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Short Communication

Efficacy and Safety of CisLean™ in Adults with Overweight or Class I Obesity: A Randomized, Double-Blind, Multicenter, Placebo-Controlled Clinical Trial

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Abstract

Obesity is a major global health concern associated with metabolic and cardiovascular disorders. This randomized, double-blind, multicenter, placebo-controlled clinical study evaluated the efficacy and safety of CisLean™, a 500 mg Cissus quadrangularis extract capsule, in healthy obese adults. Sixty-three participants with BMI 25–34.9 kg/m² completed the 16-week intervention and received CisLean™ or placebo twice daily. Primary outcomes were changes in body weight and BMI, while secondary outcomes included anthropometric measures, body composition, metabolic parameters, and safety. At 16 weeks, CisLean™ produced significantly greater reductions in body weight (3.51% vs. 0.42%; $p<0.05$) and BMI (3.20% vs. 0.41%; $p<0.05$) than placebo. Significant reductions were also observed in waist, hip, neck, upper mid-arm, and calf circumferences, as well as body fat percentage, total body water, lean body mass, and basal metabolic rate. Lipid profiles and well-being scores showed no significant changes. No treatment-related adverse events were reported. Overall, CisLean™ was well tolerated and demonstrated potential as a weight-management intervention.

Keywords: Cissus quadrangularis; Obesity; Overweight; Body Weight; Anthropometry; Randomized Controlled Trial

Introduction

Overweight and obesity are interconnected health conditions that profoundly affect cardiovascular, metabolic, musculoskeletal, and cancer-related health, posing a major global public health challenge [1]. In 2022, 2.5 billion adults were overweight, including 890 million with obesity, while childhood overweight and obesity also increased substantially. The primary causes include excessive calorie intake, low physical activity, obesogenic environments, genetic and psychological factors, and medical conditions. Obesity increases the risk of noncommunicable diseases (NCDs), including heart disease, diabetes, and cancer, and contributes significantly to mortality and economic burden [2]. Obesity is an abnormal accumulation of excess body fat and is a leading preventable cause of death worldwide [3-7]. High-calorie diets, processed foods, physical inactivity, and genetic susceptibility are major contributing factors [8-10], with complications including hypertension, type 2 diabetes, atherosclerosis, infertility, fatty liver, and osteoarthritis [10-12]. Although lifestyle modification, physical activity, and pharmacotherapy remain the main treatments, long-term effectiveness is limited [8,13-17]. Cissus quadrangularis has demonstrated weight-reducing effects [18-20]. However, evidence for CisLean™ remains limited. Therefore, this study evaluated its efficacy and safety over 16 weeks in overweight and obese participants.

Materials and Methods

This randomized, double-blind, multicenter, placebo-controlled clinical study evaluated the efficacy and safety of CisLean™ in healthy obese participants. Following Ethics Committee approval from Nirvikar Ayurved Hospital, Pune and Mhaske Hospital and Research Centre, Pune, the study was

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registered with CTRI (CTRI/2024/01/061102; 03/01/2024) and conducted according to the Declaration of Helsinki and Good Clinical Practice from 08 January to 10 May 2024. A total of 74 participants were screened and 69 randomized; 30 CisLean™ and 33 placebo participants completed 16 weeks. Participants aged 21–55 years with BMI 25–34.9 kg/m² received identical CisLean™ (500 mg Cissus quadrangularis extract) or placebo capsules twice daily after meals for 16 weeks, without structured diet or exercise intervention. Primary outcome was change in body weight and BMI; secondary outcomes included anthropometric, body-composition, lipid, appetite, global assessment, tolerability, and safety parameters. Statistical analysis used GraphPad InStat 3.6, with appropriate parametric/non-parametric tests and chi-square test; $p<0.05$ was considered significant.

Observations and Results

The demographic characteristics were comparable between the CisLean™ capsule and placebo groups, with similar mean ages (36.60 vs. 37.03 years) and no significant differences in demographic parameters, TSH, or blood glucose levels. The CisLean™ group comprised 10 males (33.33%) and 20 females (66.66%), while the placebo group comprised 9 males (27.27%) and 24 females (72.72%); one placebo participant had controlled pre-existing hypertension **(Table 1, Figure 1)**.

The CisLean™ capsule group showed a significant, progressive reduction in body weight from 74.75 ± 9.50 kg at baseline to 72.12 ± 8.16 kg at 16 weeks, with significant weight loss evident from week 8, unlike the non-significant change in the placebo group ($p<0.05$). BMI similarly declined significantly from week 8 onward, with a 3.2% reduction at 16 weeks versus 0.41% with placebo ($p<0.05$) **(Table 2; Figure 2)**.

At 16 weeks, the CisLean™ capsule group demonstrated significantly greater reductions than placebo in waist (5.65% vs. 3.86%), hip (5.24% vs. 2.78%), neck (8.12% vs. 1.92%), upper mid-arm (7.79% vs. 3.72%), and calf circumference (5.94% vs. 1.98%), with between-group significance generally emerging from weeks 8–12 onward ($p<0.05$; **Table 3, Figure 3**). Body fat percentage, total body water, and lean body mass also decreased significantly in the CisLean™ group, with 16-week reductions of 3.99%, 3.69%, and 1.66%, respectively, compared with 0.24%, 0.19%, and 0.58% with placebo ($p<0.05$; **Table 3**); basal metabolic rate decreased by 1.68% vs. 0.08%.

Notably, waist, hip, and neck circumference reductions exceeded the commonly referenced ≥5% benchmark for clinically meaningful anthropometric improvement. Given that reduced waist circumference is associated with favorable cardiometabolic outcomes, these findings suggest potential clinical benefit of CisLean™, although confirmation in larger studies is warranted.

Lipid profile parameters remained stable from baseline to week 16 in both groups, with no notable trends. Safety assessments, including CBC, liver and renal function tests, and vital signs, showed no significant changes or between-group differences,

Table 1: Assessment of demographic parameters.

Parameter	CisLean™ Group (n=30)	Placebo Group (n=33)
Age (Years)	36.60±7.20	37.03±7.17
Male	10 (33.33%)	9 (27.27%)
Females	20 (66.66%)	24 (72.72%)
Weight (Kg)	74.75±9.50	74.90±12.05
BMI (Kg/m²)	28.57±2.35	29.17± 3.33
TSH (mIU/L)	2.14 ±1.17	2.90±1.77
Blood Sugar Fasting (mg/dL)	89.00±9.85	88.03±8.71

Data is represented as the number of participants and Mean ± Standard Deviation.

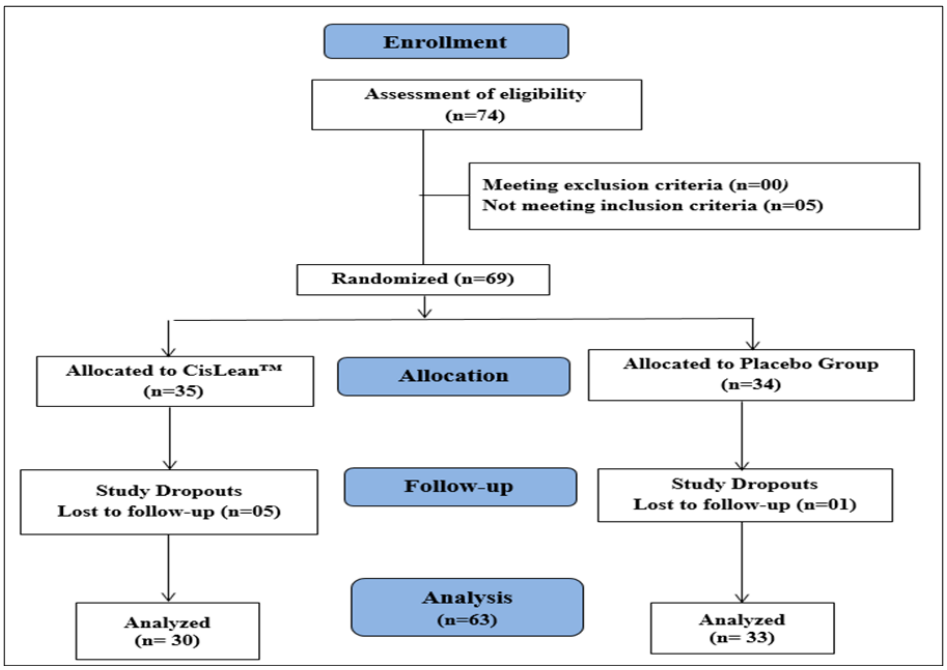

Figure 1: Consort Diagram.

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Table 2: Assessment of change in weight and BMI.

Visit	Baseline	4 weeks	8 weeks	12 weeks	16 weeks
Weight (Kg)					
CisLean™ capsule	74.75±9.50	74.21± 9.01 (0.72%)	73.41±8.43* (1.79%)	72.74±8.16* (2.76%)	72.12±8.16* (3.51%)
Placebo capsule	74.90±12.05	74.90±11.95	74.98±11.99 (0.10%)	74.84±11.97 (0.08%)	74.58±12.05 (0.42%)
P-value	0.753	0.565	0.045	0.031	0.022
Body Mass Index [BMI (kg/m^2)]					
CisLean™ capsule	28.57±2.35	28.38±2.21 (0.06%)	28.10±2.34* (1.64%)	27.86±2.49* (2.48%)	27.64±2.56* (3.20%)
Placebo capsule	29.17 ±3.33	29.17 ±3.35 (0.00%)	29.20 ±3.33 (0.44%)	29.15 ±3.37 (0.06%)	29.05 ±3.40 (0.41%)
P-value	0.433	0.343	0.044	0.033	p<0.030

*Data is represented as Mean ± Standard Deviation. *represents significant change (p<0.05) within the group.*

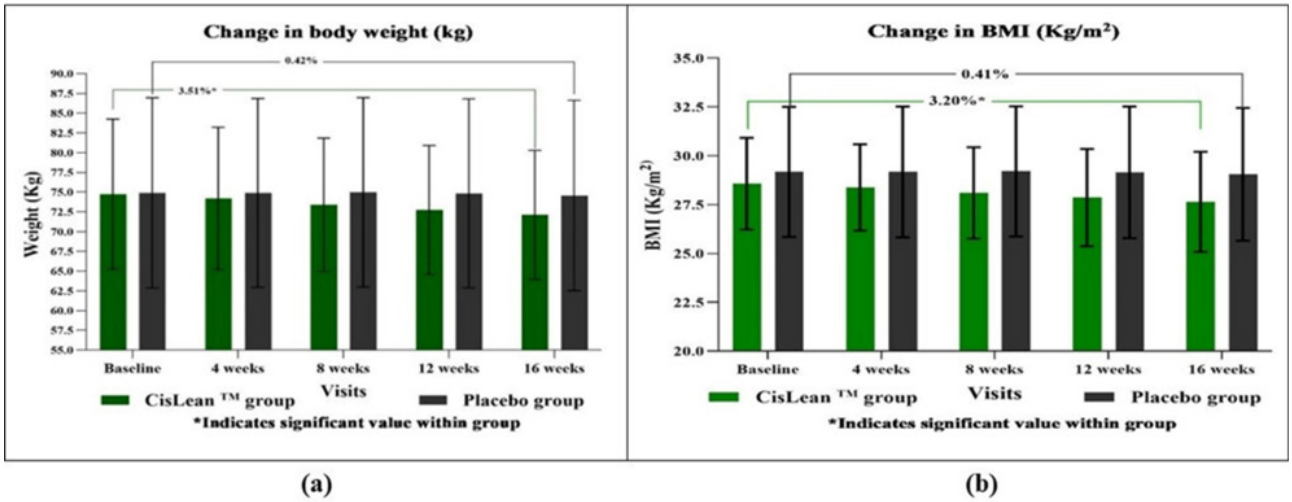

Figure 2: Change in body weight and BMI over 16 weeks.

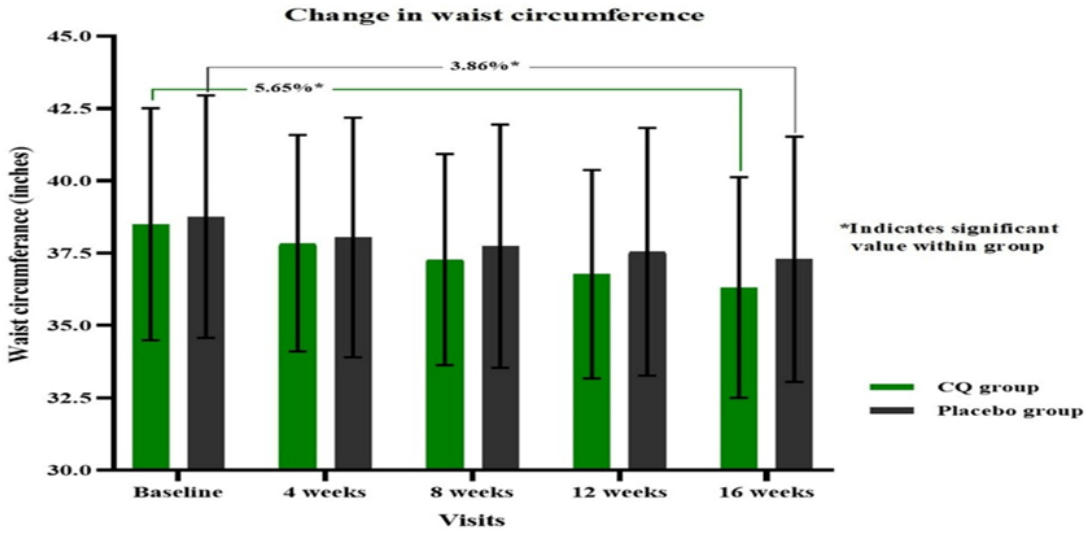

Figure 3: Change in waist circumference over the study period.

with all values remaining within normal ranges throughout the study. A total of 23 adverse events were reported in 20 participants in the CisLean™ group and 29 events in 21 placebo participants; none were considered related to the study product or procedures.

Discussion

The present study evaluated the efficacy and safety of CisLean™ capsules in healthy obese participants. CisLean™ significantly reduced body weight (3.51% vs. 0.42%) and BMI (3.2% vs. 0.41%) versus placebo at 16 weeks (p<0.05), consistent with previous Cissus quadrangularis findings [18]. Waist (5.65%), hip (5.24%), neck, upper-arm, and calf circumferences also decreased significantly versus placebo, supporting earlier CisLean™ and CQR-300 findings [19,20]. Body fat, basal metabolic rate, total body water, and lean body mass showed greater reductions from week 12 onward, while lipid parameters and general well-being remained unchanged. Proposed mechanisms of C. quadrangularis include leptin modulation, reduced adipocyte glycerol release, and UCP1-mediated thermogenesis [19,22,23], although formulation-specific evidence is not yet available. CisLean™ was well tolerated, with no clinically significant safety changes or related adverse effects. Limitations included the small sample size, 16-week duration, healthy obese population, and limited lifestyle control. Larger, longer-term studies are warranted.

Table 3: Assessment of Anthropometric measurements.

Visits	Baseline	4 weeks	8 weeks	12 weeks	16 weeks
Waist Circumference (inches)					
CisLean™ capsule	38.50± 4.01	37.84±3.74 (1.70%)	37.28± 3.65* (2.76%)	36.77± 3.60* (3.12%)	36.31±3.81* (5.65%)
Placebo capsule	38.76±4.19	38.04±4.14 (1.85%)	37.74*±4.20 (2.63%)	37.55*±4.28 (3.12%)	37.29*±4.24 (3.86%)
P-value	0.565	0.409	0.654	0.878	0.050
Hip Circumference (inches)					
CisLean™ capsule	42.14± 2.81	41.46±2.69 (1.61%)	40.99± 2.74* (2.72%)	40.50± 2.97* (3.89%)	39.93± 3.06* (5.24%)
Placebo capsule	43..06±4.43	42.64± 4.79 (0.97%)	42.48± 4.89 (1.34%)	42.26± 5.04 (1.85%)	41.86± 5.10* (2.78%)
P value	0.242	0.099	0.045	0.044	0.023
Neck Circumference (inches)					
CisLean™ capsule	13.78± 1.01	13.46±0.94 (2.32%)	13.24± 0.96* (3.91%)	12.98± 0.98* (5.80%)	12.66± 1.11* (8.12%)
Placebo capsule	14.02±1.39	13.91±1.54 (0.78%)	13.92±1.64 (0.71%)	13.83±1.79 (1.35%)	13.75±1.88 (1.92%)
P value	0.388	0.087	0.039	0.010	0.012
Upper Mid Arm Circumference (inches)					
CisLean™ capsule	14.76±2.26	14.33±2.17 (2.91%)	14.15±2.08* (4.13%)	13.90±1.88* (5.82%)	13.61±1.83* (7.79%)
Placebo capsule	15.56±1.91	15.09±2.09 (3.02%)	15.11±2.11 (2.98%)	15.04±1.99 (3.32%)	14.98±2.03 (3.72%)
P value	0.098	0.234	0.050	0.0239	0.022
Calf Circumference (inches)					
CisLean™ capsule	13.97± 1.39	13.73±1.22 (1.71%)	13.58±1.19 (2.79%)	13.35±1.08* (4.43%)	13.14±1.08* (5.94%)
Placebo capsule	14.22±1.83	14.10±1.99 (0.84%)	14.08±2.05 (0.98%)	14.00±2.08 (1.54%)	13.94±2.11 (1.98%)
P value	0.112	0.099	0.047	0.012	0.019
Body Fat Percentage					
CisLean™ capsule	36.07±7.14	35.73±7.14 (0.94%)	35.37±7.45 (1.94%)	34.80±7.59* (3.52%)	34.63±7.74* (3.99%)
Placebo capsule	37.15±7.56	37.18±7.64 (0.08%)	37.27±7.55 (0.32%)	37.15±7.65	37.06±7.65 (0.24%)
P value	0.109	0.121	0.178	0.032	0.012
Basal Metabolic Rate (Kcal/day)					
CisLean™ capsule	1470.37±208.65	1464.10±204.04 (0.42%)	1456.17±198.30 (0.97%)	1449.13±194.35* (1.44%)	1445.93±191.67* (1.68%)
Placebo capsule	1449.48±224.58	1450.30±223.10 (0.05%)	1451.06±223.10 (-0.10%)	1449.79±222.38 (0.02%)	1448.24±222.29 (0.08%)
P value	0.121	0.045	0.034	0.044	0.032
Total Body Water (liters)					
CisLean™ capsule	36.52±6.57	36.35±6.43 (0.46%)	36.10±6.21 (1.15%)	35.90±6.09* (1.69%)	35.71±5.98* (3.69%)
Placebo capsule	35.88±7.01	35.87±6.96 (0.02%)	36.12±6.93 (0.66%)	35.85±6.92 (0.08%)	35.81±6.91 (0.19%)
P value	0.221	0.088	0.096	0.010	0.040
Lean Body Mass (Kg)					
CisLean™ capsule	49.12±8.95	50.02±9.88 (1.83%)	48.75±8.58 (0.75%)	48.52±8.42* (1.22%)	48.30±8.27* (1.66%)
Placebo capsule	47.76±9.41	47.55±9.31 (0.44%)	47.57±9.32 (0.39%)	47.50±9.26 (1.25%)	47.48±9.26 (0.58%)
P value	0.129	0.129	0.221	0.431	0.040

*Data is represented as Mean ± Standard Deviation. *Represents significant value (P<0.05) within group.*

Conclusion

In this short-term clinical trial in healthy obese adults, CisLean™ was associated with modest but statistically significant reductions in body weight, BMI, and multiple anthropometric measures, particularly those related to central adiposity. No meaningful changes were observed in lipid profile parameters. The product was well tolerated over 16 weeks, with no safety concerns identified. Larger, longer-duration, and controlled studies are needed to confirm these findings and to further evaluate the efficacy and safety of CisLean™ in broader clinical populations.

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Drafting of the manuscript: Vineet K. Malhotra, Aishwarya Gandas, Nilesh Londhe, Sarika Londhe, Girish S. Soman, Arati D. Soman, Sanjay Tamoli
Critical review of the manuscript for important intellectual content: Vineet K. Malhotra, Aishwarya Gandas, Nilesh Londhe, Sarika Londhe, Girish S. Soman, Arati D. Soman, Sanjay Tamoli
Supervision: Vineet K. Malhotra, Aishwarya Gandas, Nilesh Londhe, Sarika Londhe, Girish S. Soman, Arati D. Soman, Sanjay Tamoli.

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Conflict of Interest Statement: Girish Sudhakar Soman, and Dr. Arati Devendra Soman are associated with Nisarga Biotech Pvt. Ltd. Other authors declare no conflict of interest.

Data Availability Statement: The datasets generated and/or analysed during the current study are not publicly available due to intellectual property constraints.

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