

### Effect of the Vemma Formula on Immune Function and Inflammation in Humans: A Randomized Double-Blind Placebo-Controlled Trial

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### **ABSTRACT**

**OBJECTIVES:** To examine anti-inflammatory, immune-regulatory and liver bile duct-protective effects of the Vemma formula found in the Vemma Nutrition Program in the human body. This program is a multivitamin/antioxidant liquid supplement containing a full spectrum of vitamins, plant-sourced minerals, mangosteen fruit and pericarp, aloe vera and green tea.

**DESIGN, SETTINGS, AND PATIENTS:** A randomized, double-blind, placebo controlled clinical trial was conducted using 30 men and 30 women age 40 to 65. Participants were randomly divided into two groups, the Vemma formula or a placebo (a liquid that looks and tastes like Vemma, but with no active ingredients) with the same number of male and female participants in each group. The duration of the trial was 30 days.

**INTERVENTION MEASURES:** When the baseline tests were completed, participants received a dose (2 ounces/59 ml) of either the Vemma formula or an identical inactive placebo each morning before breakfast. Full compliance was assured by onsite monitoring. Blood samples were collected from each subject before (Day 0) and after consumption (Day 30) of the test formula to determine the indices of interest.

#### IMMUNE FUNCTION

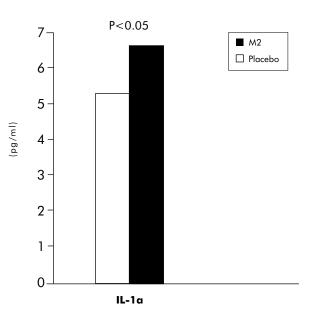
**RESULTS:** T Helper cell (Th cells), Interleukin -1a (IL-1a), Complement 3 (C3), Complement 4 (C4), and C Reactive Protein (CRP) all showed positive statistical significance in differences when compared to placebo after 30 days of Vemma consumption.

The increase in the percentage of the Th cells in the Vemma group was relatively greater than that in the control group. As a result, at the end of the study period, the percentage of Th cells in the Vemma group was statistically significantly higher than that at the baseline. This indicates a significant increase in immune enhancement and function.

At the end of the study period the IL- $1\alpha$  level in the Vemma group was statistically significantly higher than that in the control group, implying that the IL- $1\alpha$  level was increased by Vemma during the trial. This again shows a significant increase in immune enhancement and function.

The increases in serum C3 and C4 concentrations were statistically significantly higher in the Vemma group than in the control at the end of the trial. The C3 and C4 systems are involved in defense against microorganisms, the processing of immune complexes and apoptotic (resulting from cell death) debris, and the development of an appropriate immune response.

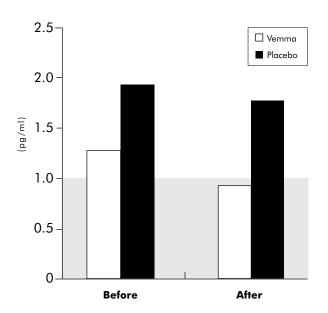
### Changes in Serum IL-1 $\alpha$ Concentration



## C-REACTIVE PROTEIN - INFLAMMATION

In the present study, Vemma also decreased serum C-Reactive Protein (CRP), an indicator of acute inflammation level, suggesting that consumption of the Vemma formula may be beneficial to the immunological system. Serum CRP concentration decreased in a statistically significant way after consumption of the Vemma, whereas no significant change was observed in the control group. CRP is one of the acute phase proteins that increases during systemic inflammation, which is a normal response to many physical states including fever, injury and infection. It is now believed to play a role in the initiation and progression of cardiovascular disease. Our results showed the participants of the Vemma group were reduced to the low risk range (<1 mg/L) of CRP levels. Our finding suggests that consumption of Vemma may be able to lead to a statistically significant reduction in inflammation in the body.

#### **Serum CRP Concentration**



Shaded area indicates that only Vemma had low risk range (<1 mg/L) of CRP levels. White area is high risk range of CRP levels.

# SELF REPORTED HEALTH STATUS

30 (100%) of the subjects in the Vemma formula group reported that they felt that their health status improved after drinking the formula, significantly more so than that in the control group. Among those who reported improvement, only 7 (24%) in the placebo group reported that they feel much improved, significantly less than the 23 (77%) subjects in the Vemma formula group.

**CONCLUSIONS:** Our findings showed that consumption of the Vemma formula was beneficial to the subjects' overall health status realizing a statistically significant increase in immune function and a statistically significant decrease in CRP (inflammation). Further studies are needed to ascertain the long term effect.

## **Self Reported Health Status**

