

# THE NUMBERS ARE IN:

Clinical trial proves  
two Zeals per day make  
a real Zeal difference



## Feeling the Zeal difference means different things to different people.

But now a clinical study backs up that there definitely *is* a Zeal difference. Recent clinical trial results from independent third-party research firm KGK Synergize\* confirm that the positive benefits of drinking Zeal include improved mood, stronger vigor and vitality, and less anxiety and fatigue. Under the highest scientific standards, the study was conducted on healthy and active people not trying to improve mood or enhance their current health. Yet, after just 28 days of drinking Zeal twice a day, 85% felt better. The difference was significant.

\*KGK Synergize is a highly respected Canadian-based firm specializing in human research and clinical trials for the health, nutrition, biotechnology and pharmaceutical industries.



# Zurvita Clinical Trial – Highlights

## Objectives:

The objective of this study was to investigate the effect of Zeal on healthy, moderately stressed adults using standardized measures of mood states, including overall feelings of vitality.

The study design called for 100 healthy, moderately stressed adults with 25 participants randomized equally to each of the 4 study arms in a double-blind manner.

## Definition of the Study Populations:

The Per Protocol Population consisted of 84 of the 99 participants who actually started the trial and who did not have any major protocol violations, and completed all study visits and procedures connected with measurement of the primary variable.

These eighty-four participants were analyzed in the “Per Protocol” Population, with 21 participants in the Zeal once daily group, 20 participants in the Zeal twice daily group, 23 participants in the Placebo once daily group, and 20 participants in the placebo twice daily group.

## Demographics at screening:

Ninety-nine participants with an age range of 18 – 65 years and a BMI of 18.4 – 30.1 kg/m<sup>2</sup> were enrolled in this study. Participants were predominantly Caucasian and non-smokers with 62% females and 38% males. All participants were deemed healthy by physical examination and as per their screening laboratory parameters.

The stress levels of participants, based on the Stress/Vitality questionnaire confirmed that they were moderately stressed. 71% percent of the participants confirmed self-reported moderate stress. 81% self-reported ups and downs in energy level and 65% were tired by mid-afternoon during the day. Forty percent did not engage in any exercise while 38% were engaged in moderate levels of exercise. 88% were non-smokers and 52% were light alcohol drinkers ( $\leq 1$  drink/week). 30% of the participants were married and 68% did not have children. 53% worked full time while 23% were either seeking employment or were unemployed. 36% percent consumed a typical American diet, 87% did not take supplements and 79% consumed caffeine in the form of coffee (54%).

## Compliance:

Compliance with the study protocol in all groups were >90%.

## Location of the Study Participants:

All subjects were recruited from the Orlando, Florida metropolitan area and the study was completed prior to any of the recent occurrences in the Orlando area.

## Key Points Regarding the Analysis of the Results:

Based on the results of the two placebo groups, they were combined in order to gain additional statistical power.

The results of this analysis were provided both by the results of the intent-to treat and the per-protocol analysis. However, this summary focuses on the 2-day Zeal results to be consistent with the use recommendations of Zurvita. An extension of the POMS, the POMS Iceberg profile, designed for assessing active/healthy individuals was also analyzed.

### **Overall Conclusions of the Study:**

Zeal at a dose of 28 grams per day, consumed as two doses of 14 grams, one in the morning and one mid-afternoon, significantly improved mood states and reduced stress levels within 29 days in moderately stressed but otherwise healthy individuals. This “Gold Standard” randomized double-blind, placebo-controlled clinical study scientifically validated Zeal in a healthy population by testing the efficacy of the product using proven research tools that test mood states.

Though this study had a 16% placebo effect, statistically significant improvements in Profile of Mood State-Total Mood Disturbance were achieved compared to a combined Placebo group. Participants reported a significant decrease of approximately 7% in the POMS-TMD and its subdomain, Anger and Hostility compared to the combined Placebo when they consumed 28 g of Zeal daily in two separate doses, one in the morning and one mid-afternoon.

2-dose Zeal improved the POMS Iceberg profile with a significant within group increase in Vigor and Activity. This improvement was associated with a significant within group decrease in the POMS subdomains of Tension and Anxiety, Depression and Dejection, Anger and Hostility, Fatigue and Inertia, Confusion and Bewilderment.

Rejuvenation of mood states, particularly reductions in anxiety and depression in this study corroborates earlier investigations into the anxiolytic and mood supporting properties of multiple food derived ingredients in the Zeal formulation, including Maca (*Lepidium meyenii*) (Stojanovska L et al., 2015) and grape seed extract (Terauchi M et al., 2014).

Importantly, the safety and efficacy profile of Zeal in this study strengthens evidence for its use in a healthy population to address moderate stress.

### **Summary of the Efficacy Results of the 2-day Zeal Group that followed the protocol fully compared to Placebo with regard to Total Mood Disturbance:**

Participants in 2-dose-Zeal group reported a significant 7.7% decrease in POMS-TMD vs. combined Placebo group at day 29 ( $p < 0.047$ ).

In summary, 2-dose Zeal supplementation resulted in a significant decrease in POMS-TMD in 29 days compared to the combined Placebo.

When comparing the Per Protocol Group vs. Combined Placebo Group in the POMS subdomains at Day 29, participants in 2-dose-Zeal group reported a significant decrease in Anger and Hostility of 8.6% vs. combined Placebo group at day 29 ( $p < 0.022$ ).

Within Group Changes (Not necessarily statistically significant between groups) supporting 2-dose versus 1-dose per day

The Per Protocol group supplemented with 2-dose-Zeal reported a 23.6% improvement in POMS-TMD over baseline by day 29 ( $p < 0.001$ ) within the group.

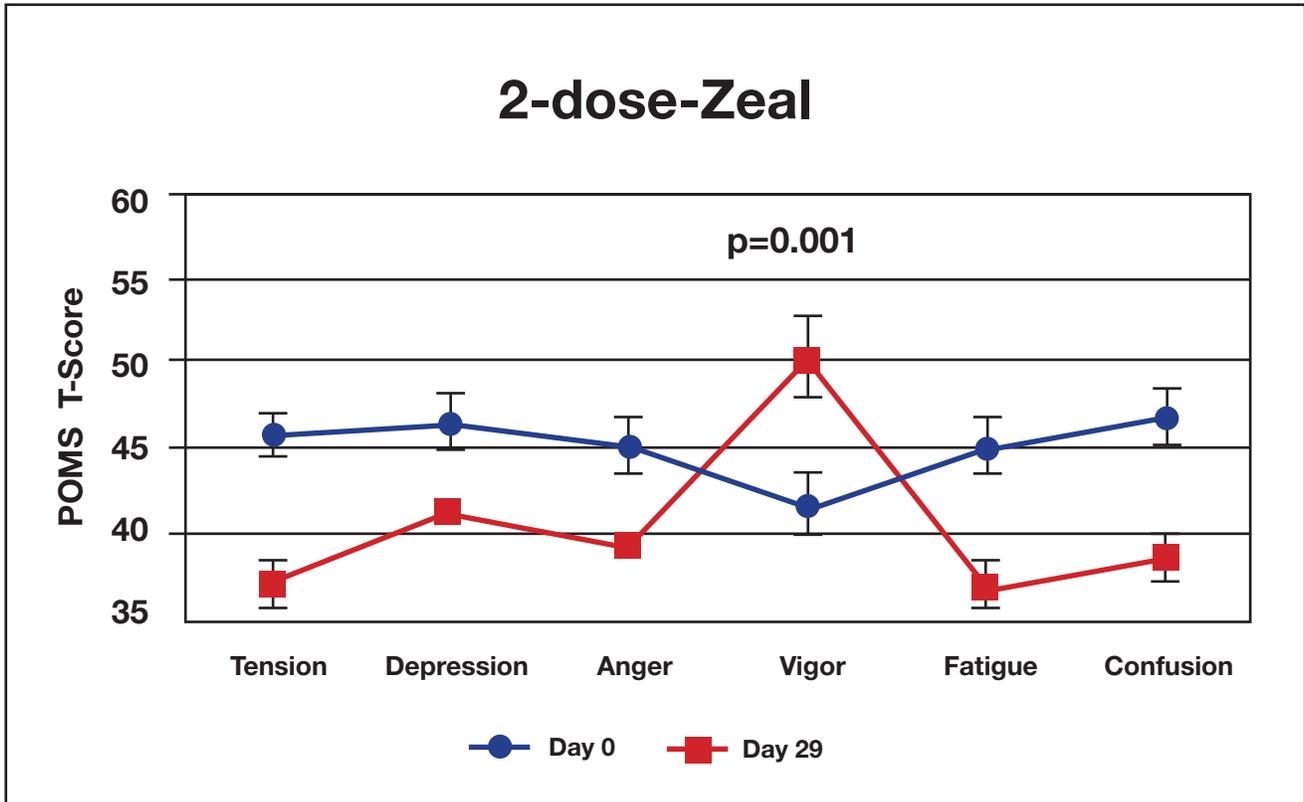
In further analyses of the subdomains, improvements were seen in the 2-dose-Zeal group with participants reporting decreases of 14.3% in Anger and Hostility ( $p < 0.001$ ), 19.6% in Fatigue-Inertia ( $p < 0.001$ ), 19% in Confusion-Bewilderment ( $p < 0.001$ ), 12.8% in Depression-Dejection ( $p = 0.002$ ), 19.4% in Tension-Anxiety ( $p < 0.001$ ) and an increase of 23.1% in Vigor-Activity ( $p = 0.002$ ) over baseline by day 29.

Improvements were also seen in the 1-dose-Zeal group, although to a lesser extent than in the 2-dose group, with participants reporting decreases of 4.5% in Anger and Hostility, 10% in Fatigue-Inertia ( $p = 0.021$ ), 12.9% in Confusion-Bewilderment ( $p = 0.003$ ), 4.9% in Depression-Dejection, 12.8% in Tension-Anxiety ( $p = 0.002$ ) and an increase by 3.5% in Vigor-Activity over baseline by day 29.

After only 8 days of supplementation, participants in 2-dose-Zeal reported a 12.4% within-group improvement in POMS-Total Mood Disruption over baseline.

Participants in 2-dose-Zeal also reported significant improvements over baseline in impact of stress on mood at day 8, day 15 and day 29.

**Figure 1: POMS Profiles for Participants in 1-dose-Zeal, 1-dose-Placebo, 2-dose-Zeal, and 2-dose-Placebo**



**What we found out:**

Zeal has a positive impact on improving overall POMS (TMD) scores and the subsets relating to Anger and Hostility. These effects were statistically significant when comparing the results of two doses per day to placebos over a 29 day period.

2-dose Zeal improved the POMS Iceberg profile that measures subsets of POMS relating the Vigor and Vitality, with a significant within-group increase in Vigor and Activity. These improvements were associated with significant decreases (improvements) within the 2-dose group in the POMS subdomains of Tension and Anxiety, Depression and Dejection, Anger and Hostility, Fatigue and Inertia, Confusion and Bewilderment.

While there were significant improvements in most areas measured for both 2-dose and 1-dose Zeal, only improvements in Total Mood Disturbance and the subdomain of Anger and Hostility associated with 2-dose Zeal resulted in statistically significant changes compared to the placebo groups.

That said, the overall conclusions of the investigators were that Zeal makes a positive impact on multiple parameters of mood state in healthy individuals who are moderately stressed.