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The Beneficial Effects of Ingredient Optimization Technology on Whey Protein for Body Composition and Senior Physical Fitness Test Performance in Elderly Persons

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Abstract

Age-related health complications such as muscle loss (sarcopenia), declining strength, and decreased physical performance are expected to become more common as the median age of the United States increases. This study explored whether daily supplementation with an Ingredient Optimized™ (io) whey protein dietary supplement would improve muscle mass, body composition, and physical strength in elderly persons without an exercise regimen. Twenty adults between the ages of 65 and 80 were divided randomly into two groups which supplemented once daily with either the ioProtein™ supplement or a comparator protein supplement powder for 12 weeks. At baseline and after 12 weeks of the supplementation regimen, each participant was evaluated for muscle mass and body composition, resting metabolic rate, and physical strength and performance by a series of standardized Senior Fitness Tests. The experimental measurements were compared between the two supplementation groups by a one-way *t*-test. After 12 weeks of supplementing, the ioProtein™ group had significantly greater muscle mass (p=0.031) and lower fat mass (p=0.011) than the comparative group, while there was a trend of a higher lean body mass in the ioProtein™ group (p=0.056). Likewise, the ioProtein™ group experienced a significant increase in resting metabolic rate from baseline to 12 weeks (p=0.03). A greater number of participants from the ioProtein™ group experienced increased lean body mass and muscle strength from baseline to 12 weeks compared to the comparator supplement group. Overall, these findings suggest that ioProtein™ supplementation could be an effective means to counter age-related muscle decline and associated complications and promote healthy aging, and that Ingredient Optimized™ technology enhances the body's absorption and utilization of supplemented protein without exercise. As no physical activity regimen was implemented during this study, the improvements noted can be considered to be a conservative quantification of the minimum effectiveness of ioProtein™ supplementation.

Keywords: Protein supplement; Aging, Muscle strength; Body mass, Ingredient optimized™

Introduction

Age-related changes such as a loss of muscle mass and strength, reduced physical function, and decreased fat-free mass (also known as lean body mass), are associated with a high incidence of falling [1], longer hospitalization times [2], early institutionalization [3], and loss of independence among older individuals [4-8]. Sarcopenia, which refers to age-related muscle loss, has been linked to an increased risk of falling as well as various functional deficits [9]. This particular condition is a world-wide health problem that is consistently increasing due to the aging population.

Physical inactivity is one of the contributing factors for this condition, and subsequently numerous programs have been developed which aim at enabling elderly persons to remain at home while maintaining, or more importantly improving, physical function. However, a reduction in protein consumption is also linked to decreased muscle mass with age [10]. Indeed, large numbers of elderly persons are not currently meeting the recommended daily intake for protein and this health issue may worsen if the daily requirement increases with age as research suggests [11,12]. Research further indicates that protein supplementation can help boost muscle mass and subsequently physical function in older adults [13-15]. In particular, several systematic reviews have demonstrated that protein supplementation has positive effects on muscle strength and mass as well as muscle protein synthesis, although such studies only involved short treatment periods and the results were deemed to be of little clinical relevance [13-15]. Therefore, there is a pertinent need to better understand the potential benefit of protein supplementation on enhancing physical function in older adults.

Previous research describes the use of Senior Fitness Tests to measure physical function in older individuals [16]. This combination of tests is widely used due to the ability to evaluate many health outcomes in men and women of different ages and physical fitness levels as well as the ease of administration in a variety of settings [16-18]. An even greater advantage of the Senior Fitness Tests is that the standardized use allowed norms to be developed for male and female elderly community residents in 5-year age categories for individuals between the ages of 65 and 94 [16]. For a measurement of their ability to remain independent, community dwellers are typically asked to perform a chair stand test. This test, in which an individual is asked to stand up from a chair as often as possible for 30 seconds, assesses endurance and strength as well as the capacity to independently rise up from a seated position through functional movement [18].

Accordingly, the purpose of this study was to evaluate whether older

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individuals between the ages of 65 and 80 who consumed an Ingredient Optimized™ (io) whey protein (referred to as ioProtein™) supplement daily for 12 weeks would demonstrate significant improvements in body composition and increased physical function on Senior Physical Fitness Test measurements when compared to their counterparts who consumed a non-optimized, non-treated whey protein product. It was hypothesized that the participants who consumed ioProtein would experience heightened performance on certain fitness measurements in comparison to the control (comparator product) group. It was also proposed that improving protein supplementation could support increased fat-free mass and muscle strength in addition to enhanced physical function. Therefore, additional exploratory outcomes included: changes in body composition (fat-free mass and fat mass), muscle quality, resting metabolic rate, and different physical functions (e.g., flexibility, balance, and endurance).

Plasma Nutrition is a United States-based company that has developed a novel protein supplement through the use of atmospheric plasma which increases the key characteristics of a protein peptide. These enhancements should heighten digestibility and absorption of Ingredient Optimized™ (io) whey protein leading to a potential increased bioavailability. From a functional viewpoint, ioProtein should quicken the transportation of individual amino acids into muscle fibers where enhanced protein synthesis would occur, thereby supporting increased lean muscle mass, muscle strength, and overall physical function for older adults.

Recruitment and Subjects

To demonstrate whether Ingredient Optimized protein could improve body composition and Senior Physical Fitness Test performance after a 12-week intervention period in comparison with a non-optimized, non-treated whey protein supplement with a power of 0.80, and an alpha of 0.05, it was determined that a minimum of seven participants were needed for each supplementation group, assuming equal variation in study parameters [19]. In order to account for a 30% drop-out rate, however, 10 participants were recruited for each group. A total of 20 participants (N=20) were recruited from the community through advertisements placed in newspapers, flyers at retirement residences, radio announcements, and by informing organizations for elderly adults.

Eligibility criteria

To be eligible for the study participants needed to: 1) be between 65 and 80 years old, 2) score between the 25th and 75th percentile for sex and age group on the chair stand test during the baseline assessment, 3) be willing to participate in the 12-week intervention which consisted of consuming a protein supplement daily, 4) not have consumed protein supplements during the past six months, and 5) consume a minimum of 1.5 g/kg of protein in their regular diet.

Exclusion criteria

A person was not allowed to participate in this study if they had any known allergies to milk, soy, eggs, peanuts, tree nuts, fish, crustaceans/shellfish, or wheat products as this supplement is manufactured in a facility that handles these ingredients. Conditions resulting in ineligibility included a history of metabolic disorder including heart disease, arrhythmias, thyroid disease or hypogonadism, diabetes, hypertension, pulmonary disease, musculoskeletal disorders, hepatorenal disease, autoimmune disease, neuromuscular/neurological diseases, peptic ulcers, anemia, or cancer. In addition, individuals taking any medications to treat any condition listed above or who took androgenic medications were also ineligible for this study, as well as those who had taken ergogenic levels of nutritional supplements that may affect muscle mass or aerobic capacity (e.g., creatine, HMB, or anabolic/catabolic steroid hormone analogs such as androstenedione or DHEA, etc.) within six months prior to the start of the study.

Additional participation conditions

As with all whey protein products, mild gastrointestinal disturbances may occur as a result of usage. Therefore, patients with existing gastrointestinal issues were advised to consult with the research team before entering the study. People who reported any unusual adverse events associated with this study and who were in consultation with the supervising physician were also advised to drop out from the study.

Group assignment and supplementation

For the 20 participants who were recruited, a randomized block strategy was used to assign 10 participants into each of the two groups for the intervention period of 12 weeks. Group One received the ioProtein supplement and Group Two received a non-optimized, non-treated whey protein supplement. Participants were instructed to consume one scoop (37 g or 28 g of protein, respectively) of ioProtein or the comparator product mixed with 12 ounces of water every day. The supplements were provided for four weeks at a time, and the participants were asked to return the unconsumed product, if there was any. All measures of body composition and physical performance were tested at baseline and after 12 weeks of supplementation.

Exploratory outcomes

One exploratory outcome was body composition, which was assessed through fat and fat-free mass measurement using a BOD POD air displacement plethysmograph (COSMED USA, Inc., Concord, CA) [20]. Additional physical functions that were measured by the Senior Fitness Tests included agility, strength, flexibility, and endurance. In particular, the Timed Up and Go test (agility), arm curls (strength), back scratch (flexibility), and the 6-minute walk test (endurance) was administered in addition to two balance tests. Muscle quality was also assessed by measuring the maximum load of four leg press exercises using a standard maximal load for one repetition protocol while doing a leg press [21]. The recorded value for strength was divided by the total fat-free mass as an indicator of muscle quality. Resting metabolic rate was measured by using an indirect calorimetry protocol [22].

Physical activity was measured both pre- and post-intervention to control for baseline differences between the groups, as well as the amount of time spent performing the exercises. Physical activity was assessed with a waist-mounted accelerometer (Actigrah GTX3+, Pensacola, FL USA) for seven days, using a validated cut-off to identify different intensities of physical activity (e.g., moderate intensity >1316.5 counts/min) [23]. The participants were also asked to fill out a physical activity logbook to report the type and duration of physical activities during the intervention period. It is generally accepted that seven days of accelerometry is sufficient to demonstrate an individual's typical physical activity level [24]. Furthermore, by using a standard procedure, diet was assessed with a 24-hour recall at the pre- and post-intervention evaluations in order to control for baseline differences between the groups as well as the pre- and post-intervention differences in diet, especially for protein consumption [25]. After all information was collected, the data were analyzed using ESHA's Food Processor Nutrition Analysis software (ESHA Research, Salem, OR) [26].

Anthropometric/Body Composition	% of participants who improved 0-12 week		% of change 0-12 week	
	Experimental Group N=7	Control Group N=8	Experimental Group N=7	Control Group N=8
Total Lean Body Mass (kg)	5 (71.4%)	3 (37.5)	+0.12%	-2.65%
Muscle Quality (grip strength/MM)	6 (85.7%)	4 (50.0%)	+11.08%	+4.68%
Physical Capacity				
Handgrip strength (lbs)	6 (85.7%)	6 (75%)	+10.7%	+5.3%
Resting Metabolic Rate (kcal Day)	7 (100%)	6 (75)	+12.2%	+12.4%
Respiratory Quotient (RQ)*	4 (57.1%)	4 (50%)	-3.33%	-0.02%

*The RQ ranges from 0.70 to 1.00. When participants have a RQ of .70, most of the body's energy source is from fat, while a RQ of 1.00 represents the complete oxidization of a carbohydrate molecule (body using only carbohydrate). With age, the value starts to be about 8.00, indicating a greater usage of proteins.

Table 1: Proportion of participants from baseline to week 12 improvements and percent changes.

Results

The statistical analysis method used to assess changes in the study variables from pre- to post-intervention was an independent samples, one-way t-test using IBM SPSS Statistics Package for Mac, Version 19 (IBM Corp., Armonk, NY). Differences were examined using a 95% confidence interval. Findings were considered statistically significant provided that they achieved a p-value of less than 0.05. Both within-group and between-group differences were explored. The results of the t-test indicated that there were significant differences in terms of body mass index [BMI] (p=0.031) and fat mass (p=0.011) between the ioProtein group and the comparator supplement group. Fat-free mass trended towards significance with a p-value of 0.056. The group receiving ioProtein also showed a statistically significant increase in resting metabolic rate (RMR) (p=0.03) from pre- to post-intervention.

Table 1 shows the number of participants whose body composition improved and the percent changes from baseline to week 12 for both groups. The final number of participants was as follows: Group One (ioProtein): N=7; Group Two (comparator supplement): N=8. In Group One, 71.4% (N=5) of the participants demonstrated improvements and a +0.12% change in total lean body mass, in comparison to 37.5% (N=3) of the participants in Group Two, who demonstrated a -2.65% change in total lean body mass by week 12. Furthermore at week 12, 85.7% (N=6) of the participants who consumed ioProtein experienced a +11.08% change in muscle quality (grip strength), when compared to a +4.68% change in muscle quality for 50.0% (N=4) of those who consumed the comparator supplement. The fitness tests for physical capacity measured handgrip strength, resting metabolic rate, and respiratory quotient. The largest percent change between the groups was observed for handgrip strength, with Group One demonstrating a +10.7% change in comparison to +5.3% for Group Two. For the Fat Mass 2-way ANOVA a significant difference was observed for protein type (p=0.021). The preceding results are presented in visual form in the Appendix, Figures 1 - 10.

Discussion

Research has implicated that protein supplementation can help boost physical function by improving muscle strength and mass [13-15]. It was proposed that the consumption of a novel protein supplement, ioProtein, developed using Plasma Nutrition's Ingredient Optimization process could support greater overall improvement in body composition measurements, including BMI, fat mass and fat-free mass, when compared to existing whey protein sources. Accordingly, the results of this study provide evidence to support previous findings of the existence of a relative benefit of Ingredient Optimization technology on whey protein when compared to a non-optimized, non-treated whey protein.

In particular, the larger percent increase in total lean body mass, muscle quality, and handgrip strength that was observed for the ioProtein group in comparison to the non-optimized, non-treated whey protein group indicated that this advanced supplement enhanced the digestibility and absorption of the protein, thereby heightening the transportation of individual amino acids into muscle tissue and improving protein synthesis. This is in accordance with the hypothesis that this novel protein offers improved bioavailability compared with existing whey protein offerings, something that could be investigated directly in a future investigation. A significant difference was also observed in fat mass as well as a trend towards significant differences in fat-free mass for those who consumed ioProtein as anticipated. These changes suggest that older individuals who enhance their protein intake could benefit from better physical function as a result of improved body composition. This is of significant importance as the last few decades have seen a continuous upwards shift in the mean age of the adult population.

Subjects who consumed Ingredient Optimized protein also saw a statistically significant improvement to their pre-test resting metabolic rate (RMR). RMR is an important indicator of physical health and carries particular significance in the elderly as well as in other demographics for which the addition of an intensive exercise regimen might prove burdensome. With a demonstrated positive impact on RMR, ioProtein could hold significant benefits in product applications designed to support weight management or healthy aging.

It is also important to note that these significant improvements to body composition were achieved without the introduction of an accompanying exercise regimen. This demonstrates that any relative improvement achieved by ioProtein when compared to a non-optimized, non-treated whey protein was achieved as a direct result of the intervention. As it is generally understood that the benefits of protein supplementation are heavily aided by accompanying physical activity, these results can be said to represent the most conservative impact possible. The consumption of ioProtein in conjunction with an exercise training regimen could heighten the relative benefits even more, and this insight could provide guidance for the design of future studies.

More specifically, the World Health Organization reports that by 2050 the age of individuals over 60 will double [27]. As physical function and protein intake are highly associated with the health of elderly persons as well as their ability to remain at home and living independently, it is essential to promote lifestyle habits that support the maintenance or improvement of physical capacity with age. This study demonstrates the beneficial effects that adding a highly advanced protein supplement to their daily regimen can have for older individuals in terms of body composition and physical fitness.

Overall, sustaining and/or enhancing physical function in elderly persons is crucial towards their ability to live independently. As the results of this 12-week study support the proposed health benefits of protein supplementation, future investigations will aim at evaluating the benefits in a clinical population such as older adults with dynapenic obesity or the comparison of ioProtein to an exercise program and a placebo treatment. Finally, it will be necessary to conduct a study which is longer than 12 weeks in order to assess the long-term effects and safety of protein supplementation in an older population.

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Appendix

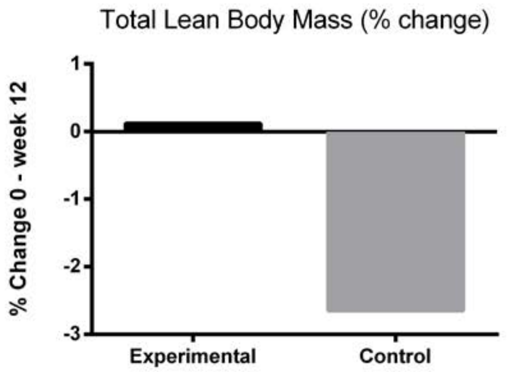

Figure 1: Comparison of Total Lean Body Mass (kg) of Experimental Protein Group and Control Protein Group % of change 0 - week 12

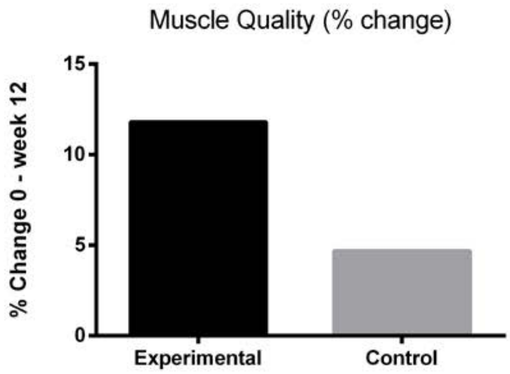

Figure 2: Comparison of Muscle Quality (grip strength/MM) of Experimental Protein Group and Control Protein Group % of change 0 - week 12

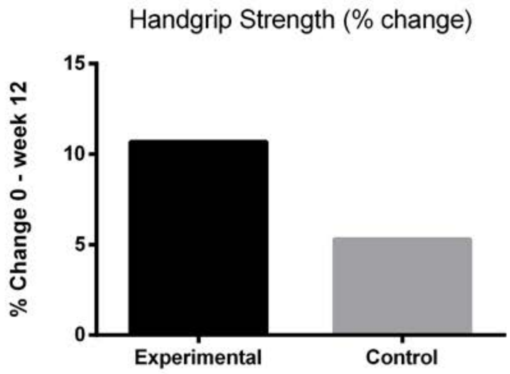

Figure 3: Comparison of Handgrip Strength (lbs) of Experimental Protein Group and Control Protein Group % of change 0 - week 12

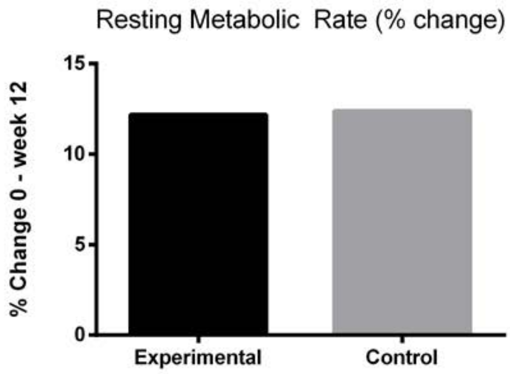

Figure 4: Comparison of Resting Metabolic Rate (kcal / Day) of Experimental Protein Group and Control Protein Group % of change 0 - week 12

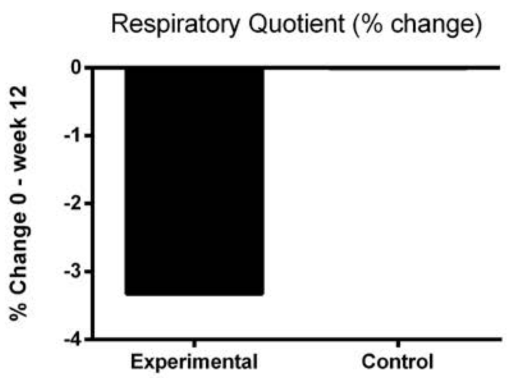

Figure 5: Comparison of Respiratory Quotient (RQ) of Experimental Protein Group and Control Protein Group % of change 0 - week 12

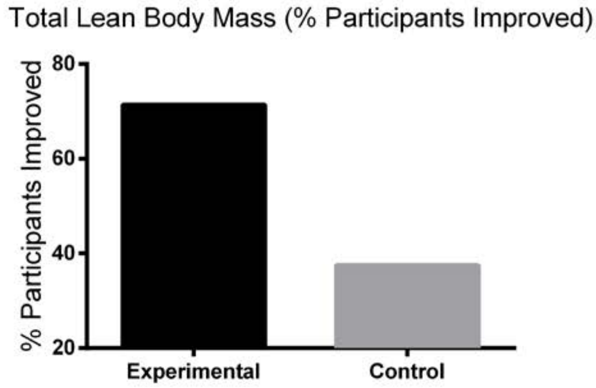

Figure 6: Comparison of Total Lean Body Mass (kg) of Experimental Protein Group and Control Protein Group % of participants who improved 0 - week 12

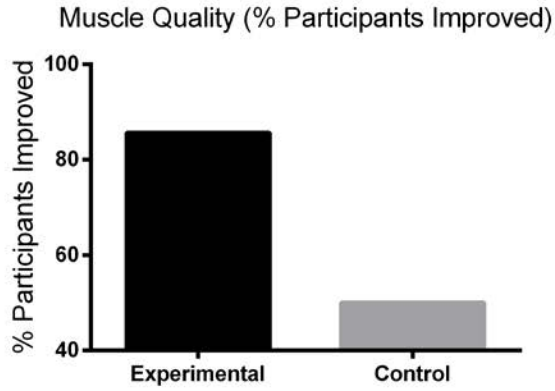

Figure 7: Comparison of Muscle Quality (grip strength/MM) of Experimental Protein Group and Control Protein Group % of participants who improved 0 - week 12

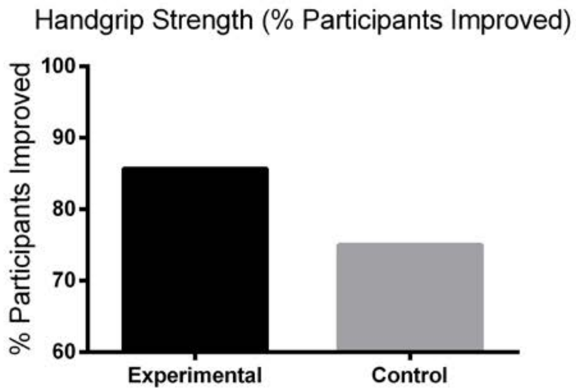

Figure 8: Comparison of Handgrip Strength (lbs) of Experimental Protein Group and Control Protein Group % of participants who improved 0 - week 12

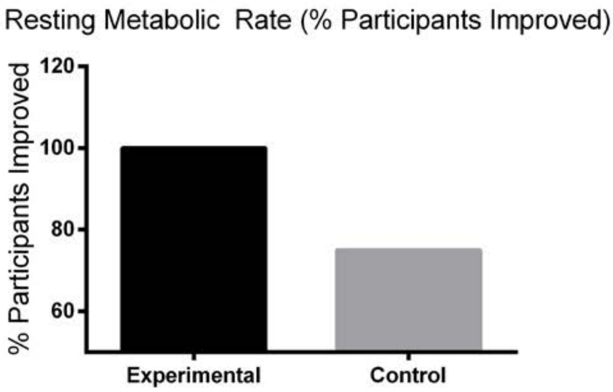

Figure 9: Comparison of Resting Metabolic Rate (kcal / Day) of Experimental Protein Group and Control Protein Group % of participants who improved 0 - week 12

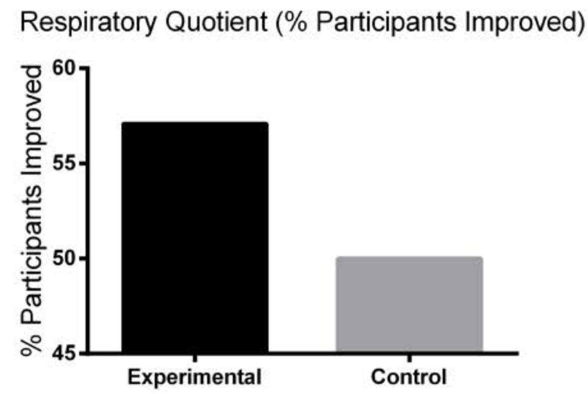

Figure 10: Comparison of Respiratory Quotient (RQ) of Experimental Protein Group and Control Protein Group % of participants who improved 0 - week 12