



A 28-day lifestyle intervention program incorporating a pea and potato protein-based meal replacement shake improves indices of human health: a preliminary study

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INTRODUCTION

Overweight (25-30 kg/m²) and obesity (>30 m/kg²) are risk factors for numerous morbidities, including type 2 diabetes as well as cardiovascular disease. However, weight loss reduces the risk for, and improves symptoms of, many of these same conditions. Moreover, both physical and mental aspects of health-related quality of life are significantly improved by weight loss. As such, there is considerable evidence that innumerable health benefits, particularly among overweight and obese individuals, are derived from weight loss.

Meal replacement shakes have been used as an effective strategy for weight loss. The consumption of meal replacement shakes and attendant weight loss may also improve biochemical health indices such as plasma levels of glucose, insulin, cholesterol and triglycerides. We have developed a pea and potato protein-based meal replacement shake that contains neither soy, dairy, eggs, or gluten and which is designed as an aid for weight management. Moreover, it is a low glycemic index (GI) beverage. Compared to high GI foods, low GI foods may confer numerous health benefits, including increasing satiety and decreasing post-meal calorie consumption, enhancing weight loss, and improving blood lipid profiles and insulin sensitivity.

OBJECTIVE

The objective of this clinical trial was to determine whether a pea and potato protein-based meal replacement shake, as part of a 28-day lifestyle intervention program, could improve anthropometric measures (i.e., BMI, % body fat), indices of cardiovascular health, glycemic control, insulin sensitivity, as well as self-perceived health status in a group of individuals considered to be in generally good health.

METHODS

The lifestyle intervention program was 28 days in duration, and incorporated a pea and potato protein-based meal replacement shake (230 cal/serving), low GI foods and modest exercise practices. The lifestyle intervention program consisted of 3 phases:

- Phase I (Reset; day 1 – day 5) – consume 3 weight-loss shakes/day; up to 4 low-g.i. snacks (up to 400 calories total)
- Phase II (Transform; day 6 – day 14) – consume 2 weight-loss shakes/day; 1 low g.i. meal/day; up to 2 low-g.i. snacks (up to 200 calories total)
- Phase III (Maintain; day 15 – day 28) – consume 1 weight-loss shake/day; 2 low g.i. meals/day; 1 low-g.i. snack/day (up to 100 calories total)

- anthropometric, blood pressure and blood glucose assessments were collected at baseline, and at the end of Phase I, Phase II and Phase III
- hematological (i.e., cardiovascular markers) and quality of life assessments were collected at baseline and at the end of Phase III only.

RESULTS

Table 1 – Baseline characteristics of female and male participants.

	Females	Males	p-value
n	16	15	
Age (years)	39.2 ± 11.1	33.5 ± 8.5	0.125
Height (inches)	63.2 ± 1.9	67.5 ± 3.3	<0.001*
Weight (lbs)	162.2 ± 30.8	194.5 ± 35.8	0.011*
Body mass index (kg/m ²)	28.5 ± 5.2	29.9 ± 5.0	0.424
Waist circumference (inches)	32.9 ± 3.9	37.3 ± 4.2	0.005*
% body fat	35.9 ± 5.6	27.3 ± 4.9	<0.001*

All values reported as mean ± SD. P values for comparison of baseline variables between groups using independent samples t-test. * - indicates significant difference between groups at p < 0.05

Table 2 – Indices of cardiovascular health in female and male subjects before (baseline) and after (final) the 28-day weight loss program

	Females			Males		
	Baseline	Final	p-value	Baseline	Final	p-value
Total cholesterol(mg/dl)	190.8 ± 34.6	177.2 ± 21.1	0.059	197.8 ± 27.9	175.9 ± 25.4	<0.001*
HDL cholesterol (mg/dl)	57.8 ± 13.0	52.8 ± 12.8	0.014*	48.7 ± 6.8	42.1 ± 6.0	0.001*
LDL cholesterol (mg/dl)	109.2 ± 26.9	105.0 ± 15.4	0.518	121.1 ± 20.3	112.5 ± 20.6	0.037*
Triglycerides (mg/dl)	92.6 ± 31.9	94.3 ± 30.6	0.774	124.8 ± 44.7	107.0 ± 37.1	0.061
Homocysteine (umol/l)	7.3 ± 1.6	8.4 ± 2.3	0.001*	8.7 ± 1.1	10.6 ± 1.4	<0.001*
Systolic BP (mmHg)	115.8 ± 13.3	110.4 ± 11.6	0.032*	124.1 ± 11.1	116.7 ± 8.5	0.016*
Diastolic BP (mmHg)	79.3 ± 6.7	73.8 ± 6.4	<0.001*	77.2 ± 10.0	71.1 ± 8.7	0.005*

All values reported as mean ± SD. P values for comparison of baseline variables between groups using independent samples t-test. * - indicates significant difference (p < 0.05) between baseline and final values within the same group

Table 3 – Other indices of physical and mental health in female and male subjects before (baseline) and after (final) the 28-day weight loss program

	Females			Males		
	Baseline	Final	p-value	Baseline	Final	p-value
CRP-1	1.9 ± 2.3	1.6 ± 1.0	0.553	1.2 ± 0.5	1.0 ± 0.5	0.158
Insulin	10.1 ± 4.8	8.5 ± 3.7	0.212	9.6 ± 4.9	7.1 ± 3.5	0.011*
Glucose	89.1 ± 7.9	89.1 ± 6.5	0.969	85.9 ± 5.2	86.7 ± 6.6	0.548
MSQ	38.7 ± 24.2	19.7 ± 13.8	0.006*	36.4 ± 26.6	13.3 ± 11.5	0.002*

MSQ – Medical Symptom Questionnaire
All values reported as mean ± SD. P values for comparison of baseline variables between groups using independent samples t-test. * - indicates significant difference (p < 0.05) between baseline and final values within the same group

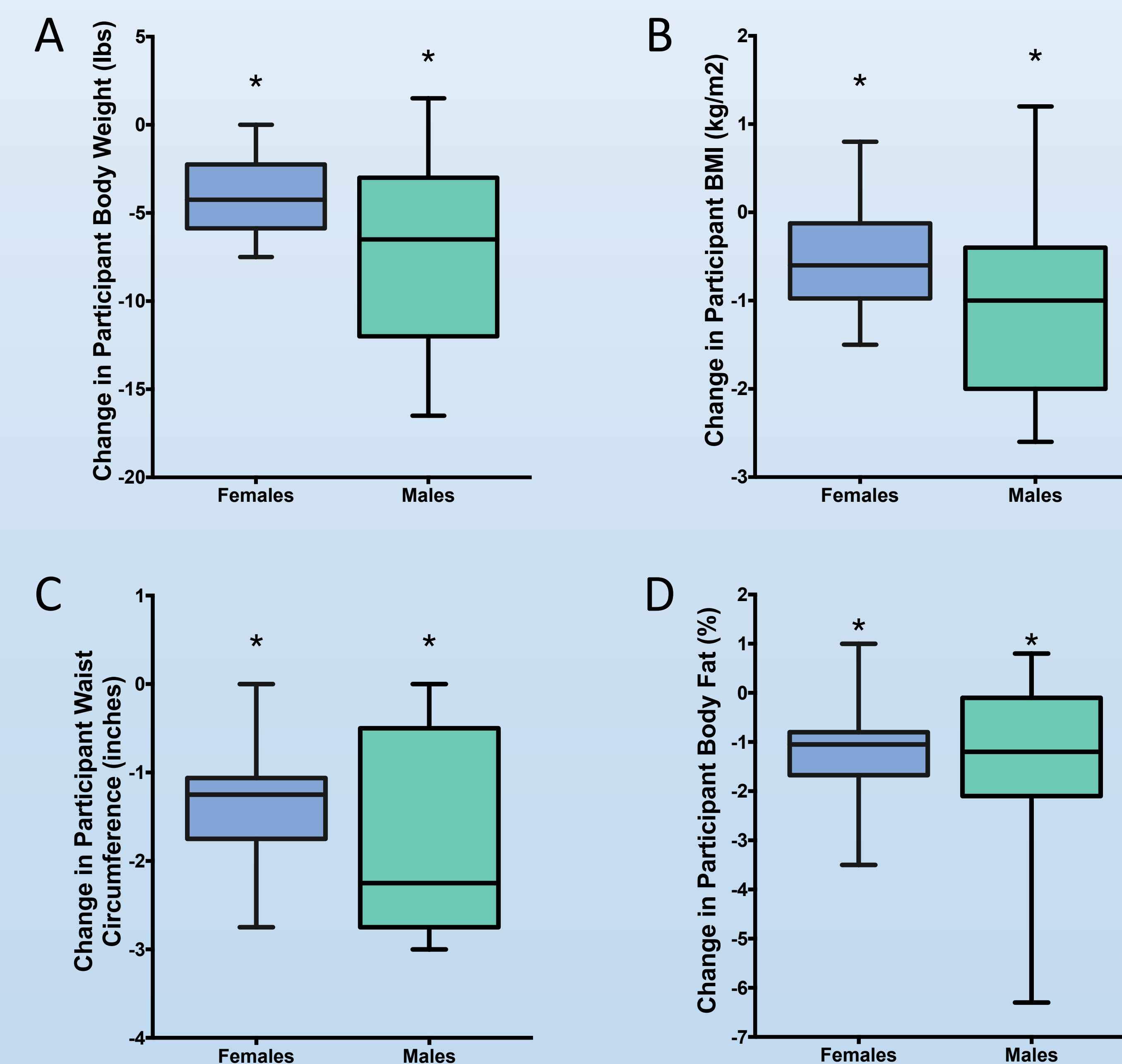


Figure 1 – Changes in anthropometric measures in female and male participants. Participant body weight (A), BMI (B), waist circumference (C) and body fat %(D) declined significantly from baseline to the end of the study in both female and male subjects. * indicates significantly different from 0 at p<0.01 by within-group paired t-test

DISCUSSION

In this study, we sought to determine if a 28-day lifestyle intervention program, which incorporated the consumption of a pea and potato protein-based meal replacement shake, low GI foods as well as modest exercise practices, could improve physiological as well as self-perceived measures of health in a population of male and female subjects considered to be in generally good health. The results of this study indicate that:

- 1) numerous anthropometric, biomedical and self-perceived health indices improved following the 28-day dietary intervention
- 2) this intervention strategy yields visible results that could provide incentive and enhance compliance among individuals that utilize this lifestyle intervention program

Finally, because this study employed an uncontrolled, open-label methodology, cause-and-effect inferences can only be confirmed when a double-blind, randomized placebo-controlled trial is performed.