**Selected by
Benno Brinkhaus
Berlin**

Latest Publications You Should Not Miss

Witt CM, Mannheimer E, Hammerschlag R, Lüdke R, Lao L, Tunis SR, Berman BM: How well do randomized trials inform decision making: systematic review using comparative effectiveness research measures on acupuncture for back pain. PLoS One 2012;7:e32399.

Background: For Comparative Effectiveness Research (CER) there is a need to develop scales for appraisal of available clinical research. Aims were to 1) test the feasibility of applying the pragmatic-explanatory continuum indicator summary tool and the six CER defining characteristics of the Institute of Medicine to RCTs of acupuncture for treatment of low back pain, and 2) evaluate the extent to which the evidence from these RCTs is relevant to clinical and health policy decision making.

Methods: We searched Medline, the AcuTrials™ Database to February 2011 and reference lists and included full-report randomized trials in English that compared needle acupuncture with a conventional treatment in adults with non-specific acute and/or chronic low back pain and restricted to those with ≥ 30 patients in the acupuncture group. Papers were evaluated by 5 raters.

Principal findings: From 119 abstracts, 44 full-text publications were screened and 10 trials (4,901 patients) were evaluated. Due to missing information and initial difficulties in operationalizing the scoring items, the first scoring revealed inter-rater and inter-item variance (intraclass correlations 0.02–0.60), which improved after consensus discussions to 0.20–1.00. The 10 trials were found to cover the efficacy-effectiveness continuum; those with more flexible acupuncture and no placebo control scored closer to effectiveness.

Conclusion: Both instruments proved useful, but need further development. In addition, CONSORT guidelines for reporting pragmatic trials should be expanded. Most studies in this review already reflect the movement towards CER and similar approaches can be taken to evaluate comparative effectiveness relevance of RCTs for other treatments.

Flower A, Witt CM, Liu JP, Ulrich-Merzenich G, Yu H, Lewith G: Guidelines for randomised controlled trials investigating Chinese herbal medicine. J Ethnopharmacol 2012;140:550–554.

Ethnographic relevance: Clinical trials investigating Chinese herbal medicine (CHM) have been frequently criticised for their lack of scientific rigour. As part of the GP-TCM project a team of experienced clinical researchers and CHM practitioners have developed clinical trial guidelines for CHM that combine an appreciation for traditional methods of practice with detailed and practical advice on research methodology.

Materials and methods: This paper presents an executive summary of this work. It introduces the practice of CHM and the key considerations that need to be addressed whilst researching this traditional medical system.

Results: These guidelines emphasise the importance of identifying best practice, and then developing and applying appropriate and rigorous research methodologies to investigate CHM as a whole system.

Conclusions: It is hoped that this will encourage a thoughtful and meticulous process of investigation that will clarify the contribution that CHM can make to our future healthcare. Innovative new approaches are considered including the application of the new 'omic' technologies and systems biology as a way of enhancing our understanding of traditional practice.

Langhorst J, Klose P, Dobos GJ, Bernardy K, Häuser W: Efficacy and safety of meditative movement therapies in fibromyalgia syndrome: a systematic review and meta-analysis of randomized controlled trials. Rheumatol Int 2012; DOI: 10.1007/s00296-012-2360-1.

A systematic review with meta-analysis of the efficacy and safety of meditative movement therapies (Qigong, Tai Chi and Yoga) in fibromyalgia syndrome (FMS) was carried out. We screened Clinicaltrials.gov, Cochrane Library, PsycINFO, PubMed and Scopus (through December 2010) and the reference sections of original studies for meditative move-

ment therapies (MMT) in FMS. Randomized controlled trials (RCT) comparing MMT to controls were analysed. Outcomes of efficacy were pain, sleep, fatigue, depression and health-related quality of life (HRQOL). Effects were summarized using standardized mean differences (SMD [95% confidence interval]). Outcomes of safety were drop out because of adverse events and serious adverse events. A total of 7 out of 117 studies with 362 subjects and a median of 12 sessions (range 8–24) were included. MMT reduced sleep disturbances (-0.61 [-0.95 , -0.27]; 0.0004), fatigue (-0.66 [-0.99 , -0.34]; <0.0001), depression (-0.49 [-0.76 , -0.22]; 0.0004) and limitations of HRQOL (-0.59 [-0.93 , -0.24]; 0.0009), but not pain (-0.35 [-0.80 , 0.11]; 0.14) compared to controls at final treatment. The significant effects on sleep disturbances (-0.52 [-0.97 , -0.07]; 0.02) and HRQOL (-0.66 [-1.31 , -0.01]; 0.05) could be maintained after a median of 4.5 (range 3–6) months. In subgroup analyses, only Yoga yielded significant effects on pain, fatigue, depression and HRQOL at final treatment. Drop out rate because of adverse events was 3.1%. No serious adverse events were reported. MMT are safe. Yoga had short-term beneficial effects on some key domains of FMS. There is a need for high-quality studies with larger sample sizes to confirm the results.

Lauche R, Cramer H, Hohmann C, Choi KE, Rampp T, Saha FJ, Musial F, Langhorst J, Dobos G: The effect of traditional cupping on pain and mechanical thresholds in patients with chronic nonspecific neck pain: a randomised controlled pilot study. Evid Based Complement Alternat Med 2012;2012:429718.

Introduction: Cupping has been used since antiquity in the treatment of pain conditions. In this pilot study, we investigated the effect of traditional cupping therapy on chronic nonspecific neck pain (CNP) and mechanical sensory thresholds.

Methods: Fifty CNP patients were randomly assigned to treatment (TG, $n = 25$) or waiting list control group (WL, $n = 25$). TG received a single cupping treatment. Pain at rest (PR), pain related to movement (PM), quality of life (SF-36), Neck Disability Index (NDI), mechanical detection (MDT), vibration detection (MDT), and pressure pain thresholds (PPT) were measured before and three days after a single cupping treatment. Patients also kept a pain and medication diary (PaDi, MeDi) during the study.

Results: Baseline characteristics were similar in the two groups. After cupping TG reported significantly less pain (PR: -17.9 mm VAS, 95% CI -29.2 to -6.6 ; PM: -19.7 , 95% CI -32.2 to -7.2 ; PaDi: -1.5 points on NRS, 95% CI -2.5 to -0.4 ; all $P < 0.05$) and higher quality of life than WL (SF-36, Physical Functioning: 7.5, 95% CI 1.4 to 13.5; Bodily Pain: 14.9, 95% CI 4.4 to 25.4; Physical Component Score: 5.0, 95% CI 1.4 to 8.5; all $P < 0.05$). No significant effect was found for NDI, MDT, or VDT, but TG showed significantly higher PPT at pain-areas than WL (in lg(kPa); pain-maximum: 0.088, 95% CI 0.029 to 0.148, pain-adjacent: 0.118, 95% CI 0.038 to 0.199; both $P < 0.01$).

Conclusion: A single application of traditional cupping might be an effective treatment for improving pain, quality of life, and hyperalgesia in CNP.

MacLaughlin BW, Wang D, Noone AM, Liu N, Harazduk N, Lumpkin M, Haramati A, Saunders P, Dutton M, Amri H: Stress biomarkers in medical students participating in a mind body medicine skills program. Evid Based Complement Alternat Med 2011;2011:950461.

Georgetown University School of Medicine offers an elective Mind-Body Medicine Skills (MBMS) course to medical students to promote self-care and self-awareness. Participating medical students reported better man-

agement of academic stress and well-being than non-participants. In this study, we sought to assess the stress-reducing effects of MBMS by measuring physiological changes in first-year medical students. Saliva samples were collected before (January, time 1 (T1)-pre-intervention) and upon completion of the course (May, time 2 (T2p)-post-intervention), as well as from non-participating medical students (May, time 2 (T2c)-control). The T2p and T2c collections coincided with the period of final examinations. Cortisol, dehydroepiandrosterone-sulfate (DHEA-S), testosterone and secretory immunoglobulin A (sIgA) were measured. The mean morning salivary cortisol at T2p was 97% of the mean at baseline T1 which was significantly lower than for T2c (2.4) (95% confidence interval (CI) 0.57–1.60, $P = .001$); DHEA-S showed similar pattern as cortisol where the T2p levels were significantly lower than T2c ($P < .001$) in both morning and evening collections. Testosterone ratio at T2p (0.85) was also lower than T2c (1.6) (95% CI 0.53–1.3, $P = .01$). sIgA levels were not statistically different. On direct comparison, the T2c and T2p means were significantly different for all cortisol, DHEA-S and testosterone values. Participants maintained their hormonal balance within the normal range throughout the academic semester while the control group showed significantly increased levels, probably exacerbated by the end of the semester exam stress. To our knowledge, this is the first study to assess the physiologic benefits of a MBMS program in medical students.

Huang W, Pach D, Napadow V, Park V, Long X, Neumann J, Maeda Y, Nierhaus T, Liang F, Witt CM: Characterizing acupuncture stimuli using brain imaging with fMRI – a systematic review and meta-analysis of the literature. PLoS One 2012;7:e32960.

Background: The mechanisms of action underlying acupuncture, including acupuncture point specificity, are not well understood. In the previous decade, an increasing number of studies have applied fMRI to investigate brain response to acupuncture stimulation. Our aim was to provide a systematic overview of acupuncture fMRI research considering the following aspects: 1) differences between verum and sham acupuncture, 2) differences due to various methods of acupuncture manipulation, 3) differences between patients and healthy volunteers, 4) differences between different acupuncture points.

Methodology/principle findings: We systematically searched English, Chinese, Korean and Japanese databases for literature published from the earliest available up until September 2009, without any language restrictions. We included all studies using fMRI to investigate the effect of acupuncture on the human brain (at least one group that received needle-based acupuncture). 779 papers were identified, 149 met the inclusion criteria for the descriptive analysis, and 34 were eligible for the meta-analyses. From a descriptive perspective, multiple studies reported that acupuncture modulates activity within specific brain areas, including somatosensory cortices, limbic system, basal ganglia, brain stem, and cerebellum. Meta-analyses for verum acupuncture stimuli confirmed brain activity within many of the regions mentioned above. Differences between verum and sham acupuncture were noted in brain response in middle cingulate, while some heterogeneity was noted for other regions depending on how such meta-analyses were performed, such as sensorimotor cortices, limbic regions, and cerebellum.

Conclusions: Brain response to acupuncture stimuli encompasses a broad network of regions consistent with not just somatosensory, but also affective and cognitive processing. While the results were heterogeneous, from a descriptive perspective most studies suggest that acupuncture can modulate the activity within specific brain areas, and the evidence based on meta-analyses confirmed some of these results. More high quality studies with more transparent methodology are needed to improve the consistency amongst different studies.