

The Effects of GABA, L-Theanine, Passiflora Incarnata and Prunus Cerasus in Reducing the Symptoms of Nervousness in Individuals with Anxiety and/or Depression

Gerry Lane*

Metabolic and Genetic Research Institute, Largo, Florida, USA

Abstract: *Introduction:* Affecting more than 21 million American children and adults, anxiety with or without depression is the leading cause of disability in the USA for individuals ages 15 – 44. Treatment, traditionally has been with prescription medication that is addictive, prone to pharmaceutical abuse and if prescribed appropriately, requires intensive physician involvement and monitoring. The utilization of herbal supplementation has been successfully utilized for many years to treat mood disorders, however scientific analysis of benefits has been lacking. The objective of this study is to scientifically analyze the effectiveness of the combination of GABA, L-theanine, passiflora incarnata and prunus cerasus in the treatment of the symptoms associated with Anxiety.

Methods: Two cohorts of volunteers received study compound (n=30) or placebo (n=30). Subjects were instructed to take 4 capsules daily for 7 consecutive days. Every participant completed both the HAM-A (Hamilton anxiety scale) and the SAS (Zung Self Rating Anxiety Scale). Both scales were completed pre & post study. The Student – T test was performed on all data.

Results: HAM-A: Subjects receiving active study compound showed marked improvements in the HAM-A global score. SAS: The Zung SAS symptom scores of all subjects receiving active study compound were markedly improved. There were no side effects reported by any of the study participants.

Conclusions: Subjects receiving this unique study compound (GABA, L-theanine, passiflora incarnata and prunus cerasus) received marked improvement in their symptoms of anxiety as demonstrated via two separate and clinically significant assessment tools (HAM-A & Zung SAS) when compared to placebo group. This combination of supplements represents a viable and safe adjunct to the short term treatment of mild to moderate anxiety without the use of prescription medication.

Keywords: Anxiety, GABA, L-theanine, passiflora incarnata, prunus cerasus.

INTRODUCTION

The combination of anxiety with depression is a chronic illness that exacts a significant toll on America's health and productivity. It affects more than 21 million American children and adults annually and is the leading cause of disability in the United States for individuals ages 15 to 44. Lost productive time among U.S. workers due to anxiety and depression is estimated to be in excess of \$42 [1] billion per year. Historically, the treatment of anxiety states includes the utilization of antipsychotics, hypnotics and addictive medications. When properly prescribed, the therapeutic approach would include frequent monitoring by a physician and close attention to the expression of side effects caused by medications [2]. The beneficial effects of the primary elements of this compound (GABA [3], L-theanine [4, 5], passiflora incarnata [6], prunus cerasus [7]) have been postulated to reduce anxiety and depression and have been used to control many of the symptoms associated with these disorders. In as much as each element has been studied

independently, this is the first research project to evaluate the effectiveness of this combination of ingredients. Following an extensive literature search, it is concluded that this combination of elements represents a truly novel and unique compound. This study is being performed to document the

METHODS

60 adult participants were randomized into 2 cohorts. 30 subjects received study compound and 30 subjects received placebo (200 mg capsule containing rice flour & gelatin, less than 1 calorie per capsule). All randomized subjects completed the Zung Self-Rating Anxiety Scale (SAS) [8] and the Hamilton Anxiety Rating Scale (HAM-A) [9] prior to randomization and then upon completion of a 7 day course of study compound taken 4 times per day. Individuals were enrolled based upon a self reporting of sign/symptoms of anxiety with or without depression. Those individuals were instructed to also obtain approval from their treating physician in order to continue with the study. All subjects were instructed to maintain their current treatment protocol including any psychoactive medications (antidepressants, anxiolytics and/or hypnotics). The SAS and HAM-A assessments were

*Address correspondence to this author at the Metabolic and Genetic Research Institute, Largo, Florida, USA; E-mail: ifmresearch@aol.com

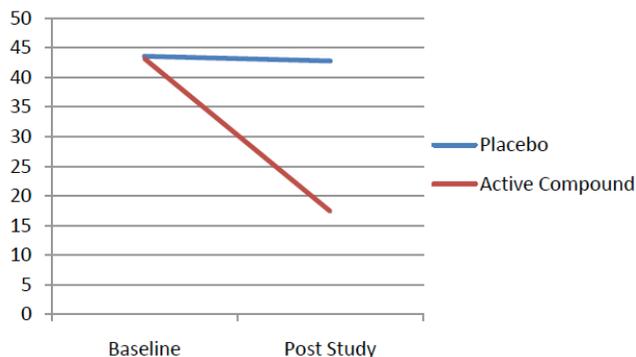
used to measure the subjective symptomology associated with anxiety and depression (i.e.: "I feel more nervous, I feel afraid for no reason, I get upset, I feel panicky, I feel like I'm falling apart etc.") as well as a measure of somatic signs associated with these feelings (i.e.: "my arms and legs shake and tremble, I have headaches and back pain, I feel my heart racing, I have stomach pain, I have nightmares, etc."). Two separate clinical measures were utilized in order to validate reproducibility and to eliminate bias that may be associated with only one assessment tool.

RESULTS

Independent Student-t test were performed to compare the active compound (n=30), vs. placebo (n=30)

HAM-A RESULTS: Subjects receiving active study compound showed marked improvements in the HAM-A global score. Average baseline score was 43.4 (range: 33-51, s.d.= 4.9) for all subjects. There was no significant difference between study group (43.2) and placebo group (43.6). The group receiving active compound had a post-study HAM-A mean score of 17.4 (range 8-25, s.d.=4.4), a reduction in their anxiety score of 59.7% ($p \leq 0.05$). Placebo group demonstrated a reduction in HAM-A score to 42.8 (range 36-45, s.d.=2.4), representing a decrease of subjective symptoms of only 3.9%, n.s.

HAM-A SCORES PRE & POST STUDY



ZUNG SAS RESULTS: The Zung SAS symptom scores of all subjects (n=30) receiving active study compound was markedly improved. Global SAS score decreased from an average of 3.6 to 1.4 (an improvement of 61.11%), ($p \leq 0.05$). Also marked improvement in the following parameters:

I feel more nervous and anxious than usual. (83.78% improvement), $p \leq 0.05$

I get upset easily or feel panicky. (72.47% improvement), $p \leq 0.05$

I feel like I'm falling apart and going to pieces. (68.39% improvement), $p \leq 0.05$

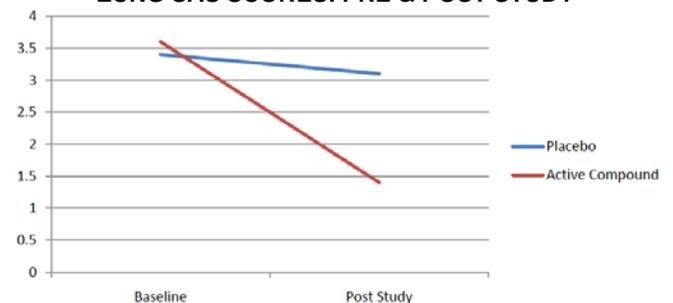
I feel calm and can sit still easily. (78.92% improvement), $p \leq 0.05$

I fall asleep easily and get a good night's rest. (70.71% improvement), $p \leq 0.05$

I have nightmares. (62.4% improvement), $p \leq 0.05$

Conversely, the placebo group demonstrated a change in the measurement of SAS scores from an average of 3.4 to 3.1 (improvement by 8.82%), n.s.

ZUNG SAS SCORES: PRE & POST STUDY



CONCLUSIONS

Subjects receiving this unique study compound (GABA, L-theanine, passiflora incarnata and prunus cerasus) received marked improvement in their symptoms of anxiety as demonstrated via two separate and clinically significant assessment tools (HAM-A & Zung SAS) when compared to placebo group. Statistical analysis revealed statistical significance ($P \leq 0.05$) demonstrating that the study compound has a direct influence in the modulation and improvement of the symptoms associated with anxiety. This combination of natural herbal supplements represents a viable and safe adjunct to the short term treatment of mild to moderate anxiety with or without the use of prescription medication. There were no side effects reported by any of the study participants (n=60).

ACKNOWLEDGEMENT

Dr. Lane is the Scientific Director of Metabolic and Genetic Research Institute: Largo, Florida. He is a graduate of Ohio University College of Osteopathic Medicine, Athens, Ohio and Past Associate Medical Director for Hilltop Research and Radiant Research, Columbus Ohio. Past Associate Professor of Medicine,

Ohio University, College of Osteopathic Medicine, Dept of Family Medicine & Geriatrics, Athens, Ohio.

REFERENCES

- [1] ADA. The Journal of Clinical Psychiatry 1999; 60(7).
- [2] Weich S, Pearce HL, Croft P, Singh S, Crome I, Bashford J, Frisher M. Effect of anxiolytic and hypnotic drug prescriptions on mortality hazards: retrospective cohort study. *BMJ* 2014; 348.
- [3] Inoue K, Shirai T, Ochiai H, *et al.* Blood-pressure-lowering effect of a novel fermented milk containing gamma-aminobutyric acid (GABA) in mild hypertensives. *Eur J Clin Nutr* 2003; 57: 490-495.
<http://dx.doi.org/10.1038/sj.ejcn.1601555>
- [4] Theanine. Natural Medicines Comprehensive Database. Therapeutic Research Faculty, 2013. 8 November 2013.
- [5] Wakabayashi C. *et al.* Behavioral and molecular evidence for psychotropic effects in L-theanine. *Psychopharmacology* 2011.
- [6] Dhawan K, Kumar S, Sharma A. Anxiolytic activity of aerial and underground parts of *Passiflora incarnate*. *Fitoterapia* 2001; 72 (8): 922-6.
[http://dx.doi.org/10.1016/S0367-326X\(01\)00322-7](http://dx.doi.org/10.1016/S0367-326X(01)00322-7)
- [7] Akhondzadeh S, Naghavi HR, Va M, Shayeganganpour A, Rashidi H, Khani M. Passionflower in the treatment of generalized anxiety: A pilot double-blind randomized controlled trial with oxazepam. *Journal of Clinical Pharmacology and Therapeutics* 26(5): 363-367.
- [8] Zung William WK. A rating instrument for anxiety disorders. *Psychosomatics* 1971.
[http://dx.doi.org/10.1016/S0033-3182\(71\)71479-0](http://dx.doi.org/10.1016/S0033-3182(71)71479-0)
- [9] Hamilton M. The assessment of anxiety states by rating. *Br J Med Psychol* 1959; 32: 50-55.
<http://dx.doi.org/10.1111/j.2044-8341.1959.tb00467.x>

Received on 06-11-2014

Accepted on 16-12-2014

Published on 22-12-2014

DOI: <http://dx.doi.org/10.6000/1929-5634.2014.03.04.5>