Original Article

Noni-based nutritional supplementation and exercise interventions influence body composition

Afa K. Palu, MSc., Brett J. West, MSc., Jarakae Jensen, MSc.

Noni Benefits Research, Tahitian Noni International Research Center, 737 E. 1180 S. American Fork, Utah, 84003 USA.

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Abstract

Background: The prevalence of obesity and overweight in the Unites States has reached unprecedented levels, and so has the need for effective exercise and nutritional programs for prevention of unhealthy weight gain or safe weight loss. **Aims:** The present study was conducted in overweight men and women to assess the impact of noni-based nutritional supplementation and exercise interventions on body composition. **Materials and Methods:** Twenty two participants (16 women and 6 men), ages 18-65, were enrolled in a 12-week, open-label trial of a weight-loss program involving noni-based dietary supplements, gender-specific daily calorie restriction, and exercise interventions. Weight, percent body fat, and body mass index were measured before and after the trial. **Results:** All participants experienced weight loss. The average decrease in fat mass was highly significant ($P < 0.0001$), as were decreases in percent body fat and body mass index. Individual weight and fat mass losses were 17.55 ± 9.73 and 21.78 ± 8.34 lbs., respectively, and individual percent body fat and body mass index decreases were 8.91 ± 3.58 % and 2.6 ± 1.32, respectively. **Conclusion:** The nutritional and exercise interventions significantly influenced body composition among participants.

Keywords: Noni, body mass index, percent body fat, bioactive, body composition, exercise.

Correspondence to: Afa K. Palu. 737 East 1180 South, American Fork, Utah, USA. Tel.: 801-234-3624; Fax: 801-234-1158, Email: afap@tni.com

Introduction

Obesity is becoming a world-wide health problem but it is more pronounced in more economically developed countries, due to increased food availability, sedentary lifestyle, and socioeconomic status within the community [1]. Obese adults are more likely to develop cardiovascular diseases, diabetes, and other forms of cancer. In fact, it has been estimated every year that obesity contributes to about 112,000 preventable deaths [2] in the U.S. Obesity is defined as body weight that is much greater than what is considered to be healthy. Therefore overweight adults have a body mass index (BMI) between 25 kg/m^2 and 30 kg/m^2 while obese adults have BMI ≥ 30 kg/m^2 [2, 3].

The causes of obesity can be synthesized down to interplay between genetics, environment, excessive caloric intake, and physical inactivity. But, the impact of obesity on the economy was found to be a huge economic challenge. In fact, it has been estimated that the cost of inactivity in 1995 was 24 billion dollars, while the direct cost of obesity in the same year was 75 billion dollars. Hence, the direct cost of inactivity and obesity accounted for about 9.4% of the national health care expenditures in the United States alone [3]. However, health care costs associated with obesity and inactivity related conditions are expected to increase. Finkelstein and colleagues [4] reported that the cost of medical care due to obesity was about $147 billion dollars in the U.S. alone.

Just as the obesity-related health care costs have increased over the years, the effort to discover that one effective anti-obesity drug, medicinal plant and/or diet and exercise program has also increased exponentially over the last few years. However, majority of the weight-loss programs lack scientific validation [5]. Miller and colleagues [5] pointed out in their meta-analysis of weight loss research published during a 25 year period that weight loss programs were narrowly focusing on moderately obese middle age populations, with only short periods of intervention. Even so, the data shows that both a 15-week

diet and diet plus exercise program produce weight losses of about 11 kg, with respective weight losses of 6.6 ± 0.5 and 8.6 ± 0.8 kg being maintained for one year. However, perhaps the most important findings of the meta-analysis was the fact that diet plus exercise produced three-to-five fold changes in body compositions. Therefore a successful weight-loss program must have specific plans for a healthy daily diet, the right types and amount of exercises, and for an appropriate length of time [6-8].

Morinda citrifolia L. (family Rubiaceae), commonly known as noni, has been used in Polynesia for food and medicine for thousands of years [9]. As medicine, it was used by traditional healers for a variety of ailments, including diabetes, hypertension, gout, bruises, cuts, boils, pain, cancer, and much more [10, 11], but very little is known about its potential impact on obesity and weight loss.

In vitro and *in vivo* research have shown that noni fruit juice possesses potential anti-obesity activity. Nishioka and Nerurkar [12] found that five weeks of noni juice consumption reduced adipose tissue weight, triglyceride levels, and body weight by 25% while improving glucose tolerance in mice fed a high fat diet. Pak-Dek and colleagues found that noni leaf and noni fruit juice inhibited lipoprotein lipase activity, in a concentration dependent manner [13]. Further, Nerurkar & Eck [14] found that noni juice may reduce obesity-related insulin resistance via inhibition of reactive oxygen species and mitochondrial damage. In his survey of 25,314 consumers of a major source of noni juice, Tahitian Noni Original® Bioactive™ (TNOB), Solomon [15] found that 5,526 consumers used noni for weight problems, with 62.5% reporting successful weight loss. However, there has been no formal scientific evaluation of a noni-based weight management program. With a high margin of safety [16-18] and *in vivo* efficacy, it is imperative that noni juice be assessed for its potential benefit within the context of a weight management program as a mean to reduce obesity-related diseases. Therefore, our objective was to evaluate the effects of a weight management program, TNI's FIT (TM), on body composition.

Materials and Methods

Study Participants

Male and female volunteers, ages 18-65, with BMI's greater than 25 were recruited. They signed written informed consent forms and provide their medical history which was used to determine their eligibility. Those excluded from the trial did not meet the age or BMI criteria, could not participate in the recommended exercise program, due to injury or other medical condition, could not consume the dietary or nutritional supplements, either due to allergies or contraindications with medication or other medical condition, or had medical histories that indicated unacceptable health risk from participating in the trial. The flow of participants through the trial is summarized in Figure 1.

Study Interventions

All participants followed a supplementation and exercise program for 12 weeks in an open label pilot study. Participants were instructed to follow the prescribed exercise program, as well as the nutritional and dietary supplementation schedule in addition to daily journal entries regarding details of their food and supplement intake and exercise.

The overall description of the interventions is given in Table 1, but more detailed information about the program can be found at www.tni.com/fit. Briefly, the intervention period was divided into two phases. Week 1 involved lower caloric intake and involved a fruit juice and herbal cleanse supplement. Week 2, daily calorie intake was raised by 300 with no fruit juice and herbal cleanse supplement. A high protein and fiber bar supplement was introduced at this time. During week 1, participants abstained from foods rich in carbohydrates (non-dietary fiber carbohydrates) and simple sugars. Participants also replaced one meal during the day with one serving of the protein beverage, along with fruits and vegetables. The nutritional and dietary supplements were provided by Tahitian Noni International, Inc. (Provo, Utah, USA).

The exercise program involved both strength training and aerobic (walking, jogging, zumba dance, etc.) activities. Strength training was conducted during two nonadjacent days of the week, with a different regimen for each day (workout 1 and workout 2). Thirty minutes of aerobic exercise were completed on four other days of the week, with the remaining day as a rest day.

Study Measurements

Pre and post body weights were measured for all participants. BMI's were calculated for each individual, pre and post study, according to the following formula: BMI = weight (lbs.)/[height (in)]^2 x 703. Initial and final body fat percentages of all volunteers were measured by a validated [19] bioelectrical impedance method and instrument (Omron® Body Logic Analyzer, Model HBF-306C, Omron Healthcare Inc., Bannockburn, Illinois, USA). Pre and post visual anthropometric changes were documented using photography. The pilot study was conducted in conformity with Ethical Principles for Medical Research Involving Human Subjects as described in the Declaration of Helsinki and in OCR HIPAA Privacy.

Statistical Analysis

Descriptive statistics, such as the median and mean ± standard deviation (SD), were calculated for initial and final weights, percentage body fat, and BMI. Initial and final measurements and changes in average BMI by gender were compared by ANOVA and Student's two-tailed *t*-test. Changes in study measurements were assessed with the paired *t*-test and changes in BMI category, by initial BMI category, were assessed with a two-tailed Fisher's exact test with 95% level of confidence.

Table 1 Calorie restriction, noni-based supplementation and exercise intervention schedule.

	Morning	Mid-morning	Noon	Afternoon	Evening
			Week 1		
Supplementation	1) TNOB, 2) Vitamin/mineral supplement	1) Probiotic, 2) Protein beverage		1) Fruit juice and herbal cleanse beverage	1) Fiber beverage
Exercise	Strength training (1 hour)*		Aerobic exercise (30 min.)**		
Daily Calories					
Men	1500				
Women	1200				
			Weeks 2 - 12		
Supplementation	1) TNOB, 2) Vitamin/mineral supplement	1) Probiotic, 2) Protein beverage		1) Protein & fiber snack bar	1) Fiber beverage
Exercise	Strength training (1 hour)*		Aerobic exercise (30 min.)**		
Daily Calories					
Men	1800				
Women	1500				

*: Strength training on only two days in the week, **:Aerobic exercise on four days in the week.

Table 2 Mean ± SD of weight and percent body fat losses, as well as changes to BMI.

Variable	Mean ± SD	Minimum	Median	Maximum
Weight loss (lbs.)	17.55 ± 9.73	3.00	16.50	34.00
Fat loss (lbs.)	21.78 ± 8.34	6.19	23.55	35.40
Reduction in % fat	8.91 ± 3.58	3.00	10.10	15.40
Reduction in BMI	2.6 ± 1.32	0.55	2.80	4.46

Results

Caucasian and Hispanic volunteer participants were predominant in the trial. There were more than twice as many females enrolled than males and majority of the volunteers were between the ages of 21 and 40 years. Comparisons of initial and final average fat weight, percent body fat, and BMI are listed in Figure 2. The average decrease in fat mass was highly significant ($P < 0.0001$). Decreases in percent body fat and BMI were also statistically significant. Every participant in the trial experienced weight loss. The range of individual weight loss over 12 weeks was 3 to 34 lbs., with an average of 17.55 ± 9.73 lbs. (Table 2). Reductions in percent body fat were from 3 to 15.4 % during the same time period, with an average of 8.91 ± 3.58% lbs. The combined initial weight for all participants was 4275 lbs. and it was reduced by 386 lbs. post-trial. The total weight of fat lost among all participants was 485 lbs, with an average of 21.78 lbs. The corresponding total lean body mass gain was 99 lbs, with an average 4.22 lbs. per participant. The weight loss was higher in participants with weights in the 165-244 lbs. range, wherein ≥ 20 lbs. each was lost by the end of the 12 weeks. Five changed from the overweight to normal category while another five changed from obese to overweight. However, the frequency of BMI category change was not associated with the participants' initial status. Comparison of BMI reduction by gender revealed that males tended to experience a greater change than females (-3.47 ± 0.88 vs. -2.26 ± 1.33) with a $P = 0.02$.

No adverse events associated with any of the interventions were reported by any of the participants during the trial. Causes of study drop outs were not related to conditions of the study. The five drop outs had simply moved, mid-trial, from the area in which the trial was conducted and could not be reached.

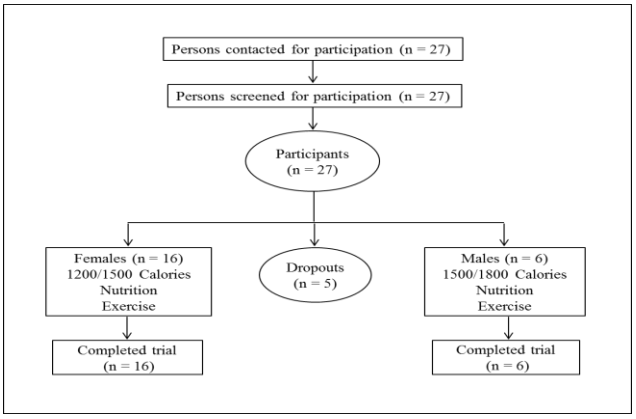

Fig. 1 Flow of participants through the study.

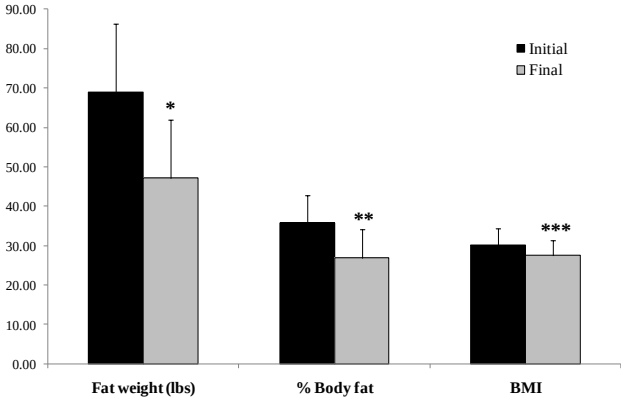

Fig. 2 Initial and final average fat weight, percent body fat and BMI of participants before and after the trial. *:$P < 0.0001$ compared to initial fat weight, **: $P < 0.001$ compared to initial % body fat, ***: $P < 0.05$ compared to initial BMI

Discussion

The current trial demonstrates the utility of combining nutritional and dietary supplementation with caloric restriction and exercise in achieving significant changes to body composition. Most significant are the loss in fat mass and corresponding decreases in percent body fat and BMI. Realizing the potential inaccuracy of using BMI alone to determine obesity-related health risk, some researchers have investigated other useful indicators of body composition [20]. As BMI does not distinguish between fat and lean mass, the additional measurement of percent body fat is necessary for a more accurate assessment of the weight management program.

The average change in percent fat in the current trial (8.91 ± 3.58 %) was greater than a trial of a low carbohydrate diet (<25 g/day) with no calorie restriction [6]. The decrease (mean ± SD) in percent body fat in those consuming the low carbohydrate diet was 2.9 ± 3.2 %. This is less than half the loss occurring in the current trial. It should be noted that in the low calorie diet trial, aerobic exercise was encouraged but no formal program was provided. This resulted in only half of the participants being involved in exercise three or more times per week. The lower results of the low carbohydrate diet trial serve to underscore the need for regular exercise as part of any weight management program.

A randomized trial involving overweight and obese girls revealed that 12 weeks of aerobic training did not result in fat loss, even though fitness and insulin sensitivity did improve [21]. Further, the recommended 30 minutes of daily aerobic exercise is considered by many experts to be insufficient to produce significant weight loss alone, without any dietary management [22-24]. Moderate exercise alone seems to provide only marginal advantage over caloric restriction measures [25]. Therefore, the components of the dietary interventions and exercise used in the current trial were important contributors to the significant losses in fat mass.

Even though this trial resulted in weight loss for all participants, significant weight-loss was more pronounced in some participants than others. For example, BMI changes in males were greater than in females. Further research is therefore warranted using the same program in this trial but with more male participants, and more participants from each ethnicity that participated. Therefore, a longer trial period may be also useful in further assessing the efficacy of using the bioactive noni-based products as part of the nutritional intervention, in combination with exercise, to positively affect body composition thereby ameliorating obesity and obesity-related problems.

Conclusion

Noni-based nutritional supplementation and exercise interventions positively affect body composition without side effects and are recommended to be used in combination for combating weight gain.

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