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**Are soy-based proteins, meals, and diets an effective treatment in reducing waist circumference in overweight and obese adults ages 20-75 years?**

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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 evidence based medicine review is to determine whether or not soy-based proteins, meals, and diets are effective treatments in reducing waist circumference in overweight and obese adults ages 20-75 years.

**Study design:** Review of three published, randomized controlled trials (RCTs) published in 2003, 2007, and 2011. All English language.

**Data Source:** The three randomized controlled trials that used in this review were found using PubMed.

**Outcomes measured:** The outcomes measured were improvement of patient's overweight and obesity status and their overall quality of life through the indication of reduced waist circumference. By measuring patient's waist circumference before, during, and after treatment of soy-based proteins, meals, and diets with measurement methods between the lower rib and iliac crest at the level of the navel, a non-distensible tape measure, and an inelastic scale.

**Results:** In a RCT by Allison et al. (2003), soy-based meal replacement formula reduced waist circumference for overweight and obese adults in a 12 weeks period with an estimate treatment effectiveness of  $P < 0.001$  as a result. In a RCT by Liao et al. (2007), soy-based diet reduced waist circumference for overweight and obese adults in a 8 weeks period with an estimate treatment effectiveness of 95% CI 1.6-2.8 as a result. In a RCT by Takahira et al. (2011), soy protein reduced waist circumference for overweight and obese adults in a 20 weeks period with an estimate treatment effectiveness of  $P < 0.05$  as a result.

**Conclusions:** The result of all three randomized controlled trials suggest that soy-based proteins, meals, and diets, as a form of treatment for reduction in waist circumference is effective in regards of patient's overweight and obesity status and their overall quality of life. This topic does warrant additional research. Further studies conducted should include if patient needs a post-life-long maintain diet with soy-based proteins and meals after they have achieve a normal BMI waist circumference. In addition, will this be available for patients with mild soy-allergy, but controlled with anti-histamines.

**Key words:** Soybean proteins, Obesity

## **Introduction**

Overweight and obesity are chronic conditions defined by the BMI of a patient.<sup>1</sup> This paper evaluates three randomized controlled trials (RCTs) comparing the efficacy of soy-based proteins, meals, and diets as an add-on regimen for the treatment of reducing waist circumference in overweight and obese adults ages 20-75 years.

Obesity affects more than one-third of U.S adult, which is about 36.5%.<sup>2</sup> Obesity is a risk factor for other major chronic diseases including type 2 diabetes mellitus, coronary artery diseases, osteoarthritis, and stroke, which can lead to a detrimental impact on the patient's quality of life.<sup>2</sup> The annual medical cost of obesity in the U.S was estimated to \$147 billion in 2008 and continues to increase annually.<sup>1,3</sup> There are 928.6 million reporting of health care visit treatment for obesity, which is about 54.6% on average visits to the primary care physician.<sup>3</sup> Everyday both physician assistants and physicians are working to treat and control obesity in their patients, with the goal to improve quality of life and limit risk factors for major chronic diseases.

Obesity is a state of excess adipose tissue mass.<sup>4</sup> Obesity is a result of behavioral and genetic factors. Behaviors factors include: dietary food choices, lack of physical activities, medication use, economic status, and education.<sup>4</sup> Genetic factors include: hypothyroidism, type 1 diabetes mellitus, polycystic ovary syndrome, and leptin abnormalities.<sup>4</sup>

Obesity is sufficiently diagnostic through physical examination in detecting excess body fat in conjunction with a more quantitative evaluation, the BMI.<sup>4</sup> The BMI correlates with excess adipose tissue by the measurement of body weight in kilograms by the height in meters squared.<sup>4</sup> The BMI classification are as followed: normal BMI as

18.5–24.9, overweight BMI as 25–29.9, class I obesity BMI as 30–34.9, class II obesity BMI as 35–39.9, and class III (extreme) obesity BMI as greater than 40.<sup>4</sup>

There are multiple treatments available for obesity. The initial treatment for obesity is diet modifications: lowering caloric intake (800–1000 kcal/day), lowering the amount of sugar and fat in the diet, and increase physical activities daily (at least 1 hour of exercise a day).<sup>4</sup> Over the counter medications or prescription medications can be used as a conjunction as well as an alternative treatment when patient fails diet modifications. Catecholaminergic medications are approved for short-term use such as: phentermine, diethylpropion, benzphetamine, and phendimetrazine.<sup>3,4</sup> Long-term medications include orlistat.<sup>3,4</sup> In 2014, the FDA approved other alternative medications for weight loss including liraglutide and combination of bupropion and naltrexone drugs.<sup>3,4</sup> In severe cases of obesity (BMI >40 or BMI >35 with significant co-morbidities) bariatric surgery is an alternative option.<sup>4</sup> Bariatric surgery include: Roux-en-Y gastric bypass (RYGB), vertical banded gastroplasty, and sleeve gastrectomy.<sup>4</sup>

The treatments available such as: diets, exercise, over the counter medications, prescription medications, and surgeries are effective for overweight and obesity patients; however, the thought of using soy-based proteins, meals, and diets can be another option or add-on regimen to help improve diet modifications to decrease waist circumference and the overall health status of overweight and obesity adults' ages 20-75 years.

### **Objective**

The objective of this selective EBM review is to determine whether or not “Are soy-based proteins, meals, and diets an effective treatment in reducing waist circumference in overweight and obese adults ages 20-75 years?”

## **Methods**

The investigation chosen in these three randomized controlled trials (RCTs) are reduction of waist circumferences due to soy-based proteins, meals, and diets. The selection of the studies is based on the target population, interventions used to compare control group and experimental group, and the outcomes measured. The target population was limited to overweight and obese adults between the ages of 20-75 years. The intervention of interest used for participants was soy-based proteins, meals, and diets.<sup>5,6,7</sup> The experimental group was put on soy-based proteins, meals, and diets, while the control group was put on a non-soy-based proteins, meals, and diets.<sup>5,6,7</sup> Outcomes were based on measurement methods between the lower rib and iliac crest at the level of the navel, a non-distensible tape measure, and an inelastic scale.<sup>5,6,7</sup> Three randomized controlled trials (RCTs) were used in this type of study to further answer the investigation of soy-based proteins, meals, and diets as a treatment option for reducing waist circumference in overweight and obese adults ages 20-75 years.

Key words soybean proteins and obesity were searched using the following search engines: PubMed and Cochrane Database. Articles selected were written in the English language, peer-reviewed journals, and published in 2003, 2007, and 2011 and had not been previously used in a systematic review or meta-analysis. Inclusion criteria for these studies were RCTs that were published after 1996 based on their relevance and importance of the outcome to the patient (Patient Oriented Evidence That Matters, POEMS) and that investigated the effectiveness of soy-based proteins, meals, and diets as a treatment option for reducing waist circumference in overweight and obese adults (Table 1). Exclusion criteria consisted of studies that investigated patients who were not

considered overweight or obese adults who are under 20 or over 75 years old. Statistics were reported using p values, standard deviation, and mean change from baseline.

**Table 1-** Demographics and Characteristics of included studies<sup>5,6,7</sup>

Study	Type	# Pts	Age (yrs )	Inclusion Criteria	Exclusion Criteria	W/ D	Interventions
Allison DB, Gadbury G, Schwartz LG, 2003 (1)	RCT	100	35-65	Patients with BMI of 28-41, ages 35-65, and medically fit for safe weight loss through a physical exam.	Patients with weight loss >5kg in the past 3 months, use weight loss medication within the past 6 wks, BMI > 90 <sup>th</sup> percentile, and any medical or psychological contradictions.	25	Randomize meal replacement treatment group: 5 Scan Diet Shakes,1200kcal=day) or control group: 1200kcal=day. Both received dietary counseling for weight loss and followed 12wks.
Liao FH, Shieh MJ, Yang SC, Lin SH, Chien YW 2007 (2)	RCT	30	20-60	Patients with BMI 29-30, ages 20-60.	Patient with history of: CVD, kidney disease, DM, and females who are pregnant or breastfeeding.	0	Soy-based low-calorie group consumed only soy protein and traditional low-calorie group consumed 2/3 animal proteins and 1/3 plant protein in 1200 kcal/d 8wks diet. Anthropometric data recorded every week and biochemical data before and after 8wks compared.
Takahira M, Noda K, Fukushima M, 2011 (3)	RCT	48	22-72	Patients ages 20-75 with visceral fat area $\geq$ 100 cm <sup>2</sup> and able to consume	Patients with 2nd obesity, DM, CVD, kidney or GI or thyroid disease, stroke, pregnancy, breastfeeding,	0	Trial formula (SP) and control formula (MP) given for 20 wks. Each contains 170kcal/pack. Patients recorded by: food and

				formula shakes.	and substance abuse.		drink intake for 3 days before their visits on weeks: 0, 12, and 20.
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### **Outcomes Measured**

The outcomes measured were improvement of patient's overweight and obesity status indicated by waist circumference reduction in hoping this is the first step improving their overall quality of life. The patient's waist circumferences were measured before, during, and after treatment of soy-based proteins, meals, and diets. Allison et al. (2003) measured waist circumference with a non-distensible tape measure.<sup>5</sup> Liao et al. (2007) measured waist circumference with an inelastic scale.<sup>6</sup> Takahira et al. (2011) measured waist circumference between the lower rib and iliac crest at the level of the navel with a tape measure.<sup>7</sup>

### **Results**

In the study done by Allison et al. (2003), the reported statistics compared soy-based meal replacement formula as the experimental group with single session of dietary counseling and a pamphlet describing good weight loss practices as the control group in a 12 weeks period. The results of waist circumference reduction for soy-based meal replacement formula (n=50) and control group (n=50) were recorded as a mean  $\pm$  standard deviation at baseline within a 12 weeks period (Table 2).<sup>5</sup> The results of soy-based meal replacement formula and control group were evaluated in a 12 weeks period with an estimate treatment effectiveness of  $P < 0.003$  and standard deviation 4.2.<sup>5</sup>

**Table 2:** Intention-to-treat analysis of waist circumference: change, mean  $\pm$ SD<sup>5</sup>

Study Period	Treatment, Mean (s.d.)	Control, Mean (s.d.)	P-value
4 weeks	-3.2 (4.0)	-2.9 (4.0)	0.553

8 weeks	-5.4 (4.5)	-3.9 (8.3)	0.324
12 weeks	-6.0 (4.2)	-2.9 (3.7)	0.003

In the study done by Liao et al. (2007), the reported statistics compared soy low-calorie diet as the experimental group with traditional low-calorie diet as the control group in a 8 weeks period.<sup>6</sup> The results of waist circumference reduction for soy low-calorie diet (n=15) and control group (n=15) where recorded as mean  $\pm$  standard deviation at baseline within a 8 weeks period (Table 3).<sup>6</sup> The treatment effect between the soy low-calorie diet and control group were evaluated in a 8 weeks period with an estimate treatment effectiveness of mean change from baseline:  $-2.5 \pm 3.5$ ,  $P < 0.05$ , and 95% Confidence Interval (CI) 1.6-2.8, as a result.<sup>6</sup>

**Table 3:** Intention-to-treat analysis of waist circumference (cm): change, mean  $\pm$ SD<sup>6</sup>

Soy group			Traditional group		
Beginning	End	Change	Beginning	End	Change
87.3 $\pm$ 11.0	84.8 $\pm$ 10.3 <sup>a</sup>	-2.5 $\pm$ 3.5	90.2 $\pm$ 13.7	87.3 $\pm$ 12.3 <sup>a</sup>	-2.9 $\pm$ 3.3

In the study done by Takahira et al. (2011), the reported statistics compared soy protein as the experimental group with milk protein as the control group in a 20 week period.<sup>7</sup> The results of waist circumference reduction for soy protein and control group where recorded as mean  $\pm$  standard deviation at baseline, 95% Confidence Interval (CI), and p-value of a 20 weeks period (Table 4 and Table 5).<sup>7</sup> The treatment effect between the soy protein and control group was evaluated in a 20 weeks period with an estimate treatment effectiveness of  $P < 0.05$  and mean change from baseline:  $-2.2 \pm 0.5$ , as a result.<sup>7</sup>

**Table 4:** Intention-to-treat analysis of waist circumference (cm): change, mean  $\pm$ SD<sup>7</sup>

Soy protein group			Milk protein group		
0 weeks	12 weeks	20 weeks	0 weeks	12 weeks	20 weeks
98.1 $\pm$ 2.1	97.0 $\pm$ 2.1	95.4 $\pm$ 1.9	98.1 $\pm$ 1.8	96.6 $\pm$ 1.8	96.1 $\pm$ 1.7

	(-1.7 ± 0.6)	(-2.2 ± 0.5)		(-1.5 ± 0.5)	(-2.0 ± 0.7)
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**Table 5:** Intention-to-treat analysis of waist circumference (cm): CI and P-value <sup>7</sup>

Estimate (95% CI)	P value
-0.003 (-0.009 to 0.003)	0.3446

In these three randomized controlled trials (RCTs), the experimental groups were soy-based proteins, meals, and diets and the control groups were non-soy based products and diet plans. Each study had specific tolerability and adverse events. In the study done by Allison et al. (2003), five subjects withdrew from the study due to adverse events: three subjects experienced diarrhea, one subject experienced gastric reflux, and one subject experienced generic ‘symptoms unbearable’). <sup>5</sup> In the study done by Liao et al. (2007), there were no reports of withdrawal or adverse effects when study was conducted of all thirty subjects. <sup>6</sup> In the study done by Takahira et al. (2011), there were no reports of withdrawal or adverse effects when study was conducted of all forty-eight subjects. <sup>7</sup>

### **Discussion**

The results from all three randomized controlled trials Allison et al. (2003), Liao et al. (2007), and Takahira et al. (2011) suggest soy-based proteins, meals, and diets have been effective in reducing waist circumference for overweight and obese adults ages 20-75 years, which respectively help improve patient’s overweight and obesity status and possibly the first step in improving their overall quality of life. However, soy is not well-known for treating obesity and reducing waist circumferences. Soy is well-known for an add-on treatment for diseases including: breast cancer, prostate cancer, cardiovascular disease, and reduction of bone fractures due to bioactive components of saponins, protease inhibitors, phytic acid, and isoflavone. <sup>8</sup> Since soy is inexpensive and seen in

many everyday products as an add-on ingredient; it is not difficult for patients to use soy routinely as an add-on diet to reduce waist circumference, patient's overweight and obesity status as well as improving their overall quality of life.

The relatively new concept of using soy-based proteins, meals, and diets as an add-on regimen to reduce waist circumference for overweight and obese adults has its limitations due to its original use of treating other diseases such as: breast cancer, prostate cancer, cardiovascular disease, and reduction of bone fractures.<sup>8</sup> Major limitations in these three randomized controlled trials studies were small study size groups and short experimental time frame which made long-term effects of treatment inconclusive. In the study done by Allison et al. (2003), there were 100 participants in a 12 weeks experimental period; as the study states due to limited durations the long-term effects of the treatment on study outcomes were not evaluated.<sup>5</sup> In the study done by Liao et al. (2007) there were 30 participants in an 8 weeks experimental period and the study done by Takahira et al. (2011) there were 48 participants in a 20 weeks experimental period; although these studies were successful in reporting statically the reduction of waist circumference by using soy-low calorie diet and soy protein it did not discuss long-term effects of treatment due to limited durations of study period.<sup>6,7</sup>

## **Conclusion**

In conclusion, there are statistical evidences suggesting soy-based proteins, meals, and diets as an add-on regimen for reducing waist circumference in overweight and obese adults ages 20-75 years is an effective treatment indicated in three randomized controlled trials Allison et al. (2003), Liao et al. (2007), and Takahira et al. (2011),<sup>5,6,7</sup> Although each of these studies has a relatively small sample size group and short-experimental

duration, the results found were still considered statistical significant in favor of soy-based proteins, meals, and diets as an add-on regimen for the treatment. However, all three studies could have had larger sample sizes and longer-experimental duration to provide stronger evidence that soy-based proteins, meals, and diets as an add-on regimen is effective for both short-term and long-term use without severe complications or adverse effects in reducing waist circumference. Future study is warranted to evaluate if patient needs a lifetime maintain diet with soy-based proteins and meals after they have achieve a normal BMI waist circumference.

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