

## ABSTRACT

**Objective:** There is a great consumer interest in using products and programs to support digestive function, improve elimination and enhance feelings of well-being. It is also reported that certain individuals who begin a weight management program will have a variety of possible intestinal side effects that can interfere with their compliance and success with weight loss. As such, we evaluated the safety, tolerability and efficacy of a 7-day cleanse program combining herbal formulas with prescribed dietary requirements.

**Methods:** Subjects (n=28) were randomly divided into two groups. Group I (n=17) took a combination of probiotics + alfalfa extract + herbal blend containing milk thistle extract + fiber tablets + gentle laxative herbal blend. Group II (n=11) took all formulas given in Group I minus the laxative herbal blend. All subjects were instructed to take fruits and vegetables, drink copious of water ad lib and have a main evening meal consisting of a large plate of steamed vegetables with ½ avocado and full-fat dressing. The study was conducted at three sites for 7 days. Anthropometric measurements and quality of life questionnaires were administered at the beginning and end of the study.

**Results:** The 7-day programs were well-tolerated with no adverse event. 53% of the subjects in Group I reported improved elimination/bowel movements versus 27% in Group II. Additionally, 88% of the subjects in Group I felt improvement in bloating/gassiness compared to 55% in Group II. Overall, more than 80% of the subjects felt improved energy levels and decreased cravings.

**Conclusions:** The results indicated that both programs were safe and well-tolerated. The addition of a gentle laxative herbal blend was more effective in promoting elimination/bowel movements and reducing bloating/gassiness. This program may be used as an adjunct prior to a weight loss program.

## BACKGROUND AND OBJECTIVES

There is a considerable consumer interest in using cleanse programs to support digestive function, improve elimination and enhance feelings of well-being. It is also reported that certain individuals who begin a weight management program will have a variety of possible intestinal side effects that can interfere with their compliance and success with weight loss. Therefore, cleanse programs can be used prior to or as an adjunct to weight management programs. As such, we evaluated the safety, tolerability and efficacy of a 7-day cleanse program combining herbal formulas with prescribed dietary requirements.

## METHODS

**Design:** Open label study conducted in three sites. Participants were advised by a physician, registered dietician, or Certified Nutrition Specialist to use one of the two cleanse programs for 7 days. Participants were healthy, normal weight to obese adults with initial BMI between 21 and 40 kg/m<sup>2</sup>.

**Cleanse programs:** Group I (n=17): probiotics (Optiflora) + alfalfa extract (Alfalfa Complex) + milk thistle blend (Liver DTX) + fiber tablets (Fiber Plan Tablets) + gentle laxative herbal blend (Herb-Lax). Group II (n=11): all formulas in Group I minus Herb-Lax.

**Diet:** All subjects were instructed to take fruits and vegetables, drink copious of water *ad lib* and have a main evening meal consisting of a large plate of steamed vegetables with ½ avocado and full-fat dressing. Protein in the form of smoothes or steamed/broiled fish or chicken was permissible for those who had tendencies towards hypoglycemia or who had unmanageable hunger during the 7 days. Those who normally consumed caffeine were encouraged to reduce their normal intake in half but not eliminated because of potential for withdrawal headaches.

**Data collection:** Anthropometric measurements and quality of life questionnaires were administered at the beginning and end of the study.

**Statistics:** Student's *t*-test (two-tailed) was used for comparisons between two data points. *P*-values less than 0.05 were considered to be statistically significant.

## RESULTS

**Table 1. Demographic characteristics of participants at baseline**

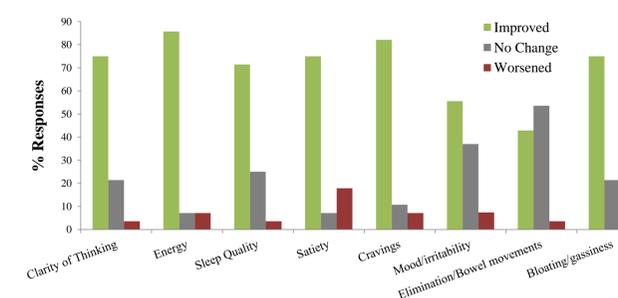
Parameter	Overall (n=28)	Group I (n=17)	Group II (n=11)
Female [n (%)]	23 (82.1)	13 (76.5%)	10 (90.9%)
Age (year)	50.92 ± 2.63	47.47 ± 3.35	56.10 ± 3.89
Weight (lb)	182.89 ± 6.82	182.08 ± 7.86	184.14 ± 12.90
Height (in)	65.76 ± 0.58	65.80 ± 0.87	65.65 ± 0.71
BMI (kg/m <sup>2</sup> )	29.95 ± 1.08	30.08 ± 1.38	29.79 ± 1.81
Waist (in)	38.69 ± 0.85	38.74 ± 1.10	38.63 ± 1.40
Hip (in)	43.49 ± 0.84	43.42 ± 0.98	43.61 ± 1.49

Values are expressed as Mean ±SEM wherever applicable

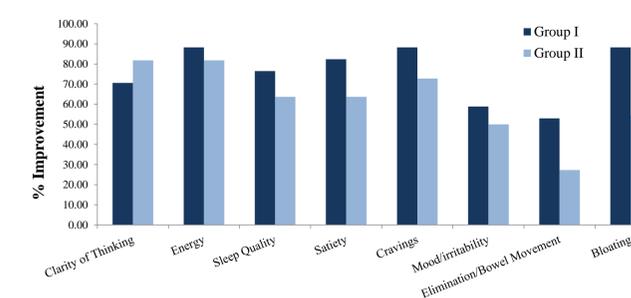
**Table 2. Change in anthropometric properties after 7 days**

Parameter	Group I				Group II			
	Baseline	7 Days	Δ vs. Baseline	P-value	Baseline	7 Days	Δ vs. Baseline	P-value
Weight (lb)	182.08±7.86	175.28±7.56	6.80±0.76	<0.0001	184.14±12.90	178.21±12.35	5.93±0.66	<0.0001
BMI (kg/m <sup>2</sup> )	30.08±1.38	28.96±1.33	1.12±0.14	<0.0001	29.79±1.81	28.83±1.73	0.96±0.10	<0.0001
Waist (in)	38.74±1.10	36.90±1.09	1.84±0.40	<0.0005	38.63±1.40	37.35±1.37	1.28±0.17	<0.0001
Hip (in)	43.42±0.98	42.31±0.95	1.11±0.22	<0.0005	43.61±1.49	42.28±1.37	1.33±0.29	<0.005

**Figure 1. Overall Experience with the Program (Both Groups)**



**Figure 2. Percent Improvement: Group I vs. Group II**



## SUMMARY

- The 7-day programs were well-tolerated with no adverse event.
- Significant reductions in body weight, BMI, waist and hip circumferences were observed in both groups after 7 days (Table 2).
- Overall, more than 80% of the subjects felt improved energy levels and decreased cravings (Fig. 1).
- 53% of the subjects in Group I reported improved elimination/bowel movements versus 27% in Group II (Fig. 2).
- 88% of the subjects in Group I felt improvement in bloating/gassiness compared to 55% in Group II (Fig. 2).

## CONCLUSIONS

The results indicated that both programs were safe and well-tolerated. The addition of a gentle laxative herbal blend was more effective in promoting elimination/bowel movements and reducing bloating/gassiness. This program may be used as an adjunct prior to a weight loss program.