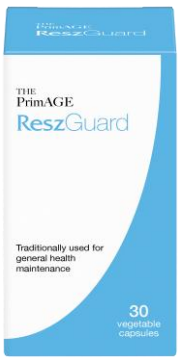
ReszGuard

Sleep Efficiency | Cognitive | Mood

THE PrimAGE

TECHNICAL DATA SHEET

*These statements is intended for medical professionals reference only. This product is not intended to diagnose, treat, cure, or prevent any disease.



ReszGuard

Formulated with patent phytonutrients to support serotonin/melatonin metabolism and improve sleep quality. It is scientifically proven product to improve your sleeping quality and wellbeing. The unique blend of phytonutrients enable you to realign your sleep pattern, providing you with a more rejuvenating sleep, alleviate your mood and support your immune system.

KEY INGREDIENTS

Maizinol™ Corn grass (Zea mays leaf) - a proprietary extract derived from the leaves of specifically grown, non-genetically modified Zea mays (corn or maize) using commercial strains of corn approved for human consumption. Maizinol is a patented and natural mood health product that contains 6-methoxybenzoxazolinone (6-MBOA), which can act as a positive regulator of the melatonin system to enhance serotonin levels and improve mood. In addition, Maizinol has been clinically shown address both mental/mood imbalances and to provide sleep-improvement benefits that are superior to melatonin-based sleep aids.

BioKesum™ is a patented, standardized water-extract which functions as an all-around anti-aging ingredient. The raw material is sourced from Malaysian Kesum plant that is readily available all year round. BioKesum™ shows strong antioxidant properties that slow the oxidative processes and free radical damage. It has been clinically shown to improve cognitive function and memory function.

CLINICAL STUDIES

J Int Soc Sports Nutr. 2013; 10(Suppl 1): P26.

Effect of Monocot Grass Extract (MGE) on mood state and sleep patterns in moderately stress subjects
SM Talbott and JA Talbott

Abstract

Background

Overtraining syndrome (OTS) is a stress-related phenomenon experienced by elite-level and recreational athletes alike. Athletes are subjected to stressors from physical, psychological, and biochemical sources that may lead to OTS and significant decrements in mental and physical performance. OTS may be characterized by elevated perceived stress, reduced mood quality, increased tension/anxiety, and disrupted sleep quality/quantity; each of which can influence and compound the other, leading to a vicious cycle of increasingly poor performance, increased stress, and disrupted sleep patterns.

Methods

In this study, we supplemented moderately stressed subjects with an extract of monocot grasses (corn grass, wheat grass, and bamboo). Previous animal studies have shown significant anti-stress and relaxation benefits of monocot grass extracts (MGE), likely due to their content of plant metabolite 6-MBOA (6-methoxybenzoxazolinone) and its ability to influence serotonin levels. Fifty-two subjects were randomly assigned in double-blind fashion to receive MGE (N=27, 18 Female & 9 Male) or Placebo (N=25, 17 Female & 8 Male) for 4 weeks. We measured Mood State (Profile of Mood States), Sleep Quality (Pittsburgh Sleep Quality Index), and Sleep Patterns (ZEO Sleep Monitor) before and after 4 weeks of supplementation. Differences between MGE/Placebo at week 4 were analyzed by paired t-tests with an alpha level of 0.05 and reported as percent-difference between groups.

Results

Compared to the Placebo group, the MGE group (all $p < 0.05$):

- Had 8% less Tension (7.9 + 5.9 v. 8.6 + 5.5)
- Had 15% less Depression (6.8 + 6.9 v. 8.0 + 7.9)
- Had 25% less Irritability (6.4 + 5.0 v. 8.0 + 7.9)
- Fell asleep 33% faster (0.63 + 0.79 v. 0.84 + 0.90)
- Had 50% better sleep "efficiency" (0.26 + 0.59 v. 0.52 + 0.71)
- Had 40% better sleep "quality" (0.67 + 0.48 v. 1.12 + 0.97)
- Woke up 30% fewer times each night (2.1 + 2.5 v. 3.0 + 1.5)
- Experienced 24% more time in deep REM sleep (1.85 + 0.46h v. 1.41 + 0.30h)

Conclusion

Overall, these results indicate that the MGE supplement is effective in improving sleep quality and improving stress-related mood states in a population of moderately stressed subjects. Future studies are warranted to evaluate the specific effects of MGE in alleviating OTS in athletes and possibly improving physical and mental performance.

Foods 2015, 4, 130-139.

A Prospective Randomized Double-Blind Study Evaluating UP165 and S-Adenosyl-L-Methionine on Depression, Anxiety and Psychological Well-Being.

DS Kalman, S Feldman, RR Vazquez, and DR Krieger

Abstract

Background

The primary objective of this pilot clinical trial was to evaluate the effects of UP165 (derived from Zea mays L., commonly known as corn) over time. The secondary objective was the comparison for outcomes versus S-adenosyl-methionine (SAM-e). Subjects with mild depression or anxiety were given the Beck Depression Inventory second edition (BDI-II), the Beck Anxiety Inventory (BAI), and the Schwartz Outcome Scale (SOS-10). Forty-two subjects (21–65 years old) were randomized to eight-weeks of supplementation with UP165 or SAM-e with questionnaires being administered at randomization, week four and eight. Those receiving UP165 achieved significant reduction from baseline at weeks four and eight, respectively for the BDI-II, as well as a trend for reduction in BAI at week four and significance at week eight. There was a trend for improvement on the SOS at week four and significance at week eight. SAM-e demonstrated a trend for improvement on the BDI-II by week eight over the UP165 with no differences between the two for the BAI or

the SOS. Overall, this study indicates that there may be benefit to UP165 for mood enhancement in those with mild depression or anxiety. Randomized placebo comparator trials appear warranted.

CLINICAL DATA – Unpublished Research & Development Results (Unigen Pharma)

Summary

- Maizinol shows significant mood improvement in adults with a clinical diagnosis of mild to moderate depression.
- Maizinol shows significant improvement in ameliorating depression and anxiety among adults with mild to moderate depression and anxiety.
- Maizinol is equally effective as SAM-e in supporting mood and well-being but at a lower serving size and more convenient once-a-day dosage.
- Safe for human consumption at the recommended daily dosages.
- Non-habit forming and fewer possible side effects than SAM-e. The following section refers to the three human clinical trials that were performed to evaluate the efficacy and safety of Maizinol.

CLINICAL TRIAL #1

Study Design

The first human trial was performed with an extract of natural corn leaves spiked with a dose of 15 mg/daily dose of synthetic 6-MBOA, based on early anecdotal reports of use of this dose in humans without adverse effects and with reports of positive effects on animal models. The trial was a double blind, placebo-controlled, cross over trial in 15 healthy males. Screened subjects did not have a clinical diagnosis of depression; however, 2 enrolled subjects exceeded the Hospital Anxiety and Depression Scale (HAD) threshold for evidence of depression (Threshold=20; scores were 21.0 and 23.0).

The trial consisted of 3 phases:

- Phase 1 - subjects were randomly assigned to receive the 6-MBOA spiked extract or placebo for 14 days.
- Phase 2 - consisted of a seven-day washout, during which no study product was taken.
- Phase 3 - subjects were crossed-over to the alternate arm, while maintaining the blind.

Measurement & Analysis

During the 3 phases, the HAD and the Arizona Sexual Experience Index (ASEX, for sexual dysfunction) were administered weekly. In addition, physical exams and laboratory analysis were performed prior to Phase 1, between the Phases, and at the end of Phase 3. General comments about the study products were also elicited after the trial was completed. Fourteen subjects completed the trial.

Results

Including those subjects without initial evidence of depression on the HAD scale, a significant improvement in mood as assessed by this instrument was seen in 12 out of 14 subjects during the 2 weeks they were on the 6-MBOA spiked extract; no statistical change occurred during the 2 weeks in which subjects were on placebo. No changes were seen for subjects on the ASEX scale during either the 6-MBOA or placebo phases; however, subjects did spontaneously report improved sexual functioning during the end-of-study interview.

It is notable that no adverse effect on sexual functioning was detected during the trial, for a product with anti-depressant activity as this is a common side effect of prescription anti-depressant drugs.

CLINICAL TRIAL #2

Study Design & Measurement

The second clinical trial involved open-label, non-controlled administration of 20 mg synthetic 6-MBOA to 8 females with confirmed clinical depression (scored > 20 on the HAD Index) for 6 weeks. Assessments were performed every 2 weeks on the female subjects.

Results

Six out of the eight subjects showed responses to the open-label 6-MBOA, with an average decrease of 10.5 on the HAD Index over the 6 weeks. Although only 8 subjects were involved, the decreases in HAD scores obtained significance ($p<0.031$). No negative effects on sexual function were reported. (Internal communication from Seroctin Technologies, non-published data.)

Safety

In each of the aforementioned pilot human clinical studies, 15-20mg of synthetic 6-MBOA administered once a day was well-tolerated. The only side effect reported that could be potentially related to 6-MBOA was reports of mild gastrointestinal upset (transient nausea and indigestion).

CLINICAL TRIAL #3

A third human clinical trial evaluated the safety of the current formulation of Maizinol containing natural 6-MBOA. The 8-week study compared Maizinol to SAM-e (S-adenosylmethionine), a dietary supplement currently marketed for support of mood function.

Study Design

This was a randomized, double-blind, positive-controlled study of the safety of Maizinol and its effects on assessments of depression, anxiety, and well-being. This study enrolled adult male and female subjects, age 21–65 (inclusive), with complaints of mild depression and/or anxiety and with scores between 10 and 19 on the BDI-II and/or between 10 and 21 on the BAI (inclusive). Subjects were not currently taking nor had taken medications for depression and or anxiety in the past year. Subjects were either diagnosed with very mild depression and/or anxiety, or had no prior diagnosis of either disorder. Subjects with moderate or severe depression as defined by a score of > 19 on the BDI-II or subjects with moderate or severe anxiety as defined by a score of > 21 on the BAI were excluded from the trial.

The products tested were as follows:

- Maizinol (which contained not less than 0.2% natural 6-MBOA) 250 mg /day
- SAM-e (S-adenosylmethionine) 400 mg /day
- Placebo - microcrystalline cellulose with 0.5% magnesium stearate

The SAM-e group received a 200mg tablet in the AM dose and a 200mg tablet as the PM dose; the Maizinol group received a 250mg tablet in the AM dose, and placebo matched tablet in the PM dose.

Objectives

The primary efficacy objective of this study was to evaluate the effect of Maizinol on measures of depression, anxiety, well- being and sexual activity and compare to SAM-e in 40 subjects with mild depression and/or anxiety. The secondary efficacy objective of this study was to compare the effects of Maizinol to the dietary supplement SAM-e with regards to depression, anxiety, well-being and sexual functioning as measured by BDI-II, BAI, SOS-10, and ASEX scores in subjects with complaints of mild depression and anxiety.

Results

Both treatment groups showed significant decreases (improvements) in BDI-II scores from baseline to Week 4 and to Week 8. In addition, Maizinol is also shown to be equivalent to SAM-e with respect to ameliorating depression. Maizinol shows significant improvement in ameliorating depression and is equivalent to SAM-e in efficacy.

Based on the results summarized, there were significant (or near significant) decreases (improvements) in the Beck Anxiety Inventory score from baseline to Weeks 4 and Week 8 in both groups. Maizinol was demonstrated to be non-inferior to SAM-e in efficacy, with respect to the amelioration of anxiety. Maizinol was also shown to be equivalent to SAM-e in efficacy (a stronger result than non-inferiority), with respect to amelioration of anxiety.

SAFETY

No serious adverse events were noted during this trial. Adverse events were generally mild, were judged to be not related, or probably not related to study product, and were of similar prevalence and distribution over organ systems in the two products. No clinically important changes in vital signs (heart rate and blood pressure) or safety laboratory tests were observed. No product safety concerns were raised from this study. No significant changes were observed on the clinical safety chemistry and complete hematology profiles collected at baseline at 4 weeks and 8 weeks.

CONCLUSIONS

Based on the results of this clinical trial, Maizinol and SAM-e both produced significant improvements in the two efficacy endpoints (Depression, Anxiety). Maizinol was shown to be equivalent to SAM-e with respect to amelioration of depression (by the BDI-II scale). In addition, Maizinol was also shown to be equivalent to SAM-e with respect to amelioration of anxiety (by the BAI scale).

Clinical Interventions in Aging. 2015;10:1505-1520. doi:10.2147/CIA. S86411

The effect of Polygonum minus extract on cognitive and psychosocial parameters according to mood status among middle-aged women: a randomized, double-blind, placebo-controlled study.

Shahar S, Aziz AF, Ismail SNA, et al.

Abstract

Background

Polygonum minus (PM) or locally known in Malaysia, as "kesum" is rich in micronutrients and natural antioxidants. However, its beneficial effect on outcome associates with oxidative stress including cognitive function is yet to be discovered. We assessed the efficacy of PM extract (LineMinus™) on cognitive function and psychosocial status among middle-aged

women in Klang Valley of Malaysia.

Methods

A randomized, double-blind, placebo-controlled trial among 35 healthy middle-aged women was performed, and subjects were randomized to receive either 250 mg PM or placebo of 100 mg maltodextrin each were taken twice daily for 6 weeks. Subjects were assessed for neuropsychological test, psychosocial status, and anthropometric at baseline, week 3, and week 6. Biomarkers were also determined at baseline and week 6.

Results

The supplementation of PM showed significant intervention effect on Digit Span test ($P<0.05$) social functioning domain of 36-Item Short Form Health Survey ($P<0.05$) among subjects with mood disturbance. While, among subjects with good mood, PM supplementation improved Wechsler Abbreviated Scale of Intelligence (WASI) for IQ verbal ($P=0.016$) and Full Scale IQ of WASI ($P=0.004$). There were no adverse effects reported for the supplementation as indicated using biomarkers, including liver function and clinical symptoms.

Conclusion

Supplementation of PM is safe to be consumed for 6 weeks, with potential benefits to attention, short-term memory, improved quality of life, and mood, as well as IQ.

Evidence-Based Complementary and Alternative Medicine, vol. 2013, Article ID 238454, 10 pages, 2013. doi:10.1155/2013/238454

Effects of SuperUlam on Supporting Concentration and Mood: A Randomized, Double-Blind, Placebo-Controlled Crossover Study

Jay K Udani

Abstract

Background

SuperUlam is a proprietary blend of natural ingredients aimed at supporting brain health. We aimed to evaluate the effect of SuperUlam on attention and mood in healthy adults.

Methods

Twenty healthy individuals aged 35–65 were enrolled in this randomized, double-blind, placebo-controlled, crossover study. Study duration was 3 weeks and consisted of 3 visits. Measurement of cognitive function included computer-based testing of reaction time, complex attention, working memory, sustained attention, and executive functioning. Mood testing was performed via the profile of mood states (POMS) survey and the Chalder fatigue scale.

Results

Cognitive function testing demonstrated a significant improvement from baseline in executive functioning, cognitive flexibility, reaction time, and working memory in the product group only (). When comparing the study product to placebo, the data demonstrated a significant decrease in tension, depression, and anger ($P<0.05$)). There was

no significant difference between the product and placebo in the other measures of mood, including vigor, fatigue, confusion, and total mood disturbance. No adverse events were reported. Conclusions. Supplementation with SuperUlam is safe to consume with potential benefits to cognitive function and mood.

Pflugers Arch. 2012; 463(1): 121–137. Published online 2011 Nov 10. doi: 10.1007/s00424-011-1044-0

Sleep and immune function

Luciana Besedovsky,Tanja Lange,and Jan Born

Abstract

Sleep and the circadian system exert a strong regulatory influence on immune functions. Investigations of the normal sleep–wake cycle showed that immune parameters like numbers of undifferentiated naïve T cells and the production of pro-inflammatory cytokines exhibit peaks during early nocturnal sleep whereas circulating numbers of immune cells with immediate effector functions, like cytotoxic natural killer cells, as well as anti-inflammatory cytokine activity peak during daytime wakefulness. Although it is difficult to entirely dissect the influence of sleep from that of the circadian rhythm, comparisons of the effects of nocturnal sleep with those of 24-h periods of wakefulness suggest that sleep facilitates the extravasation of T cells and their possible redistribution to lymph nodes. Moreover, such studies revealed a selectively enhancing influence of sleep on cytokines promoting the interaction between antigen presenting cells and T helper cells, like interleukin-12. Sleep on the night after experimental vaccinations against hepatitis A produced a strong and persistent increase in the number of antigen-specific Th cells and antibody titres.

Together these findings indicate a specific role of sleep in the formation of immunological memory. This role appears to be associated in particular with the stage of slow wave sleep and the accompanying pro-inflammatory endocrine milieu that is hallmarked by high growth hormone and prolactin levels and low cortisol and catecholamine concentrations.