Impact of a fibre and herbal extract nutritional supplement programme on individual quality of life

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Abstract

Overweight and obesity are common conditions in developed countries and are associated with adverse effects on health and quality of life (QoL). Nutritional supplements are known to assist in efforts to achieve and maintain a healthy weight and improve QoL. In this study we evaluated the effects of a programme of nutritional supplements consisting of a supplement containing glucomannan (a water-soluble dietary fibre), magnesium and saffron (Arbonne Evolution Full Control, Watermelon Kiwi Flavor Supplement Powder) and a herbal supplement containing Svetol® green coffee extract, green tea extract, natural caffeine and quercetin (Arbonne Evolution Thermobooster Supplement Tablet) combined with a calorie-controlled diet, adequate protein intake and moderate exercise. Adult subjects (n=77) who were overweight or obese were tested for QoL improvement using a validated questionnaire (SF-36). After 16 weeks, the subjects completing the study (n=66; 86%) reported improvements in general health (97.0% responded positively to a question assess-

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ing current general health compared with 69.7% at baseline, while 60.7% responded positively to a question assessing improvement in health during the past year compared with 21.2% at baseline). An improvement was also seen with regard to energy (83.3% responded positively to a question assessing current energy level at week 16 compared with 68.2% at baseline). Improvements were seen in seven of eight subscales of the SF-36. The supplement programme was well tolerated and well accepted by users. Statistically significant improvements versus baseline in body composition parameters, including weight, were observed at some intermediate time points. A statistically significant improvement in waist/hip ratio (-2.0%) was observed at week 16. This combination of nutritional supplements is well accepted by consumers and may help to improve QoL when used as part of an ongoing programme to maintain a healthy weight.

Introduction

Recent decades have witnessed a dramatic increase in the prevalence of overweight and obesity in developed countries [1]. This increase has been associated with adverse effects on the overall health and quality of life (QoL) of individuals. As a result of the obesity epidemic, many researchers are working to identify lifestyle changes and nutritional interventions that may assist people in

achieving and maintaining a healthy weight and optimal QoL. This study evaluated the effects of a programme of nutritional supplements consisting of a product containing glucomannan (a watersoluble dietary fibre), magnesium and saffron (Arbonne Evolution Full Control, Watermelon Kiwi Flavor Supplement Powder) and a herbal product containing Svetol® green coffee extract, green tea extract, natural caffeine and quercetin (Arbonne Evolution Thermobooster Supplement Tablet) on QoL in obese and overweight adult subjects.

The physical effects of individual components of this nutritional supplement programme have been examined in previous studies. In a double-blind study, 10 obese women lost significantly more weight than did the control group when ingesting 500 mg of glucomannan along with 250 ml of water 1 h before each of three daily meals over an 8-week period [2]. In an uncontrolled 14-week trial, 29 sedentary adults with a body mass index (BMI) ranging from 25 to 36, ingesting 5 g glucomannan in 500 ml water 5-10 min before each meal, two to three times daily, lost a significant amount of weight and body fat. In addition, the regimen reduced waist measurement significantly compared with baseline [3]. A meta-analysis of 14 randomized controlled trials that evaluated a total of 531 subjects revealed that the use of glucomannan appeared to lower body weight significantly, although statistical heterogeneity was observed in the body weight endpoint [4]. In studies lasting a mean of 5.2 weeks, the meta-analysis found that there was a small but statistically significant weight reduction with glucomannan. Several previous studies have concluded that glucomannan increases satiety [5].

Svetol®, also known as Coffea arabica L. and/or Coffea canephora Pierre ex A. Froehner (Rubiaceae), is a green coffee bean extract that is rich in chlorogenic acids. Green coffee bean extract is mentioned in The Health Canada Natural Health Product monograph for weight management [6]. Research has shown that after 60 days on a bland, low-calorie diet, 30 subjects with a BMI >25 who ingested a Svetol® capsule twice a day with a meal experienced a significantly greater weight loss and increase in the muscle mass-to-fat mass ratio compared to a control group containing 20 subjects [7].

In a 12-week study of 30 overweight individuals, subjects ingesting instant coffee enriched with chlorogenic acid lost significantly more weight than the control group which ingested instant coffee that was not enriched [8]. The same researcher also measured plasma glucose concentrations in 12 adults with BMI <25 after ingestion of chlorogenic acid-enriched coffee versus coffee that was not enriched, and reported that the enriched coffee induced a significant 6.9% reduction in glucose absorption compared with non-enriched coffee. Similarly, a test group administered chlorogenic acid-rich green decaffeinated coffee extract in a 40-day study demonstrated a significant decrease in post-prandial glycaemia compared with baseline [9].

Green tea extract, which contains epigallocatechin gallate (EGCG), is also mentioned in The Health Canada Natural Health Product monograph for weight management [10]. One cross-over study in 10 healthy men compared the effects of EGCG (90 mg) plus caffeine (50 mg), caffeine alone (50 mg), and placebo ingested three times a day and observed a significant increase in 24 h energy expenditure and fat oxidation in the green tea plus caffeine group relative to the placebo group and caffeine group, suggesting that green tea has thermogenic properties beyond those contributed by its caffeine content alone [11]. A 3-day study using three servings per day of a 250 ml beverage containing 94 mg EGCG and 100 mg caffeine resulted in a significant increase in 24 h energy expenditure of 4.6% (445.2 kJ) [12]. Long-term studies support the beneficial effects of green tea extract on weight loss and weight maintenance. A meta-analysis of over 11 long-term (12-24 weeks) studies showed that green tea extract significantly contributed to weight loss and prevented weight regain [13]. One of these studies reported that body weight was decreased by 4.6% and waist circumference by 4.5% after 3 months in 70 overweight Caucasian subjects using green tea extract containing 270 mg EGCG and 150 mg caffeine per day [14]. Another study demonstrated that after 12-week administration of a 350 ml tea beverage daily (592.2 mg green tea catechins), energy expenditure and dietary fat oxidation were increased [15].

We hypothesized that use of glucomannan and green coffee/green tea extract supplements may influence QoL through changes in appetite and energy levels. In addition to general questions, the 36-Item Short Form Health Survey (SF-36), a multi-purpose, short-form health survey with 36 questions that yields an eight-scale profile of functional health and well-being [16], was used to measure QoL responses. The SF-36 has proven useful in surveys of general and specific health, and in differentiating the health benefits produced by a wide range of clinical regimens.

Materials and methods

Objective

The objective of this study was to evaluate the effects of a nutritional supplement regimen consisting of products containing glucomannan and green coffee/green tea extracts on QoL. Body composition parameters were also assessed.

Study Design and Population

This 16-week, open-label, uncontrolled study recruited men and women aged 21-60 years of age in general good health with a BMI ranging from 25 to 35 as measured by the InBody 520 Professional Body Composition Analyzer (Biospace, Seoul, Korea) [17]. Subjects had to want to lose weight and be willing to comply with all the requirements of the study. Subjects were excluded if they had acute or chronic disease or a severe medical condition, were currently following a weight loss programme or diet, were currently or had recently (within the last 4 weeks) used weight loss products or supplements, were using medications known to have effects on weight, were pregnant or intended to become pregnant, or were known to be allergic to any of the components of the products. A total of 77 enrolled subjects were required to ensure that at least 70 subjects would complete the study. The study was conducted at the IRSI Clinical Facility, Port Chester, NY, USA.

Interventions

All subjects received the nutritional supplement products to use for the duration of the study, along with written and verbal use instructions. Each subject was instructed to mix the glucomannan powder (one scoop, 3.4 g) with 250 ml of water and take it before or with each meal three times daily. The subjects were also instructed to take one tablet of the green coffee/green tea supplement twice daily, 30 min before a meal. Each tablet contains 317 mg green tea extract (45% EGCG/80% catechins), 200 mg Svetol® (a green coffee bean extract with standardized chlorogenic acid and polyphenol levels), 100 μg chromium chloride, and 49.5 mg of a proprietary herbal blend of cocoa, ginger, cayenne and black pepper.

To ensure adequate protein intake, subjects were given a protein supplement powder (Arbonne Essentials Protein Shake mix; 20 g protein, 220 calories per serving) with instructions to add to 270 ml cold water, shake vigorously, and consume one glass of protein shake once daily as part of a meal. All subjects were required to adhere to a caloric intake maximum of 2,500 calories per day (including the calories provided by the protein shake) for the duration of the study. Subjects were also required to perform a moderate exercise regimen for the duration of the study. Subjects who did not exercise regularly at enrolment were instructed to exercise or walk for a minimum of 15-20 min three times per week (intensity of walking not specified). Subjects who exercised on a regular basis at enrolment continued to do so for the duration of the study. Exercise was recorded in subject diaries.

Visits and Assessments

At the baseline visit and at designated time intervals during the study, all subjects completed the QoL questionnaire (SF-36) together with questionnaires evaluating the subject's history of weight control and perception of the investigational products, and underwent clinical vital sign and body measurements, InBody assessments of body composition, weight, waist/hip ratio, digital photography and laboratory assessments of key blood and saliva markers. Study visits occurred at screening (2 weeks before the baseline visit), at baseline, and at weeks 2, 4, 6, 8, 10, 12 and 16. Samples of saliva were collected from a subpopulation of subjects at baseline and week 16 for analysis of mRNA markers and satiety biomarkers (to

be reported separately). Compliance was assessed based on subject diary records and returned product; a subject was determined to be compliant if they used at least 80% of the nutritional supplement products.

Statistical Analysis

The per-protocol population was used for statistical analysis at each time point. The per-protocol population is defined as the subset of subjects that complied with the protocol sufficiently to ensure that their data are likely to exhibit the effects of the treatment. Descriptive statistics (mean±SD) were reported for demographic characteristics and measurements at baseline and after treatment. The paired t-test was used to determine the significance of post-treatment values compared with baseline values. Statistical significance was set at $p \le 0.05$. SF-36 subscales were calculated using the RAND Corporation method [16]. In addition, each item of the SF-36 was assessed using McNemar's test for change in response from baseline to after treatment. Multivariate regression analysis with one dependent variable (responder) and baseline age, weight, waist/hip ratio, basal metabolic rate, body fat mass and lean body mass as independent variables was performed to evaluate body composition parameters associated with response.

Results

Population

The study was completed by 66 (86%) of the 77 subjects enrolled. Four the subjects who did not complete the study withdrew due to the time commitment, one due to the exercise commitment, two due to lack of efficacy, and one due to a need to change their diet, while two were withdrawn for non-compliance. One subject withdrew due to a report of an adverse event (light-headedness). Most subjects who withdrew (9 of 11) did so in the first 8 weeks of the study. The per-protocol population consisted of 52 women and 14 men, with a mean (SD) age of 43.4 (11.52) years. Thirty-six participants reported their race as white (54%), 23 as black (35%) and 7 did not respond (11%). BMI was between 25 and 30 for 44 subjects (67%) and between 31 and 35 for the remaining 22 (33%).

Quality of Life

SF-36 individual items

The majority of SF-36 individual items underwent either a numerical increase or a negligible change between baseline and week 16 in the patients responding favourably to the item. The most notable improvements were seen in the general health questions 'In general, would you say your health is excellent, very good, good, fair, or poor?', to which 69.7% of subjects responded positively at baseline compared with 97.0% at week 16, and 'Compared to one year ago, how would you rate your health in general now-much better, somewhat better, about the same, somewhat worse, or much worse?', to which 60.7% of subjects responded positively at week 16 compared with 21.2% at baseline. This change from baseline was significant by McNemar's test (p<0.0001). A marked change was also seen with regard to energy, in that the percentage of subjects responding favourably to the question 'Did you feel full of pep all of the time, most of the time, a good bit of the time, some of the time, a little bit of the time, or none of the time?' increased from 68.2% at baseline to 83.3% at week 16 (*p*<0.0253; McNemar's test). Significant improvements versus baseline responses were also seen for items assessing physical health problems (items 13, 14 and 16) and emotional health (items 17 and 19).

SF-36 subscales

Positive changes were observed for all SF-36 subscales except Physical functioning, which saw a decrease from baseline to week 16 (Fig. 1). The largest improvements were observed in the subscales for Energy/fatigue and Social functioning.

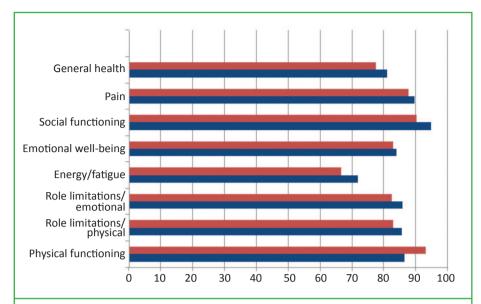
Subject evaluation of supplements

Subjects reported favourable perceptions of the supplements and their effects as reported in responses to a questionnaire at week 16 (Table 1). The subjects' acceptance of product use was also demonstrated by good compliance with the product regimen by most subjects; only two subjects were withdrawn from the study for non-compliance.

Body Composition

No statistically or clinically meaningful changes in body composition parameters as measured by the InBody analyzer were observed at week 16, although some statistically significant changes were seen at intermediate time points (Table 2).

The waist/hip ratio decreased from a mean (SD) of 0.86 (0.08) at baseline to 0.84 (0.08) at week 16 (change from baseline: -2.0%; *p*=0.006). A decrease in the waist/hip ratio was experienced by 49 (74.2%) of 66 subjects. When multivariate regression analysis with one dependent variable (responder) and baseline age, weight, waist/hip ratio, ba-



Scoring was by the RAND Corporation method

The following SF-36 items were included in each subscale: Physical functioning: items 3–12; Role limitations due to physical health: items 13–16; Role limitations due to emotional problems: items 17–19; Energy/fatigue: items 23, 17, 19, 31; Emotional well-being: items 24, 25, 26, 28, 30; Social functioning: items 20, 32; Pain: items 21, 22; General health: items 1, 33, 34, 35, 36

Figure 1 - Changes in quality of life: values for SF-36 subscales at baseline (red) and week 16 (blue)

		Percent				
Question	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	responding favourably
I ate healthier while using the test products.	13 (19.7)	38 (57.6)	14 (21.2)	1 (1.5)	0 (0.0)	77.3
My physical activity/exercise regimen increased while using the test products.	10 (15.4)	44 (67.7)	10 (15.4)	1 (1.5)	0 (0.0)	83.1
The test products were easy to use.	23 (34.8)	31 (47.0)	10 (15.2)	2 (3.0)	0 (0.0)	81.8
The test products tasted good.	17 (25.8)	21 (31.8)	18 (27.3)	10 (15.2)	0 (0.0)	57.6
The test products helped improve my quality of life.	6 (9.1)	27 (40.9)	28 (42.4)	4 (6.1)	1 (1.5)	50.0
I felt no negative effects while using the test products.	25 (37.9)	27 (40.9)	5 (7.6)	9 (13.6)	0 (0.0)	78.8
I would recommend these test products to others.	19 (28.8)	32 (48.5)	11 (16.7)	3 (4.5)	1 (1.5)	77.3

 Table 1 - Perceptions questionnaire results at week 16

Parameter	Time point									
	Baseline	Week 2	Week 4	Week 6	Week 8	Week 10	Week 12	Week 16		
Weight (lbs)	182.17	181.42*	180.97	181.17*	180.96	181.73	182.20	182.20		
	(24.04)	(24.30)	(24.49)	(24.83)	(24.61)	(25.02)	(25.13)	(25.49)		
Body fat mass (lbs)	68.58	67.13*	67.08	66.53*	66.42*	66.81*	67.57	67.92		
	(14.33)	(14.38)	(14.87)	(14.82)	(14.83)	(14.83)	(15.30)	(16.57)		
Lean body mass (lbs)	113.58	114.37*	113.89	114.64*	114.54*	114.91*	114.62*	114.28		
	(21.76)	(21.88)	(22.09)	(22.00)	(22.14)	(22.25)	(22.28)	(22.54)		
Body mass index	30.05	30.07	30.00	30.03	30.01	30.13	30.19	30.17		
	(2.74)	(2.75)	(2.75)	(2.83)	(2.85)	(2.99)	(2.95)	(3.13)		
Percent body fat	37.54	37.18	37.17	36.80*	36.81*	36.84*	37.19	37.34		
	(7.07)	(7.14)	(7.26)	(7.14)	(7.22)	(7.40)	(7.23)	(7.68)		
Basal metabolic rate	1482.96	1488.56*	1485.81	1493.27*	1492.26*	1495.90*	1493.10*	1489.67		
	(213.31)	(213.75)	(216.43)	(215.60)	(216.89)	(218.02)	(218.43)	(220.79)		

*p<0.05 vs. baseline

Table 2 - Changes in body composition parameters over 16 weeks of supplement use

sal metabolic rate, body fat mass and lean body mass as independent variables was performed, the waist/hip ratio at baseline was shown to be predictive of whether or not subjects responded to treatment. When response was defined as a weight loss greater than 2.7 kg (6 lb), an increase of two points or more in lean body mass, or a decrease of two points or more in body fat mass, 31 subjects (47%) were considered responders.

Lipid Parameters

Comparison of mean results at baseline to those at the week 16 visit revealed statistically significant improvements in low density lipoproteins and high density lipoproteins (Table 3). No statistically significant changes were observed in other lipid parameters.

Safety

There were no clinically meaningful changes in mean blood pressure, pulse or respiratory rate from baseline to week 16. Comparison of mean results at baseline to those at the week 16 visit revealed statistically significant increases in serum creatinine and haemoglobin, which remained within normal ranges. The minor increases in creatinine (8%) from baseline may be explained by subjects increased consumption of protein throughout the 16-week study [18]. No statistically significant or clinically meaningful changes were observed in mean results for glucose, white blood count or haematocrit.

One subject reported adverse events. She experienced flu-like symptoms which resolved within 2 days and whose relationship to the test product was deemed remote by the investigator. The same subject also experienced mild light-headedness with intermittent dizziness and nausea that resolved when test product use was discontinued and reappeared when use resumed.

Discussion

Overweight and obesity are prevalent in the United States and have negative effects on the QoL of individuals and on overall public health. Identification of specific regimens and interventions that can promote healthy weight and improve QoL are of ongoing interest in the scientific medical community. Substantial research has investigated aspects of personal motivation [19] and dietary approaches [20] that may affect weight control. In this study, use of a specified nutritional supplement programme including products which contain glucomannan, green tea and green coffee extracts in combination with other weight management elements (calorie management, protein supplementation, moderate exercise) were associated with favourable changes in subjects' assessment of general health and energy levels compared to baseline values. These changes are consistent with the benefits of the supplement ingredients for maintenance of healthy weight as noted in national monographs [6, 10] and the clinical literature [11, 12, 15]. Important-

ly, this nutritional supplement programme was well accepted and rated favourably by users, leading to increased compliance. This favourable perception of the products is critical, as users will not experience the benefits of any health programme if they are unwilling to continue it.

Although significant changes were not observed in body compo-

Assessment	Normal range (mg/dl)	Time point	Mean±SD	Mean percent change from baseline	p Value			
Total cholesterol (mg/dl)	≤200	Baseline Week 16	183.57±38.15 185.34±31.59	1.09	0.681			
LDL (mg/dl)	0-130.00	Baseline Week 16	105.61±36.41 102.12±28.79	-1.68	0.050			
HDL (mg/dl)	≥60	Baseline Week 16	58.17±13.63 61.86±13.86	7.89	0.007			
VLDL (mg/dl)	5.0-40.0	Baseline Week 16	19.79±10.51 21.36±14.81	7.93	0.490			
Triglycerides (mg/dl)	≤150	Baseline Week 16	98.96±52.56 106.81±74.09	7.73	0.490			
HDL high density lipoproteins, LDL low density lipoproteins, VLDL very low density lipoproteins								

Table 1 - Changes in lipid parameters over 16 weeks of supplement use

sition parameters at week 16, nominally significant changes were observed at several time points. In addition, the waist/hip ratio decreased significantly over 16 weeks, and significant changes in serum lipids were also seen. Multivariate analysis to explore the body composition parameters associated with favourable changes in weight, fat mass or lean body mass indicated that subjects with a higher waist/hip ratio at baseline were more likely to have positive changes when using the programme. This observation may be helpful in identifying people most likely to experience a benefit.

This was a pilot study with no control group, so it is not possible to determine if the positive changes observed versus baseline values were solely the result of product use. Clearly, the absence of a concurrent control group is a significant limitation. QoL measures are subjective and may be influenced by other factors, including trial participation, in addition to the use of the nutritional supplements. Significant changes in body composition may be seen compared with a control group that are not evident when compared with baseline values. It would be valuable to determine whether the positive effects on QoL, waist/hip ratio and lipids are duplicated in a placebo-controlled study.

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Conflict of interest

The authors are employees of Arbonne International, LLC which sponsored this study and markets nutritional supplements.

Human rights

This study was overseen by an independent Institutional Review Board to ensure the protection of the rights, safety and well-being of subjects. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975 and its later amendments.

Informed consent

All subjects gave written informed consent prior to participation in any study-related activities.

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