

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

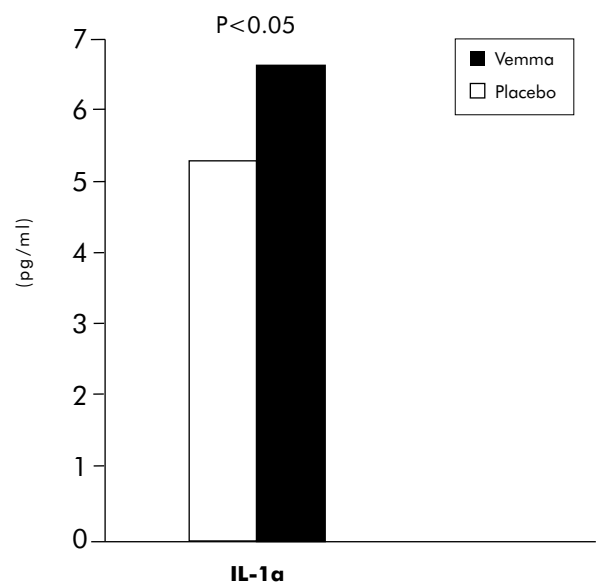
RESULTS: T Helper cell (Th cells), Interleukin -1a (IL-1a), Complement 3 (C3), Complement 4 (C4), and C Reactive Protein (CRP) all showed positive statistical significance in differences when compared to placebo after 30 days of Vemma consumption.

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 α level in the Vemma group was statistically significantly higher than that in the control group, implying that the IL-1 α 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.

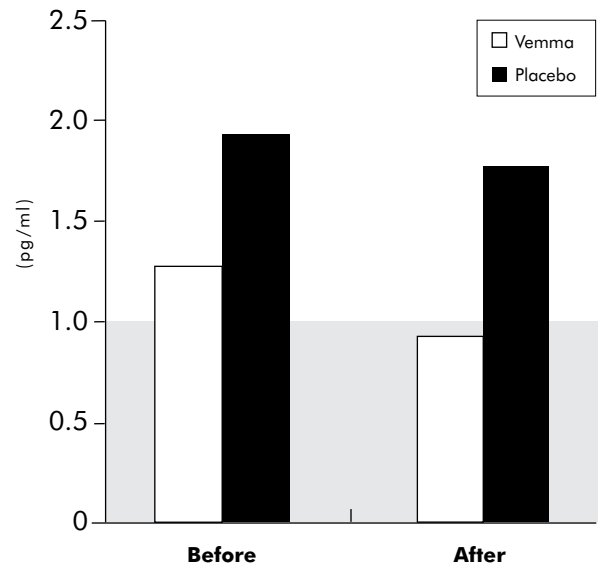
Changes in Serum IL-1 α Concentration



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



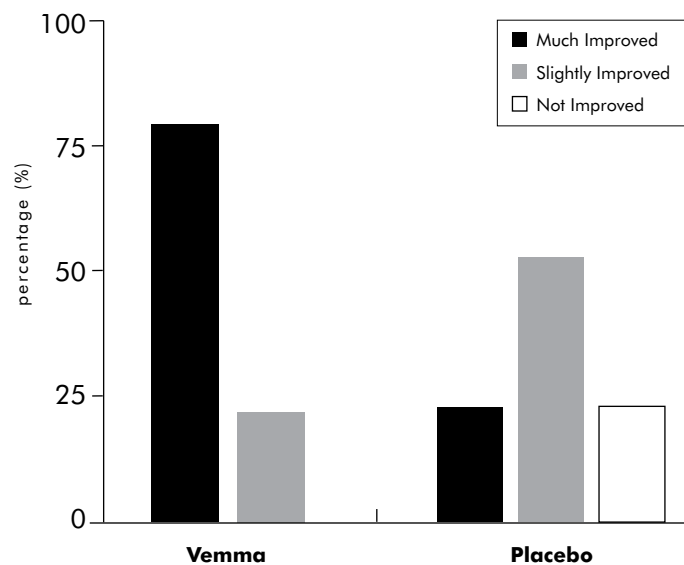
Shaded area indicates that only Vemma had low risk range (<1 mg/L) of CRP levels. White area is high risk range of CRP levels.

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



Bioavailability and Antioxidant Effects of the Vemma Formula in Humans

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ABSTRACT

OBJECTIVES: To determine the overall bioavailability 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.

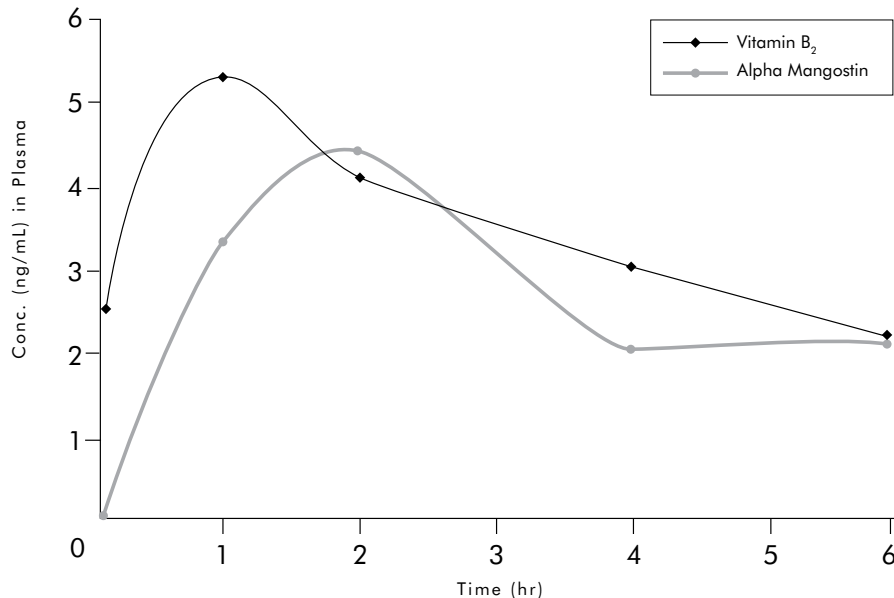
DESIGN, SETTINGS, AND PATIENTS: A randomized, double-blind, placebo controlled clinical trial was conducted using 20 participants, 10 men and 10 women age 40 to 65. Participants were randomly divided into two groups, placebo and the Vemma formula, with the same number of male and female participants in each group. The trial duration was 24 hours.

INTERVENTION MEASURES: After the baseline tests were completed, participants received either a single dose (2 ounces/59ml) of the Vemma formula or a placebo (a liquid that looks and tastes like Vemma, but with no active ingredients) before breakfast on one morning. Trial participants stayed onsite for the duration of the study (24 hours) to ensure total compliance. Blood samples were collected from each subject before and after consumption of the Vemma formula or the placebo to determine the indices of interest.

BIOAVAILABILITY

RESULTS: Bioavailability was seen in Vitamins B₂, B₃, B₅, D₃, xanthone α -Mangostin and antioxidant capacity. Bioavailability is defined as the proportion in a substance that is absorbed and utilized by the body. Until a nutrient is absorbed from the gastrointestinal tract and enters the systemic circulation, it is not available for use by the body. In the experiment group, within two hours after consumption of the Vemma formula, Vitamins B₂, B₃, B₅, ORAC (antioxidant levels) and alpha-mangostin reached their maximum concentrations in these patients.

Concentration of Markers in Human Plasma after 60mL of Vemma

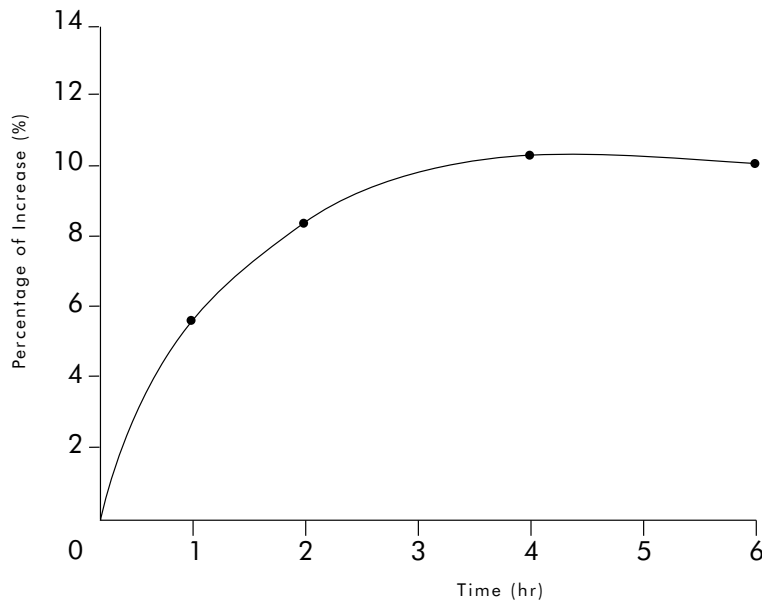


ANTIOXIDANT CAPACITY

Antioxidants are thought to help because they can neutralize free radicals, which are toxic byproducts of natural cell metabolism. The human body naturally produces antioxidants but the process isn't 100 percent effective and that effectiveness declines with age. The ORAC score (Oxygen Radical Absorbance Capacity) is a method of measuring the antioxidant potency. Antioxidants help prevent oxidation by counteracting free radicals. They do this by binding to them and transforming them into non-damaging compounds. Xanthones, a particular class of plant nutrients, are highly, biologically active and are unique because they possess very potent antioxidant properties. The xanthone source of the Vemma formula consists of whole fruit mangosteen and pericarp (rind) extract. Vitamins as we all know serve many functions and purposes in a healthy body.

The human serum antioxidant capacity increased by approximately 10 percent by hour 4 and stayed elevated through hour 6, the last blood draw in the trial. In the placebo group, which did not receive the Vemma formula, no change was observed on Vitamins B₂, B₃, B₅ and D₃. In addition, alpha-mangostin was not detected in the placebo group.

Plasma Antioxidant Capacity after Vemma



CONCLUSIONS: Consumption of a single 2 ounce dose of Vemma resulted in a statistically significant increase in Vitamins B₂, B₃, B₅, D₃, xanthone α -Mangostin and antioxidant capacity in the blood plasma. The elevated level of human serum antioxidant capacity was sustained through hour 6 of the study after the intake of the Vemma formula. In the placebo group, no change was observed.