



# Mills and Bone Academy

Educational Article

## The Resurgence of Kava – Kerry Bone

Late last century the herb kava (*Piper methysticum*) was emerging as a serious player in the battle against anxiety. Several clinical trials had confirmed its efficacy and the experience of herbal clinicians was that it worked well in real life. But then concerns began to emerge about kava causing liver toxicity in a few users, not because it was toxic to the liver itself, but because it triggered a rare response in the immune system. This reaction caused the immune cells of some unhappy users to attack their livers, apparently resulting in severe damage in some cases.

The phenomenon is known as drug-induced liver injury (DILI) and occurs at varying frequencies for most orthodox drugs. Under political pressure over this issue, the German health authority decided to ban the therapeutic use of kava in June 2002. This was despite the fact an extensive analysis suggested that the incidence of DILI from kava use was lower than the rate with conventional sedative drugs, such as the benzodiazepines.<sup>1</sup> One by one, the international authorities in Europe, Canada and Japan moved to stop the sale of kava products. In Australia, after careful examination of the issues by an expert committee (of which I was a member), the regulators decided to only allow traditional

forms of kava, namely the root powder or a water extract of the root. Extracts made with solvents such as ethanol (alcohol) and acetone were not permitted.

This decision in Australia made sense, given its close proximity to Pacific island communities such as Fiji and Vanuatu, where kava is safely consumed in its traditional form as commonly as coffee is in the west. Banning water extracts of kava in Australia would have baffled and inconvenienced the many expatriate islanders and their descendants now calling Australia home. To them it would have been the equivalent of banning coffee because of safety concerns!

In the US, the FDA did not move to restrict the sale of kava. However insurance companies offering liability cover to marketers of kava were spooked by all the negative publicity and raised their premiums, effectively restricting the sale of kava products on commercial grounds.

The future of kava looked bleak, with both clinicians and patients effectively denied perhaps the most effective herb in their daily battle against stress and anxiety. However, a

group of scientists in Australia led by Dr Jerome Sarris decided to test out the efficacy and safety of a kava water (aqueous) extract. Ironically, they undertook the very first clinical trials on this ancient (and potentially safer) way of taking kava.

Here is a summary of what they found. The water soluble extract of kava was first confirmed to be effective in treating anxiety and improving mood in people with chronic anxiety in a short-term placebo-controlled, double blind, crossover trial.<sup>ii,iii</sup> After one week of placebo (pretreatment phase), 41 adults with one month or more of elevated generalised anxiety received aqueous kava extract providing 250 mg/day of kava lactones or placebo tablets for one week (phase 1). Participants then swapped treatments for an additional week (phase 2). HAMA (a measure of anxiety) scores were found to be reduced by an average of 9.9 points when kava was received during phase 1, compared to a reduction of just 0.8 for placebo. Considering both phases of the trial, the effect of kava in reducing anxiety was highly significant compared to placebo ( $p < 0.0001$ ). The reduction of 11.4 points over placebo on HAMA compared favorably to benzodiazepine drug efficacy. Significant reductions in depression were also evident and no serious adverse effects were observed.

The group then followed up with a longer study. In this trial, a total of 75 people with generalised anxiety disorder (GAD), but without depression, were enrolled in a 6-week, double blind trial of an aqueous extract of kava versus placebo.<sup>iv</sup> The kava dose contained 120 mg of lactones per day, but this was increased to 240 mg if there was no response. Kava significantly reduced anxiety after 6 weeks (by 7.6 points on the HAMA scale), versus a

placebo effect of 4.2 points. This was a significant result that was most evident in participants with more severe anxiety. In addition, 26% of people in the kava group had their anxiety brought into remission, versus only 6% in the placebo group, again a significant result ( $p = 0.004$ ). Also in people with pure GAD and no other comorbid anxiety disorder, the effect of kava was stronger.

In terms of safety and addiction, there were no serious adverse effects in the kava group, and certainly no signs of hepatotoxicity.<sup>v</sup> Results on the Arizona Sexual Experience Scale (ASEX) showed that kava caused no reduction in sexual performance or enjoyment. In fact, amongst the women there was an indication of improved sexual function with kava, including an increase in their libido! In a separate study, the Australian researchers also found that normal doses of kava aqueous extract do not impair driving ability, whereas 30 mg of the drug oxazepam did.<sup>vi</sup>

These positive clinical findings have been good news for kava and are leading a renaissance in its use for anxiety, just as overblown fears regarding hepatotoxicity are beginning to abate on the lack of convincing new cases.

## References

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<sup>i</sup> Mills S, Bone K, (eds) *The Essential Guide to Herbal Safety*. Elsevier, St Louis. 2005, pp155-219

<sup>ii</sup> Sarris J, Kavanagh DJ, Byrne G The Kava Anxiety Depression Spectrum Study (KADSS): a randomized, placebo-controlled crossover trial using an aqueous extract of *Piper methysticum* *Psychopharmacology (Berl)* 2009; **205**(3): 399-407

<sup>iii</sup> Sarris J, Kavanagh DJ, Adams J Kava Anxiety Depression Spectrum Study (KADSS): a mixed methods RCT using an aqueous extract of *Piper methysticum* *Complement Ther Med* 2009; **17**(3): 176-178

<sup>iv</sup> Sarris J, Stough C, Bousman CA et al Kava in the Treatment of Generalized Anxiety Disorder: A Double- Blind, Randomized, Placebo-Controlled Study *J Clin Psychopharmacol* 2013; Apr 30 [epub ahead of print]

<sup>v</sup> Sarris J, Stough C, Teschke R et al Kava for the Treatment of Generalized Anxiety Disorder RCT: Analysis of Adverse Reactions, Liver Function, Addiction, and Sexual Effects *Phytother Res* 2013 Jan 24 [epub ahead of print]

<sup>vi</sup> Sarris J, Laporte E, Scholey A, et al Does a medicinal dose of kava impair driving? A randomized, placebo- controlled, double-blind study *Traffic Inj Prev* 2013; **14**(1): 13-7