSQM1/p62, ATG7 and Bcl-2 were found. Apoptosis and autophagy were confirmed by increased expression of caspases-3 and LC3. Our findings suggest that prevention by RRE of apoptosis and autophagy is a good indicator for its use as a therapeutic agent against MDS-related complications.

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### P06.24 LB

**Whole-Systems Ayurveda and Yoga Therapy for Obesity: Complete Outcomes of a Pilot Study**

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**Purpose:** The CDC reports that 37% of American adults and 17% of children were obese in 2009–2010, regardless of gender.
Conventional medical approaches have demonstrated limited success in the treatment/prevention of obesity. A recent review of weight-related clinical trials of yoga therapy found it frequently effective in promoting weight loss and/or improvements in body composition.

**Methods:** Ayurvedic lifestyle and diet modification combined with yoga therapy as treatment for obesity focuses on establishing simple routines enhanced by self-awareness to correct physiological and psycho-spiritual imbalance. Yoga and Ayurveda are whole practice disciplines, emphasizing tailored treatments and multi-target therapies. The application and outcomes of Ayurveda/Yoga are multi-factorial and complex. A whole-systems (WS) Ayurveda and Yoga therapy intervention was designed to create integrated, sustainable lifestyle change with minimal practitioner intervention.

**Results:** Twelve participants, aged 18–70, with BMI between 25–45 enrolled in a 3-month WS Ayurveda and Yoga therapy protocol for obesity, including thrice-weekly yoga classes and bi-monthly Ayurvedic assessments. Participants were yoga novices who met dual diagnosis criteria of BMI 25<45 and a predetermined Ayurvedic constitution/imbalance profile associated with simple obesity. Follow-up outcomes at 6 and 9 months measured the sustainability of change. The intervention protocol was standardized but flexible, allowing for tailored treatments. Biomedical and Ayurvedic outcomes were collected, including adherence measures, psychosocial variables and self-efficacy scales.

**Conclusion:** Average weight loss, at 3 months was 7.8 lbs, increasing to 12.4 lbs. at 6-months and 12.9 lbs. at 9 months. Average BMI was reduced from 33.2 to 31.3 and average body fat % went from 43.2 to 39.4. Waist and hip circumferences/ratios decreased. Self-efficacy scores increased at 3, 6 and 9 months while perceived stress decreased. Water intake and elimination increased, while appetite and food cravings decreased. Unique Ayurvedic outcome instruments were designed to simultaneously increase self-awareness. Participant satisfaction averaged above 90% at all time points.

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**P06.25 LB**

**Impact of Broadcast Intention on Autism Spectrum Behaviors**

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**Purpose:** Children and adults on the autism spectrum experience significant difficulty with normal development and awareness in the physical domain. This pilot study utilized an intention host device (IHD) imprinted with intention to assist autistic individuals, located around the globe, to integrate into their physical bodies and experience.

**Methods:** An IHD imprinted with an intention to support integration, was broadcast to thirty-nine subjects. Baseline and monthly skills were monitored utilizing the Autism Treatment and Evaluation Checklist (ATEC) and addressed speech/language/communication, sociability, health/physical/behavior and social cognitive awareness. The subjects (age range: 3 to 27 years old; 80% male) reside in North America, Australia, Japan, Canada and Finland. ATEC scores were analyzed using generalized estimation equation (GEE). Paired T test was used to compare data at 3, 6 and 12 month to the baseline.

**Results:** The performance of subjects improved over time and a significant positive trend is found overall (p-value <0.0001) and on all subscales (communication: p-value = 0.0004; sociability: p-value = 0.0001; cognitive awareness p-value = 0.0003; physical behavior p-value < 0.0001) There was no difference in gender found in overall ATEC score (p-value = 0.4064), however, significant differences between the three intermediate time points and the baseline measure were documented (p-value = 0.0009, = 0.0005 and < 0.0001 Overall).

**Conclusion:** Intention broadcast by an IHD resulted in significant gains in communication, sociability, behavior and social cognitive awareness, with increased improvements over time. Increased performance in all areas indicated improved awareness in the physical domain, for these subjects. Communication and cognitive awareness, typically considered the most challenging obstacles for this population, can be significantly improved via IHD. Our results indicate that the novel strategy of intention broadcasts, with a focus on integration, for individuals on the autism spectrum merits study in larger groups.

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**P06.26 LB**

**Effect of Nutritive Shakti ladoo (Ayurveda and Yoga Diet Energy Food) on Weight of the Pre-School Children**

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**Purpose:** The aim of this paper is to address, in a large population-based study, longitudinal occurrence patterns and course of malnutrition among pre-school children and to compare these patterns among clinically and anthropometrically defined malnutrition.

**Methods:** Study has the design of pre–post control group design. A sample of 57 pre-school (Anganwadi) children of age 2 to 6 years was enrolled. One is of controlled group of 24 children and study group of 33 children. The two government anganwadis selected of Harlapur, which is under developed rural area in Harihar town, Karnataka, India. Two-month contacts were organized making up 15 days of follow-up and giving preparation of Shakti ladoo, weekly thrice. Ingredients of Shakti ladoo (a wholesome Ayurveda and Yoga diet food) is Powders of Green gram whole, soya whole, wheat, jaggery and ghee (nutritive values-protein-12.45%, carbohydrate-72.52%, energy-356.3 kcal/100 gms-tested in Pristine laboratories, Bangalore, Karnataka, India). It increases protein and carbohydrates which is essential nutrient for preschoolers. Due to mudga i.e. green gram helps in digestion and balancing the tridoshas (Vata, Pitta and Kapha). Due to jaggery, increases rakta dhatu (HB%) nourishes body.

**Results:** Weight was analyzed before and after two months. In experimental group it was observed the increase in the weight, which was significant (paired sample t-test was applied p<0.05). While in control group no significant changes were observed.

**Conclusion:** Shakti ladoo (Ayurveda Nutritive diet) increases the weight of the pre-school children significantly in experimental group when compared to control group.

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P06.27 LB
Immunohematopoietic Modulation by the Alga Chlorella in Obese Mice

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Purpose: The purpose of this study was to investigate the modulating effects of the prophylactic treatment with the alga Chlorella on the medullar and extramedullar hematopoiesis and cytokine production of obese mice. I am interested in oral presentation only

Methods: For the study of interaction between stromal cells and hematopoietic progenitor cells we used the long-term bone marrow culture. Growth and differentiation of bone marrow and spleen progenitors (CFU-GM) were studied by clonal culture. Cytokines determined by ELISA.

Results: In obese mice, reduced capacity of stromal cell layer to support the growth and differentiation of granulocyte-macrophage progenitor cells (CFU-GM), concomitantly to decreased numbers of total non-adherent cells and reduced local production of IL-6 and IL-1z, were observed in LTBMC cultures. Accordingly, bone marrow CFU-GM was also reduced in these animals. A pioneer finding was the presence of extramedullar (spleenic) hematopoiesis, which might be related to the accumulation of macrophage in adipose tissue, a common feature in human and experimental obesity. The study of serum cytokines in obese mice revealed increased levels of IL-1, IL-6, TNF-alfa, TGF-beta and reduced levels of IL-10. Prophylactic treatment with CV restored all these changes to normal values, with the exception of TGF-beta and IL-6, which were reduced below control levels.

Conclusion: Additional findings, already published (Vecina et al, 2013) were also pioneer demonstrating that prevention by CV of high-fat diet-induced insulin resistance in obese mice is due to improvement in insulin signaling pathway by increasing phosphorylation levels of IR, IRS-1 and Akt and reducing phosphorylation levels of IRS-1ser307. We also found that CV prevents high-fat diet-induced dyslipidemia by reducing triglyceride, cholesterol and free fatty acid levels. Altogether our findings suggest that prevention by CV of the deleterious effects induced by high-fat diet is a good indicator for its use as a prophylactic agent against obesity-related complications.

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P06.28 LB
Psychological Intervention of Symptoms for Depression in College Students with REBT: Implementation in Design and Practice

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P06.29 LB
Effect of Yoga on Prakriti of the Children-A Randomized Control Study

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Purpose: Exploring the effectiveness of psychological intervention for depression symptoms in college students with REBT in group.

Methods: CES-D and HAMD were used for measuring for 1270 students in Beijing, standard score CES-D(≤16), HAMD (7 ≤ 17) 24 students went in group with Informed Consent Agreement. There are 8 steps in intervention: (1) psychological supporting union setting up from a warm-up game, relax skill learning and sharing; (2) REBT learning and discussing; (3) self-persuading, a new view setting; (4) irrational beliefs debating; (5) evidence finding by Socratic midwifery, exaggerated, substitutive etc.; (6) delightful event recording; (7) act plan making; (8) reviewing and roles taking off. Frequency: 50 minutes each, once a week, 8 weeks total. 2 psychotherapists who involved through whole process of intervention, homework (DRDT) is asked for 6 times, it is checked by a secretary who is responsible for intervention recording too. During be checking, puzzle be found from the students whose problem is discussed and experience be shared in the group.

Results: Retest score shows that there is a significant differences both CES-D and HAMD with T test (P<0.05). Mean from 9.38 ± 1.92 to 4 ± 2.5 ± 2.71 in HAMD, from 27.38 ± 5.50 to 11.00 ± 7.67 in CES-D. The main changes from the items of Block, Cognitive impairment and Somatic symptoms in HAMD.

Conclusion: Psychological intervention with REBT in group is effectively to manage symptoms of depression, Especially for Block, Cognitive impairment and Somatic symptoms.

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P06.30 LB
Effect of Udvartana (Powder Massage) On Obesity
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Purpose: Udvartana (Ayurveda massage with powder) has been described as being effective in Obesity. Studies on effect of Ayurveda formulations on obesity are available. The present study was intended to check the effect of Udvartana (powder massage) on body weight.

Methods: Study was carried out in Shri Ramakrishna Kerala Ayurveda Center, Davangere. Sampling design was purposive sampling. Design of the study was single group pre-post design. Ten samples of obesity (BMI >30), age group between 35–50 were selected. Data was collected before and after seven days of Ayurveda Panchakarma treatment Udvartana (a massage done with powder in opposite direction) by Kola kulathadi Churna. Weight was assessed before and after seven days. Paired sample T-test was applied to check the significance of the mean difference.

Results: It was observed mean weight was reduced from 84.7 to 81.8 which was significant (p<0.005).

Conclusion: The study has shown Udvartana has resulted in significant change in weight in obesity patients. However study has to be carried out by adopting randomized sampling design and on more samples.

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P06.31 LB
Building up Integrative Approaches in Cancer Care with Chinese Medicine in Australia
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This abstract reports on building up integrative approaches in cancer care in Australia with Chinese medicine. Cancer is a common disease worldwide; it affects 1 in 2 Australians in their lifetime by the age of 85 and it is a leading cause of death in Australia. Although the life expectancy for many patients has been increasing because of improvements in early diagnosis and treatment, in turn, this has led to specific problems encountered by patients who experience adverse effects from conventional treatments and long-term cancer survivors for relapse and metastasis. Many turn to complementary and alternative medicine (CAM) including Chinese medicine (CM) for answers. Attempts with integrative oncology approaches have been made in many countries; this includes government funded medical schemes allowing access of acupuncture and herbal medicine in public hospitals in China; and acupuncture is made available for public access in prestigious medical oncology centres in America. Despite there has been tremendous public interest in and use of CM; acceptance from the medical professionals and access for patients to quality service with integrative care in Australia is limited. This research initiative aims to explore an integrated model of health-care provision in effective cancer care in Australia through conducting various research activities and projects. Under this research theme, the goal of research activities is to establish formal dialogues between medical oncologists in Australia and integrative oncologists in China. The purposes of research projects are to investigate potential effectiveness and safety of CM for managing treatment related side effects; and to understand the perceptions of patients and CM practitioners who treat cancer patients in Australia.

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P02.154
Perceived Fatigue Interference vs Severity Level: Comparison of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome and Breast Cancer Patients
Daniel Hall (1), Emily Lattie (1), Sara Czaja (1), Suzanne Lechner (1), Charles Carver (1), Michael Antoni (1)
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Purpose: Both Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and breast cancer (BCa) patients nominate fatigue as among the most distressing and impairing aspects of their illness. However, few direct comparisons between these patient groups have been reported in the literature, and no studies have explored group differences in perceived impairment given one’s fatigue severity, or one’s ‘‘fatigue ratio.’’ If evident, group differences in fatigue ratio presentation may have implications for treatment response to interventions in ME/CFS and BCa patients.

Methods: For this study, 95 women with ME/CFS and 223 women with BCa completed measures of fatigue (Fatigue Symptom Inventory; FSI) and of depressed mood (ME/CFS patients completed the CES-D and the POMS Depression/Dejection subscale; BCa patients completed the HAM-D). A ratio of FSI fatigue interference score to the severity score (I:S) was calculated for each participant. An independent samples t-test compared I:S means of ME/CFS and BCa patients. Hierarchical regression models tested associations between standardized I:S ratios and depressed mood variables to demonstrate whether higher I:S scores were associated with greater depression, after controlling for patient age.

Results: ME/CFS patients’ I:S scores (M = 1.04, SD = 0.25) were significantly higher than BCa patients’ (M = 0.85, SD = 0.39), t(297.7) = 5.06, p < .001. Among ME/CFS patients, I:S scores were significantly associated with greater depressed mood in both CES-D and POMS-Depression/Dejection subscale scores, βs > .24, t’s > 2.61, p’s < .01. For BCa patients, I:S scores were similarly significantly related to elevated depressed mood in HAM-D scores, β = .22, t = 2.63, p < .01.

Conclusion: Our findings indicate that ME/CFS patients more commonly perceive greater interference given their level of fatigue than do BCa patients. Moreover, in both patient groups, a higher interference-to-severity fatigue ratio related to more depression and greater depressed mood. These results provide preliminary evidence for a group difference in patients’ experiences of fatigue, and warrant further investigation to elucidate potential mechanisms for intervention.

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P04.54
A Wellness Curricular Intervention for Family Medicine Residents to Reduce Depression and Burnout
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(2) Maine Medical Center, Portland, ME, USA
**Purpose:** Research demonstrates that burnout is common during residency training and is more likely to persist in the setting of depression. We hypothesized that exposure to mind-body therapies via a brief wellness curriculum would improve mood scores and reduce burnout among Family Medicine residents.

**Methods:** All Family Medicine residents were invited to participate in qi gong, yoga, and mindfulness meditation during dedicated didactic session time over three years. A single sample, repeated design will be used with each subject participating for up to three years. Measures include Maslach Burnout Inventory (MBI), Patient Health Questionnaire-9 (PHQ-9) and demographic data. Demographic variables were summarized using means and proportions; paired T-tests and ANOVA will be used to test our hypothesis using SPSS software. Institutional IRB approval was obtained.

**Results:** At baseline 17 of 21 (80%) participants completed the survey. Participants were primarily female (82.4%). Mean age was 27.9 yrs (range 27–54) with 61% between the ages of 30–49 years. Pre-implementation MBI professional efficacy score was high (mean 30.12, SD 3.68). Exhaustion (mean 14.53, SD 5.43), and cynicism scores (mean 8.41, SD 6.96) were moderate. Mean depression score on PHQ-9 was minimal 3.35 (SD 2.42). We assessed results by year in training–PGY-1 (29%), PGY-2 (17.6%), and PGY-3 (52.9%). These residents endorse personal competence, successful achievement in their work, and experience minimal mood disruption, but also feel exhausted and somewhat cynical at baseline.

**Conclusion:** Preliminary results support existing literature. We expect added wellness elements will decrease scores for exhaustion and cynicism during residency training at the individual level. Our pilot study of residents participating in a brief mind-body curriculum demonstrates it is a feasible, well-received intervention. Ongoing study will evaluate if these elements woven into didactic sessions support resident well-being and protect against burnout.

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### Abstract Author Index

<table>
<thead>
<tr>
<th>Name</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abravanel, Sarah</td>
<td>P02.92</td>
</tr>
<tr>
<td>Abrams, Michael</td>
<td>P02.43</td>
</tr>
<tr>
<td>Ackerman, Debora</td>
<td>OA07.04</td>
</tr>
<tr>
<td>Acree, Michael</td>
<td>OA09.02</td>
</tr>
<tr>
<td>Adam, Emma</td>
<td>P02.42</td>
</tr>
<tr>
<td>Adams, James</td>
<td>P01.21</td>
</tr>
<tr>
<td>Adams, Jon</td>
<td>OA12.03</td>
</tr>
<tr>
<td>Adhvar, Megna</td>
<td>P01.24 LB</td>
</tr>
<tr>
<td>Adler, Shelley</td>
<td>P02.52</td>
</tr>
<tr>
<td>Alræk, Terje</td>
<td>P04.06</td>
</tr>
<tr>
<td>Alrasheid, Abdullah</td>
<td>P03.26 LB</td>
</tr>
<tr>
<td>Ali, Ather</td>
<td>OA02.01</td>
</tr>
<tr>
<td>Ali, Hadi</td>
<td>OA16.02</td>
</tr>
<tr>
<td>Allen, Nathanial</td>
<td>P04.43 LB</td>
</tr>
<tr>
<td>Almond, Patrick</td>
<td>OA07.04</td>
</tr>
<tr>
<td>AlMedaaleh, Abdullah</td>
<td>P03.26 LB</td>
</tr>
<tr>
<td>Al-Shaheh, Mohamad</td>
<td>P06.15 LB</td>
</tr>
<tr>
<td>Alirek, Terje</td>
<td>P04.06</td>
</tr>
<tr>
<td>Amit, Sood</td>
<td>P02.150 LB</td>
</tr>
<tr>
<td>Amiri, Hakima</td>
<td>OA04.03</td>
</tr>
<tr>
<td>Amsterdam, Jay</td>
<td>OA16.03</td>
</tr>
<tr>
<td>Anderson, Belinda</td>
<td>P03.01</td>
</tr>
<tr>
<td>Ando, Shin-ichi</td>
<td>P02.142 LB</td>
</tr>
<tr>
<td>Andrea, Sarah</td>
<td>P02.09</td>
</tr>
<tr>
<td>Angelina, Hernandez</td>
<td>P06.03</td>
</tr>
<tr>
<td>Antoni, Michael</td>
<td>P02.154</td>
</tr>
<tr>
<td>AR, Arazya</td>
<td>P02.100</td>
</tr>
<tr>
<td>Arnao, Zahi</td>
<td>OA07.01</td>
</tr>
<tr>
<td>Arnhem, Abdullah</td>
<td>P06.15 LB</td>
</tr>
<tr>
<td>Arnon, Zahra</td>
<td>P06.01</td>
</tr>
<tr>
<td>Aschbacher, Kirstin</td>
<td>P02.34</td>
</tr>
<tr>
<td>Asher, Gary</td>
<td>P04.41</td>
</tr>
<tr>
<td>Athens, Josie</td>
<td>P02.133 LB</td>
</tr>
<tr>
<td>Atkins, Samuel</td>
<td>OA07.01</td>
</tr>
<tr>
<td>Avilés-Santa, M. Larissa</td>
<td>P05.26 LB</td>
</tr>
<tr>
<td>Avis, Nancy</td>
<td>P02.35, P02.41, P02.42</td>
</tr>
<tr>
<td>Azizi, Hoda</td>
<td>P02.02, P02.03, P02.120</td>
</tr>
<tr>
<td>Baa, Wesley</td>
<td>P02.146 LB</td>
</tr>
<tr>
<td>Baccetti, Sonia</td>
<td>P04.30</td>
</tr>
<tr>
<td>Baldini, Editha</td>
<td>P06.07</td>
</tr>
<tr>
<td>Balneaves, Lynda</td>
<td>P03.04</td>
</tr>
<tr>
<td>Bao, Wuye</td>
<td>P01.30 LB</td>
</tr>
<tr>
<td>Barbieri, Riccardo</td>
<td>P05.17</td>
</tr>
<tr>
<td>Bardacke, Nancy</td>
<td>OA10.03</td>
</tr>
<tr>
<td>Barkley, Rachel</td>
<td>P03.19</td>
</tr>
<tr>
<td>Barnes, Mary Ann</td>
<td>P04.16 LB</td>
</tr>
<tr>
<td>Barnes, Patricia</td>
<td>P06.18 LB</td>
</tr>
<tr>
<td>Barnhart, Janice</td>
<td>P05.26 LB</td>
</tr>
<tr>
<td>Barone, Donald</td>
<td>OA13.04</td>
</tr>
<tr>
<td>Barrett, Luke</td>
<td>OA13.02</td>
</tr>
<tr>
<td>Barrett, Richard</td>
<td>P02.95</td>
</tr>
<tr>
<td>Barrett-Connor, Elizabeth</td>
<td>OA13.03</td>
</tr>
<tr>
<td>Bartels-Velthuis, Agna</td>
<td>P02.111, P05.04</td>
</tr>
<tr>
<td>Bartmess, Elizabeth</td>
<td>P02.67</td>
</tr>
<tr>
<td>Basudan, Omar</td>
<td>P05.01</td>
</tr>
<tr>
<td>Bauer, Brent</td>
<td>P02.104</td>
</tr>
<tr>
<td>Bauml, Joshua</td>
<td>OA05.03</td>
</tr>
<tr>
<td>Baxter, G David</td>
<td>P02.133 LB, P05.25 LB</td>
</tr>
<tr>
<td>Baylin, Ana</td>
<td>P02.32</td>
</tr>
<tr>
<td>Beattie, Tara</td>
<td>OA15.02</td>
</tr>
<tr>
<td>Beaumont, Jennifer</td>
<td>P02.125 LB</td>
</tr>
<tr>
<td>Bechard, Elizabeth</td>
<td>OA09.03</td>
</tr>
<tr>
<td>Beck, Danielle</td>
<td>OA06.01</td>
</tr>
<tr>
<td>Becker, Werner J</td>
<td>P02.33</td>
</tr>
<tr>
<td>Beer, Andre Michael</td>
<td>P04.24</td>
</tr>
<tr>
<td>Beil, Kurt</td>
<td>P05.16</td>
</tr>
<tr>
<td>Bemihorn, Curtiss</td>
<td>OA14.04 LB</td>
</tr>
<tr>
<td>Ben-Arye, Eran</td>
<td>OA07.01</td>
</tr>
<tr>
<td>Benn, Rita</td>
<td>P03.21, P04.38</td>
</tr>
<tr>
<td>Benson, Herbert</td>
<td>P02.43, P02.44</td>
</tr>
<tr>
<td>Bensoussan, Alan</td>
<td>P02.64, P06.31 LB</td>
</tr>
<tr>
<td>Berenji, Fariba</td>
<td>P02.120</td>
</tr>
<tr>
<td>Berkowitz, Carla</td>
<td>P02.125 LB</td>
</tr>
<tr>
<td>Berkowitz, Danielle</td>
<td>P02.82</td>
</tr>
<tr>
<td>Berman, Brian</td>
<td>P02.131 LB</td>
</tr>
<tr>
<td>Berntsen, Gro K. Rosvold</td>
<td>OA12.04</td>
</tr>
<tr>
<td>Beroes, Jessica</td>
<td>P02.143 LB</td>
</tr>
<tr>
<td>Berra, Alma</td>
<td>P02.107, P03.18</td>
</tr>
<tr>
<td>Berra, Jorge Luis</td>
<td>P02.107, P03.18</td>
</tr>
<tr>
<td>Bertram, Mathias</td>
<td>P02.117</td>
</tr>
<tr>
<td>Beryl, Primrose</td>
<td>P05.28 LB</td>
</tr>
<tr>
<td>Bethell, Christina</td>
<td>P01.09, P04.22</td>
</tr>
<tr>
<td>Bhasin, Manoj</td>
<td>P02.43</td>
</tr>
<tr>
<td>Bian, Zhao Xiang</td>
<td>OA02.03</td>
</tr>
<tr>
<td>Birch, Brian</td>
<td>P02.60, P02.61</td>
</tr>
<tr>
<td>Birdee, Gurjeet</td>
<td>P02.36</td>
</tr>
<tr>
<td>Bishop, Felicity</td>
<td>OA08.02, OA12.02, P04.27</td>
</tr>
<tr>
<td>Bittner, Ava</td>
<td>P02.51</td>
</tr>
<tr>
<td>Black, David</td>
<td>OA09.01 LB</td>
</tr>
<tr>
<td>Bloom, Julie</td>
<td>P02.125 LB</td>
</tr>
<tr>
<td>Blödt, Susanne</td>
<td>P02.37</td>
</tr>
<tr>
<td>Bogenschutz, Lois</td>
<td>OA11.04, P02.89</td>
</tr>
<tr>
<td>Boineau, Robin</td>
<td>OA01.01, OA01.02</td>
</tr>
<tr>
<td>Bonato, Paolo</td>
<td>OA11.01</td>
</tr>
<tr>
<td>Boon, Heather</td>
<td>P06.10</td>
</tr>
<tr>
<td>Bormann, Jill</td>
<td>OA06.01</td>
</tr>
<tr>
<td>Borstad, Alexandra</td>
<td>P04.36</td>
</tr>
<tr>
<td>Bos, Elke</td>
<td>P05.04</td>
</tr>
<tr>
<td>Bossart, Chase</td>
<td>P02.36</td>
</tr>
<tr>
<td>Boulangere, Karen</td>
<td>P06.05</td>
</tr>
<tr>
<td>Bourdette, Dennis</td>
<td>OA08.01</td>
</tr>
<tr>
<td>Bouttemy, Alexis</td>
<td>P01.21 LB</td>
</tr>
<tr>
<td>Bowman, Marjorie</td>
<td>OA05.03</td>
</tr>
<tr>
<td>Bradley, Ryan</td>
<td>P02.108, P02.140 LB, P02.141 LB</td>
</tr>
<tr>
<td>Braun, Lesley</td>
<td>OA07.03, P02.85</td>
</tr>
<tr>
<td>Braun, M. Miles</td>
<td>P05.02</td>
</tr>
<tr>
<td>Braun, Tosca</td>
<td>P02.73, P06.03</td>
</tr>
<tr>
<td>Breen, Elizabeth</td>
<td>OA09.01 LB</td>
</tr>
<tr>
<td>Brockhaus, Johannes</td>
<td>P03.08</td>
</tr>
<tr>
<td>Brodsky, Marc</td>
<td>P03.03</td>
</tr>
<tr>
<td>Bronfort, Gert</td>
<td>P06.13</td>
</tr>
</tbody>
</table>
## Abstract Author Index

Brooks, Audrey .......... OA04.04, P03.14, 03.15, 03.19
Brooks Holliday, Stephanie .. P04.43 LB, P04.46 LB, P04.47 LB
Broom, Alex ................ OA12.03, P04.14
Brown, Simon ............... P02.58
Bruggemann, Richard .......... P02.111
Bruner, Deborah .......... OA05.03
Bu, Youngmin ............... P02.112
Buckenmaier, Chester .. P06.02
Budhrai, Pinky .......... P02.127 LB
Bulayeva, Natiya .......... P02.140 LB, P02.141 LB
Buring, Julie ................. OA01.04 LB
Burke, Adam ................. P03.27 LB
Burlis, Amanda .............. P02.152 LB
Buysse, Daniel .......... P02.122 LB
Büssing, Arnld .............. P02.40
C
Cacciatore, Tim .......... P02.58
Calabrese, Carlo .......... P04.25
Calvin, Steven .............. P04.49 LB
Cambron, Jerrilyn ........ P06.05
Campbell, Richard .......... P05.20
Campbell, Tavis .......... P02.48
Cantor, Dara .......... P05.24
Cao, Huijuan .......... P02.05
Cao, Jia ........................ P01.31 LB, P01.32 LB
Card, Cynthia ........ P03.04
Carle, Adam ................. P04.22
Carlson, Linda .......... OA15.02, P02.48, P03.04
Carman, Cindy .............. P02.38
Carraana, Irina .......... P02.148 LB
Carver, Charles .......... P02.154
Cassidy, J David .......... P02.30
Casteneda, Sheila .......... P05.26 LB
Caulfield, Tim .......... P06.10
Cayton, Julien .......... P02.101
Cha, Stephen .......... P02.104
Chacko, Sara A .......... P04.39
Chai, Qianyun .......... OA05.04, P02.04, P02.05, P05.08, P05.21
Chalk, Caroline .......... P02.58
Chamberlin, Steve .......... P04.40
Chan, Caroline .......... P02.84
Chan, Nori Yanki .......... OA03.04 LB
Chang, Alexandra M .......... P02.86, P04.17
Chang, Dennis .......... P02.06
Chang, Kun-Chen ........ OA16.02
Chao, Mania .......... P02.07, P02.86, P04.17, P04.53 LB, OA10.03
Chao, Wei ................. P05.06, P05.07
Cheng, Yu ............. P02.122 LB
Cherin, Daniel .......... P02.31, P02.133 LB, P05.25 LB
Cheryl, Hawk .......... P06.09
Chesak, Sherry .......... P03.12
Chesney, Margaret .......... P02.131 LB
Chettiar, Shiva ........ P01.24 LB
Cheung, Hoi Cheung .... OA04.02, P03.10, 03.11
Chinh, Kelly .......... OA06.02
Chirinos, Diana .......... P05.26 LB
Chittenden, Eva .......... P03.15
Cho, Michael .......... P01.06
Cho, Seung-Yeon .......... P03.17
Cho, Yu-Min .......... P02.15 LB
Choi, Byunghee .......... P04.04, P04.05
Choi, Hyun-Ju .......... P02.114
Choi, Kyung-Eun .......... P02.55
Choi, Sun-Mi .......... P02.157 LB
Chokshi, Sagar K .......... P02.87
Chow, Elaine .......... P03.27 LB
Chung, J.W.Y. .......... P02.121 LB
Chung, Wayne ........ P04.05
Cidral Filho, Francisco Jose .......... P01.17, P01.18, P02.88, P02.94
Clarke, Tainya .......... P06.17 LB, P06.18 LB, P06.19 LB, P06.20 LB, P02.149 LB
Clemow, Lynn .......... P02.149 LB
Cohen, Evan .......... OA13.04
Cohen, Lorenzo .......... P01.04 LB, P02.38, P02.129 LB, P02.147 LB, P04.42 LB, P05.18
Cohen-Mensfield, Jiska .......... P02.57
Cohn, Michael .......... OA10.03
Cole, Roger .......... OA13.03
Conboy, Lisa .......... OA09.04, P02.08, P02.84
Cook, Andrea J .......... P02.31
Cook, Joseph .......... OA10.03
Cook, Paula .......... OA04.04, P03.14, P05.19
Copson, Ellen .......... P02.59
Corber, Lance .......... P02.28
Corey, Sarah .......... OA13.03
Corson, Marilyn .......... P02.51
Costa, Madalena D .......... OA15.04
Costa-Mallen, Paola .......... P02.108
Cotter, Ann C .......... P03.17
Cottion, Sian .......... OA11.04, P02.89, P02.130 LB, P02.146 LB
Cramer, Greg .......... P06.09
Cramer, Holger .......... OA11.02, OA13.01, P02.39, P02.40, P02.116, P05.11
Crawfish, Roger .......... P04.36
Crawford, Cindy .......... P06.02
Cray, Lori .......... P06.14
Creager, Mark .......... P02.43
Crespin, Daniel .......... P02.136 LB, P02.137 LB, P04.51 LB, OA11.05
Cui, Xiaolan .......... P01.15
Cusnik, Mike .......... P05.20
Cutshall, Susan .......... P03.12
Czaja, Sara .......... P02.154

## D
D’Ambrosio, Carolyn .......... P02.75
Dagnelle, Gislín .......... P02.51
Dai, Jin-gang .......... P02.81
Dallman, Mary ............ OA09.02 LB, OA10.04, P01.13
Danhauer, Suzanne .......... P02.35, P02.41, P02.42
Darcel, Nicolas .......... P01.13
Daubenmier, Jennifer .......... OA09.02 LB, OA10.04, P02.67
Davidenko, Olga .......... P01.13
Davies, Joseph .......... P02.76
Daviglus, Martha .......... P05.26 LB
Davis, Makayla .......... P02.73
Davis, Roger .......... OA01.04 LB, OA11.01, OA15.04, P04.26, P04.37, P04.39
De Jong, Joop .......... P02.111, P05.04
De Jonge, Peter .......... P02.05
De Souza, Flavia .......... P02.90
DeBusk, Ruth .......... P04.38
Delagran, Louise .......... P03.13
Delbello, Melissa .......... P02.130 LB
Delebinski, Catharina .......... OA16.01, P01.16, P06.12
Delgado, Roxana .......... P04.50 LB, P06.02
DeMichele, Angela .......... OA05.03
Dempsy, Catherine .......... P02.131 LB
Denninger, John .......... P03.43, P03.44, P03.15
Desai, Krupali .......... P02.87
Desbiens, Jean-François .......... P03.06
Desbordes, Gaelle .......... OA15.01
Dey, Moul .......... OA03.01
Dhruva, Anand .......... P02.52, P02.91, P02.98, P02.93
Di Stefano, Mariella .......... P04.30
Diacciati, Sara .......... P06.07
Diezel, Helene .......... P03.09
Dima, Alexandra .......... P04.27
Dimitrova, Alexandra .......... P02.09
Dmitrieva, Natalia .......... OA09.03
Do, Daniel .......... P02.45
Dobos, Gustav .......... OA11.02, OA13.01, P02.39, P02.40, P02.55, P02.115, P02.116, P05.11
Dobson, Dawn .......... P04.21
Dodds, Nathan .......... OA08.03
Dodds, Sally .......... OA04.04, P03.14, P05.19
Doherty-Gilman, Anne .......... P02.92
Dong, Changsheng .......... P01.12
Donnelly, Robert .......... OA13.04
Donovan, Nancy J. .......... OA06.03
Doslin, James .......... P02.52
Dorman, Eric .......... P02.56
Dossett, Michelle .......... P04.26
Dragan, Simona .......... P01.19
Dresner, Danielle .......... OA10.01, P02.46, P02.78

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ACM-2014-6000-abstracts-ver9-Author-Index_6P.3d 05/06/14 3:23pm Page 151
ABSTRACT AUTHOR INDEX

A

Drisko, Jeanne .......... OA01.01, OA01.02, P03.19, P03.20
Du, Lian ................. P01.25 LB
Duda, Joachim ........... P02.18
Duncan, Larissa .......... OA10.03, P02.86
Dusek, Jeffery .......... OA07.02, OA11.05, P02.32, P02.80, P02.89, P02.136 LB, P02.137 LB, P04.49 LB, P04.51 LB, P05.23

E

Eaves, Emery .......... P06.11
Edelhäuser, Friedrich .... OA04.01, P03.08, P04.23
Egan, Shayna .......... P04.46 LB, P04.47 LB
Eisenmann, Clemens ...... P02.39
Elder, William G. ...... OA14.02, P02.29
Ellelmy, Ahmed .......... P06.15 LB
Elshab, Ibrahim .......... P03.26 LB
Elwy, Rani .......... OA06.01
Emer, Aline A .......... P01.17, P01.18, P02.94
Engebretson, Joan ...... P05.18
Engle, Rosalinda ...... P02.38
Engebretson, Joan ...... P05.18
Enstad, C.J. .......... P02.54
Epel, Elissa .......... OA09.02 LB, OA10.04, OA13.03, P02.34, P02.144 LB
Eranezhath, Sujith ...... P05.14
Erdogmus, Deniz .......... OA15.03
Ervin, Ayla D. .......... P03.25 LB
Esmany, Habilollah ..... P02.02, P02.03
Esmore, Donald .......... OA07.03
Espinoza, Rebeca .......... P05.26 LB
Esternberg, Esther ...... P02.19
Evans, Randall .......... P03.19
Evans, Roni .......... P03.01, P03.13, P06.09, P06.13
Eyles, Caroline .......... P02.59

F

Faham, Erin .......... P02.73
Faeli, Laura .......... OA02.02
Falkenberg, Torkel .... P02.34, P02.44 LB
Faramah, Seyed Kazem .... P02.02, P02.10
Faris, Peter .......... OA15.02
Farrarr, John .......... OA05.03
Farvardi, Maryam ...... P02.10
Faurot, Keturah .......... P05.26 LB
Fei, Yutong .......... P02.04, P02.05, P05.12, P05.21
Fellman, Bryan .......... OA14.04 LB, P04.42 LB
Feng, Run .......... P04.02
Ferns, Gordon A .......... P02.10
Flick, Laura .......... OA15.02
Fippilippi, Amanda .... P04.11, P02.109
Finch, Michael .......... OA07.02, OA11.05, P02.136 LB, P02.137 LB, P04.49 LB, P04.51 LB
Finne, John .......... P02.140 LB, P02.141 LB
Fishbain, Daniel .......... OA13.02
Fisher, Peter .......... P04.52 LB
Fitzpatrick, Annette .... P02.108
Fletcher, Carol E .... P02.32
Florindez, Daniella ...... P02.83
Flower, Andrew .......... P02.62, P05.09
Flury, Jill .......... P04.42 LB
Fonareva, Irina .......... P02.71
Forman, Jeffrey .... P02.27
Foss, Nina .......... OA12.04, P02.33
Foster, Nadine .......... OA05.02, P04.27
Franchi-Jr, Gilberto C. .... P06.23 LB
Franken, Ulla .......... P04.14
Fricchione, Gregory .... P02.43, P02.44
Fridman, Eitan .......... P02.57
Fristad, Mary .......... P02.134 LB, P02.135 LB
Fromentin, Gilles .... P01.13
Fung, Lei-Chun .......... P03.27 LB
Furusyo, Norihiro ...... P02.142 LB
Forestell, Barry .......... P02.46, P02.78, P02.109, P04.11, P05.26 LB
Gar, Melissa .......... P02.95
Gardiner, Paula .......... OA10.01, P02.46, P02.78, P02.109, P04.11, P05.26 LB
Garland, Sheila .......... P04.48, P02.79
Gass, Florian .......... P02.39
Gauthier, Lynne .......... P04.36
Gautier, Tina .......... P02.132 LB
Ge, Jian .......... OA11.03
Geller, Gail .......... P04.13, P04.35
Georgi, Susanna .......... P06.12
Geraghty, Adam .......... P02.58
Gere, Benjamin .......... OA10.01, P02.46, P02.78
Ghanbavi, Majid ...... P02.10
Ghani, Ayaz .......... P02.97, P02.112
Ghildayal, Neha .......... P04.31
Giese-Davis, Janine .... OA15.02
Gilbert, Amanda .......... P02.34, P02.144 LB
Gilbard, Dina .......... P02.44
Glick, Ronald .......... OA08.03, OA14.01, P02.122 LB
Glickman, Mark .......... OA06.01
Goertz, Christine .......... OA01.01, OA01.02, OA01.03, P02.28
Gold, Jeffrey .......... P02.123 LB, P02.126 LB, P02.132 LB
Goldman, Veronica .......... OA09.02 LB
Gombechav, Narangerel .. OA01.09, P04.22
Gomes, Stacy .......... P02.103
González, Hector .... P05.26 LB
Goodrich, Elena .......... OA15.03, P02.68, P02.69
Gordon, Sandra .......... OA06.04
Gottschling, Sven .......... P04.23
Gould Fogerite, Susan .... OA13.04
Gow, Brian J .......... OA15.04
Graziosi, Barbara ...... P02.134 LB, P02.135 LB
Graham-Getty, Leslie ... P02.147 LB
Grant, Suzanne J .......... P02.06, P02.66
Graves, Kristi .......... OA04.03
Greco, Carol .......... OA08.03, P02.122 LB
Greenlee, Heather .......... OA02.02
Grege, Dagmar .......... P02.132 LB
Grimberg, Ofra .......... OA07.01
Gronowicz, Gloria .... P01.20
Gronwald, Benjamin ... P04.23
Gross, Cynthia .......... P02.49
Grunfeld, Carl .......... OA09.02 LB
Gudavalli, Manutti Ram ... P02.28
Guernsey, Linda .......... P01.05
Guerrera, Mary .......... P03.21
Günawan, Margaretha ... OA07.03
Guo, Tianwei .......... OA03.02, OA05.01, P02.124 LB, P06.28 LB
Guo, Zhuo .......... OA03.02, OA05.01, P02.23, P02.124 LB, P02.156 LB, P06.28 LB
Gurfein, Blake .......... P01.13
Gutierrez, Ian A .......... P06.03
Gutierrez, Sandra .... P02.125 LB
Guyatt, Gordon .......... P02.01

H

Haas, Mitchell .......... OA08.04, OA11.03, OA14.01, P06.09
Haaz-Moonaz, Steffany .... P02.51
Hadar, Nira .......... P05.15
Haddad, Nadia .......... P05.27 LB
Hagihara, Keesuke .......... P02.139 LB
Haim, Vivian .......... P02.50, P03.15
Hajiarabi, Elaheh .......... P02.110
Hall, Kathryn .......... OA01.04 LB
Hall, Martica .......... P02.122 LB
Haller, Heidemarie .......... OA11.02, P05.11
Hammerslag, Richard .... P05.24
Han, Gajin .......... P02.97, P02.112
Han, Mei .......... P04.18
Handley, Margaret .......... P04.53 LB
Hanes, Douglas .......... OA08.01, OA12.01, P02.118, P05.16
Hankins, Matthew .......... P04.27
Hansen, J. Norman .... P01.11
Hanson, Linda .......... P06.13
<table>
<thead>
<tr>
<th>Name</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manor, Brad</td>
<td>OA15.04</td>
</tr>
<tr>
<td>Mao, Jun</td>
<td>OA05.03, OA16.03, P02.79, P02.87</td>
</tr>
<tr>
<td>Marantz, Paul</td>
<td>P03.01</td>
</tr>
<tr>
<td>Mark, Daniel B.</td>
<td>OA01.01, OA01.02</td>
</tr>
<tr>
<td>Martins, Daniel F.</td>
<td>P01.17, P01.18, P02.88, P02.94</td>
</tr>
<tr>
<td>Marx, Benjamin</td>
<td>P05.24</td>
</tr>
<tr>
<td>Maschino, Alexandra</td>
<td>OA05.02</td>
</tr>
<tr>
<td>Maston, Adam</td>
<td>P01.05</td>
</tr>
<tr>
<td>Matter, Ibrahim</td>
<td>OA07.01, P06.01</td>
</tr>
<tr>
<td>Maung, David</td>
<td>P04.36</td>
</tr>
<tr>
<td>Max, Sonja</td>
<td>P02.108</td>
</tr>
<tr>
<td>McCarron, Ken</td>
<td>P03.20</td>
</tr>
<tr>
<td>McConnell, Kimberly</td>
<td>OA06.04</td>
</tr>
<tr>
<td>McCreary, Megan</td>
<td>P02.108</td>
</tr>
<tr>
<td>McDaniel, Jodi</td>
<td>P02.128 LB</td>
</tr>
<tr>
<td>Meers, Molly</td>
<td>P02.134 LB</td>
</tr>
<tr>
<td>Mehal, Waqiahah</td>
<td>P01.23 LB</td>
</tr>
<tr>
<td>Mehta, Darshan</td>
<td>P02.44, P03.15</td>
</tr>
<tr>
<td>Meier, Beate</td>
<td>P02.39</td>
</tr>
<tr>
<td>Meier, Emily</td>
<td>P02.103</td>
</tr>
<tr>
<td>Meier, Larissa</td>
<td>P02.18</td>
</tr>
<tr>
<td>Meleger, Alec</td>
<td>OA11.01</td>
</tr>
<tr>
<td>Melzig, Matthias F.</td>
<td>P06.12</td>
</tr>
<tr>
<td>Meng, Fengxian</td>
<td>P01.22 LB</td>
</tr>
<tr>
<td>Meng, Hong</td>
<td>P02.15, P02.16</td>
</tr>
<tr>
<td>Meyer, Rika</td>
<td>P02.126 LB</td>
</tr>
<tr>
<td>Meyer, Sascha</td>
<td>P02.132 LB</td>
</tr>
<tr>
<td>Miike-Lye, Isomi</td>
<td>P02.143 LB</td>
</tr>
<tr>
<td>Miaskowski, Christine</td>
<td>P02.91, P02.98</td>
</tr>
<tr>
<td>Michael, Irwin</td>
<td>OA09.01 LB</td>
</tr>
<tr>
<td>Michalsen, Andreas</td>
<td>P02.18, P02.55</td>
</tr>
<tr>
<td>Midtun, Christopher</td>
<td>P02.88</td>
</tr>
<tr>
<td>Mike, Acree</td>
<td>P02.67</td>
</tr>
<tr>
<td>Mikolai, Jeremy</td>
<td>P02.118</td>
</tr>
<tr>
<td>Milbury, Kathrin</td>
<td>OA14.04 LB</td>
</tr>
<tr>
<td>Miller, Joyce</td>
<td>P02.38, P02.129 LB, P02.147 LB, P04.42 LB</td>
</tr>
<tr>
<td>Miller, Judith</td>
<td>P03.02</td>
</tr>
<tr>
<td>Miller, Kathleen</td>
<td>P02.44</td>
</tr>
<tr>
<td>Miller, Meghan</td>
<td>OA15.03, P02.68, P02.69</td>
</tr>
<tr>
<td>Miller, Suzy</td>
<td>P06.25 LB</td>
</tr>
<tr>
<td>Mills, Paul</td>
<td>P02.103</td>
</tr>
<tr>
<td>Milush, Jeffrey</td>
<td>P01.13, OA09.02 LB</td>
</tr>
<tr>
<td>Min, Seorim</td>
<td>P02.13</td>
</tr>
<tr>
<td>Minichiello, Vincent</td>
<td>P02.75</td>
</tr>
<tr>
<td>Mior, Silvano</td>
<td>P02.30, P06.10</td>
</tr>
<tr>
<td>Miskevics, Scott</td>
<td>P04.19</td>
</tr>
<tr>
<td>Mist, Scott</td>
<td>OA07.04, P02.151 LB</td>
</tr>
<tr>
<td>Mitchell, Ellen</td>
<td>P06.14</td>
</tr>
<tr>
<td>Mittleman, Murray</td>
<td>OA01.04 LB</td>
</tr>
<tr>
<td>Miyano, Satoshi</td>
<td>P02.24</td>
</tr>
<tr>
<td>Mo, Yu ping</td>
<td>P01.26 LB, P01.31 LB, P01.32 LB</td>
</tr>
<tr>
<td>Mohammad Javad</td>
<td>P02.02</td>
</tr>
<tr>
<td>Mohammadi, Ghazaleh</td>
<td>P02.10</td>
</tr>
<tr>
<td>Mohammadi, Maryam</td>
<td>P02.10</td>
</tr>
<tr>
<td>Mohammadi, Shabnam</td>
<td>P02.10</td>
</tr>
<tr>
<td>Mohammadi Isfahani</td>
<td>P02.02</td>
</tr>
<tr>
<td>Mohan, Parvathy</td>
<td>P02.100, P05.14</td>
</tr>
<tr>
<td>Molho, Rosana</td>
<td>P02.107, P03.18</td>
</tr>
<tr>
<td>Molsberger, Albrecht</td>
<td>P01.21</td>
</tr>
<tr>
<td>Montross, Lori</td>
<td>P02.103</td>
</tr>
<tr>
<td>Mooney, Aimee</td>
<td>P02.69</td>
</tr>
<tr>
<td>Moore, Caroline</td>
<td>P02.61</td>
</tr>
<tr>
<td>Moore, Michael</td>
<td>P02.62, P05.09</td>
</tr>
<tr>
<td>Moran, Patricia J.</td>
<td>OA10.04, OA09.02 LB</td>
</tr>
<tr>
<td>Morin, Karen</td>
<td>P03.12</td>
</tr>
<tr>
<td>Morone, Natalia</td>
<td>OA08.03</td>
</tr>
<tr>
<td>Moscoso, Manoleti</td>
<td>P02.148 LB</td>
</tr>
<tr>
<td>Moss-Morris, Rona</td>
<td>P04.27</td>
</tr>
<tr>
<td>Motamed, Farzaneh</td>
<td>P02.110</td>
</tr>
<tr>
<td>Motz, Kevin</td>
<td>OA04.03</td>
</tr>
<tr>
<td>Mudeleda, Sreenivasu</td>
<td>P02.74</td>
</tr>
<tr>
<td>Mueller, Juergen</td>
<td>P02.119</td>
</tr>
<tr>
<td>Muke, Haru</td>
<td>P02.142 LB</td>
</tr>
<tr>
<td>Munakata, Kaori</td>
<td>P02.24</td>
</tr>
<tr>
<td>Munk, Niki</td>
<td>OA14.02, P02.29</td>
</tr>
<tr>
<td>Murata, Masayuki</td>
<td>P02.142 LB</td>
</tr>
<tr>
<td>Murchison, Charles</td>
<td>P02.09</td>
</tr>
<tr>
<td>Musial, Frauke</td>
<td>P02.55, P04.06</td>
</tr>
<tr>
<td>Nada, Shadia</td>
<td>OA03.03</td>
</tr>
<tr>
<td>Nader, Elias</td>
<td>P02.134 LB</td>
</tr>
<tr>
<td>Nager, Alan</td>
<td>P02.123 LB</td>
</tr>
<tr>
<td>Nahin, Richard</td>
<td>P06.17 LB, P06.18 LB, P06.19 LB, P06.20 LB</td>
</tr>
<tr>
<td>Najafi, Bijan</td>
<td>P02.19</td>
</tr>
<tr>
<td>Narang, Neetu</td>
<td>P06.06</td>
</tr>
<tr>
<td>Nation, Jill</td>
<td>P03.04</td>
</tr>
<tr>
<td>Necyk, Candace</td>
<td>OA16.04</td>
</tr>
<tr>
<td>Neff, John</td>
<td>P04.22</td>
</tr>
<tr>
<td>Negi, Lobang Tenzin</td>
<td>OA15.01</td>
</tr>
<tr>
<td>Nelson, Christopher</td>
<td>OA01.04 LB</td>
</tr>
<tr>
<td>Nelson Oliver, Miriam</td>
<td>P02.44</td>
</tr>
<tr>
<td>Nerdilek, Moni</td>
<td>OA08.04</td>
</tr>
<tr>
<td>Neuendorf, Rachel</td>
<td>P02.72, P02.101</td>
</tr>
<tr>
<td>Newachuck, Paul</td>
<td>P04.22</td>
</tr>
<tr>
<td>Nezamfar, Hooman</td>
<td>OA15.03</td>
</tr>
<tr>
<td>Ng, Bacon</td>
<td>P03.16</td>
</tr>
<tr>
<td>Ng, Sze Tuen</td>
<td>OA02.03</td>
</tr>
<tr>
<td>Nguyen, Thao</td>
<td>P03.04</td>
</tr>
<tr>
<td>Nguyen, Tung T.</td>
<td>P03.27 LB</td>
</tr>
<tr>
<td>Nguyen, Unity</td>
<td>P02.07</td>
</tr>
<tr>
<td>Nicholls, Carolyn</td>
<td>P02.58</td>
</tr>
<tr>
<td>Niles, Halsey</td>
<td>P02.43</td>
</tr>
<tr>
<td>Nishimura, Genichi</td>
<td>P02.20</td>
</tr>
<tr>
<td>Nixon, Douglas</td>
<td>OA09.02 LB, P01.13</td>
</tr>
<tr>
<td>Nkodo, Amelie-Francoise</td>
<td>P02.51</td>
</tr>
<tr>
<td>Noh, Seung He</td>
<td>P02.12, P05.03, P05.05</td>
</tr>
<tr>
<td>Noland, Diana</td>
<td>P03.19</td>
</tr>
<tr>
<td>Novak, Vera</td>
<td>OA15.04</td>
</tr>
<tr>
<td>Nowill, Alexandre</td>
<td>P06.23 LB</td>
</tr>
<tr>
<td>Noworolski, Susan</td>
<td>OA09.02 LB</td>
</tr>
<tr>
<td>O</td>
<td>OA15.03</td>
</tr>
<tr>
<td>O'Brien, Maeve</td>
<td>P02.30</td>
</tr>
<tr>
<td>O'connor, P.J.</td>
<td>P02.54</td>
</tr>
<tr>
<td>O'neill, Margaret</td>
<td>P02.73</td>
</tr>
<tr>
<td>O'Reilly, Gillian</td>
<td>OA09.01 LB</td>
</tr>
<tr>
<td>O'Reilly, Gilly</td>
<td>P02.58</td>
</tr>
<tr>
<td>Ogawa, Eiichi</td>
<td>P02.142 LB</td>
</tr>
<tr>
<td>Ogawa, Keiko</td>
<td>P02.20, P02.139 LB</td>
</tr>
<tr>
<td>Oh, Eun-Young</td>
<td>P02.21</td>
</tr>
<tr>
<td>Oken, Barry</td>
<td>OA15.03, P02.09, P02.68, P02.69, P02.70, P02.71, P02.101</td>
</tr>
<tr>
<td>Oliveira, Andreia</td>
<td>P06.27 LB</td>
</tr>
<tr>
<td>Oliven, Arie</td>
<td>OA07.01</td>
</tr>
<tr>
<td>Olmstead, Rachel</td>
<td>OA09.01 LB</td>
</tr>
<tr>
<td>Onifer, Stephen</td>
<td>P01.01</td>
</tr>
<tr>
<td>Onyemeh-Sea, Amica</td>
<td>OA14.04 LB, P02.129 LB, P02.147 LB, P04.42 LB</td>
</tr>
<tr>
<td>Opsiahl, Michael</td>
<td>OA07.04</td>
</tr>
<tr>
<td>Osei-Bonsu, Princess</td>
<td>OA06.01</td>
</tr>
<tr>
<td>Ostermann, Thomas</td>
<td>OA11.02, P02.18, P02.40, P02.117, P04.24, P05.11</td>
</tr>
<tr>
<td>Overhamm, Tatiana</td>
<td>P02.40</td>
</tr>
<tr>
<td>P</td>
<td>OA15.01</td>
</tr>
<tr>
<td>Pace, Thaddeus W. W.</td>
<td>P02.37</td>
</tr>
<tr>
<td>Paeizi, Reza</td>
<td>P02.120</td>
</tr>
<tr>
<td>Paillé, Pierre</td>
<td>P03.06</td>
</tr>
<tr>
<td>Palesh, Oxana</td>
<td>P05.27 LB</td>
</tr>
<tr>
<td>Palme, Rupert</td>
<td>P01.13</td>
</tr>
<tr>
<td>Palmer, Debra</td>
<td>P04.54</td>
</tr>
<tr>
<td>Pande, Reena</td>
<td>P02.43</td>
</tr>
<tr>
<td>Paolini, Brielle</td>
<td>P01.10</td>
</tr>
<tr>
<td>Papp, Kathryn V.</td>
<td>OA06.03</td>
</tr>
<tr>
<td>Paris, Ruth</td>
<td>P02.56</td>
</tr>
<tr>
<td>Park, Crystal L.</td>
<td>P06.03, P02.73</td>
</tr>
<tr>
<td>Park, Elyse</td>
<td>P03.15</td>
</tr>
<tr>
<td>Park, Hi-Joon</td>
<td>P02.13, P03.17</td>
</tr>
<tr>
<td>Park, Jae-Woo</td>
<td>P02.97, P02.112</td>
</tr>
<tr>
<td>Park, Ji-Yeon</td>
<td>P02.13</td>
</tr>
<tr>
<td>Park, Jong</td>
<td>P06.21 LB</td>
</tr>
</tbody>
</table>
ABSTRACT AUTHOR INDEX

Secor, Eric .................................. P01.05, P01.20
Seidel, Ilana ................................ P06.06
Seifert, Georg ............................ OA16.01, P01.16, P06.12
Sebzischki, Christina ........ P02.87
Senders, Angela .............. OA08.01, P02.77, P02.101
Sequeira, Paola.................. P02.83
Shah, Zahoor ...................... OA03.03
Shannon, Vickie ............... P02.38
Shapiro, Martin .............. P04.29
Sharma, Rajiv ..................... OA11.03
Sharma, Varun .................. P02.150 LB
Sharp, Debbie .................... P02.58
Shaw, Kelly ....................... P01.07
Shaw, Stephanie ............. P02.78
Shekelle, Paul .................. P02.143 LB
Sherman, Karen J. ........ P02.31, P06.11
Sherman, Scott .............. P02.19
Shi, Rongxing .................. P01.30 LB, P02.156 LB
Shi, Yujing .............................. P01.15
Shieh, Biehuoy ................. OA16.02
Shin, Byung-Cheul .......... P02.50
Shin, Minsun .................... P04.04
Shinjo, Lyne ...................... OA08.01, P02.77
Sibbritt, David ................... OA12.03, P04.14
Siddiqui, Nasir .................. P05.01
Siega-Riz, Anna-Maria .. P05.26 LB
Sierpina, Victor ............... P03.03
Siles, Amelia ..................... P04.36
Silva, Maria Júlia .......... P02.102
Silva, Mariella .............. OA13.04
Simmons, Toyia ............. P02.149 LB
Singh, Jasvinder ............. P01.08
Singh, Maharaj .............. P02.76
Singleton, Omar ............. OA03.04 LB
Sirois, Fuschia ............... P04.12, OA12.01
Smith, Peter ...................... P03.20
Snapp, Cathy ..................... P04.38
Soares, Heloisa .............. P05.20
Socaciu, Carmen .......... P01.19
Soeller, Irene ................. OA16.03
Sohl, Stephanie J. .......... P02.41
Solloway, Michele ........... P02.143 LB
Sommers, Elizabeth ....... P04.02
Sommers, Jayne ................ P04.28
Song, Hong-Tao ................ P01.26 LB
Song, Jiaxin ...................... P02.14, P02.16
Song, Liangyu ..................... P01.32 LB
Song, Miyoung .................. P06.22 LB
Song, Sang-Wook ............ P02.153 LB
Song, Yingzhao ............... P01.30 LB
Sood, Amit ....................... P03.12
Soteropoulos, Patricia .... OA13.04
Sozio, Randall ............... P01.01
S.P. Suchitra .................... P06.29 LB
Spano, Michael ................ P02.147 LB
Speca, Michael .............. OA15.02
Speed, Shaun ................... P04.07, P04.08
Speer, Diane ................. OA13.04
Spelman, Amy ........................ OA14.04 LB, P02.38, P02.129 LB, P02.147 LB, P04.42 LB
Spitzer, Ondine ................ P02.85, OA07.03
Spruijt-Metz, Donna .... P02.83
Sroka, Gideon .................. OA07.01, P06.01
Stahl, Katja ...................... OA04.01
Stahl, Lauren ................. P02.130 LB
Stainken, Cameron ........ P02.79
Stanbery, Kimberly .......... P02.41
Stange, Rainer ................ P02.119
Stanguts, Cathy ............. OA07.03, P02.85
Stapelfeldt, Elmar ........... P02.18
Staubfacher, Raphaël .......... P02.105
Steibbings, Simon .... P02.133 LB, P05.25 LB
Steinbner, Erin .................. OA15.02
Steckler, Nicole A ........ OA3.25 LB
Steel, Annie ...................... OA12.03, P03.09, P04.14
Steel, Colìn ........................ P02.58
Steinsbekk, Aslak ............. P04.06
Stephanopoulos, Ourania ........ P03.20
Stephenson, Kelly ........ P02.41
Stephens, Joel .................. OA14.01
Stevens, Matthew ........... P04.54
Stevens, Richard ........... P02.152 LB
Stevens, Sarah ............... OA12.02
Stewart, Anita .................. P02.67
Stewart, Susan ............... P03.27 LB
StJohn, Meredith ............ OA09.04
Stokes, Maria .................. P02.58
Streeter, Chris C ............. P02.80
Stricker, Carrie ............. OA05.03
Stuart, Beth ...................... P02.58
Sub, Trine ......................... P04.06
Stuck, L.H. ....................... P02.54
Stussman, Barbara .... P06.17 LB, P06.18 LB, P06.19 LB, P06.20 LB
Stylianou, Mario ........ OA01.02
Su, Chun-Xiang ................ P02.65, P02.66
Sullivan, Debra ............... P03.19
Sullivan, Patrick .......... P04.46 LB, P04.47 LB
Sumer, Sat-Siri ................ OA14.04 LB
Sun, Lan ........................ OA03.02, OA05.01, P02.23, P02.124 LB, P06.28 LB
Sun, Linlin ......................... OA05.01, OA05.02, OA05.01, P02.14, P02.15, P02.16, P02.124 LB, P02.156 LB
Sundaram, Jayasree .......... P02.103
Sundberg, Tobias ........... OA02.04
Surtees, George ............ P04.27
Sykes, Sabrina ................. P02.134 LB, P02.135 LB
Sigg, Sabrina ................. OA03.20
Sillaro, Sabrina .............. OA03.20
Sills, Amanda ................. OA03.20
Steebings, Simon ........ OA15.02
Steeley, Erin .................... OA13.02
Steinbner, Erin ................ OA15.02
Steinbner, Erin ............. OA15.02
Steel, Amie ...................... OA12.03, P03.09, P04.14
Steel, Colìn ...................... P02.58
Steinsbekk, Aslak ............. P04.06
Stefanopoulos, Ourania ........ P03.20
Stephenson, Kelly ........ P02.41
Stevans, Joel .................... OA14.01
Stevens, Matthew .......... P03.20
Stevens, Richard .......... P02.152 LB
Stevens, Sarah .............. OA12.02
Stewart, Anita ............... P02.67
Stewart, Susan ............... P03.27 LB
StJohn, Meredith ............ OA09.04
Stokes, Maria .................. P02.58
Streeter, Chris C ............. P02.80
Stricker, Carrie ............. OA05.03
Stuart, Beth ...................... P02.58
Sub, Trine ......................... P04.06
Stuck, L.H. ....................... P02.54
Stussman, Barbara .... P06.17 LB, P06.18 LB, P06.19 LB, P06.20 LB
Stylianou, Mario ........ OA01.02
Sù, Chun-Xiang ................ P02.65, P02.66
Sullivan, Debra ............... P03.19
Sullivan, Patrick .......... P04.46 LB, P04.47 LB
Sumer, Sat-Siri ................ OA14.04 LB
Sun, Lan ........................ OA03.02, OA05.01, P02.23, P02.124 LB, P06.28 LB
Sun, Linlin ......................... OA05.01, OA05.02, OA05.01, P02.14, P02.15, P02.16, P02.124 LB, P02.156 LB
Sundaram, Jayasree .......... P02.103
Sundberg, Tobias ........... OA02.04
Surtees, George ............ P04.27
Sykes, Sabrina ................. P02.134 LB, P02.135 LB
Tague, Sarah .................. P03.20
<table>
<thead>
<tr>
<th>Author Index</th>
<th>Abstract Author Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vavrek, Darcy</td>
<td>Yang, Changsop</td>
</tr>
<tr>
<td>OA08.04,</td>
<td>P06.22 LB</td>
</tr>
<tr>
<td>OA11.03</td>
<td></td>
</tr>
<tr>
<td>Vazquez-Benitez, C.X.</td>
<td>Yang, Chunjiao</td>
</tr>
<tr>
<td>P02.54</td>
<td>P05.21</td>
</tr>
<tr>
<td>Vecina, Juliana F.</td>
<td>Yang, Chunjyi</td>
</tr>
<tr>
<td>P06.27 LB</td>
<td>P02.38</td>
</tr>
<tr>
<td>Vegella, Patricia</td>
<td>Yang, Gi Young</td>
</tr>
<tr>
<td>P02.131 LB</td>
<td>P02.12, P05.03,</td>
</tr>
<tr>
<td>Veira, Karla P.</td>
<td>P05.05</td>
</tr>
<tr>
<td>P06.23 LB</td>
<td></td>
</tr>
<tr>
<td>Venkatappa, Vinayaka</td>
<td>Yang, Guo-Yan</td>
</tr>
<tr>
<td>P06.30 LB</td>
<td>P05.07</td>
</tr>
<tr>
<td>Vesco, Anthony</td>
<td>Yang, Guoyan</td>
</tr>
<tr>
<td>P02.134 LB,</td>
<td>OA05.04, P02.63, P04.18</td>
</tr>
<tr>
<td>P02.135 LB</td>
<td></td>
</tr>
<tr>
<td>Vickers, Andrew</td>
<td>Yang, Hong</td>
</tr>
<tr>
<td>OA05.02</td>
<td>P02.05, P04.18</td>
</tr>
<tr>
<td>Vickers Douglas, Kristin</td>
<td>Yang, Michael</td>
</tr>
<tr>
<td>OA03.12</td>
<td>P01.06</td>
</tr>
<tr>
<td>Victorsen, David</td>
<td>Yang, Peilian</td>
</tr>
<tr>
<td>P02.125 LB</td>
<td>P02.01</td>
</tr>
<tr>
<td>Vihstadt, Corrie</td>
<td>Yang, Sung Pil</td>
</tr>
<tr>
<td>P03.13</td>
<td>P04.44 LB</td>
</tr>
<tr>
<td>Vining, Robert D.</td>
<td>Yang, Xingjing</td>
</tr>
<tr>
<td>P02.28,</td>
<td>OA03.02, OA05.01, P02.23, P02.124 LB, P02.156 LB, P06.28 LB</td>
</tr>
<tr>
<td>P01.03</td>
<td></td>
</tr>
<tr>
<td>Vinjamury, S. Prasad</td>
<td>Yang, Xueqin</td>
</tr>
<tr>
<td>P03.02</td>
<td>OA06.28 LB</td>
</tr>
<tr>
<td>Vito, Alessandra</td>
<td>Yao, Haijiang</td>
</tr>
<tr>
<td>P04.30</td>
<td>P01.26 LB, P01.31 LB, P01.32 LB</td>
</tr>
<tr>
<td>Vlieger, Arine</td>
<td>Yardley, Lucy</td>
</tr>
<tr>
<td>P04.21</td>
<td>P02.58</td>
</tr>
<tr>
<td>Vohra, Sunita</td>
<td>Yeh, Gloria</td>
</tr>
<tr>
<td>OA16.04,</td>
<td>OA06.03, P04.39, P02.82, P04.26, P04.37</td>
</tr>
<tr>
<td>P02.30</td>
<td></td>
</tr>
<tr>
<td>Vollbehr, Nina</td>
<td>Yeoh, Inkwon</td>
</tr>
<tr>
<td>P02.111,</td>
<td>P02.97, P02.112</td>
</tr>
<tr>
<td>P05.04</td>
<td></td>
</tr>
<tr>
<td>W</td>
<td></td>
</tr>
<tr>
<td>Wagner, Leigh</td>
<td>Yeung, Albert</td>
</tr>
<tr>
<td>P03.19</td>
<td>P02.44</td>
</tr>
<tr>
<td>Wahbeh, Helane</td>
<td>York, Alexandra</td>
</tr>
<tr>
<td>OA15.03,</td>
<td>P06.02</td>
</tr>
<tr>
<td>P02.68, P02.69, P02.70, P02.72, P02.101</td>
<td></td>
</tr>
<tr>
<td>Walach, Harald</td>
<td>York, Vanessa</td>
</tr>
<tr>
<td>P04.03</td>
<td>P01.13</td>
</tr>
<tr>
<td>Walker, Amy</td>
<td>Yoshino, Tetsuhiro</td>
</tr>
<tr>
<td>OA09.03</td>
<td>P02.24</td>
</tr>
<tr>
<td>Wallace, B. Alan</td>
<td>Yost, Kathleen</td>
</tr>
<tr>
<td>OA15.01</td>
<td>P05.10</td>
</tr>
<tr>
<td>Walsh, Jacquelyn N.</td>
<td>Young, Andrea</td>
</tr>
<tr>
<td>OA06.03</td>
<td>P02.134 LB, P02.135 LB</td>
</tr>
<tr>
<td>Walz, Martin K.</td>
<td>Young, Laura</td>
</tr>
<tr>
<td>P02.39</td>
<td>P05.26 LB</td>
</tr>
<tr>
<td>Wang, Chenchun</td>
<td>Young, Lauretta</td>
</tr>
<tr>
<td>P02.74, P02.75</td>
<td>P03.25 LB</td>
</tr>
<tr>
<td>P02.75</td>
<td>Yu, John</td>
</tr>
<tr>
<td>Wang, Congcon</td>
<td>P02.72</td>
</tr>
<tr>
<td>P02.04</td>
<td></td>
</tr>
<tr>
<td>Wang, Hongcai</td>
<td>Yu, Lan</td>
</tr>
<tr>
<td>P02.15</td>
<td>OA08.03</td>
</tr>
<tr>
<td>Wang, Jun</td>
<td>Yuko, Horiba</td>
</tr>
<tr>
<td>P03.27 LB</td>
<td>P02.25</td>
</tr>
<tr>
<td>Wang, Juyong</td>
<td>Yun, Young-Ju</td>
</tr>
<tr>
<td>P01.12</td>
<td>P02.114, P04.15</td>
</tr>
<tr>
<td>Wang, Liqiong</td>
<td></td>
</tr>
<tr>
<td>P02.63, P05.08, P02.66, P05.06</td>
<td></td>
</tr>
<tr>
<td>Wang, Sihan</td>
<td>Yun, Young-Ju</td>
</tr>
<tr>
<td>OA03.02, OA05.01, P02.23, P02.124 LB, P02.156 LB, P06.28 LB</td>
<td>P02.114, P04.15</td>
</tr>
<tr>
<td>Wang, Siying</td>
<td></td>
</tr>
<tr>
<td>P01.03, P01.04</td>
<td></td>
</tr>
<tr>
<td>Wang, Tianfang</td>
<td></td>
</tr>
<tr>
<td>P01.03, P01.04</td>
<td></td>
</tr>
<tr>
<td>Wang, Wenjian</td>
<td></td>
</tr>
<tr>
<td>P03.24 LB</td>
<td></td>
</tr>
<tr>
<td>Wang, Xin</td>
<td></td>
</tr>
<tr>
<td>P01.31 LB, P01.32 LB</td>
<td></td>
</tr>
<tr>
<td>Wang, Yu</td>
<td></td>
</tr>
<tr>
<td>OA03.02, OA05.01, P02.23, P02.156 LB</td>
<td></td>
</tr>
<tr>
<td>Wang, Yuyi</td>
<td></td>
</tr>
<tr>
<td>P04.18, P05.08</td>
<td></td>
</tr>
<tr>
<td>Wang, Zhengtao</td>
<td></td>
</tr>
<tr>
<td>P01.12</td>
<td></td>
</tr>
<tr>
<td>Wangyal, Tenzin</td>
<td></td>
</tr>
<tr>
<td>P02.38</td>
<td></td>
</tr>
<tr>
<td>Ward, Lesley</td>
<td></td>
</tr>
<tr>
<td>P02.133 LB, P05.25 LB</td>
<td></td>
</tr>
<tr>
<td>Wardle, Jonathan</td>
<td></td>
</tr>
<tr>
<td>P03.09</td>
<td></td>
</tr>
<tr>
<td>Watanabe, Kenji</td>
<td></td>
</tr>
<tr>
<td>P02.24</td>
<td></td>
</tr>
<tr>
<td>Watts, Sam</td>
<td></td>
</tr>
<tr>
<td>P02.60, P02.61</td>
<td></td>
</tr>
<tr>
<td>Wayne, Peter M.</td>
<td></td>
</tr>
<tr>
<td>OA06.03, OA15.04, P02.82, P02.84</td>
<td></td>
</tr>
<tr>
<td>Weaver, Kathryn</td>
<td></td>
</tr>
<tr>
<td>P02.35</td>
<td></td>
</tr>
<tr>
<td>Wee, Christina C.</td>
<td></td>
</tr>
<tr>
<td>P04.39</td>
<td></td>
</tr>
<tr>
<td>Wei, Qi</td>
<td></td>
</tr>
<tr>
<td>P02.129 LB, P02.147 LB</td>
<td></td>
</tr>
<tr>
<td>Wei, Vicki</td>
<td></td>
</tr>
<tr>
<td>OA14.04 LB</td>
<td></td>
</tr>
<tr>
<td>Weigensberg, Marc</td>
<td></td>
</tr>
<tr>
<td>P02.83</td>
<td></td>
</tr>
<tr>
<td>Wellman, Robert</td>
<td></td>
</tr>
<tr>
<td>P02.31</td>
<td></td>
</tr>
<tr>
<td>Wells, Rebecca E.</td>
<td></td>
</tr>
<tr>
<td>OA06.03</td>
<td></td>
</tr>
<tr>
<td>Welton, Richard</td>
<td></td>
</tr>
<tr>
<td>P04.50 LB</td>
<td></td>
</tr>
<tr>
<td>Wertenbaker, Delphi</td>
<td></td>
</tr>
<tr>
<td>P02.36</td>
<td></td>
</tr>
<tr>
<td>Westaway, Michael</td>
<td></td>
</tr>
<tr>
<td>P02.30</td>
<td></td>
</tr>
<tr>
<td>Wheeler, Amy</td>
<td></td>
</tr>
<tr>
<td>P02.36</td>
<td></td>
</tr>
<tr>
<td>White, Laura</td>
<td></td>
</tr>
<tr>
<td>P04.11</td>
<td></td>
</tr>
<tr>
<td>Whitebird, R.R.</td>
<td></td>
</tr>
<tr>
<td>P02.54</td>
<td></td>
</tr>
<tr>
<td>Whitham, Ruth</td>
<td></td>
</tr>
<tr>
<td>OA08.01</td>
<td></td>
</tr>
<tr>
<td>Whitsel, Eric</td>
<td></td>
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<tr>
<td>P05.26 LB</td>
<td></td>
</tr>
<tr>
<td>Wieland, Lisa</td>
<td></td>
</tr>
<tr>
<td>P05.15</td>
<td></td>
</tr>
<tr>
<td>Wiemer, Klaus</td>
<td></td>
</tr>
<tr>
<td>OA07.04</td>
<td></td>
</tr>
<tr>
<td>Wilkins, Tamera</td>
<td></td>
</tr>
<tr>
<td>P03.25 LB</td>
<td></td>
</tr>
<tr>
<td>Williams, Jane</td>
<td></td>
</tr>
<tr>
<td>P02.129 LB, P04.42 LB</td>
<td></td>
</tr>
<tr>
<td>Williams, Travis</td>
<td></td>
</tr>
<tr>
<td>P02.21 LB</td>
<td></td>
</tr>
<tr>
<td>Wilson, Kathleen</td>
<td></td>
</tr>
<tr>
<td>OA06.02</td>
<td></td>
</tr>
<tr>
<td>Winter, Michelle</td>
<td></td>
</tr>
<tr>
<td>P03.20</td>
<td></td>
</tr>
<tr>
<td>Winterbottom, Melissa</td>
<td></td>
</tr>
<tr>
<td>P06.10</td>
<td></td>
</tr>
<tr>
<td>Wissink, Theodore</td>
<td></td>
</tr>
<tr>
<td>P04.54</td>
<td></td>
</tr>
<tr>
<td>Witt, Claudia M</td>
<td></td>
</tr>
<tr>
<td>OA05.02, P02.37</td>
<td></td>
</tr>
<tr>
<td>Wolever, Ruth</td>
<td></td>
</tr>
<tr>
<td>OA09.03</td>
<td></td>
</tr>
<tr>
<td>Wolf, Martin</td>
<td></td>
</tr>
<tr>
<td>P02.106</td>
<td></td>
</tr>
<tr>
<td>Wolf, Ursula</td>
<td></td>
</tr>
<tr>
<td>P02.105, P02.106</td>
<td></td>
</tr>
<tr>
<td>Wong, Ching</td>
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<td>Yan, Li-Jiao</td>
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</table>
ABSTRACT AUTHOR INDEX

Zhang, Yunjiao .......... P06.08
Zhang, Yuqing .......... P02.01
Zhang, Zhang Jin ....... OA02.03
Zhao, Bai Xian ........ P02.03
Zhao, Chenlai ......... P02.14, P02.15, P02.16
Zhao, Jiayong .......... P02.15
Zhao, Lihong .......... P01.03, P01.04
Zhao, Shibeil ......... OA06.01
Zheng, Huimin .......... P02.14, P02.16
Zhou, Xian ............ P02.64
Zhou, Xue-Lei ........ P01.25 LB
Zhu, Xiaoshu .......... P02.64, P06.31 LB
Zibrat, Zachary ....... P02.07
Zick, Suzanna ........ OA14.03
Zusman, Randall ...... P02.43
Zuzak, Tycho ........... OA04.01, P04.23
Zwickey, Heather ...... P01.07, P02.95, P02.118, P04.25