

A double blind comparative pilot trial evaluating the effect of whey protein isolate and isolated soy protein in healthy adults

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INTRODUCTION

This paper covers the results from “A comparative pilot trial evaluating the effect of whey protein isolate and isolated soy protein in healthy adults”. This study was funded by Davisco Foods International, and was conducted at Peak Wellness, Inc. in Greenwich, CT.

With all the accumulating evidence regarding the beneficial properties of whey protein isolate (WPI) and soy protein isolate, commonly referred to as isolated soy protein (ISP), it is desirable to compare some of the benefits these protein sources may offer to a person seeking and living a healthy lifestyle. Research has revealed positive health benefits from both WPI and ISP. For example, soy protein is believed to reduce cholesterol (Gardner, Newell et al. 2001), reduce the incidence of certain cancers (Hakkak, Korourian et al. 2000; Ronis, Rowland et al. 2001), maintain bone mineral density important for the prevention of osteoporosis, and reduce menopausal symptoms. Whey protein has been extensively researched in clinical trials for its effect on the immune system (Bounous, Batist et al. 1989; Bounous, Gervais et al. 1989; Bounous, Batist et al. 1991; Bounous and Gold 1991; Bounous, Barauchel et al. 1992; Bounous and Molson 1999), for enhancing protein synthesis and athletic recovery (Schena, Guerrini et al. 1992; Esmarck, Anderson et al. 2001), and for its content of bioactive peptides (Meisel, Frister et al. 1989; Guimont, Marchall et al. 1997; Mullally, Meisel et al. 1997).

However, despite both these proteins being promoted in the consumer market, limited comparative data exist with respect to their effects on blood and other parameters as indices of general health.

OBJECTIVE

The objective of this pilot trial was to define the effect of WPI and ISP, in healthy exercising adults, in terms of body composition, exercise performance, immune system parameters, serum amino acids, sex hormones, thyroid function and blood lipid profile.

STUDY DESIGN

The design of the study was a double blind, prospective and randomized pilot trial that was 12 weeks long. To participate in the study, subjects were required to be greater than 18 years of age, and have a minimum of 6 months of weight training experience. In total 30 adults were recruited for the study and randomized into 1 of 2 groups. Fifteen (15) subjects received WPI, specifically **BiPRO**® manufactured by Davisco Foods International, Inc. and 15 subjects received ISP, specifically **SUPRO**® manufactured by Protein Technologies, Inc.

As a brief comparison, the composition and protein quality of WPI and ISP is shown in Figure 1. WPI has a higher protein content of 97.5% on a dry weight basis, compared to 92.5% protein on a dry weight basis for ISP. There are only minor differences in the other components. For protein quality, both proteins have the maximum value of 1.0 for PDCAAS, protein digestibility corrected amino acid score, indicating that both proteins have the ability to supply essential amino acids in the minimum amounts needed to meet human requirements.

Figure 1. Composition and Protein Quality

COMPOSITION	WPI¹	ISP²
Protein (% db)	97.5	92.5
Fat (%)	1.0	3.0
Ash (%)	3.0	4.1
Moisture (%)	5.0	5.0
Carbohydrate (%)	1.0	0.0
PROTEIN QUALITY		
PDCAAS	1.0	1.0

¹Davisco Foods International, Inc.

²Protein Technologies, Inc.

For this study, protein supplements in the form of chocolate flavored powdered beverage mixes were developed. The beverages were formulated to contain 30g protein per serving and were flavored to mask any difference in taste between WPI and ISP. Researchers and subjects were blinded to the identity of the protein supplement. Participants were instructed to consume 2 servings daily for a total of 60g protein per day.

Subjects performed resistance training 3 times per week. This training was a full body type program that was supervised at the facility by the exercise physiology department. Participants also completed 24-hour diet recalls and met biweekly with a registered dietician to ensure dietary and supplement compliance.

A brief summary of the data collected throughout the study included body composition measurements and blood analysis. Body composition tests included monitoring of body weight and percentage of body fat, with body fat percentage tested using bioelectric impedance analysis and Lange calipers. Specific blood tests were taken at Week 0 (baseline), Week 6 and Week 12. These blood tests included the amino acids glutamate, cystine, methionine, lysine and the antioxidant glutathione. There was also blood withdrawn for thyroid function (T3, T4 and TSH), cholesterol, including total cholesterol, HDL, LDL, triglycerides, and the hormones, testosterone and estradiol.

DATA ANALYSIS

In total, 12 weeks of data were analyzed. Data were analyzed for differences between the groups, meaning the WPI supplemented group and the ISP supplemented group. Data were also analyzed for differences between the sexes in each group to determine a gender

effect. P values < 0.05 were considered statistically significant. Of the 30 participants that started the study, 3 people dropped out during the study and therefore 27 participants were included in the analysis, with 14 subjects in the whey group and 13 subjects in the soy group. By gender, there were 16 females and 11 males in the study.

RESULTS

The following graphs will illustrate the significant results from the study.

Glutathione

Figure 2 shows the glutathione (GSH) results from analyzing the data for all subjects. There was a significant increase in GSH within the WPI group at both Week 6 and Week 12. There was no significant change in GSH within the ISP group over the 12 weeks of the study.

Figure 2. Glutathione Results for All Subjects

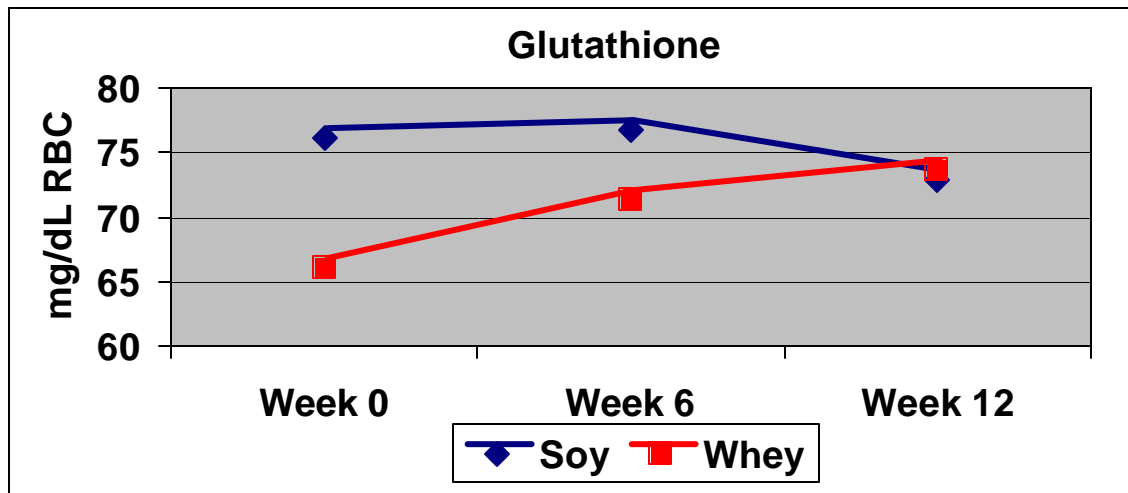
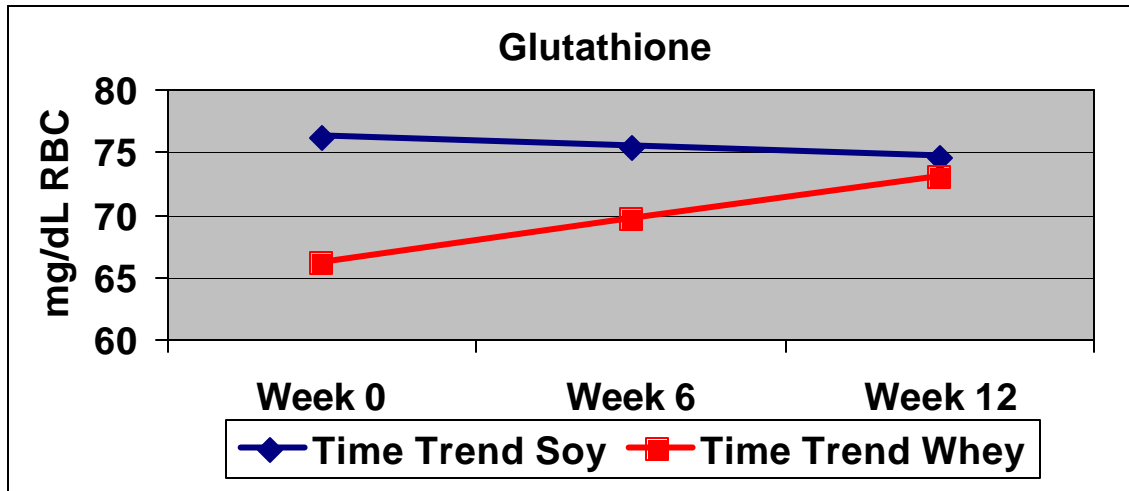


Figure 3 shows the same data as Figure 2 but represents the time trend analysis. The time trend represents the mean change in GSH at 6-week intervals. Group analysis revealed significantly different time trends between the two groups. Within the WPI group, the average GSH value increased 3.46 units per 6 weeks, while in the ISP group, the average GSH value decreased 0.79 units per 6 weeks. These results indicate that WPI bolsters glutathione, a key antioxidant in the red blood cell, which may prolong the life of the cell, enhance immunity and promote health in general, while ISP may not have the same effect on cellular health.

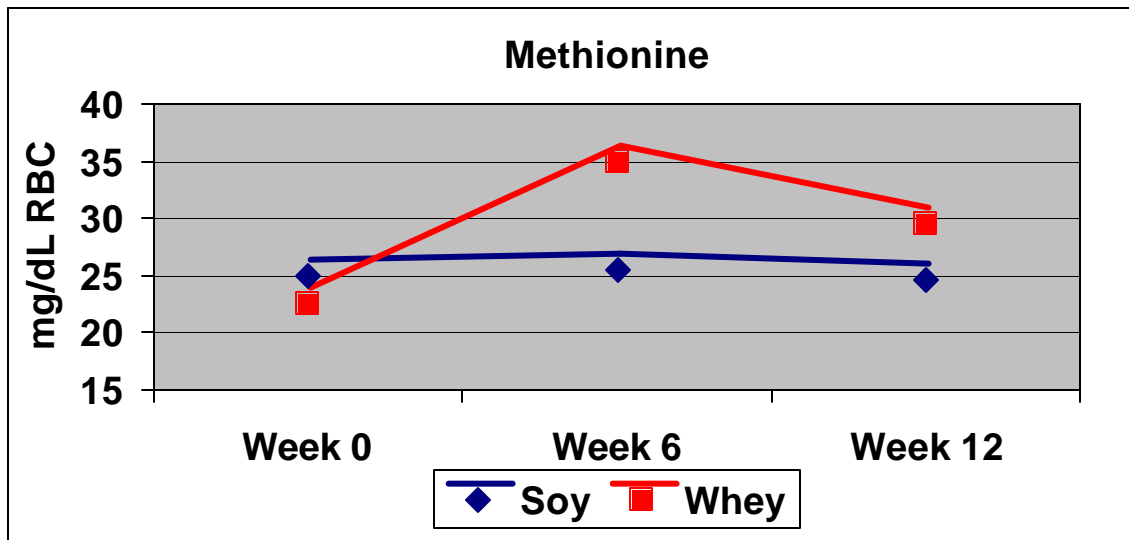
Figure 3. Glutathione Results for All Subjects (time trend data)



Methionine Results for All Subjects

Shown in Figure 4 are the methionine results, from analyzing the data for all subjects. Within the WPI group, over six weeks, there was a significant increase in methionine levels of 12.29 units from Week 0 values. Over the 12 weeks, the WPI group also showed a significant increase in methionine, an increase of 7.5 units from Week 0. The ISP group did not have any significant changes in serum methionine over 6 or 12 weeks. These results indicate that although WPI and ISP have the same PDCAAS values, indicating high protein quality, only WPI had an impact on serum methionine levels which may be attributable to the higher methionine levels in WPI compared to ISP.

Figure 4. Methionine Results for All Subjects

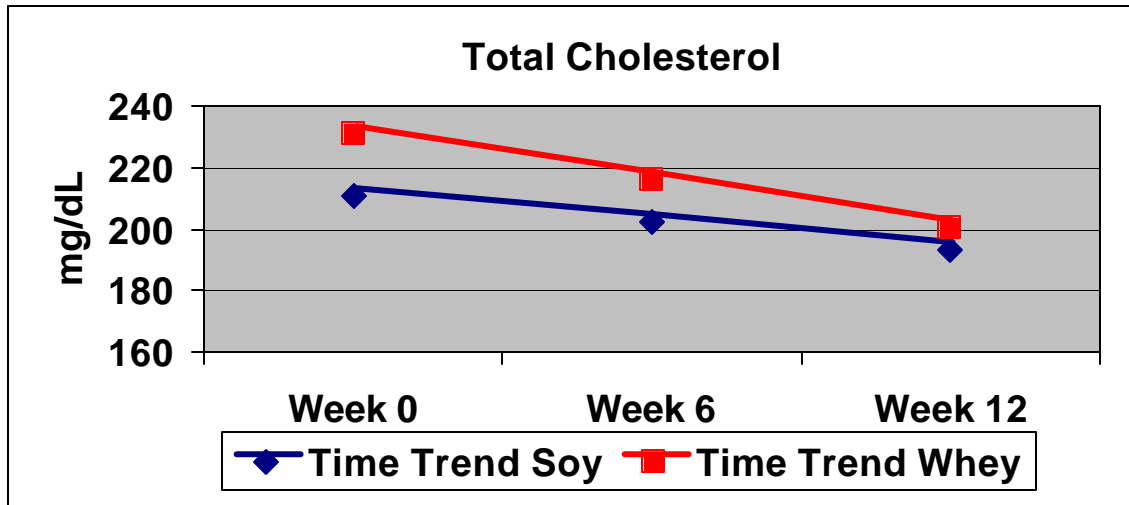


Blood Lipids

Total Cholesterol Results for All Subjects

Shown in Figure 5 are the time trend results for total cholesterol. There was a significant decrease in total cholesterol within both the WPI group and the ISP group after 12 weeks, a decrease of 15% for WPI and 6% for ISP. However, there was no significant difference between groups. These results are promising for WPI, given the numerous publications showing the cholesterol lowering effect of soy protein and the recently approved health claim in the United States for soy protein and cardiovascular health.

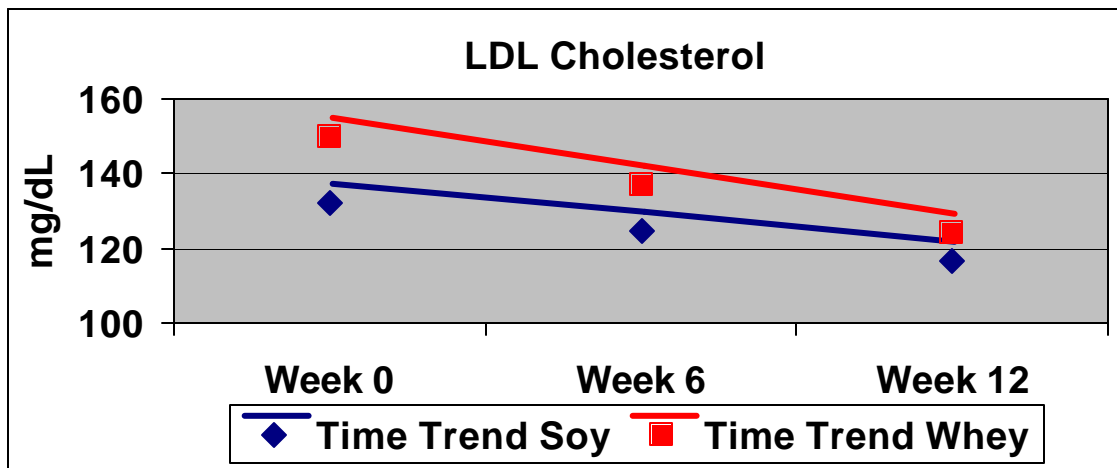
Figure 5. Total Cholesterol Results for All Subjects (time trend data)



LDL Cholesterol Results for All Subjects (time trend data)

Shown in Figure 6 are the time trend data for LDL cholesterol. There was a significant decrease in LDL cholesterol within each group, a drop of 10% for the ISP group, and a drop of 20% for the WPI group. However, there was no significant difference between groups.

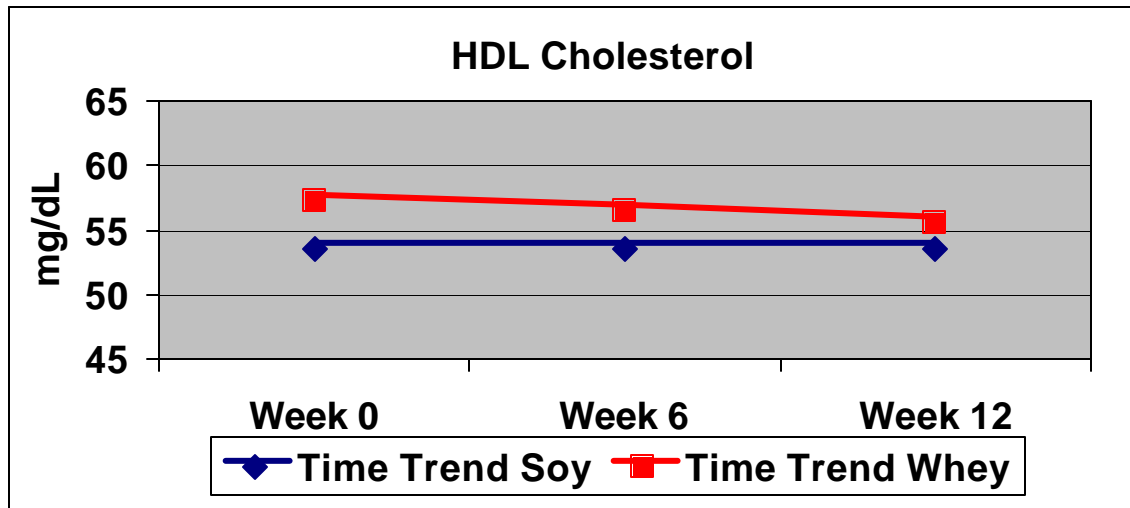
Figure 6. LDL Cholesterol Results for All Subjects (time trend data)



HDL Cholesterol Results for All Subjects

Shown in Figure 7 are the time trend data for HDL cholesterol. No significant changes in HDL cholesterol were seen in either group.

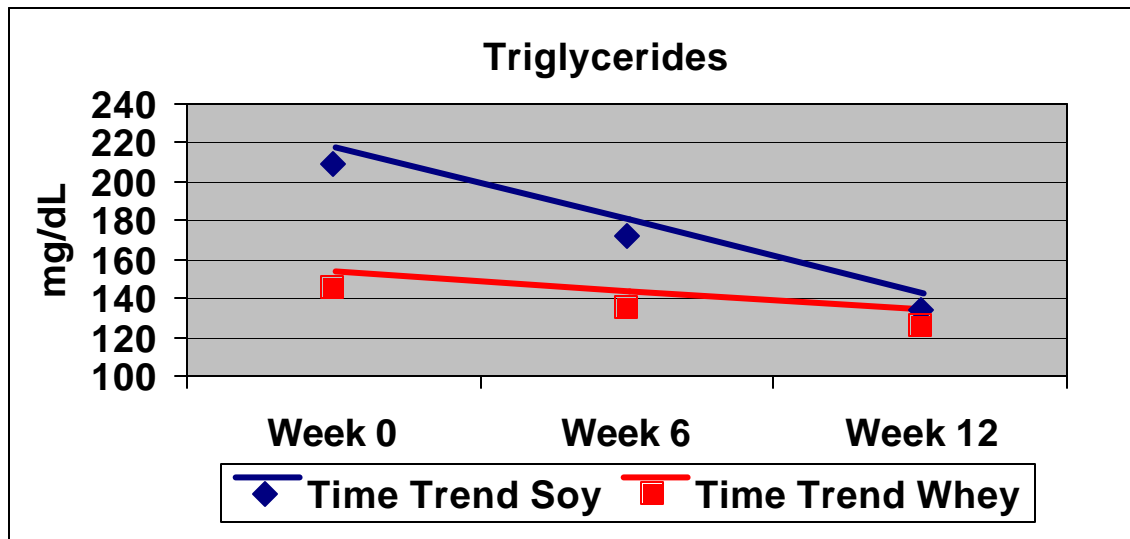
Figure 7. HDL Cholesterol Results for All Subjects (time trend data)



Triglyceride Results for All Subjects (time trend data)

Figure 8 shows the time trend data for triglycerides. There was only a significant drop in triglycerides within the ISP group.

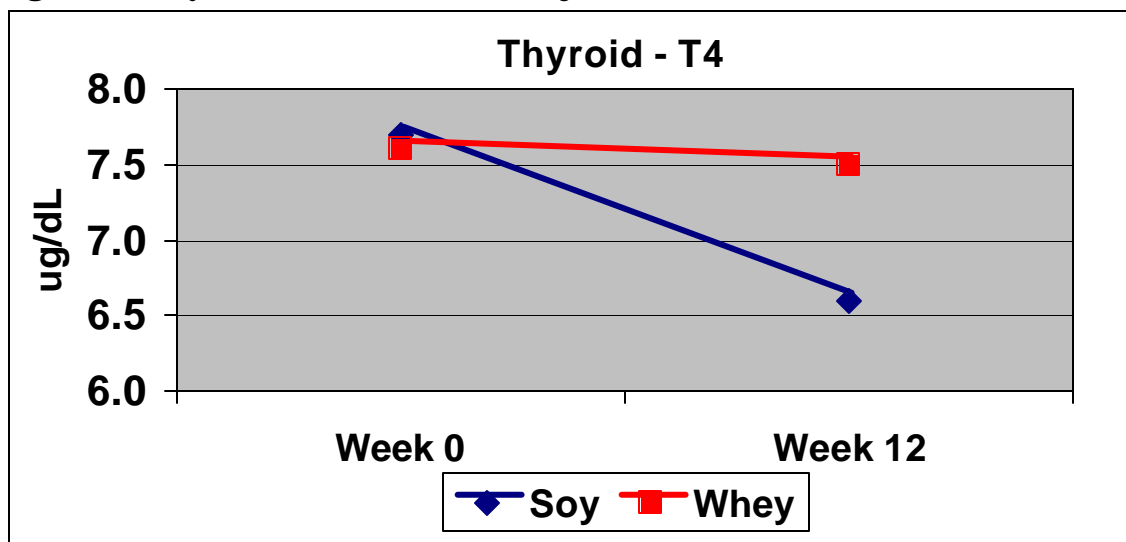
Figure 8. Triglyceride Results for All Subjects (time trend data)



Thyroid Results for Male Subjects

Looking at gender differences, shown in Figure 9 are the results for T4 thyroid hormone for male subjects in the study. Although there were no significant differences within groups due to the small sample sizes, at Week 12, the males in the ISP group had a significantly greater decrease in T4 value from Week 0 than that of the WPI group. There was a mean change from Week 0 of 1 unit for the males in the ISP group, from 7.7 to 6.6ug/dL compared to a mean drop from Week 0 of 0.1 unit for the men in the WPI group, or a drop from 7.6 to 7.5ug/dL. These results indicate that 60g of ISP ingested daily by men may alter thyroid function. The fact that ISP was found to effect thyroid is consistent with animal and human data.

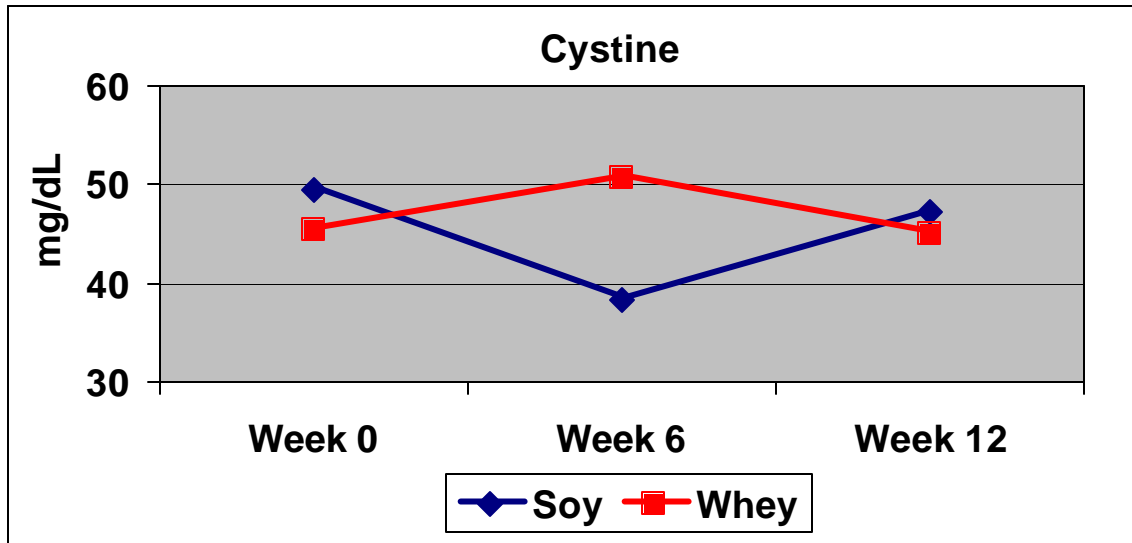
Figure 9. Thyroid Results for Male Subjects



Cystine Results for Male Subjects

Figure 10 shows the cystine results for male subjects in the study. At Week 6, the men in the WPI group had a significantly greater change from Week 0 value for cystine than men in the ISP group, a mean increase from Week 0 of 5.2 units for the men in the WPI group and a mean decrease from Week 0 of 9 units for men in the ISP group. These results are significant since cystine is a sulfur containing amino acid important for many processes in the body and is the direct precursor to glutathione within the cell.

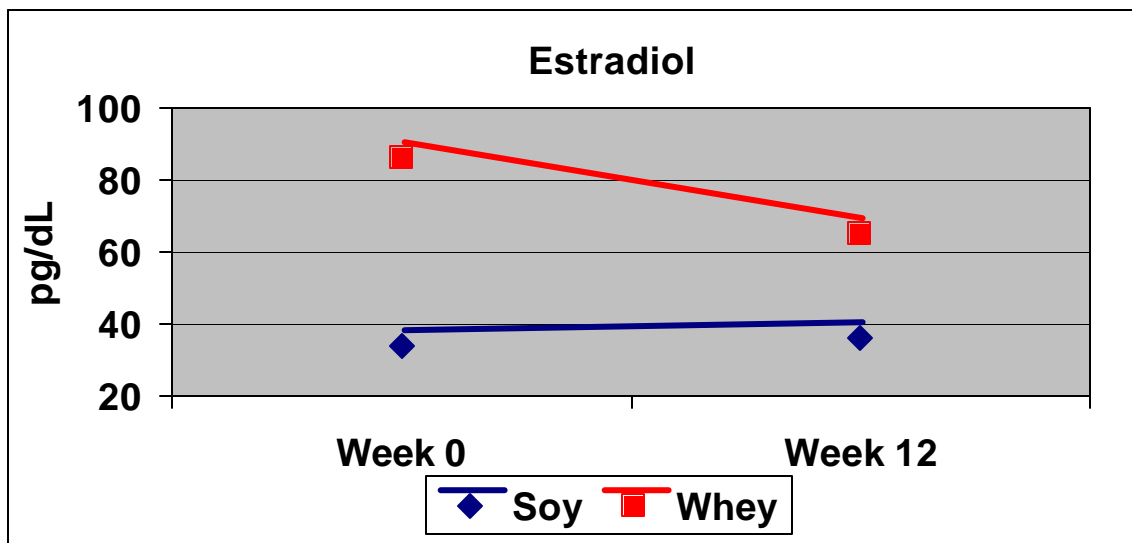
Figure 10. Cystine Results for Male Subjects



Estradiol Results for Female Subjects

Shown in Figure 11 are the estradiol results for women. At Week 12, the WPI group had a significantly greater decrease from Week 0 estradiol value than that of the ISP group, a decrease from Week 0 of 21.4 units for the women in the WPI group and a mean decrease from Week 0 of 0.2 units for women in the ISP group. This indicates that WPI may have antiestrogenic effects. This finding, coupled with recent work by Dr. Badger (Hakkak, Korourian et al. 2000), showing that whey protein may reduce the size of breast tumors in animal studies is worthy of more research.

Figure 11. Estradiol Results for Female Subjects

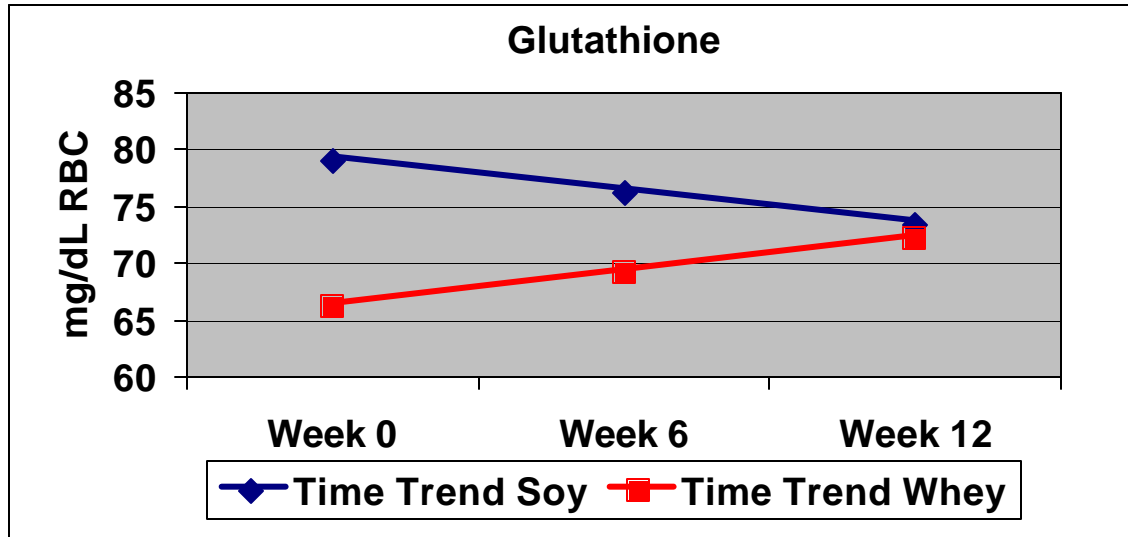


Glutathione Results for Female Subjects

Figure 12 shows the glutathione time trend results for women. There were significantly different time trends between the WPI group and the ISP group. In the WPI group, the

average GSH value increased 2.99 units per 6 weeks, while in the ISP group, the average GSH value decreased 2.89 units per 6 weeks. The results indicate that WPI contains the naturally occurring precursors that can enhance glutathione.

Figure 12. Glutathione Results for Female Subjects (time trend data)



SUMMARY

In general, our findings demonstrate that the daily ingestion of 60g of WPI or ISP had a positive effect on lipid profiles over the 12 weeks of the study, as indicated by the drop in total cholesterol and LDL cholesterol in both groups.

In addition our data demonstrate that ISP significantly lowered T4 levels in men, confirming earlier reports of a possible adverse effect of ISP on thyroid function, with unknown long-term side effects. WPI exhibited no such adverse influence.

WPI decreased estradiol in women indicating that WPI may have anti-estrogenic effects whereas ISP may not offer any protection against estrogen driven adverse health conditions.

WPI did significantly increase intracellular GSH which confirms whey protein's immunoenhancing properties.

In summary, our findings from this pilot study demonstrate that WPI had a more positive impact than ISP on biomarkers of good health in exercising adults. Further studies need to be conducted to explore these results more fully.

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