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# Kava

Making Your  
Patients Happy!





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In a published randomised, double-blind, placebo-controlled trial, researchers from Universities in Australia and Germany have shown that Kava significantly reduces anxiety in sufferers of generalised anxiety disorder (GAD).

This is the latest study in an ongoing research project which has resulted in several papers published in peer-reviewed medical journals. MediHerb supplied the water extract of Kava (*Piper methysticum*) root, standardised for kavalactones.

Overall, the results from all of the studies combined show that the Kava extract reduces anxiety, especially in the medically-defined generalised anxiety disorder, and has a good safety profile in terms of liver function and alertness while driving.

Here is a summary of the Clinical Trials and Results:

### Kava in the Treatment of Generalised Anxiety Disorder (GAD)<sup>1</sup>

In press 2013

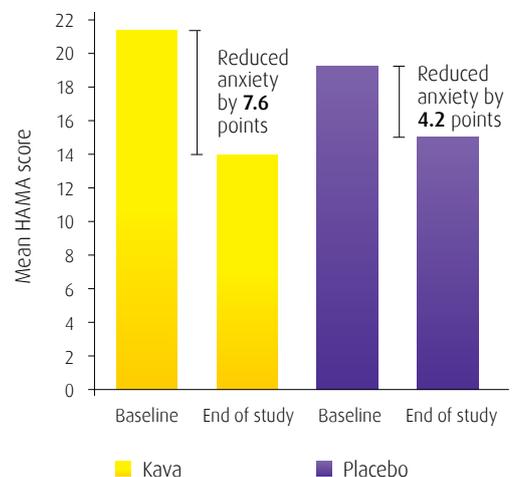
#### Trial Details

- randomised, double-blind, placebo-controlled; 8 weeks<sup>SA</sup>
- dosage: 120–240 mg/day\* of kava lactones

#### Results

- moderate but statistically significant reduction in anxiety for the Kava group compared to placebo group
  - reduction of 7.6 points on HAMA for Kava compared to 4.2 points for placebo ( $p = 0.046$ )
- anxiolytic effect was larger among those with moderate to severe GAD<sup>†</sup>
- there was significant reduction in anxiety for Kava (8.5 points, HAMA) compared to placebo (2.3 points) for those with pure GAD<sup>†</sup> ( $p = 0.02$ )
- at the end of the controlled phase (i.e. week 7), 26% of the Kava group were classified as remitted (HAMA score  $\leq 7$ ) compared to 6% of the placebo group ( $p = 0.04$ )
- specific GABA transporter polymorphisms appear to potentially modify the anxiolytic response to Kava<sup>\*\*</sup>

#### Reduction of anxiety in Patients with GAD



## Kava in the Treatment of Chronic Anxiety

Published 2009/10

### Trial Details

- double-blind, placebo-controlled, crossover; 3 weeks<sup>8B</sup>
- dosage: 250 mg/day of kava lactones

### Results

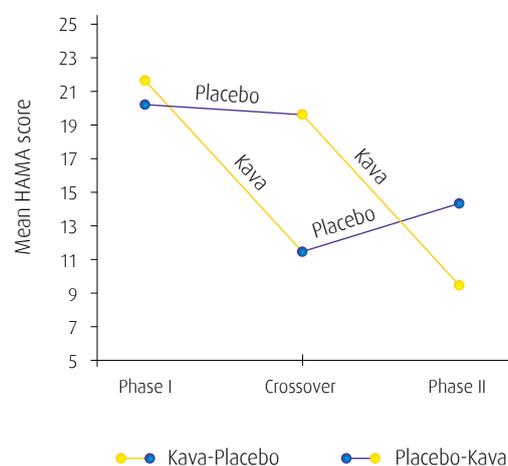
#### Quantitative Research<sup>2</sup>

- HAMA scores reduced by 9.9 points when Kava was received during phase 1, compared with a reduction of 0.8 for placebo
- HAMA scores reduced by 10.3 points when Kava was received during phase 2, compared with an increase of 3.3 for placebo
- considering both phases of the trial, Kava was highly significant in reducing anxiety compared to placebo ( $p < 0.0001$ )
  - reduction of 11.4 points over placebo on HAMA compared favourably to benzodiazepine efficacy
- highly significant relative reductions in depression were also evident

#### Qualitative (descriptive) Research<sup>3</sup>

- majority of participants experienced positive effects while taking Kava tablets: lessening of anxiety, enhanced mood, improvement in sleep, some beneficial effects on the physical signs of anxiety
- some negative experiences were reported (Kava and placebo)
- a specific theme was identified: Kava reduced muscular or physical tension

### Results on HAMA scale for patients with chronic anxiety



## Kava GAD Study: Analysis of Adverse Reactions, Liver Function, Addiction and Sexual Effects<sup>4</sup>

In press 2013

### Trial Details

- randomised, double-blind, placebo-controlled; 8 weeks<sup>5A</sup>
- dosage: 120-240 mg/day\* of kava lactones

### Results

- no significant differences between the Kava and placebo groups for liver function tests<sup>A</sup>
- no significant adverse reactions could be attributed to Kava
- withdrawal or addictive effects were not observed
- Kava significantly increased women's sexual drive compared to placebo – which may have been due to the anxiolytic effect; no significant negative effects on sexual function observed in men

## Kava and Oxazepam and Driving Safety<sup>5</sup>

Published 2013

### Trial Details

- acute, controlled (placebo and drug), crossover trial using a driving simulator (computer)<sup>5C</sup>
- single dose: 180 mg of kava lactones

### Results

- no impairing effects on driving outcomes were found for Kava compared to placebo
- oxazepam caused significantly slower braking reaction time compared to placebo and Kava
- Kava caused significantly fewer lapses of concentration than oxazepam
- results were not affected by driving experience
- oxazepam significantly decreased alertness ( $p < 0.001$ ), but no significant reduction was found for Kava or placebo

## Abbreviations

GABA: gamma-aminobutyric acid; HAMA: Hamilton Anxiety Rating Scale

## Notes

§ A. One week placebo run-in, followed by 2 x 3 weeks of treatment/placebo, followed by one week post-study observation. B. One week pretreatment phase, followed by one week each of Kava/placebo. C. Single dose Kava, oxazepam, placebo on three separate days, one week apart \* Started at the lower dosage and increased if not responding to treatment: of the 58 participants, at the end of the first 3-week control phase, 13 (45%) of the Kava group and 16 (55%) of the placebo group did not respond and had their tablets increased to the double dose ‡ Assessed on MINI Plus: nine (16%) participants had mild, 34 moderate (59%), and 15 (25%) severe level symptoms † Pure GAD: GAD with no other comorbid anxiety disorders \*\* Polymorphisms may be linked to increased incidence of anxiety disorders or differing therapeutic effects of anti-anxiety agents; within the Kava group, GABA transporter polymorphisms rs2601126 and rs2697153 were associated with significant reductions in HAMA scores. Δ Albumin, bilirubin, alanine aminotransferase, aspartate aminotransferase, gamma-glutamyl transpeptidase, alkaline phosphatase

## References

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3. Sarris J, Adams J, Kavanagh DJ. *Aust J Med Herb* 2010; **22**(1): 12-16
4. Sarris J, Stough C, Teschke R et al. *Phytother Res* In Press
5. Sarris J, Laporte E, Scholey A et al. *Traffic Inj Prev* 2013; **14**(1): 13-17

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