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# **Is White Bean Extract a Safe and Effective Treatment for Weight Loss?**

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies  
Philadelphia College of Osteopathic Medicine  
Philadelphia, Pennsylvania

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## ABSTRACT

Objective: The objective of this systematic review is to determine whether or not white bean extract is a safe and effective treatment for weight loss.

Study Design: Systematic review of three primary studies, two published in 2007 and one in 2004, written in the English language.

Data Sources: Three randomized, controlled, double blind studies published after 1996 relating to white bean extract and weight loss were obtained using MedLINE, PubMed, and Cochrane databases.

Outcomes Measured: All three studies measured weight loss. Additional outcomes measured were change in waist, hip, and thigh circumference and body composition. Subjects were evaluated at baseline and at the completion of the study and the results were compared.

Results: Three randomized controlled, double blind studies were included in this review. All three studies demonstrated that both test and control subjects lost weight and had decreases in other outcomes measured; however, only one study, by Cellano et al., found a statistically significant difference between the test group and the control groups, suggesting that white bean extract is an effective treatment for weight loss and other outcomes measured. None of the studies reported negative side effects or adverse events related to the study intervention.

Conclusion: Based on this systematic review, white bean extract cannot be recommended as an effective treatment for weight loss for overweight/obese individuals in the general population at this time. The only study with results to suggest otherwise, by Cellano et al., used a pre-screening procedure, excluding subjects who were less compliant with study protocols. This indicates that white bean extract may be an effective means for weight loss, when combined with diet and exercise modification, in a very compliant population. There is, however, no indication that white bean extract is unsafe. Additionally, white bean extract is not regulated by the FDA; therefore, any supplements currently available may be widely varied, again enforcing reservations surrounding effectiveness for white bean extract as a treatment for weight loss.

Key words: white bean extract, overweight, obesity, weight loss

## Introduction

Weight gain and obesity rates are growing health concerns in the United States. Currently, more than 50% of the adult population is considered overweight or obese.<sup>1,2</sup> The condition of being overweight can be defined as having a body mass index (BMI) greater than ideal body weight or a BMI of 25-29.9. The condition of obesity is characterized as a BMI of 30-39.9, and a BMI of  $\geq 40$  is considered morbidly obese.<sup>2</sup> Overweight and obese individuals are at increased risk for developing a myriad of diseases and conditions such as diabetes, hypertension, cancer, coronary artery disease, myocardial infarction, osteoarthritis, stroke and infertility.

There is no single factor that causes an individual to become obese or overweight, the development of these conditions are multifaceted. Lifestyle, genetics and environment all contribute to weight gain. Diets high in fats, sugars, simple carbohydrates and low in fiber appear to contribute to the condition. Decreased activity or a sedentary lifestyle seems to be to an additional factor. Certain populations such as African American women and Hispanic populations appear to have a genetic influence.<sup>3</sup> Additionally, where an individual lives may play an important role. Nine of the U.S. states have residents with higher rates of obesity as compared to other U.S. states; Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Missouri, Oklahoma, Tennessee, and West Virginia all have  $\geq 30\%$  obesity rates.<sup>3</sup>

Considering a significant portion of the current patient population is overweight/obese, treatment and management is a major concern for a healthcare provider. Being overweight/obese is associated with increased morbidity and mortality and may require additional medical needs, interventions and a significant financial investment. The estimated healthcare costs associated

with obesity as of 2009 were \$147 billion<sup>3</sup>. It is also estimated that obese patients spend \$395 more annually on healthcare than healthy weight patient.<sup>1</sup> Increased cost is evidenced by overweight and obese patients visiting their primary care providers a greater number of times as compared to normal weight individuals.<sup>4</sup> Also, obese patients have lengthier healthcare visits and a greater number of prescriptions per visit as compared to normal weight individuals.<sup>5</sup>

Many current weight loss methods are available such as diet modification/behavioral modification, pharmaceuticals, and surgery. Each of these methods may have a place in treatment, but each can have varying degrees of effectiveness, unwanted side effects and compliance issues. Popular diet modifications and behavioral modification include options like nutritional counseling, Atkins diet, Weight Watcher's diet™ or Curve's™ programs and hypnotism. Though some individuals may have success with these options, compliance appears to be a major hurdle. Pharmaceuticals are an additional option for overweight or obese individuals. Some medications are now available over the counter, such as Orlistat (Alli, Xenical), whereas others such as Diethylpropion (Tenuate, Tenuate Dospan) and Phentermine (Adipex-P, Fastin), require a prescription from a clinician. The maximum recommended usage for some of these medications is one year, whereas others are only recommended for 3 months.<sup>6</sup> Additionally, these medication can have unwanted and even unsafe side effects such as steatorrhea, increased blood pressure, and the potential for addiction<sup>7</sup>. Lastly, bariatric surgery is now an option for some individuals. However, these procedures are invasive, may only be warranted for certain patients, and can have negative physiologic consequences and complications.<sup>6, 8</sup>

This paper examined 3 RCTs to explore the option of white bean extract as a safe and effective treatment for weight loss among overweight/obese adults. The supplement is extracted

from white beans, scientific name *phaseolus vulgaris*, not derived from harsh or artificial chemicals. The method is considered an easy, non-invasive and a natural alternative to traditional weight loss therapies. Carbohydrate intake and absorption may be a component of diet that can contribute to weight gain. White bean extract prevents the breakdown of larger carbohydrates by blocking an enzyme called amylase. This in turn prevents the absorption of smaller carbohydrates (disaccharides called maltose) and thus prevents the absorption of excess calories.<sup>9</sup> Patients do not need to modify their diets and may continue to consume carbohydrates while taking white bean extract, the excess carbohydrate calories are not absorbed.

### Objective

The objective of this systematic review is to determine whether or not white bean extract is a safe and effective treatment for weight loss in overweight/obese individuals.

### Methods

Specific criteria were used for the selection of studies included in this review. The populations used in these studies were subjects over 18 years of age who were overweight or obese and needed/wanted to lose weight. The intervention was white bean extract in a pill form. The control was a placebo pill. Outcomes measured included: weight loss and body modifications such as fat mass vs. lean mass, and waist, hip and thigh circumference.

Literature searches were performed by the author using the PubMed, Ovid MEDLINE and Cochrane databases during December 2009-February 2010. Key words “white bean extract”, “phaseolus vulgaris”, “obesity” and “weight loss” were used in combinations to search for published, primary journal articles written in the English language. Only peer-reviewed, randomized controlled, double blind trials with outcomes that would matter to patients (patient

oriented evidence that matters POEMs) published after 1996 were included. Articles that used white bean extract in combination with other weight loss interventions such as diet, exercise and/or therapy were considered as long as the control group received the same type of intervention. Any studies that used animal subjects, used white bean extract in a non-pill form, or did not report weight loss as an outcome were excluded. These criteria yielded three clinical trials included in this review: 1) “Blocking Carbohydrate Absorption and Weight Loss: A Clinical Trial Using a Proprietary Fractionated White Bean Extract” by Udani and Singh published in 2007<sup>10</sup>, 2) “Dietary Supplement Containing Standardized Phaseolus Vulgaris Extract Influences on Body Composition for Overweight Men and Women” by Cellano, et al. published in 2007<sup>11</sup> and, 3) “Blocking Carbohydrate Absorption and Weight Loss: A Clinical Trial Using Phase 2 Brand Proprietary Fractionated White Bean Extract” by Udani, Hardy and Madsen published in 2004.<sup>12</sup> Statistics reported by these trials included change in mean from baseline (Ave + SEM) and inter- and intra-group analyses (using t-tests and ANOVA) represented by P-values with 95% CIs.

### Outcomes Measured

Udani & Singh measured subjects’ weights in pounds at the beginning of their study to obtain a baseline measurement and then repeated the measurement at the conclusion of the study. Weight loss was measured as a change from baseline. Additionally, subjects’ waists were measured, in inches, at the beginning of the study to establish a baseline measurement and at the conclusion of the study. Decrease in waist size was measured as a change from baseline.

Cellano et al. measured weight loss, body composition, waist circumference, hip circumference and right thigh circumference. Weight loss was measured in kg and circumference was measured in cm. Subjects were weighed initially to establish a baseline, and weights were

measured at the completion of the study to determine if there was a change from baseline. Body compositions (fat mass vs. lean mass) were measured in kg initially and at the conclusion of the study. Values were calculated to determine if there was a change from baseline. Waist, hip and right thigh circumference were measured initially to establish a baseline and lengths were measured at the completion of the study to determine if there was a change from baseline.

Udani, Hardy and Madsen measured weight loss in their study. Weight loss was measured in pounds at the beginning of the study to establish a baseline measurement and then again at week 2, week 4, week 6 and week 8 (the conclusion of the study). Weight loss was averaged across weeks and compared to baseline.

## Results

The major characteristics and demographics of each study included in this review are displayed in Table 1. Each study had similar inclusion criteria, namely that subjects included were all over the age of 18, and were considered overweight or obese. The exclusion criteria for each study are similar as well. The interventions varied slightly from study to study. Each study used white bean extract in pill form, though the amount of active supplement in each pill and the number of pills was varied between studies. Each study had varied results regarding the effectiveness of the white bean extract intervention, these results are described below.

Table 1. Demographics and Characteristics of included studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	w/d	Interventions
Cellano et.al. 2007	-RCT -x2 Blind -placebo controlled	60	20-45	-5-15kg overweight -Stable body wt x 6mo -Good general health -No ongoing drug tx -Commitment to eat as prescribed, avoid other wt loss products, avoid lifestyle changes during test period	-Pregnant or breastfeeding -Wt-reduction tx during the 6mo prior to study -any condition contrary to those indicated in enrollment criteria (p.46)	1	800 mg tab of 445mg of phaseolus vulgaris x once daily before main meal rich in carbs x 30 days -Diet program
Udani et. al. 2004	-RCT -x2 Blind -placebo controlled	39	20-69	- Men and women >18 -BMI $\geq$ 30 kg/m <sup>2</sup> and $\leq$ 43 kg/m <sup>2</sup> -Adequate contraception in women of childbearing age -Absence of any drugs used to treat obesity	-Active eating d/o -Hx of seizures, any significant GI (including malabsorption), cardiac, renal, hepatic, psychiatric, or endocrine disorders, drug or Etoh abuse -Abnormal baseline lab levels	12	1,500 mg of Phase 2 (white bean extract) BID with lunch and dinner x 8wks -Diet program
Udani & Singh 2007	-RCT -x2 Blind -placebo controlled	25	> 18 and < 40	- Men and women >18 and < 40 yrs old -BMI $\geq$ 25 kg/m <sup>2</sup> and $\leq$ 31 kg/m <sup>2</sup> -Agreement to maintain diet & exercise modifications, periodic F/U, (for females) use appropriate birth control method	-Use of drugs, herbs, non-script meds w/in 4 wks of screening -Abnormal labs /studies -Active eating d/o -hx of seizures, etoh abuse, medical condition (CAD, CHF, stroke, arrhythmia, uncontrolled HTN, malabsorption, GI problems) -inability to understand/follow protocol	3	1,000 mg fractionate white bean extract BID with breakfast and lunch x 4 wks -wt loss program

The Udani and Singh study from 2007 used 1,000 mg of fractionated white bean extract pills for the test group and a placebo pills for the control group. Additionally, both control and test subjects participated in a weight loss program, diet restriction program, exercise with a personal trainer and group behavioral sessions with a psychologist. The study was conducted for 4 weeks. As described in Table 2, the researchers reported a weight loss of 6 lbs for the test group (P=0.0002) and 4.7 lbs for the control group (P=0.0016) at the completion of the study. However between group analysis suggests that there was no statistically significant difference (P=0.4235) between the amount of weight lost in the test group versus the control group. Change in waist size is similar to weight loss. Both the test group and the control group had a decrease in their waist size, however when the two groups were compared, the between group analysis did not yield statistical significance. The additional outcomes measured on a subjective 10-point scale were not statistically significant and the data was not included in the published study. The data presented are continuous and cannot be converted to dichotomous because the study failed to report initial weights of individuals or average weights of each group. This study fails to show a statistically significant effect of white bean extract on weight loss and decrease in waist size when compared to a control group.

Table 2. Effect of White Bean Extract on Weight Loss and Waist Size

Udani & Singh 2007						
Outcomes Measured	Test Group	Control Group	Test Group p-value	Control Group p-value	Between Group p-value	RBI, ABI, NNT
Weight Loss	6 lbs	4.7 lbs	0.002	0.0016	0.4235	*
Waist Size	2.2	2.1	0.050	0.0001	0.8654	*

\*Unable to calculate

Cellano et al. 2007 conducted a similar study to the one described above, however initial study participants went through an additional screening process which differed from the other two studies. This extra step eliminated subjects who were considered not compliant with the

study protocol. The remaining subjects were given one 800mg pill daily that contained 445mg of active white bean extract and taken before a meal rich in carbohydrates. Control subjects took a placebo pill. Both groups participated in a diet program. The study was conducted for 30 days. As described in Table 3, researchers measured weight loss, body composition (fat mass vs. lean body mass), waist circumference, hip circumference and right thigh circumference. Data were averaged and reported as a change in mean from baseline. Since the data were averaged and weight loss for individuals was not included, it is not possible to determine which participants lost weight and how much each participant lost; therefore, converting the continuous data to dichotomous data was not possible. Intra-group analysis was done for each measured category. The weight loss category yielded statistical significance ( $P < 0.001$ ) suggesting that both groups had a decrease from baseline. When data was compared between the test group and control group, data showed statistical significance for weight loss ( $P < 0.001$ ). This illustrates that 445mg of white bean extract when given before a carbohydrate rich meal showed a statistically significant change in baseline for weight loss when compared to a placebo pill.

Table 3. Effect of White Bean Extract on Measured Outcomes

Cellano et. al. 2007						
Outcomes Measured	Test **	Control**	Test Group p-value	Control Group p-value	Between Group p-value	RBI, ABI, NNT
Body Weight (kg)	-2.93 ± 1.16	-0.35 ± 0.38	0.001	0.005	0.001	*
Fat mass (kg)	-2.4 ± 0.67	-0.16 ± 0.33	0.001	0.05	0.001	*
Lean body mass (kg)	-0.53 ± 0.45	-0.19 ± 0.17	0.001	0.02	0.05	*
Waist Circumference (cm)	-2.93 ± 2.13	-0.47 ± 0.39	0.001	0.004	0.001	*
Hip Circumference (cm)	-1.48 ± 0.66	-0.26 ± 0.46	0.001	0.05	0.001	*
Thigh (Right) Circumference (cm)	-0.95 ± 0.80	-0.26 ± 0.46	0.001	0.008	0.001	*

\* Unable to Calculate

\*\* “Ave + SEM, negative values indicate a loss from baseline”<sup>11</sup>

The final study included in this systematic review was conducted by Udani, Hardy and Madsen in 2004. These researchers required test subjects to consume two, 1,500 mg pills of white bean extract daily; one pill with lunch and one with dinner. Subjects in the control group followed the same procedure, but consumed a placebo pill. Subjects in both groups began a high fiber/low fat diet program. This study was the longest of the included studies and was conducted for 8 weeks. Results were represented as an average change in weight from baseline. Since the authors did not include subjects' weights at baseline, the continuous data provided was unable to be converted to dichotomous data. Displayed in Table 4, the test group lost an average of 3.79 lbs and the control group lost an average of 1.65 lbs. Analysis failed to show a statistical significance between the two groups ( $P=0.35$ ). This suggests that there was no statistical difference in weight loss between the test group and the control group.

Table 4. Effect of White Bean Extract on Weight Loss

Udani, Hardy & Madsen 2004				
Outcomes Measured	Test Group Ave	Control Group Ave	Between Group p-value	RBI, ABI, NNT
Weight Loss (lbs)	3.79	1.65	0.35	*

\* Unable to Calculate

Each study reported variability regarding the effectiveness of white bean extract on weight loss, however all the studies were consistent with reports on safety. No side effects or adverse reactions were reported by any of the three studies as seen in Table 5. Udani and Singh monitored kidney and liver function tests, blood counts and platelet counts of all subjects at baseline and at completion of the study. The researchers found no statistical significance between groups to suggest adverse reactions. Cellano et al. reported that all subjects were monitored for side effects or adverse events and nothing significant was reported. Udani, Hardy and Madsen measured creatinine, sodium, chloride, calcium, carbon dioxide, and AST/ALT of all subjects at

baseline and at the conclusion of the trial. Nothing significant was reported. The authors report that “no adverse events occurred that were believed to be due to the active product”.

Table 5: Profile of Safety and Adverse Events Throughout Studies

Safety Parameters Reported by Studies			
Safety Parameters	Udani & Singh 2007	Cellano et.al. 2007	Udani, Hardy & Madsen 2004
Side Effects	NR	NR	NR
Adverse Events	NR	NR	NR
Laboratory Studies**	Kidney & liver Function tests, blood counts, platelet counts	#	Cr, Na <sup>+</sup> , Cl <sup>-</sup> , Ca <sup>++</sup> , CO <sub>2</sub> , AST/ALT
NNH	*	*	*

NR: None Reported

\* Unable to calculate

\*\* All reports of laboratory studies were within normal limits

# No Laboratory studies conducted

### Discussion

White bean extract in pill form is widely available and regularly marketed as a “starch blocker” and diet aid. Because it is considered a supplement, however, its production, distribution and use are not currently regulated by the FDA. Thus, the supplement currently available and the suggested dosing could be highly varied from one source to another.

This review aimed to determine the efficacy and safety of white bean extract on weight loss by conducting a systematic review of current studies. The literature search may have been limited in the fact that only primary, randomized controlled, double blind trials written in the English language were included. However in using these criteria, it is the author’s belief that the studies represented in this review are the best scientific research available thus far on the topic.

That being stated, the best available data published still leaves room for improvement. Even though all three trials used white bean extract as a treatment and placebo for control, all three studies had additional modifications such as diet and in the case of two of the three studies,

exercise. Therefore the effectiveness of the supplement in the general overweight/obese population, who may not participate in diet modification or exercise programs, is largely unknown. Two of the three studies found no statistical significance on white bean extract's effect on weight loss. Only one study, Cellano et al. found a statistically significant difference in weight loss and other measures with treatment. This may be due to their decision to run the study under "optimal circumstances"<sup>11</sup>. They initially accepted 82 randomized subjects, but then had them undergo a "pre-screening" to determine how compliant they would be with the study design. After the prescreening was completed, 60 subjects completed the study. Arguably, this study was less random, and the data value may have limited application to a general population.

### Conclusion

Based on this systematic review, white bean extract cannot be recommended as an effective treatment for weight loss to the general population at this time; however, based on Cellano et al.'s study, white bean extract may be beneficial for weight loss when combined with diet and exercise for very compliant patients. White bean extract can be considered safe, as none of the three studies reported negative side effects or adverse events. Nevertheless it is not currently regulated by the FDA again enforcing reservations surrounding its effectiveness as a treatment for weight loss.

Given that the condition of being overweight/obese influences morbidity and mortality, current healthcare practice and financial impacts, further research exploring white bean extract as a weight loss treatment is warranted. Future trials with larger sample size and no additional interventions, such as diet and exercise, would be more representative of the effectiveness of white bean extract as a treatment for weight loss in the general obese/overweight population.

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