

April 2008

A Randomized, Double-blind, Placebo-controlled, Clinical Study of the Immunomodulation and General Effects of a Standardized *Lycium barbarum* (Goji) Juice, GoChi™

BACKGROUND

For thousands of years, the goji berry (*Lycium barbarum*) has been a mainstay of Traditional Chinese Medicine (TCM), and its remarkable and diverse health-promoting properties have earned it a reputation as Asia's most potent health food. Goji's ancient tradition is now being confirmed by modern science, and dozens of published research papers have revealed that the goji berry's broad-based health benefits are due primarily to the presence of unique molecules, not found in any other fruit, called *Lycium barbarum* polysaccharides (LBP). Unlike dried berries or any other goji product, FreeLife's GoChi™ is standardized to an unprecedented potency of the all-important LBP.

In a recent clinical study, which was accepted for publication in the peer-reviewed *Journal of Alternative and Complementary Medicine*, participants who used GoChi experienced significant improvement in 13 key aspects of health and well-being in just 14 days.* The present immune study is yet another demonstration of the remarkable power of GoChi, and it illustrates FreeLife's ongoing commitment to lead the nutrition industry in clinical research, product efficacy, and evidence-based product formulation.

REASONS FOR THE STUDY

From the earliest writings, the medical texts of Asia have declared the goji berry to be highly superior for maintaining the health and well-being of the entire body. The ancient herbalists had observed that those who used goji on a daily basis were healthier, more resistant to stress, and more resilient in their ability to recover from adversity. Today, scientists believe that these far-ranging traditionally observed benefits are directly related to the effects of goji's unique bioactive polysaccharides (LBP) on the immune system, and this connection has been demonstrated in studies by numerous researchers. These investigations, however, have been performed primarily in cell culture and in animals. Although they may be predictive of the action of LBP in humans, they are not the equivalent of a controlled human trial. And so, this study was undertaken to scientifically investigate 4000 years of tradition by examining the effect of GoChi – a juice standardized to an exceptionally high potency of LBP – on three key serum markers of immunity. FreeLife® also sought to replicate the improvements in general well-being and neurological and psychological performance that were observed in its previous research.

STUDY DESIGN

This randomized, double-blind, and placebo-controlled 30-day clinical trial was conducted at a prestigious independent research institute in Asia and was designed to conform to the spirit of FDA Good Clinical Practice. Sixty healthy adult subjects were divided into two groups selected at random to ensure fair and even distribution of age, gender, health, and immune status between the two groups. The **GoChi group** was administered 120 ml (4 fl. oz.) daily of GoChi. The **placebo group** received the same daily dosing of an inactive placebo; a control solution that tasted, smelled, and looked like GoChi, but did not contain any goji juice or LBP. Neither the participants nor the scientists had any knowledge as to which group was drinking the GoChi and which was drinking the placebo. Furthermore, the participants and scientists had no affiliation with FreeLife, and had no familiarity with GoChi or Himalayan Goji® Juice prior to the start of the study.

Before beginning the study, all participants were given questionnaires to assess their starting point values for general well-being, and neurological and psychological performance. To determine starting point immune status, extensive physical exams were given, including blood chemistry, and urine and stool analysis. There were no significant differences between the two groups at the starting point, thus confirming suitability and compatibility. After the 30-day

duration of the trial, complete workups were performed once again on all participants to determine statistically if there were any significant changes in each category between the start of the study and its completion. These tests found no abnormal changes in body weight, blood pressure, pulse rate, urine, stool, blood panel, and blood biochemistry in either group, and there were no adverse events reported by any subjects in either the GoChi or the placebo group during the study period, thus demonstrating the safety of GoChi.

RESULTS

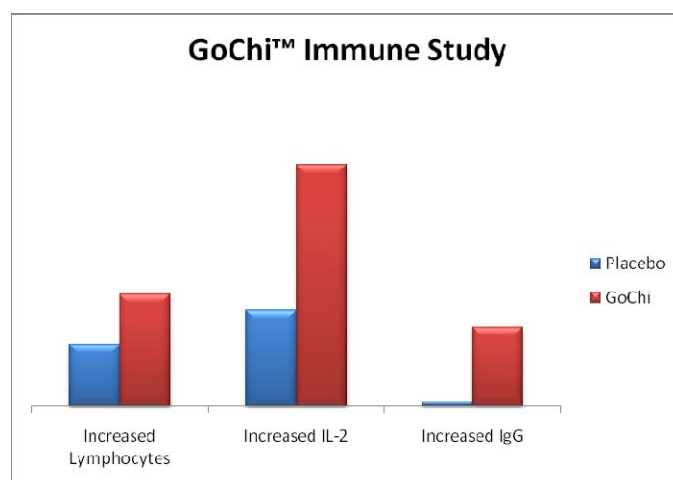
After 30 days, the GoChi group showed statistically significant ($p < 0.05$) improvements in three key markers of immune health:

- First noted was a 27% increase in **lymphocytes**. These small white blood cells defend the body against bacteria, viruses, and toxins, and they also serve to command and direct many other immune functions.
- Also found was a 58% increase in **interleukin-2 (IL-2)**, a special cell messenger protein that alerts the immune system when danger is present. IL-2 also recruits stem cells for conversion into a wide range of T-cells, a vital part of the body's targeted response to specific threats.
- Another important finding was a 19% increase in **immunoglobulin G (IgG)**, a powerful and essential antibody that seeks out bacteria, viruses, molds, yeasts, and allergens, and then marks them for destruction by other divisions of the immune system.

Unlike the GoChi group, the placebo group experienced no meaningful change in immune status. When compared to the placebo group, the GoChi group also experienced far greater and statistically significant ($p < 0.05$) improvement in well-being, with a 63% total improvement in areas such as reduced fatigue and improved sleep quality, and with a tendency toward improved short-term memory and mental focus over the trial period. These findings were consistent with those shown in previous GoChi studies.

CONCLUSION

The results shown in this randomized, double-blind, placebo-controlled clinical study clearly indicate that daily consumption of GoChi for 30 days can significantly improve three key aspects of healthy immune function, and the study re-confirms previous findings that GoChi can improve general health and well-being with no observed toxicity or side effects.*



For use in the United States, Canada, and Puerto Rico only.

* This statement has not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.