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Review Article

The efficacy of *Phaseolus vulgaris* as a weight-loss supplement: a systematic review and meta-analysis of randomised clinical trials

Igho Onakpoya*, Salsabil Aldaas, Rohini Terry and Edzard Ernst

Complementary Medicine, Peninsula Medical School, University of Exeter, Exeter, UK

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Abstract

A variety of dietary supplements are presently available as slimming aids, but their efficacy has not been proven. One such slimming aid is the bean extract, *Phaseolus vulgaris*. The aim of the present systematic review is to evaluate the evidence for or against the efficacy of *P. vulgaris*. Electronic and non-electronic searches were conducted to identify relevant human randomised clinical trials (RCT). Hand searches of bibliographies were also conducted. No age, time or language restrictions were imposed. The eligibility of studies was determined by two reviewers independently, and the methodological quality of the included studies was assessed. We identified eleven eligible trials, and six were included. All the included RCT had serious methodological flaws. A meta-analysis revealed a statistically non-significant difference in weight loss between *P. vulgaris* and placebo groups (mean difference (MD) −1·77 kg, 95 % CI −3·33, 0·33). A further meta-analysis revealed a statistically significant reduction in body fat favouring *P. vulgaris* over placebo (MD −1·86 kg, 95 % CI −3·39, −0·32). Heterogeneity was evident in both analyses. The poor quality of the included RCT prevents us from drawing any firm conclusions about the effects of *P. vulgaris* supplementation on body weight. Larger and more rigorous trials are needed to objectively assess the effects of this herbal supplement.

Key words: Obesity: Body weight: Meta-analyses

Despite the fact that various effective weight management strategies are available, overweight and obesity are increasing[1], and a variety of weight-loss dietary supplements are currently being marketed as slimming aids. The efficacy of most of these supplements has not been proven. One such supplement is the bean extract, *Phaseolus vulgaris*.

The common bean *P. vulgaris* is a legume, which is predominantly found around Mexico and Central America[2]. It can be consumed by humans and has been described as belonging to the group of starch blockers, which have been postulated to have beneficial effects on body weight[3,4]. *P. vulgaris* has been reported to possess α-amylase inhibition activity and is believed to cause weight loss by promoting the mobilisation of the body's fat reserves as a result of energy restriction[3]. *P. vulgaris* is also purported to reduce body weight through appetite suppression[5]. In addition, it has been suggested that *P. vulgaris* may possess anti-diabetic properties by causing a reduction in postprandial hyperglycaemia, as well as a decrease in insulin secretion[6].

Phaseolus vulgaris is marketed under different brand names such as Phaseolamin and Phase-2, and is available either as a single compound supplement or in combination with other dietary components. Animal studies have suggested that *P. vulgaris* causes weight loss[7], and a number of clinical trials have been conducted to assess its efficacy in human subjects.

The aim of the present systematic review is to critically evaluate the evidence for or against the efficacy of *P. vulgaris* in reducing body weight.

Methods

Electronic searches were conducted in the following databases: Medline, Embase, Amed, Cinahl and *The Cochrane Library*. Each database was searched from inception up until July 2010. The search terms used included dietary supplement, food supplement, nutritional supplement, nutraceutical, anti-obesity agent, appetite suppressant, overweight, obesity, weight loss, slimming, body weight, body fat, BMI, starch

Abbreviations: MD, mean difference; RCT, randomised clinical trial.

* **Corresponding author:** I. Onakpoya, fax +44 1392 427562, email igho.onakpoya@pcmd.ac.uk

blocker, α amylase inhibitor, kidney bean, common bean, *P. vulgaris* and derivatives of these. We also searched the Internet for relevant conference proceedings, and hand-searched relevant medical journals and our own files. The bibliographies of all located articles were also searched. No age, sex, time or language restrictions were imposed.

Only randomised, double-blind, placebo-controlled trials (RCT) were included in the present review. To be considered for inclusion, RCT had to test the efficacy of orally administered bean extract or refined *P. vulgaris* for body weight or fat reduction in overweight or obese human volunteers. Included studies also had to report body weight or body composition as an outcome measure. RCT were included irrespective of whether or not they incorporated adjustments in the participants' lifestyle (e.g. dietary restriction and exercise) or other co-interventions into the trial regimen. However, any such interventions had to be applied equally to both the *P. vulgaris* and placebo groups for studies to be considered for inclusion. Studies testing bean extract or *P. vulgaris* as part of a combination supplement, i.e. dietary interventions containing other supplements in addition to bean extract, were excluded from the review.

The eligibility of studies was assessed by two reviewers (I. O. and S. A.) independently. Data were extracted systematically by two independent reviewers (I. O. and S. A.) according to the patient characteristics, interventions and results. The methodological quality of all included studies was assessed by the use of a quality assessment checklist adapted from the Consolidated Standard of Reporting Trials guidelines[8,9]. Disagreements were resolved through discussion.

Data are presented as means and standard deviations. Mean changes in body weight and body fat mass were used as common endpoints to assess the differences between the *P. vulgaris* and placebo groups. Using standard meta-analysis software[10], we calculated mean differences (MD) and 95% CI for studies with adequate data for statistical pooling. The I^2 statistic was used to assess for statistical heterogeneity among studies.

Results

Our electronic searches returned 2512 non-duplicate citations, of which ten potentially relevant articles were identified, and the full texts of these were retrieved (Fig. 1). We also located one unpublished article via hand searching of bibliographies. We excluded one study because it was an open trial[11]. Also, two studies were excluded because they involved the use of *P. vulgaris* or bean extract as part of a combination therapy[12,13] and another two were excluded because they did not report body weight or composition[14,15]. Thus, six RCT[16–21] including a total of 247 participants met our inclusion criteria and were included. Key data are summarised in Tables 1 and 2.

All RCT had one or more methodological weaknesses (Table 1). Only one reported an appropriate randomisation

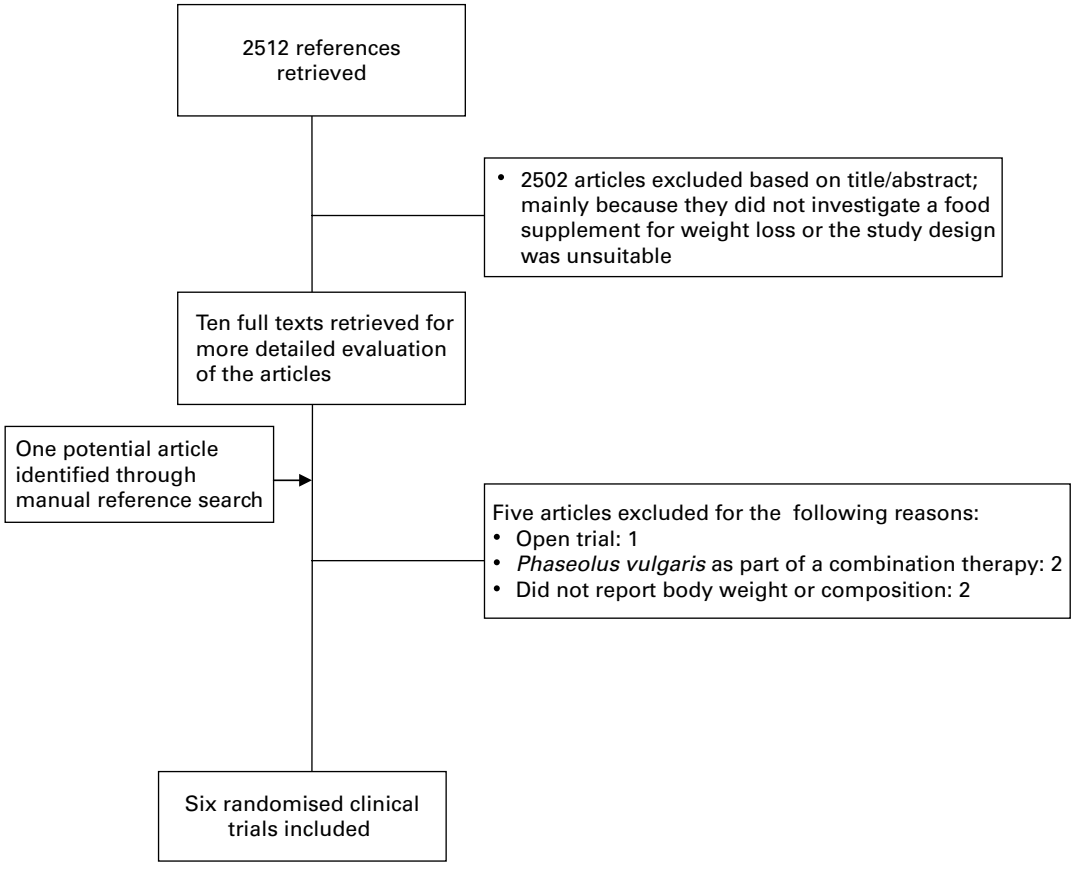

Fig. 1. Flow chart showing the process for the inclusion of randomised clinical trials.

Table 1. Methodological characteristics of randomised clinical trials

First author (year), country	Main outcome(s)	Main diagnoses of study participants	Study design	Gender M/F	Randomisation appropriate?	Allocation concealed?	Groups similar at baseline?	Similar follow-up of groups?	Outcome assessor blinded?	Care provider blinded?	Patients blinded?	Attrition bias?	ITT analysis?	Modified lifestyle?
Celleno (2007), Italy	Body weight, fat mass, waist and hip circumference	Healthy overweight subjects	Parallel	17/42	Unclear	Yes	Yes	Yes	Unclear	Yes	Yes	No	No	Yes
Udani (2007), USA	Body weight	Healthy normal-weight to overweight subjects	Parallel	N/R	Unclear	Unclear	Yes	Yes	Unclear	Unclear	Unclear	Unclear	Unclear	Yes
Birketvedt (2005), Norway	Body weight, BMI, waist circumference	Overweight and obese volunteers	Parallel	N/R	Unclear	Unclear	Yes	Yes	Unclear	Unclear	Unclear	No	No	Yes
Diaz (2004), Chile	Body weight	Healthy obese and overweight women	Parallel	0/60	Unclear	Unclear	Yes	Yes	Unclear	Unclear	Unclear	Unclear	No	Yes
Meiss (2004), USA*	Body weight	Overweight volunteers	Not clear	N/R	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Udani (2004), USA	Body weight	Healthy obese and overweight volunteers	Parallel	4/35	Yes	Unclear	Yes	Unclear	Unclear	Unclear	Unclear	No	Yes	Yes

M/F, males/females; ITT, intention-to-treat; N/R, not reported.
* Unpublished study.

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Table 2. Main results of randomised clinical trials
(Mean values, standard deviations or standard errors)

First author (year)	PVE daily dosage and formulation (mg)	Randomised/ analysed	Age (years)				Body weight at baseline (kg)				Treatment duration (weeks)	Weight loss (kg)				AE
			PVE		PLA		PVE		PLA			PVE		PLA		
			Mean	SD	Mean	SD	Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Celleno (2007)	445 mg tablets	60/59									4	2·93	1·16	0·35	0·38	No significant AE
Mean			33·7		34·2		74·1		73·4							
SEM			1·6		1·6		2·1		2·4							
Udani (2007)	1000 mg capsules	25/25	Not reported				81		81·1		4	3·4*†		2·6		None
Birketvedt (2005)	900 mg capsules	62/52	47	11	44	11	98·2	15·2	103·6	16·2	13	3·2	3·4	0·2	2·3	Soft stool, flatulence, constipation
Diaz (2004)	1000 mg capsules	30/22	34	5·5	28·1	5·2	80·5	10·5	82·2	7·7	13	6·9	2·1	7·0	1·6	No serious AE
Meiss (2004, unpublished)	445 mg unclear	60/unclear	Not reported				Not reported				13	2·9		0·3		Not reported
Udani (2004)	1500 mg unclear	39/39	36·5‡	26·95			87·8‡				8	1·7§		0·7		Tension headache

PVE, *Phaseolus vulgaris* extract; PLA, placebo; AE, adverse events.
* In terms of percentage.
† Mean values were not significantly different (P=0·4235).
‡ For all subjects.
§ Mean values were not significantly different (P=0·35).

technique[21], and only one reported an appropriate allocation concealment procedure[16]. Intention-to-treat analysis was included in only one RCT[21]. All included RCT were of parallel design, and one trial was described as having a single-blinded run-in period to exclude non-adherent subjects, in order to improve compliance to the study protocol[16].

Most of the RCT included in the present review incorporated at least one form of lifestyle adjustment into their trials. There was a wide variation in the daily energy intake of participants in the different studies, with values of as low as 5020·8 kJ[18] to as high as 9204·8 kJ[16]. To monitor the energy intake of participants[16,17,19], three studies enlisted the services of nutritionists, while two studies measured the dietary compliance of their participants using daily diet diaries[18,21]. There were two studies that described their diets as being constituted of complex carbohydrates[16,21], with one trial reporting its diet as a high-carbohydrate/low-fibre diet[21]. In one RCT, the participants received their meals twice daily from the care providers to ensure compliance with daily energy requirements and also participated in behavioural therapy sessions to improve compliance to eating requirements[17]. In one trial[17], the authors reported a significant difference in body-weight reduction in the *P. vulgaris* group compared with that in the placebo group, among subjects who had a high carbohydrate intake (P=0·0412). In three RCT[17,18,21], the authors mentioned exercise as part of lifestyle adjustment in their trials, with the authors of one trial reporting supervised exercises by a personal trainer[17]. Participants in one RCT[16] were allowed to continue with their normal lifestyle during the intervention period. In two RCT[19,20], the authors did not report exercise as part of lifestyle adjustment in their trials. Body fat was measured using bioelectrical impedance in three RCT[16,17,19], while body fat was estimated by a biodynamics fat analyser in one RCT[21]. Another RCT[18] calculated fat mass from percentage of body fat to body weight, while body fat measurement was not reported in one RCT[20].

In three RCT, the authors did not provide adequate data for statistical pooling[17,20,21]. Of these three RCT, two reported non-significant differences in body-weight reduction between the *P. vulgaris* and placebo groups[17,21]. The third trial[20] reported a mean body-weight loss of 2·9 and 0·3 kg for the *P. vulgaris* and placebo groups, respectively; there was no report on inter-group differences, and there was no information on how many participants there were in the *P. vulgaris* and placebo groups.

A forest plot (random-effect model) for RCT with suitable data for statistical pooling (Fig. 2) reveals a statistically non-significant difference in body-weight reduction between the *P. vulgaris* and placebo groups (MD −1·77 kg, 95 % CI −3·33, 0·33). The I^2 statistic (75 %) suggests considerable heterogeneity. A further meta-analysis of these three RCT (Fig. 3) revealed a statistically significant reduction in body fat favouring *P. vulgaris* over placebo (MD −1·86 kg, 95 % CI −3·39, −0·32). Heterogeneity was moderate in this analysis (I^2 = 53 %). A sensitivity analysis of two trials with similar dosages and duration of treatment[18,19] revealed a statistically non-significant difference in body-weight reduction between

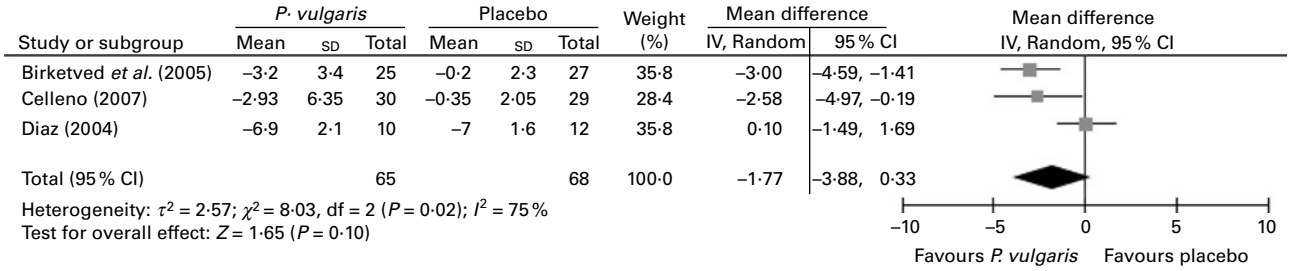

Fig. 2. Forest plot showing the effect of *Phaseolus vulgaris* on body weight.

the *P. vulgaris* and placebo groups (MD −1·45 kg, 95% CI −4·49, 1·59). Heterogeneity was considerable in this analysis ($I^2 = 86\%$).

Data on waist circumference were reported in four RCT, and two of these provided data for statistical pooling. A forest plot of the two studies with suitable data[15,16] revealed a statistically significant decrease in favour of *P. vulgaris* over placebo (MD −2·24 cm, 95% CI −3·84, −0·63). Heterogeneity was not important in this analysis ($I^2 = 0\%$). The remaining two trials[17,21] reported a non-significant difference in waist-circumference reduction between the *P. vulgaris* and placebo groups ($P = 0{\cdot}8654$ and $P > 0{\cdot}05$, respectively).

The dosages of *P. vulgaris* varied across the RCT. In two studies[16,20], the participants had a daily dosage of 445 mg, and in other studies, the doses ranged from 1000 to 1500 mg daily. There was no significant relationship between dosage and body-weight loss (data not shown).

Adverse events reported in the RCT included headache, soft stool, flatulence and constipation. No serious adverse events and no significant differences in the frequency of adverse events between the *P. vulgaris* and placebo groups were observed. In total, thirty-one dropouts were reported: seventeen in the *P. vulgaris* group and fourteen in the placebo group. In one RCT, the reasons for dropouts were not reported[21].

Discussion

The aim of the present systematic review was to assess the efficacy of *P. vulgaris* as a weight-loss supplement. The overall meta-analysis results involving three studies with 133 participants indicate that *P. vulgaris* does not generate a statistically significant reduction in body weight when compared with placebo. This result is at variance with two other studies that did not provide adequate data for statistical pooling[17,21]. Further meta-analysis suggests that *P. vulgaris* causes a statistically significant reduction in body fat when compared with placebo, but two studies without adequate data for meta-analysis reported non-significant differences in percentage of body fat between the *P. vulgaris* and placebo groups[17,21]. However, the meta-analysis results should be interpreted with caution, given the high level of heterogeneity among the studies. The clinical relevance of the results is also uncertain, as the analyses fail to provide an indication that a clinically significant weight loss, defined as at least a 5% reduction in body weight or fat from baseline was achieved[22]. The 5% weight loss that is considered to be clinically significant is usually taken at the 6-month time point, and weight loss at 12 weeks is about two-thirds of the weight loss observed at the 6-month plateau. Thus, the estimated weight loss at plateau extrapolated from overall meta-analysis would be about 2·5 kg. The weight loss of 1·77 kg from the meta-analysis was below that expected at a weight-loss plateau. However, because of the heterogeneity evident in our meta-analysis, it is not possible to ascertain as to whether or not *P. vulgaris* supplementation results in weight loss ≥2·5 kg at 6 months. Though a meta-analysis of two studies indicates that *P. vulgaris* causes a significant reduction in waist circumference compared with the placebo, this result differs from the findings of two other studies that did not provide sufficient data for statistical pooling[17,21].

All the RCT included in the present systematic review had important methodological flaws, and the trial methodologies varied considerably. All RCT had small sample sizes, with the maximum number of participants in a single trial being sixty-two. Small sample sizes are prone to produce unreliable results[23]. Most of the RCT did not report carrying out a power calculation or performing intention-to-treat analysis. Majority of the studies were also of short duration, with some as short as 4 weeks. This seems too short for assessing the effects

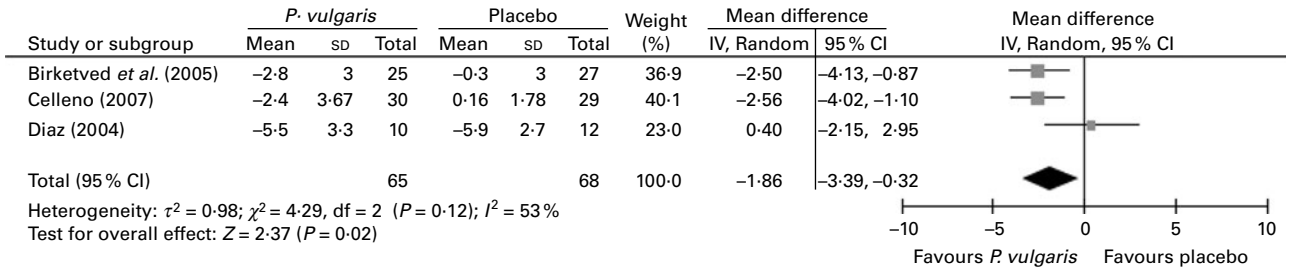

Fig. 3. Forest plot showing the effect of *Phaseolus vulgaris* on body fat.

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of *P. vulgaris* on body weight, and longer-term studies are required for this purpose.

The variety in study methodology (in relation to both quality and design), small sample sizes, variation in dosages and the generally short duration of the intervention period limit the extent to which efficacy or otherwise can be inferred, and lack of detailed reporting creates doubts regarding the internal and external validity of the included studies.

Lifestyle modification is regarded as a cornerstone in the management of obesity[24]. Though most of the RCT incorporated lifestyle modifications into their trial regimen, they differed in the amounts of average daily energy intake, as well as in the level of exercise undertaken by study participants. The degree to which the adjustment for these lifestyle factors influenced the outcome of the results in the studies is unclear.

Most of the studies suggested that the use of *P. vulgaris* appeared to be generally safe, with reported side effects being mostly mild gastrointestinal symptoms. Consumption of raw or undercooked *P. vulgaris* has been associated with a variety of serious adverse events, due to the presence of phytohaemagglutinin[16]; phytohaemagglutinin is largely inactivated in the processing stage of this supplement. This does not, however, rule out the possibility of serious adverse events if the supplement is taken on the long term. It will be prudent in future investigations to incorporate surveillance time frames into trial designs; to date, investigators have tended to stop monitoring for adverse events once the study duration is completed[25].

Most of the studies included in the review reported their source of funding. The majority of RCT involving the use of *P. vulgaris* have been commercially funded by the private industry. None of the RCT was funded exclusively by government.

The present review has several limitations. Though we searched both electronic and non-electronic sources, we may not have identified all RCT involving the use of *P. vulgaris* as a weight-loss supplement, in particular, those that remain unpublished. In addition, the methodological quality of all of the studies identified from our searches is poor, and most studies are of short duration. These factors prevent us from drawing firm conclusions about the effects of *P. vulgaris* on human body weight.

Conclusion

The evidence from RCT is not adequate enough to conclusively determine the effects of *P. vulgaris* supplementation on body weight. The methodological quality of all RCT is poor, and most are of short duration. Larger and more rigorous trials with longer duration are required to objectively assess the effects of this herbal supplement on body weight.

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