

where evidence is needed, and conditions with evidence but no guidelines were highlighted.

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<http://dx.doi.org/10.1016/j.imr.2015.04.209>

P4.007

Kava reloaded? The tip of a regulatory iceberg



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Purpose: In June 2002 the authorization of medicinal drugs with kava extracts (*Piper methysticum*), which was used for the treatment of stress-related anxiety disorders, was withdrawn by the German Institute of Drugs and Medicinal Products (BfArM) because of an unfavorable risk-benefit ratio. The decision, which initially was based on several case reports on liver toxicity in 1999 and 2000, found a worldwide resonance.

Methods: Literature on efficacy and safety of kava extracts was searched and related to the still ongoing legal dispute.

Results: Between 1990 and 2000 several randomized controlled clinical studies have been published, which were the basis for the authorization of kava products in Germany for stress-related anxiety disorders in the past. However, in the course of time since 2002, the BfArM did not any longer accept these studies as proof of efficacy because of several deficits in the study protocols. In 2002, no study was left. The case reports were re-analyzed by a specialized hepatologist, who found that the risk of hepatotoxicity was "rare" or "very rare" at its best and could not identify a specific pattern. However, the resulting publication was ignored completely by the BfArM. In fact, BfArM now considered kava extracts being a „new entity“, because of their alleged unproven efficacy. That means that based on the most recent ICH-guidelines now the complete spectrum of preclinical studies has to be performed before undertaking a clinical trial. However, the administrative court of Cologne, Germany, underlined in its decision from 10. June 2014, that current rules of the proof of efficacy of a drug should not be applied retrospectively.

Conclusion: The decision is important not only for kava, but for all drugs on the German market, e.g. for benzodiazepines, which were tested in the 1960s for efficacy. By the way, BfArM applied for revision.

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<http://dx.doi.org/10.1016/j.imr.2015.04.210>

P4.008

Tai Chi as an Intervention on Health Promotion for Older Adults: A Systematic Review



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Purpose: The purpose of this review is to systematically summarize the physiological, psychological, social, and therapeutic benefits of Tai Chi from scientific literatures used Tai Chi as an intervention for older adults.

Methods: A broad computerized literature search of Alt HealthWatch, ERIC, Medline, CINAHL, and PsycARTILES was conducted. Studies were selected if they met the following five criteria: 1) Tai Chi was used as an intervention, 2) Research design was either RCT or CCT, 3) Health benefits were used as an outcome measure, 4) Age group targeted older adults, and 5) Study was conducted in English speaking countries.

Results: Fifty four articles were selected and reviewed. Among these studies, 11 articles proved that Tai Chi improves balance, strength, flexibility, and preventing of falls. Six articles reported Tai Chi enhances the cardiorespiratory function. 14 articles demonstrated that Tai Chi is associated with life satisfaction, stress reduction, decreasing anxiety and mood disturbance, and improving subjective well-being. 16 articles showed that Tai Chi is beneficial for a variety of chronic conditions, such as hypertension, arthritis, and insomnia. Seven articles mentioned the social benefits of Tai Chi practice supported by the evidence that most Tai Chi practitioners continue to practice in a group after the studies were completed.

Conclusion: Regarding the increasing number of older population with many chronic health issues, Tai Chi may serve as a safe, low-cost, and effective program to improve the overall health and well-being for the elderly. In addition, Tai Chi can be considered as a holistic exercise modality to prevent disability and reduce medical expense through developing an active lifestyle among older people with chronic conditions.

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<http://dx.doi.org/10.1016/j.imr.2015.04.211>

P4.009

Routinely assessing pain and stress via a practice-based research model in a university-based integrative care clinic



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Purpose: Pain and stress are amongst the most common reasons for patients seeking integrative care (IC) therapies. IC clinics provide a unique opportunity to longitudinally assess