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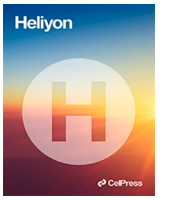

Research article

A randomized, double-blinded, placebo-controlled, single-center, comparative study evaluating Phaseolean® safety and efficacy in overweight/obese participants

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ABSTRACT

Scope: Phaseolean®, a standardized water extract of *Phaseolus vulgaris* or white kidney bean, exhibits α-amylase inhibitory property, which decreases calorie absorption by preventing or delaying carbohydrate digestion, thus supporting weight management. This randomized, double-blind, placebo-controlled, single-center comparative study (Clinical trial registration number: CTRI/2023/02/049440, Registered on: February 03, 2023) evaluated the safety and efficacy of Phaseolean® in weight management in overweight or obese participants upon regular intake at two different doses compared with placebo.

Method: Sixty-six participants were enrolled and randomly divided into three groups, considering the inclusion & exclusion criteria. Each group was assigned a specific daily dosage for three meals: Phaseolean® 1500 mg/day (500 mg per meal), Phaseolean® 3000 mg/day (1000 mg per meal), or placebo 1500 mg/day (500 mg per meal), administered thrice a day before meals for 45 consecutive days. Body weight; body mass index (BMI); skinfold fat thickness; waist, hip, and thigh circumferences; and blood biochemical parameters were monitored and analyzed to evaluate the effects of these interventions.

Results and conclusions: Of the 66 enrolled participants, 62 completed the study. Treatment with Phaseolean® 1500 mg/day reduced the weight by an average of 2.10 kg (0.33 kg/week), while that with 3000 mg/day was 1.94 kg (0.30 kg/week); 0.13 kg weight loss (0.02 kg/week) was observed in the placebo group after 45 days, showing significant differences between the Phaseolean® and placebo groups ($p < 0.01$). BMI, body fat, skinfold fat thickness, and the waist, hip, and thigh circumference were significantly reduced ($p < 0.01$) in both Phaseolean® groups compared with those in the placebo group, which showed no significant changes.

No adverse effects were observed during the clinical trial period. Phaseolean® 1500 mg/day dose was more effective in weight reduction than the 3000 mg/day higher dose. Therefore, Phaseolean® can be used to support healthy weight management.

1. Introduction

Overweight and obesity refer to excessive fat accumulation, which can potentially impair metabolism and pose significant health

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Table 1
Inclusion criteria.

Inclusion Criteria
1) Age: 18–50 years (both inclusive) at the time of consent.
2) Sex: Healthy non-pregnant/non-lactating females and Males.
3) Female of childbearing potential must have a reported negative pregnancy during screening and the end of the study.
4) Subject is generally in good health and willing to reduce weight.
5) Overweight to Obese Class - I, BMI between or equal to 25–35 kg/m^2, or total fat percentage reaching: men >25 % and women >30 % using Karada Scan.
6) Willing to observe dietetic plan in accordance with dietitian evaluation,
7) Able and willing to participate in the study by complying with the protocol procedures.
8) Subject is willing to forgo liposuction procedures or any weight loss therapy 3 months prior to and for the duration of the study.
9) Subject is able to remain on stable doses of contraceptive or replacement hormonal therapy, including no therapy, 6 weeks prior to and for the duration of the study.
10) If the female subject is of childbearing potential, is practicing and agrees to maintain an established method of birth control (IUD, hormonal implant device/injection, regular use of birth control pills or patch, diaphragm, condoms with spermicide or sponge with spermicidal jelly, cream or foam, partner vasectomy or abstinence). Females will be considered as non-childbearing potential if they are surgically sterile, have been post-menopausal for at least 1 year or have had a tubal ligation.
11) If currently using hormonal contraception, has been using this form of contraception for at least 6 months and agrees to continue using the same contraception for the duration of the study.
12) Subject is willing to participate in exercise program (Daily, 45 min s brisk walking for consecutive 45 Days of treatment period) and recording to subject diary card.
13) Subject is willing to come in fasting state for every study visit.
14) Subject is agree to consume a vegetarian/non-vegetarian diet of approximately 2000 kcal/day (14 % protein, 25 % Fat and 61 % carbohydrate).
15) Subject is willing to give written informed consent and are willing to follow the study procedure.

threats. A body mass index (BMI) of ≥25 kg/m^2 is considered overweight, whereas ≥30 kg/m^2 is an indication of obesity [1]. While overweight and obesity are primarily caused by an energy imbalance between calories consumed and expended, the other causes include a sedentary lifestyle, lack of physical activity, excessive dietary intake, or genetic factors [2].

Globally, approximately 2.3 billion individuals, including adults and children, are living with either obesity or overweight conditions; if these trends persist, approximately 2.7 billion adults could be either overweight or obese by 2025, posing a serious public health concern. The World Obesity Atlas 2022, published by the World Obesity Federation, predicts that approximately 1 billion people will be living with obesity by 2030 globally, including 1 in 5 females and 1 in 7 males [3]. India has the fastest-growing obesity rate in the world, estimated at 135 million people with obesity [4]. Overweight and obese conditions are major health risk factors for developing comorbid conditions, such as arthritis, cardiovascular disease (CVD), type 2 diabetes (T2D), respiratory problems, gastrointestinal disorders, sleep disorders, and psychological issues [5,6]. Weight loss can reduce the chances of comorbid conditions. Therefore, managing healthy weight among overweight and obese populations is essential, with the primary line of treatment being a balanced diet to limit the dietary consumption of refined carbohydrates and saturated fats, as well as establishing realistic weight-loss goals, providing motivational support and the necessary knowledge to affected individuals to help manage a healthy weight. Several plant-derived foods are known to prevent the absorption of complex carbohydrates into the small intestine by inhibiting the enzymes required for the fast digestion of carbohydrates; these plant-derived foods are, therefore, promising agents to support weight management by reducing calorie intake.

The white kidney bean (*Phaseolus vulgaris L.*), extensively grown in all major continental areas of America, Europe, Africa, and Asia [6,7], is rich in protein and considered nutraceutical due to active compounds, including total phenols, anthocyanins, tannins, flavonoids, lectins, and oligosaccharides [8], and is also rich in glycoprotein. Phaseolin, an α-amylase enzyme inhibitor, also known as "starch blocker," can inhibit the activity of salivary and pancreatic amylase, which breaks complex carbohydrates into simple sugars absorbed in the small intestine [9]. Inhibiting α-amylase activity can decrease calorie absorption, potentially supporting weight management [10]. Complex carbohydrates resistant to digestion in the intestine owing to α-amylase inactivity will enter the colon and be fermented by colonic bacteria. Considering the possible relationship between carbohydrate intake and body fat mass, reduced absorption of complex carbohydrates in the small intestine will help manage body weight and associated health risks [11]. Previous toxicological studies in rats of white kidney bean extract showed no significant toxicity or mortality following oral (gavage) administration of single doses up to 5 g/kg body weight (bw) or multiple doses for 90 days up to 1 g/kg bw/day [12]. Indeed, one toxicological study in rats (both males and females) of white kidney bean extract showed no significant toxicity or mortality following oral (gavage) administration of white kidney extract for 28 days and the no-observed-adverse-effect level (NOAEL) was 2500 mg/kg/day [13]. In vivo animal studies have shown that white kidney bean extracts can reduce appetite and body weight, thereby supporting weight management [14]. White kidney bean extract affects appetite by suppressing ghrelin secretion, which affects satiety, inducing a desire to eat less [15].

Few clinical studies have been undertaken to evaluate the role of white kidney bean extract in inducing weight loss. In one study, white kidney bean extract at a dose of 2400 mg/day (2 capsules, 800 mg per meal) with 1360 U/g α-amylase inhibiting activity was administered to participants with obesity for 35 consecutive days. The authors reported a weight loss of 2.24 kg in the treatment group compared with that in the placebo group, showing a loss of 0.29 kg body weight [9]. In another study, a common white bean water extract dose of 1500 mg (3000 mg/day) was administered twice a day before lunch and dinner for 8 weeks to 50 adults with obesity, resulting in a 1.72 kg weight reduction compared with the placebo group with 0.75 kg weight loss; clinical trends were identified for weight loss, even though statistically significant results were not obtained [7]. Another 4-week randomized, placebo-controlled,

Table 2
Exclusion criteria.

Exclusion Criteria
1) Subject has a history of allergy or sensitivity to the test treatments ingredients.
2) Subject who has a history of allergy with products containing beans, white kidney beans.
3) Subjects BMI is less than 25 and greater than 35kg/m^2.
4) Subjects having past or present history or clinically significant findings indicating cardiovascular disease, type 2 diabetes mellitus, hypertension, endocrine, pulmonary, neurological or psychological disorders, hypo or hyperthyroidism and renal disorders.
5) Subjects having drug and alcohol abuse.
6) Smokers and tobacco users.
7) Subjects having more than 5 kg variation in body weight within 3months before study entry.
8) Subjects using other weight loss medications, as well as stimulants, laxatives or diuretics taken solely for the purpose of weight loss.
9) Undergone surgery before 30 days of screening or planning to undergo surgery within the study period.
10) Subjects having chronic diarrhoeal disorders, cancer, hepatic dysfunction, and human immunodeficiency virus (HIV) infection.
11) Participation in other drugs, investigational medicinal product, any herbal products and/or cosmetics intended to weight loss clinical trials within 3 months before enrolment in this trial.
12) Any other diseases/co-morbidity that is considered by the Investigator as an exclusion.
13) With severe hepatic and/or renal impairment, liver enzyme level (ALT and/or AST) is greater than 2.5 times the upper normal limit.
14) Taking antibiotic therapy, anti-depressant treatment or treatment related to anxiety in the month preceding the study,
15) Taking anti-depressant treatment or treatment related to anxiety Subject in a state of depression.
16) Non-stable weight during the last 6 months (>5 % change in total weight)
17) Consuming food supplements or functional foods known to have an influence on weight management in the month preceding the inclusion and/or likely to take during the test.
18) Following or having followed a hypocaloric diet (energy intake <1500 kcal/day) in the month preceding inclusion and/or likely to undertake this diet during the test.
19) Diagnosed eating disorders (bulimia, anorexia nervosa, vomiting),
20) Using topical anti-cellulite treatments
21) Pregnant or breastfeeding or planning to become pregnant during the study period.
22) Subject has a history of chronic illness which may influence the cutaneous state.
23) Subjects participating in other similar nutraceuticals, food, supplemental or therapeutic trials within the last four weeks.
24) Any other condition which could warrant exclusion from the study, as per the Investigator's discretion.

double-blind clinical study with 25 healthy participants consuming white kidney bean extract or placebo 1000 mg (2000 mg/day) twice a day before meals in combination with a weight-loss management program, including diet, physical activity, and behavioral intervention, resulted in a weight loss of 2.72 kg however, the differences between the test and placebo groups were not significant [16]. An in vitro study undertaken at Radiant Research Services Pvt. Ltd., Bangalore, using the dinitro salicylate (DNS) method [17], confirmed that Phaseolean® (standardized white kidney bean extract) exhibited α-amylase inhibitory property, with an α-amylase inhibitory units value of 20,000 units/g.

The objective of this clinical study was to evaluate the efficacy of Phaseolean® in weight management and determine an effective dose from two different doses compared with the placebo. Phaseolean® was administered in capsule form before the three daily meals for 45 consecutive days, along with maintained dietary habits and physical activities. The impact of Phaseolean® on body weight in overweight or obese participants at two different doses (1500 mg/day and 3000 mg/day) was assessed at the end of the study. The two doses selected were based on previous literature, indicating that white kidney bean extract supports weight management at 2000 mg/day (2.7 kg weight loss in 30 days), 2400 mg/day (2.24 kg weight loss in 35 days), and 3000 mg/day (1.71 kg weight loss in 60 days) [7,9,16]. The findings of this study suggest Phaseolean® as a potent ingredient with weight management properties that can be used in nutraceutical or health supplement formulations for weight management in overweight or obese individuals.

Table 3
Demographic and other baseline characteristics.

Parameter	Statistic	Phaseolean® 1500 mg/day (N = 22)	Phaseolean® 3000 mg/day (N = 19)	Placebo (N = 21)	Overall (N = 62)
Gender (%)	Female	17 (77.3 %)	14 (73.7 %)	16 (76.2 %)	47 (75.8 %)
	Male	5 (22.7 %)	5 (26.3 %)	5 (23.8 %)	15 (24.2 %)
Race (%)	Asian	22 (100 %)	19 (100 %)	21 (100 %)	62 (100 %)
Age (Year)	Mean (SD)	32.5 (8.08)	37.1 (9.24)	38.0 (8.44)	35.8 (8.77)
	Median [Min, Max]	33.5 [18.0, 47.0]	41.0 [19.0, 48.0]	40.0 [23.0, 49.0]	37.5 [18.0, 49.0]
Weight (kg)	Mean (SD)	71.1 (9.52)	68.3 (10.9)	74.6 (9.83)	71.4 (10.2)
	Median [Min, Max]	70.7 [57.7, 90.0]	64.9 [56.4, 98.0]	73.3 [55.9, 93.5]	69.6 [55.9, 98.0]
Height (cm)	Mean (SD)	159 (8.27)	156 (8.26)	158 (8.44)	158 (8.29)
	Median [Min, Max]	160 [147, 174]	155 [145, 174]	157 [145, 176]	156 [145, 176]

Note: SD = Standard deviation; N = No. of Subjects.

Table-4
Effects of intervention with Phaseolean 1500 mg/day, Phaseolean 3000 mg/day and placebo on body weight, body mass index (BMI), skinfold fat thickness, hip, thigh & waist circumference.

	Phaseolean 1500 mg/day (n = 22)				Phaseolean 3000 mg/day (n = 19)				Placebo (n = 21)			
	Day 1	Day 21	Day 45	p value	Day 1	Day 21	Day 45	p value	Day 1	Day 21	Day 45	p value
Body weight (kg)	71.08 ± 9.52	70.08 ± 9.36	68.98 ± 9.17	<0.01	68.30 ± 10.85	67.11 ± 11.53	66.37 ± 11.14	<0.01	74.64 ± 9.83	74.62 ± 9.73	74.51 ± 9.61	>0.01
BMI (kg/m2)	27.89 ± 2.03	27.49 ± 1.88	27.02 ± 1.81	<0.01	27.82 ± 2.69	27.18 ± 2.94	27.06 ± 2.90	<0.01	29.59 ± 3.61	29.89 ± 3.31	29.83 ± 3.29	>0.01

2. Methods

2.1. Participants and study design

In total, 77 participants, with a 10 % dropout rate, were screened, of which 66 participants (22 participants per group) with overweight or obese health conditions were enrolled in the study. Initially the study was initiated at pilot scale to confirm the product efficacy at two different dosages. A total of 62 participants aged between 18 and 50 years with a BMI between or equal to 25–35 kg/m^2, or total fat percentage reaching >25 % for males and >30 % for females, completed the clinical study. The participants were enrolled based on the inclusion and exclusion criteria in Tables 1 and 2, respectively. Of 66 participants, 4 dropped out due to consent withdrawal.

This study was conducted in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving human participants and was approved by the Clinic Research Ethics Committee - ACEAS Independent Ethics Committee registered at CDSCO and OHRP US DHHS, with CDSCO registration number ECR/281/Indt/GJ/2017/RR-21 and OHRP US DHHS registration number IRB00011046.

At CTRI [Clinical Trial Registry of India], this clinical trial has been registered with the Trial Registered number - CTRI/2023/02/049440 [Registered on: February 03, 2023] and at Clinicaltrials.gov [Registry of clinical trials, run by the United States National Library of Medicine (NLM) at the National Institutes of Health (NIH)], with the ClinicalTrials.gov Identifier: NCT05711784. This clinical study was conducted at a single site - Novo Bliss Research Pvt. Limited, Gandhinagar, Gujarat (India). All participants signed a written, informed consent form before participating in the clinical trial study.

Participants were randomly divided into three groups, namely Treatment A (a total of 22 participants completed the study), B (a total of 19 participants completed the study), and C (a total of 21 participants completed the study) groups, and were advised to consume Phaseolean® 1500 mg/day, Phaseolean® 3000 mg/day, and placebo 1500 mg/day respectively.

The respective group participants were instructed to consume Phaseolean® or placebo, two capsules, three times a day before the three daily meals for 45 consecutive days. The Treatment A group consumed Phaseolean® 500 mg/meal (250 mg per capsule), Treatment B group consumed Phaseolean® 1000 mg/meal (500 mg per capsule), and Treatment C group consumed placebo 500 mg/meal (250 mg per capsule).

The Phaseolean® capsule contained white kidney bean extract, whereas the placebo capsule contained resistant maltodextrin. The appearance and packaging of the placebo capsule were consistent with those of Phaseolean®. The clinical parameters body weight, BMI, skinfold fat thickness, circumference of the waist, hip, and thigh, blood pressure, and heart health indicators were assessed at the baseline, day 1, day 21, and day 45, while blood biochemical parameters were measured at day 1 and the end of intervention on day 45. The outcome parameters of the clinical trial were measured by observing a significant reduction in body weight, circumference of the waist, hip, and thigh, body mass index, and skinfold fat thickness after 45 days of intervention.

2.2. Dietary control and physical activity

Participants were instructed and provided with diet plans, including calorie-counted meals, and motivated to maintain the same dietary habits and be consistent with their daily physical activities during the study period. Participants were given diet instruction from a registered dietician and instructed to complete a diary card about their daily food intake habits and physical activities undertaken during the study period. Study staff were connected to each participant for confirmation of dietary compliance and motivated to follow the same along with study treatment throughout the 45 days intervention.

2.3. Anthropometric analysis

Body weight and BMI were calculated using the Karada scan. Skinfold caliper was used to assess the skinfold thickness. The sum of four skinfolds (in mm) was measured, i.e., biceps skinfold (front side middle upper arm), triceps skinfold (back side middle upper arm), subscapular skinfold (under the lowest point of the shoulder blade), and suprailiac skinfold (above the upper bone of the hip). Waist, thigh, and hip circumferences were assessed via manual measurements (in inches) with flexible but non-stretchable tapes.

Table-5
Descriptive Statistics of body weight – Statistical comparison between Phaseolean® 1500 mg/day & Placebo, Phaseolean® 3000 mg/day & Placebo, Phaseolean® - 1500 mg/day & 3000 mg/day.

Parameter	Statistics	Phaseolean® 1500 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 3000 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 1500 mg/day	Phaseolean® 3000 mg/day	p-value
Visit - 3 (Day 21)					Visit - 3 (Day 21)					Visit - 3 (Day 21)				
	N	22	21			N	18	21			N	22	18	
Weight (kg)	Mean (SD)	−1.00 (0.76)	−0.02 (0.60)	<0.01[a]	Weight (kg)	Mean (SD)	−0.88 (0.96)	−0.02 (0.60)	<0.01[a]	Weight (kg)	Mean (SD)	−1.00 (0.76)	−0.88 (0.96)	>0.01 (NS)
	Median	−0.90	0.00			Median	−0.55	0.00			Median	−0.90	−0.55	
	Minimum	−3.40	−1.90			Minimum	−2.80	−1.90			Minimum	−3.40	−2.80	
	Maximum	−0.30	0.90			Maximum	1.00	0.90			Maximum	−0.30	1.00	
Visit - 4 (Day 45)					Visit - 4 (Day 45)					Visit - 4 (Day 45)				
	N	22	21			N	19	21			N	22	19	
Weight (kg)	Mean (SD)	−2.10 (1.03)	−0.13 (0.76)	<0.01[a]	Weight (kg)	Mean (SD)	−1.94 (1.08)	−0.13 (0.76)	<0.01[a]	Weight (kg)	Mean (SD)	−2.10 (1.03)	−1.94 (1.08)	>0.01 (NS)
	Median	−1.87	0.00			Median	−1.80	0.00			Median	−1.87	−1.80	
	Minimum	−4.10	−2.90			Minimum	−5.00	−2.90			Minimum	−4.10	−5.00	
	Maximum	−0.68	0.80			Maximum	−0.30	0.80			Maximum	−0.68	−0.30	

Note: SD = Standard deviation; N = No. of Subjects, NS = Non-significant.
[a] Significant.

Table-6

Descriptive Statistics of BMI (kg/m2) – Statistical comparison between Phaseolean® 1500 mg/day & Placebo, Phaseolean® 3000 mg/day & Placebo, Phaseolean® - 1500 mg/day & 3000 mg/day.

Parameter	Statistics	Phaseolean® 1500 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 3000 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 1500 mg/day	Phaseolean® 3000 mg/day	p-value
Visit - 3 (Day 21)					Visit - 3 (Day 21)					Visit - 3 (Day 21)				
	N	22	21			N	18	21			N	22	18	
BMI (kg/m^2)	Mean (SD)	−0.40 (0.54)	0.30 (1.43)	>0.01 (NS)	BMI (kg/m^2)	Mean (SD)	−0.49 (0.62)	0.30 (1.43)	>0.01 (NS)	BMI (kg/m^2)	Mean (SD)	−0.40 (0.54)	−0.49 (0.62)	>0.01 (NS)
	Median	−0.40	0.00			Median	−0.25	0.00			Median	−0.40	−0.25	
	Minimum	−2.60	−0.60			Minimum	−2.40	−0.60			Minimum	−2.60	−2.40	
	Maximum	0.20	6.50			Maximum	0.30	6.50			Maximum	0.20	0.30	
Visit - 4 (Day 45)					Visit - 4 (Day 45)					Visit - 4 (Day 45)				
	N	22	21			N	19	21			N	22	19	
BMI (kg/m^2)	Mean (SD)	−0.87 (0.61)	0.24 (1.45)	<0.01[a]	BMI (kg/m^2)	Mean (SD)	−0.76 (0.60)	0.24 (1.45)	<0.01[a]	BMI (kg/m^2)	Mean (SD)	−0.87 (0.61)	−0.76 (0.60)	>0.01 (NS)
	Median	−0.80	0.00			Median	−0.70	0.00			Median	−0.80	−0.70	
	Minimum	−2.90	−0.90			Minimum	−2.20	−0.90			Minimum	−2.90	−2.20	
	Maximum	0.20	6.50			Maximum	0.20	6.50			Maximum	0.20	0.20	

Note: SD = Standard deviation; N = No. of Subjects, NS = Non-significant.

[a] Significant.

Table-7
Effects of intervention with Phaseolean 1500 mg/day, Phaseolean 3000 mg/day and placebo on skinfold fat thickness, hip, thigh & waist circumference.

	Phaseolean 1500 mg/day (n = 22)				Phaseolean 3000 mg/day (n = 19)				Placebo (n = 21)			
	Day 1	Day 21	Day 45	p value	Day 1	Day 21	Day 45	p value	Day 1	Day 21	Day 45	p value
Skinfold Fat Thickness (mm)	93.59 ± 19.48	77.45 ± 16.21	68.73 ± 13.81	<0.01	91.79 ± 18.32	74.21 ± 23.72	69.42 ± 15.35	<0.01	107.06 ± 12.47	110.21 ± 12.34	107.00 ± 13.45	>0.01
Hip circumference (inches)	41.27 ± 2.35	40.38 ± 2.79	38.05 ± 3.48	<0.01	40.50 ± 2.05	40.14 ± 2.20	37.88 ± 2.54	<0.01	42.93 ± 3.50	42.09 ± 3.33	41.90 ± 3.39	>0.01
Thigh circumference (inches)	22.50 ± 2.1	21.15 ± 1.89	19.48 ± 2.31	<0.01	21.39 ± 1.93	21.00 ± 1.77	19.07 ± 2.26	<0.01	21.95 ± 2.52	21.69 ± 2.30	21.67 ± 2.32	>0.01
Waist circumference (inches)	36.05 ± 3.91	34.94 ± 3.57	33.52 ± 4.35	<0.01	35.82 ± 3.67	34.83 ± 4.21	33.39 ± 4.17	<0.01	39.05 ± 3.15	38.47 ± 3.83	38.45 ± 3.98	>0.01

2.4. Blood biochemical parameters

Random blood samples were obtained to test the blood biochemical parameters at the baseline and the end of day 45. The lipid profile, namely HDL, LDL, triglycerides, and total cholesterol, as well as serum blood glucose, serum creatinine, aspartate aminotransferase (AST), alanine aminotransferase (ALT), serum albumin, total protein, blood urea nitrogen (BUN), uric acid, HbA1C, and random insulin, were measured at day 1 and the end of day 45.

2.5. Randomization

Participants were randomly assigned in a 1:1:1 ratio to receive treatment A, B, or C. The randomization code was generated by NovoBliss Research. The randomization schedule was maintained under controlled access. The investigator/evaluator was blinded to the randomization schedule. The sequence number, as per the randomization schedule, was used as the Randomization ID.

2.6. Blinding procedure

Participants were randomly allocated to one of the three treatment groups, as per the randomization code. Neither the participant nor the investigator/evaluator was aware of the treatment allocation (i.e., double blind). To maintain blinding standards, the study staff involved in treatment dispensing and distribution were not engaged in any other study-related activities.

2.7. Statistical analysis

Statistical analysis was performed using R software with a 5 % significance level (Version: 4.2.2). The Wilcoxon signed-rank test was performed to test the sample data and compare the treatment groups. The level of significance was $p < 0.01$.

3. Results

3.1. Participants

In total, 77 participants were initially screened to obtain at least 20 participants in each group, of which 62 (47 females and 15 males) were randomized and completed the study. 22 participants under Treatment A group received Phaseolean® 1500 mg per day dose, 19 participants under Treatment B group received Phaseolean® 3000 mg per day dose, and 21 participants under Treatment C group received placebo 1500 mg per day dose for 45 consecutive days. New participants were not recruited to replace dropouts, and an intent-to-treat analysis was performed. The baseline characteristics of the study participants are listed in Table 3.

3.2. Reduction in body weight and BMI

The results of body weight reduction in participants administered Phaseolean® or placebo after 45 consecutive days are shown in Tables 4 and 5. Phaseolean® at 1500 and 3000 mg/day induced a significant body weight loss ($p < 0.01$). The average body weight reduction in the Phaseolean® 1500 mg/day group was 2.1 kg, i.e., 0.33 kg/week (71.08 ± 9.52 kg to 68.98 ± 9.17 kg, $p < 0.01$), whereas the Phaseolean® 3000 mg/day group showed an average body weight reduction of 1.94 kg, i.e., 0.30 kg/week (68.30 ± 10.85 kg to 66.37 ± 11.14 kg, $p < 0.01$), compared with the placebo group, showing an average weight reduction of 0.13 kg i.e., 0.02 kg/week (74.64 ± 9.83 kg to 74.51 ± 9.61 kg, $p > 0.01$) after 45 days.

Further, the BMI of participants administered Phaseolean® for 45 consecutive days was reduced (Tables 4 and 6). The BMI was decreased by 0.87 kg/m^2 in the Phaseolean® 1500 mg/day group and 0.76 kg/m^2 in the Phaseolean® 3000 mg/day group. After 45

Table-8

Descriptive Statistics of Hip circumference (Inches) – Statistical comparison between Phaseolean® 1500 mg/day & Placebo, Phaseolean® 3000 mg/day & Placebo, Phaseolean® - 1500 mg/day & 3000 mg/day.

Parameter	Statistics	Phaseolean® 1500 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 3000 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 1500 mg/day	Phaseolean® 3000 mg/day	p-value
Visit - 3 (Day 21)					Visit - 3 (Day 21)					Visit - 3 (Day 21)				
	N	22	21			N	18	21			N	22	18	
Hip circumference (Inches)	Mean (SD)	−0.89 (1.33)	−0.84 (2.15)	>0.01 (NS)	Hip circum ference (Inches)	Mean (SD)	−0.22 (0.83)	−0.84 (2.15)	>0.01 (NS)	Hip circum ference (Inches)	Mean (SD)	−0.89 (1.33)	−0.22 (0.83)	>0.01 (NS)
	Median	−0.50	0.00			Median	0.00	0.00			Median	−0.50	0.00	
	Minimum	−4.00	−6.50			Minimum	−1.00	−6.50			Minimum	−4.00	−1.00	
	Maximum	0.50	1.90			Maximum	2.50	1.90			Maximum	0.50	2.50	
Visit - 4 (Day 45)					Visit - 4 (Day 45)					Visit - 4 (Day 45)				
	N	22	21			N	19	21			N	22	19	
Hip circumference (Inches)	Mean (SD)	−3.22 (2.47)	−1.03 (2.06)	<0.01[a]	Hip circum ference (Inches)	Mean (SD)	−2.62 (2.14)	−1.03 (2.06)	>0.01 (NS)	Hip circum ference (Inches)	Mean (SD)	−3.22 (2.47)	−2.62 (2.14)	>0.01 (NS)
	Median	−2.75	0.00			Median	−3.00	0.00			Median	−2.75	−3.00	
	Minimum	−9.00	−6.50			Minimum	−9.00	−6.50			Minimum	−9.00	−9.00	
	Maximum	0.00	1.00			Maximum	0.00	1.00			Maximum	0.00	0.00	

Note: SD = Standard deviation; N = No. of Subjects, NS = Non-significant.

[a] Significant.

Table-9
Descriptive Statistics of Waist circumference (Inches) – Statistical comparison between Phaseolean® 1500 mg/day & Placebo, Phaseolean® 3000 mg/day & Placebo, Phaseolean® - 1500 mg/day & 3000 mg/day.

Parameter	Statistics	Phaseolean® 1500 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 3000 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 1500 mg/day	Phaseolean® 3000 mg/day	p-value
Visit - 3 (Day 21)					Visit - 3 (Day 21)					Visit - 3 (Day 21)				
	N	22	21			N	18	21			N	22	18	
Waist circumference (Inches)	Mean (SD)	−1.11 (1.67)	−0.58 (1.90)	>0.01 (NS)	Waist circum ference (Inches)	Mean (SD)	−0.89 (1.23)	−0.58 (1.90)	>0.01 (NS)	Waist circum ference (Inches)	Mean (SD)	−1.11 (1.67)	−0.89 (1.23)	>0.01 (NS)
	Median	−0.75	−0.5			Median	−0.5	−0.5			Median	−0.75	−0.5	
	Minimum	−6.50	−3.50			Minimum	−4.00	−3.50			Minimum	−6.50	−4.00	
	Maximum	2.50	4.00			Maximum	1.50	4.00			Maximum	2.50	1.50	
Visit - 4 (Day 45)					Visit - 4 (Day 45)					Visit - 4 (Day 45)				
	N	22	21			N	19	21			N	22	19	
Waist circumference (Inches)	Mean (SD)	−2.52 (2.37)	−0.60 (2.08)	<0.01[a]	Waist circum ference (Inches)	Mean (SD)	−2.42 (1.54)	−0.60 (2.08)	<0.01[a]	Waist circum ference (Inches)	Mean (SD)	−2.52 (2.37)	−2.42 (1.54)	>0.01 (NS)
	Median	−2.00	−0.40			Median	−2.00	−0.40			Median	−2.00	−2.00	
	Minimum	−11.50	−4.00			Minimum	−6.00	−4.00			Minimum	−11.50	−6.00	
	Maximum	1.00	3.50			Maximum	−0.50	3.50			Maximum	1.00	−0.50	

Note: SD = Standard deviation; N = No. of Subjects, NS = Non-significant.
[a] Significant.

Table-10
Descriptive Statistics of Thigh circumference (Inches) – Statistical comparison between Phaseolean® 1500 mg/day & Placebo, Phaseolean® 3000 mg/day & Placebo, Phaseolean® - 1500 mg/day & 3000 mg/day.

Parameter	Statistics	Phaseolean® 1500 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 3000 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 1500 mg/day	Phaseolean® 3000 mg/day	p-value
Visit - 3 (Day 21)					Visit - 3 (Day 21)					Visit - 3 (Day 21)				
	N	22	21			N	18	21			N	22	18	
Thigh circumference (Inches)	Mean (SD)	−1.35 (1.22)	−0.27 (1.26)	<0.01[a]	Thigh circum ference (Inches)	Mean (SD)	−0.31 (1.11)	−0.27 (1.26)	>0.01 (NS)	Thigh circum ference (Inches)	Mean (SD)	−1.35 (1.22)	−0.31 (1.11)	<0.01[a]
	Median	−1.50	0.00			Median	0.00	0.00			Median	−1.50	0.00	
	Minimum	−3.50	−3.00			Minimum	−2.00	−3.00			Minimum	−3.50	−2.00	
	Maximum	0.50	3.40			Maximum	2.50	3.40			Maximum	0.50	2.50	
Visit - 4 (Day 45)					Visit - 4 (Day 45)					Visit - 4 (Day 45)				
	N	22	21			N	19	21			N	22	19	
Thigh circumference (Inches)	Mean (SD)	−3.02 (2.07)	−0.28 (1.39)	<0.01[a]	Thigh circum ference (Inches)	Mean (SD)	−2.33 (2.83)	−0.28 (1.39)	<0.01[a]	Thigh circum ference (Inches)	Mean (SD)	−3.02 (2.07)	−2.33 (2.83)	>0.01 (NS)
	Median	−3.00	0.00			Median	−1.50	0.00			Median	−3.00	−1.50	
	Minimum	−7.50	−3.00			Minimum	−10.50	−3.00			Minimum	−7.50	−10.50	
	Maximum	0.00	4.10			Maximum	0.50	4.10			Maximum	0.00	0.50	

Note: SD = Standard deviation; N = No. of Subjects, NS = Non-significant.
[a] Significant.

Table-11
Descriptive Statistics of Skinfold Fat Thickness (mm) – Statistical comparison between Phaseolean® 1500 mg/day & Placebo, Phaseolean® 3000 mg/day & Placebo, Phaseolean® - 1500 mg/day & 3000 mg/day.

Parameter	Statistics	Phaseolean® 1500 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 3000 mg/day	Placebo	p-value	Parameter	Statistics	Phaseolean® 1500 mg/day	Phaseolean® 3000 mg/day	p-value
Visit - 3 (Day 21)					Visit - 3 (Day 21)					Visit - 3 (Day 21)				
	N	22	21			N	18	21			N	22	18	
Skinfold Fat	Mean	−16.14	3.16	<0.01[a]	Skinfold	Mean	−17.58	3.16	<0.01[a]	Skinfold	Mean	−16.14	−17.58	>0.01
Thickness (mm)	(SD)	(8.03)	(3.25)		Fat	(SD)	(22.40)	(3.25)		Fat	(SD)	(8.03)	(22.40)	(NS)
	Median	−15.50	3.00		Thickness	Median	−11.00	3.00		Thickness	Median	−15.50	−11.00	
	Minimum	−35.00	0.00		(mm)	Minimum	−40.00	0.00		(mm)	Minimum	−35.00	−40.00	
	Maximum	−6.00	12.00			Maximum	−100.00	12.00			Maximum	−6.00	−100.00	
Visit - 4 (Day 45)					Visit - 4 (Day 45)					Visit - 4 (Day 45)				
	N	22	21			N	19	21			N	22	19	
Skinfold Fat	Mean	−24.86	−0.06	<0.01[a]	Skinfold	Mean	−22.37	−0.06	<0.01[a]	Skinfold	Mean	−24.86	−22.37	>0.01
Thickness (mm)	(SD)	(10.48)	(4.53)		Fat	(SD)	(12.13)	(4.53)		Fat	(SD)	(10.48)	(12.13)	(NS)
	Median	−22.50	0.00		Thickness	Median	−20.00	0.00		Thickness	Median	−22.50	−20.00	
	Minimum	−48.00	−8.00		(mm)	Minimum	−50.00	−8.00		(mm)	Minimum	−48.00	−50.00	
	Maximum	−10.00	8.00			Maximum	−4.00	8.00			Maximum	−10.00	−4.00	

Note: SD = Standard deviation; N = No. of Subjects, NS = Non-significant.
[a] Significant.

Table-12
Effects of intervention with Phaseolean 1500 mg/day, Phaseolean 3000 mg/day and placebo on biochemical parameter, blood parameter. and lipid profile.

	Phaseolean 1500 mg/day (n = 22)			Phaseolean 3000 mg/day (n = 19)			Placebo (n = 21)		
Biochemical Parameter	Day 1	Day 45	p Value	Day 1	Day 45	p Value	Day 1	Day 45	p Value
Total serum protein (g/dL)	7.18 ± 0.47	7.6 ± 0.37	<0.01	7.36 ± 0.45	7.81 ± 0.43	<0.01	7.3 ± 0.46	7.62 ± 0.58	<0.01
Serum albumin (g/dL)	4.29 ± 0.33	4.26 ± 0.34	>0.01	4.34 ± 0.32	4.27 ± 0.23	>0.01	4.34 ± 0.29	4.26 ± 0.29	>0.01
Aspartate aminotransferase (U/L)	26.65 ± 5.40	30.19 ± 16.95	>0.01	26.89 ± 7.05	27.11 ± 6.47	>0.01	31.10 ± 9.55	32.73 ± 12.56	>0.01
Alanine aminotransferase (U/L)	27.08 ± 9.57	36.64 ± 21.17	>0.01	27.01 ± 11.86	28.93 ± 12.03	>0.01	33.76 ± 14.92	40.51 ± 24.63	>0.01
Blood urea nitrogen (mg/dL)	10.08 ± 2.71	10.89 ± 1.91	>0.01	11.1 ± 2.49	12.40 ± 1.68	>0.01	9.8 ± 2.86	12.26 ± 1.77	<0.01
Uric acid (mg/dL)	4.14 ± 0.88	4.25 ± 1.16	>0.01	4.02 ± 1.00	3.92 ± 0.93	>0.01	4.61 ± 1.10	4.57 ± 1.15	>0.01
Creatinine (mg/dL)	0.65 ± 0.16	0.7 ± 0.16	<0.01	0.66 ± 0.13	0.7 ± 0.14	>0.01	0.69 ± 0.13	0.73 ± 0.15	<0.01
Blood glucose (mg/dL)	107.39 ± 11.15	108.71 ± 9.07	>0.01	111.8 ± 20.68	115.5 ± 26.06	>0.01	116.79 ± 14.40	111.95 ± 19.21	>0.01
HbA1C (%)	5.45 ± 0.37	5.41 ± 0.31	>0.01	5.61 ± 0.53	5.67 ± 0.91	>0.01	5.7 ± 0.50	5.53 ± 0.67	>0.01
Random Blood Insulin (μIU/mL)	18.98 ± 20.63	32.97± 29.48	>0.01	31.48 ± 37.06	39.84 ± 25.12	>0.01	37.51 ± 52.30	55.89 ± 38.31	>0.01
HDL (mg/dL)	48.77 ± 9.91	48.27 ± 10.99	>0.01	52.95 ± 17.78	49.21 ± 11.55	>0.01	48.90 ± 6.83	46.29 ± 7.99	>0.01
LDL (mg/dL)	99.68 ± 22.05	89.86 ± 20.41	<0.01	99.19 ± 26.43	96.68 ± 21.85	>0.01	112.87 ± 31.39	101.21 ± 26.28	>0.01
Triglyceride (mg/dL)	166.83 ± 130.20	186.28 ± 171.35	>0.01	131.17 ± 42.73	133.55 ± 41.46	>0.01	168.04 ± 85.93	177.59 ± 74.92	>0.01
Cholesterol (mg/dL)	178.36 ± 30.06	168.82 ± 29.76	>0.01	177.74 ± 24.78	171.47 ± 26.63	>0.01	192.95 ± 44.79	178.48 ± 32.47	>0.01

consecutive days, the Phaseolean® at 1500 and 3000 mg/day groups showed a significant reduction in body weight and BMI ($p < 0.01$), whereas no significant body weight and BMI changes were found in the placebo group ($p > 0.01$). The Phaseolean® showed higher efficacy at the lower dose (1500 mg/day) than at the higher dose (3000 mg/day).

3.3. Reduction in skinfold fat thickness and circumference of the hip, waist, and thighs

The results of skinfold fat thickness and circumference of the hip, waist, and thigh parameters among all three groups are shown in Tables 7–11. On day 1, the skinfold fat thickness and circumference of the hip, waist, and thigh were initially measured; on day 45, a significant change in these parameters was found in the Phaseolean® groups ($p < 0.01$).

After 45 days of intervention, the skinfold fat thickness of the Phaseolean® 1500 mg/day group significantly decreased to an average of 24.86 mm (93.59 ± 19.48 mm to 68.73 ± 13.81 mm, $p < 0.01$) and that of the Phaseolean® 3000 mg/day group significantly decreased at an average of 22.37 mm (91.79 ± 18.32 mm to 69.42 ± 15.35 mm, $p < 0.01$) compared with that of the placebo, which showed a 0.06 mm reduction (107.06 ± 12.47 mm to 107.00 ± 13.45 mm, $p > 0.01$).

After 45 days of intervention, the hip, waist, and thigh circumferences showed significant differences among the three groups. The waist circumference of the Phaseolean® 1500 mg/day intervention group was reduced from an initial 36.05 ± 3.91 to 33.52 ± 4.35 inches ($p < 0.01$, decreased by an average of 2.53 inches), while that of the Phaseolean® 3000 mg/day intervention group was reduced from an initial 35.82 ± 3.67 to 33.39 ± 4.17 inches ($p < 0.01$, decreased by an average of 2.43 inches). Hip circumference of the Phaseolean® 1500 mg/day group was reduced from 41.27 ± 2.35 to 38.05 ± 3.48 inches ($p < 0.01$, decreased by 3.22 inches), while that of the Phaseolean® 3000 mg/day group was reduced from 40.50 ± 2.05 to 37.88 ± 2.54 inches ($p < 0.01$, decreased by 2.62 inches). The thigh circumference of the Phaseolean® 1500 mg/day group was reduced from 22.50 ± 2.1 to 19.48 ± 2.31 inches ($p < 0.01$, decreased by 3.02 inches), while that of the Phaseolean® 3000 mg/day group was reduced from 21.39 ± 1.93 to 19.07 ± 2.26 inches ($p < 0.01$, decreased by 2.32 inches).

There were no significant changes in the hip, waist, and thigh circumferences during the 45 days intervention in the placebo group. Notably, Phaseolean® at 1500 mg/day dose showed higher efficacy than that at 3000 mg/day.

3.4. Results of biochemical parameters

Table 12 lists the results of the biochemical parameters serum albumin, total protein, aspartate aminotransferase (AST), alanine aminotransferase (ALT), blood urea nitrogen (BUN), serum blood glucose, uric acid, creatinine levels, and random insulin in participants from all three group. In all three groups, no significant changes were found in the AST and ALT values, which are markers of healthy liver function; they remained within the respective reference ranges of normality during the clinical trial period. Further, no abnormal fluctuations was observed in the BUN, uric acid, and creatinine levels, which are markers of healthy kidney function, during

the clinical trial period; however, in the placebo group, BUN and creatinine parameters were significantly changed, while in the Phaseolean® 1500 mg/day group, only creatinine levels were significantly changed; however, these values were still within the normal range. HDL, LDL, triglyceride, and cholesterol levels did not significantly fluctuate in all treatment groups except the Phaseolean® 1500 mg/day group showed a significant reduction in LDL value, although remained within the normal ranges. Total protein values in all three groups were significantly changed, although values remained within the normal ranges. All biochemical parameters in the three groups were within the normal range, and no abnormal fluctuation was observed during the 45 days intervention.

4. Discussion

In this study, 77 participants with overweight or obese conditions were screened in a randomized, placebo-controlled, double-blinded, comparative clinical study to evaluate the degree of body weight loss induced by the regular consumption of Phaseolean®. Of these, 66 participants were enrolled, of which 62 completed the study (47 females and 15 males); 4 of 66 participants dropped out due to consent withdrawal. Twenty-two randomized participants received Phaseolean® 1500 mg/day (500 mg/meal, i.e., 250 mg active per capsule), 19 participants received Phaseolean® 3000 mg/day (1000 mg/meal, i.e., 500 mg active per capsule), and 21 participants received placebo (500 mg/meal, i.e., 250 mg resistant maltodextrin per capsule) before their daily meals for 45 consecutive days. The body weight of the participants dropped by an average of 2.1 kg after regular intake of Phaseolean® 1500 mg/day and by 1.94 kg after regular intake of Phaseolean® 3000 mg/day, indicating a greater effect on body weight reduction compared with that of the placebo showing 0.13 kg body weight reduction. The BMI significantly reduced by 0.87 kg/m^2 in the Phaseolean® 1500 mg/day group and by 0.76 kg/m^2 in the Phaseolean® 3000 mg/day group compared with that in the placebo group, which showed no significant reduction in BMI.

The thickness of skinfold fat and circumference of the hip, waist, and thighs were also significantly reduced, suggesting that Phaseolean® supports weight management. At the beginning and the end of the intervention period, the levels of total protein, serum albumin, creatinine, BUN, uric acid, AST, ALT, HDL, LDL, triglyceride, cholesterol, blood glucose, HbA1C, and random blood insulin were all within the normal range, indicating that Phaseolean® had no adverse effects on the health of the participants enrolled in the clinical study. No allergies or other adverse events were observed or reported during the clinical trial period.

Our results indicate that oral supplementation with Phaseolean® (standardized white kidney bean extract) capsules at 1500 and 3000 mg/day for 45 consecutive days significantly reduced body weight, BMI, skinfold fat thickness, and the hip, waist, and thigh circumference compared with those the placebo.

Phaseolean® at 1500 mg/day dose showed higher efficacy than that at 3000 mg/day in reducing body weight, BMI, skinfold, fat thickness, and hip, waist, and thigh circumference. This is possibly due to the saturation limit of enzymes, although further investigations remain warranted to confirm this. Therefore, Phaseolean® at 1500 mg/day is preferable over the 3000 mg/day dose for weight management. Administration of standardized white kidney bean extract with no adverse effects has also been reported in previous clinical studies associated with weight management parameters [7,9,16].

Currently, the prevalence of obesity as a disorder has increased worldwide and poses a serious health concern. Obesity is linked to cardiovascular disease, diabetes, high LDL, low HDL, dyslipidemia, and other metabolic risk factors that can worsen health conditions. Therefore, the management of weight can help to manage other associated health risk factors. Phaseolean® exhibited α-amylase inhibitory activity and clinically induced weight loss at an effective dose of 1500 mg/day. The findings of this study suggest Phaseolean® as potential ingredient for formulating weight management products in nutraceuticals or health supplements category.

The limitation of this clinical study was that it was done initially at pilot scale to confirm the effective dose of standardized white kidney bean extract in weight management. This clinical study is a small scale, short period and single centered study. Further studies using Phaseolean® 1500 mg/day dose at large scale with multiple sites, and longer study duration are required to demonstrate statistically meaningful results.

5. Conclusion

Dietary intake of Phaseolean® at 1500 or 3000 mg/day daily before meals by overweight or obese participants was found to reduce body weight and BMI compared with the placebo in 45 days. This study also confirmed that the clinical dose of Phaseolean® at 1500 mg/day was more effective in weight management than that at 3000 mg/day. Phaseolean® induced weight loss owing to its α-amylase inhibitory activity, which delayed the digestion of complex carbohydrates, thereby decreasing calorie absorption. Daily treatment with Phaseolean® at either dose showed no adverse events in our study participants. The results of the present clinical study will form the basis for initiating another clinical studies at larger scale with multiple sites and for longer duration.

Ethics statement and consent to participate

This study was reviewed and approved by Clinic Research Ethics Committee – ACEAS Independent Ethics Committee. At CTRI [Clinical Trial Registry of India] this clinical trial has been registered with the Trial Registered number – CTRI/2023/02/049440 [Registered on: February 03, 2023]. It has also been registered at Clinicaltrials.gov [Registry of clinical trials, run by the United States National Library of Medicine (NLM) at the National Institutes of Health (NIH)], having ClinicalTrials.gov Identifier: NCT05711784. All participants signed a written, informed consent form before participating in the clinical trial study.

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Data availability statement

Data will be made available upon reasonable request.

CRediT authorship contribution statement

Shashi Chandrama Singh: Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Harshpal Singh:** Software, Resources, Project administration, Methodology, Investigation, Conceptualization. **Muskan Choudhary:** Writing – original draft, Resources, Methodology, Formal analysis, Data curation.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:Shashi Chandrama Singh reports financial support was provided by Ambe Phytoextracts Pvt Ltd. SHASHI CHANDRAMA SINGH, MUSKAN CHOUDHARY, HARSHPAL SINGH reports a relationship with Ambe Phytoextracts Pvt Ltd that includes: employment. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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