



## Effect of Combination Private Label Supplement *Revive* on Depression.

5 In house clinical trial recipients with confirmed depression and anxiety symptoms.

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### **Abstract:**

Depression is a mood disorder that causes changes in physical activity, appetite, sleep and weight. The present study was aimed to investigate the effects of a combined supplement formula in the treatment of this disease.

This study was a double-blind randomized clinical trial. Five patients with depression were given combination dietary supplements with co-enzyme factored formula. Patients received daily supplementation consisting of vitamins, minerals, herbs and fatty acids; for six weeks. Severity of depression was measured using the Beck Depression Inventory at baseline and was repeated at the sixth weeks post treatment. ANOVA with repeated measure was used to compare and track the changes during the study.

The mean score of Beck test decreased significantly when patients were given the combination supplement formula at the end of week 6 ( $P < 0.01$ ) compared to the baseline measures.

***The results of the present study indicate that the combination dietary supplement formula improves depressive disorder and can be effective in the treatment of patients with depression.***

**Keywords:** depressive disorder, dietary supplement, depression, supplementation

### **Introduction:**

Depression is one of the most common diseases in the world, with high levels of associated mortality. It affects people of every region in every ethnic group (1) to the extent that one out of every 5 people referred to a physician is affected by depression (2).

About 25% of patients with depression do not respond to antidepressants and about 30% of them have a recurrence; therefore, supplementation with micronutrients are increasingly of interest as an adjunct to Nutraceutical treatment or intervention has been recognized as effective by both professionals and consumers (1). In addition, this therapeutic modality has shown fewer side effects than conventional treatments (3).

Antidepressant pharmaceuticals such as Paxil, Zoloft and Prozac are among the most commonly prescribed drugs. These drugs were designed to regulate brain serotonin levels by preventing the presynaptic resorption of synaptic serotonin. This serotonin deficiency can be suffered in various degrees, leading to a host of mental, emotional and behavioral problems. Nevertheless, the wide use of these drugs, they have an array of side effects such as headaches, drowsiness, dry mouth, sexual dysfunctions and insomnia (4). Like many other diseases, depression can be treated and relieved by lifestyles and nutritional changes.

Serotonin, the precursor to melatonin, functions as an inhibitory neurotransmitter to reduce excitatory activity. Over time it can dampen the effects of dopamine and noradrenaline that stimulate over arousal, fear, anger, tension, aggression, violence, anxiety and sleep disturbances. Serotonin plays an integral role in supporting feelings of wellbeing, calmness, security, relaxation, confidence and concentration. Conversely, a deficiency of serotonin may be central in the development of depression, sleep disorders, obesity and addictions.

The present study was designed to examine the effects of the *Private Label Revive* supplementation in patients with depression.

## **Material and Methods**

### **Participants and Procedure:**

This study was a clinical trial of five cases that was performed patients with depression. Study population was among people with depression who were referred to the Berdiel clinic in Ponce, Puerto Rico. Sampling started after obtaining approval from the patients.

The patients were aged 18-55 years. The inclusion criteria included diagnosis of depressive disorder by a psychiatrist based on DSM-IV-TR, obtaining informed consent from the patients, no supplements usage at least four weeks before the study, not taking any medication except for those associated with depression status. The exclusion criteria included pregnancy or lactation, severe psychotic symptoms, changing drug class, symptoms requiring hospitalization including suicidal thoughts and actions.

Patients received a combination supplement consisting of vitamins, minerals, herbs and fatty acids to be taken daily. The components of this combination supplement formula: 5-hydroxytryptophan (5-HTP) is an intermediate metabolite of the amino acid L-tryptophan in the biosynthesis of serotonin. Intestinal

absorption of 5-HTP does not require the presence of other amino acids; therefore, it may be taken with meals without reducing its effectiveness. Unlike L-tryptophan, 5-HTP cannot be shunted into niacin of protein production. Therapeutic use of 5-HTP bypasses the conversion of L-tryptophan into 5-HTP by the enzyme tryptophan hydroxylase, which is the rate-limiting step in the synthesis of serotonin. 5-HTP is well absorbed from an oral dose, with about 70% ending up in the bloodstream. It easily crosses the blood-brain barrier and effectively increases central nervous system (CNS) synthesis of serotonin (5). For more information, see references (6-11).Omega-3 fatty acids: The fluidity of the CNS (brain and spinal nerves) is directly linked to behavior, mood and mental functioning. Diminished brain function can cause or significantly worsen depression (12).B-complex vitamin deficiency of B-vitamins can cause many nervous disorders including depression (13).St. John's Wort (*hypericum perforatum*, 3% hyperacin),this flower is indicated for mild to moderate depression and is best known for its MAO inhibitory activity. Monoamine oxidase is an enzyme that degrades serotonin, so by inhibiting the effect of MAO will prolong the halftime of serotonin (14).Ginkgo biloba: 24% ginkgo flavone and flavone glycosides. This tree has been helpful when depression is linked to a decline in mental function, especially in the elderly. Ginkgo works primarily by improving blood flow to the brain (15).

The Beck Depression Inventory (9), physical activity questionnaire, three-day dietary recall, and anthropometric indices were completed in the beginning and end of the study. Nutritionist IV software was used to analyze a three-day dietary recall. Macro and micronutrients intake was derived from the three-day dietary recall and compared between the two groups.

Also, at the beginning and end of the study, a blood sample of 5 ml was taken after a 12-hour fasting state for general laboratory tests such as

### **Statistical Analysis:**

Data analysis was performed using SPSS version 16. The Kolmogorov - Smirnov and chi-square tests were used to determine the normal distribution of quantitative data and to compare qualitative variables between the two groups, respectively. In the case of quantitative variables with normal distribution for comparison between the beginning and end of the intervention within each group, paired t-test, and for comparison between the two groups at the beginning or end of the intervention, t-test were used. The Wilcoxon and Mann-Whitney tests were used in the case of quantitative variables with non-normal distribution. To compare and track the change of means of quantitative variables that were measured three times during the study period, analysis of variance (ANOVA) with repeated measure was done. Covariance analysis was performed to adjust for quantitative confounding factors.

### **Results:**

In this study, all 5 patients receiving the supplement formula showed improvement. The patients were alike with respect to income, smoking, and no significant difference was observed between them.

Furthermore, the patients were statistically similar in terms physical activity, weight and BMI during the study. No significant difference was observed regarding dietary intake of energy, carbohydrate, protein, cholesterol, and fiber. During the study, dietary intakes of micronutrients such as zinc, magnesium, iron, vitamins B1, B2, B3, B6, B12 and folic acid were not significantly. . Depression scores decreased significantly in the zinc group in the sixth week ( $P < 0.01$ ), and the twelfth week of the study ( $P < 0.001$ ) compared to the baseline, but this difference was not statistically significant compared to the 6th and 12th week values.

At the end of the study (6 weeks), Beck scores was significantly lower ( $p < 0.05$ , from 30 to 15). Even after adjusting for the effect of dietary confounding factors, including intake of total fat, saturated fatty acids, MUFA and PUFA fatty acids and magnesium, this difference still remained significant.

Also Homocysteine and Cholesterol values decreased significantly ( $p < 0.05$ ).

### **Discussion:**

Studies on dietary factors and their relation to depression have shown that consumption of meals containing high amounts of carbohydrates cause insulin release. Insulin causes glucose entrance into the cells, and on the other hand make more amino acids such as tryptophan to cross the blood - brain barrier. This may increase neurotransmitter levels, especially serotonin, in the brain which can lead to improved mood (16). Amino acid tryptophan can be converted to serotonin in the body. Tyrosine amino acid can be synthesized from the amino acid phenylalanine and may enter into the biochemical pathways of dopamine and norepinephrine (17). Dietary omega-3 fatty acids are provided from some especial plant and animal sources (especially some marine animals). Omega-3 fatty acids are involved in regulating corticotropin factor, stimulating the serotonergic pathway, preventing neuronal apoptosis, improving blood flow to the brain and regulating gene expression (18). Folate and B12 deficiency are associated with depression. About 10 to 30% of depressed patients have low serum folate levels and their response to antidepressants is weak. Early vitamin B12 deficiency leads to depression. This is due to the reduced synthesis of S-Adenosyl Methionine (19). S-Adenosyl Methionine is associated with mood. The low concentrations in cerebrospinal fluid of depressed patients have been observed and it was found that increasing its plasma concentrations have improved the depressive symptoms (20). Also of interest is the decrease of homocysteine and cholesterol measures which are consider risk factors to several diseases.

In the present study, the supplementation formula significantly decreased the Beck depression scores.

### **Limitations:**

Limited Number of Patients.

### **Recommendations:**

We suggest the study should be performed in a larger group of patients in a double blind placebo controlled form.

**Conflict of interest:**

Authors have nothing to declare.

**Conclusion:**

The results of this study reveal that the **Revive all natural supplementation** formula can be effective in the treatment of patients with depression.

**INTERPRETING THE BECK DEPRESSION INVENTORY (BDI-II)**

Add up the score for each of the 21 questions by counting the number to the right of each marked question. The highest possible total for the whole test would be sixty-three and

The lowest possible score for the test would be zero. This would mean you circle zero on each

Question and you can evaluate your depression according to the Table below.

**Total Score Levels of Depression:**

0-10 = Considered to be normal ups and downs of mood

11-16 = Mild mood disturbance

17-20 = Borderline clinical depression

21-30 = Moderate depression

31-40 = Severe depression

Over 40 = Extreme depression

**References:**

1. Kleinman A. Culture and depression. N Engl J Med. 2004;351:951–3.
2. Kaplan H, Sadock B. Synopsis of psychiatry. 8th eds. Williams and Wilkins; 2003.
3. Fava M, Davidson KG. Definition and Epidemiology of Treatment-Resistant Depression. The Psychiatric clinics of North America. 1996;19:179–200.
4. Knutson B, Wolkowitz OM, Cole SW, et al. Selective alteration of personality and social behavior by serotonergic intervention. AM J Psychiatry. 1998, 155: 373-79.
5. Van Praag H and Kahn R. L-5 hydroxytryptophan in depression and anxiety. Schwein Rundschau Med. 1998, 77:40-46.
6. Asberg M, Thoren P, Traskman L, et al. Serotonin depression: a biochemical subgroup within affective disorder. Science. 1976, 197:478-480.
7. Von Praag HM and Korf J. L-tryptophan in depression. Lancet. 1970, 2:612.

8. Kahan R and Westernberg H. L-5 hydroxytryptophan in the treatment of anxiety disorders. *J Affect Disord* 1985, 8:197-200.
  9. Yaryura-Tobias J and Bhagavan H. L-hydroxytryptophan in obsessive compulsive disorders. *Am J Psychiatry* 1977, 134:298-299.
  10. Persson T and Roos B. L-5 hydroxytryptophan for depression. *Lancet*. 1967ii 987.
  11. Sano I. L-5 hydroxytryptophan (L-5HTP) Therapy. *Folia Psychiat Neurol J*. 1972, 26:7.
  12. Ellis FR and Sanders TAB. Long chain polyunsaturated fatty acids in endogenous depression. *J Neural Neuro Surg Psychiatr*. 1977, 40:168-69.
  13. Bell I, et al. B Complex vitamin patterns in geriatric and young adult patients with major depression. *J Am Geriatr Soc*. 1991, 39:252-257.
  14. Harrer G and Sommer H. Treatment of mild/moderate depression with hypericum. *Phyto Medicine*. 1994, 1:3-8.
  15. Kleijnen J and Knipschild P. Ginkgo Biloba. *The Lancet*. 1992, 340:136-139.
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16. White JW, Wolraich M. Effect of Sugar on Behavior and Mental Performance. *Am j clin Nutr* 1995;62:242S–247S.
  17. Kravitz HM, Sabelli HC, Fawcett J. Dietary Supplements of Phenylalanine and Other Amino Acid Precursors of Brain Neuroamines in the Treatment of Depressive Disorders. *J Am Osteopath Assoc* 1984;84:119–123.
  16. Freeman MP, Hibbeln JR, Wisner KL, Davis JM, Mischoulon D, Peet M, et al. Omega-3 Fatty Acids: Evidence Basis for Treatment and Future Research in Psychiatry. *J clin Psychiat* 2006;67:1954–1967.
  19. Fava M, Borus JS, Alpert JE, Nierenberg AA, Rosenbaum JF, Bottiglieri T. Folate, Vitamin B12, and Homocysteine in Major Depressive Disorder. *Am J Psychiat* 1997;154:426–428.
  20. Bell KM, Potkin SG, Carreon D, Plon L. S-Adenosylmethionine Blood Levels in Major Depression: Changes with Drug Treatment. *Acta neurologi Scand Supple*. 1994;154:15–18.

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