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Research article

A clinical evaluation of Kapiva Get Slim Juice for weight management in overweight to obese adults with and without hypothyroidism

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Abstract

Obesity and overweight are global health concerns affecting over 1 billion people, as per the WHO. Phytoconstituent-based supplements are alternatives to anti-obesity drugs because of fewer side effects and less stringent guidelines during drug approvals. This clinical trial assessed the potential of Kapiva Get Slim Juice to effectively manage weight, anthropometry and improve QOL. It was a parallel-arm, open label study testing safety and efficacy of Kapiva Get Slim Juice in overweight to obese patients (Group A) and overweight to obese patients with hypothyroidism (Group B) by comparing pre-and post-treatment status of the patients from the same group. In both groups A and B, Kapiva Get Slim Juice resulted in an average weight reduction of 7.05 kg and 5.67 kg, respectively, over 90 days. Both groups exhibited significant reductions in BMI, waist circumference, hip circumference, mid-upper arm circumference, waist/hip ratio, body fat percentage, and visceral fat percentage. Participants reported enhanced QOL, improved physical and emotional aspects, and reduced symptoms. The product was safe and well-tolerated, and there were no adverse events. It can be concluded from the study that Kapiva Get Slim juice provides a promising solution for individuals looking to manage their weight effectively and enhance their overall well-being. Its efficacy, safety, and potential to address various symptoms related to obesity and hypothyroidism make it a valuable addition to weight management products in the market.

Introduction

Obesity is an endocrine and heritable disorder, which results in excessive or abnormal adipose tissue/fat accumulation in the body. It is a complex and a multifactorial disease that can cause health impairment. Imbalance between daily energy intake and expenditure leads to excessive weight gain. [1, 2].

Obesity prevalence is alarmingly on the rise over past decades in both developed and developing nations. As per WHO report, worldwide more than 1 billion people are obese. In India, over 135 million people are living with obesity; which is attributed to rapid urbanization and industrialization [3,4]. Although, after smoking it is the second most common preventable cause of death [1].

Family genetics plays a crucial role in developing obesity. Intake of high calorie food like excessive carbohydrates & sugar, ultra-processed foods with low or no nutritional content, decreased physical activity, sedentary lifestyle, poor sleep, poverty, certain medical conditions and medicines as

well as environmental factors such as workplace environment and long working hours are some of the common etiological factors for obesity. It has been associated with increased risk of development and progression of type 2 diabetes mellitus, cardiovascular disease, hypertension, hyperlipidemia, cancer, inflammatory diseases and higher mortality rates [2,5,6].

Hypothyroidism has been closely associated with obesity. Thyroid hormones play an important role in lipid and glucose metabolism, food intake and fat oxidation. Thyroid dysfunction may result in body weight & composition changes, total & resting energy expenditure. Research suggests that, in addition to decreasing thermogenesis and metabolic rate, hypothyroidism is associated with significant increase in body mass index (BMI) and obesity prevalence. Clinical evidence indicates that weight loss induces a significant improvement in thyroid function [7, 8].

Multidisciplinary approach is required in the battle against obesity, such as clinical, dietary, and pharmacological. Clinical approaches include surgery, lifestyle changes, and physical activity [9]. Dietary approaches include caloric restriction and weight-loss diet. Pharmacological approaches comprise several weight-loss drugs. Bariatric surgery and only a few approved drug therapies are effective ways to induce body weight loss [10]. Wholesome approach, that is diet, exercise, nutritional awareness, and a healthy psychological state of mind all contribute to a favorable environment in managing healthy weight [11].

Phytoconstituent based supplements have gained much attention as a reliable alternative to anti-obesity drugs, because of the side effects encountered with long time usage of synthetic drugs and stringent guidelines during drug approvals. Recently, claims and demand for herbal remedies has grown significantly. Phytochemicals found in food items and herbal preparations have potential to alter appetite beyond their nutritional loading effects. This, along with the fact that they have significantly fewer adverse effects, may provide an alternative treatment approach [12, 13]. Incorporating small changes in behavior, such as increasing physical exercise, eating a balanced diet, and supplementing with nutrients from nutraceutical goods or herbal juice, can help in preventing weight gain in the majority of the individuals. The addition of nutraceuticals into diet can help people control and maintain their weight. Additionally, it can mitigate the physical, social, and psychological burden imposed by obesity [14].

We propose that the combination of Kapiva Get Slim Juice with moderate lifestyle change in diet and lifestyle will have a synergistic effect on managing body weight. Kapiva Get Slim Juice also contains herbal extracts, such as *daru haldi, gurmar, haldi, haritaki, kutki, musta, chitrak mool, bibhitaki, giloy, garcinia, amla,* ginger, fenugreek, cinnamon, black pepper, and cumin. These ingredients have been proven to aid in the weight management by regulating the appetite, improving metabolism, reducing hunger cravings and burning fat. Investigational product was employed as an exploratory product in the current study to confirm its safety and efficacy in the management of weight, anthropometry and improvement in QOL.

Materials and methods

Study design

This is a parallel arm clinical trial validating safety and efficacy of Kapiva Get Slim Juice for weight management and to measure changes in anthropometric parameters and QOL have been determined by comparing pre- and post-treatment status of the patients from the same group. Figure 1 shows the overall study's consolidated standards of reporting trials (CONSORT) flow. (CTRI number is CTRI/2023/03/050908).

Study schedule

The duration of the study was 90 days. Screening visit (Within -7 days prior to Day 1); First visit - Baseline/ Enrollment Day (Day 1); the second visit- Day 15; Third visit- Day 30; Fourth visit- Day 45; Fifth visit- Day 60; Sixth visit- Day 75; Seventh visit- Day 90 (End of the study day).

Study objectives

The primary objectives of the study were to determine the effectiveness of investigational product in weight management by assessing anthropometric parameters, quality of life and energy levels. The secondary objectives of the study were to determine the effectiveness of investigational product on improving digestive behaviour, lipid profile and general complaints. Treatment compliance assessment along with the safety of product through monitoring adverse events was performed throughout the study.

Inclusion criteria

Male and female patients aged between 20-45 years (both inclusive) with BMI between 25-35 kg/m^2 were included in the study. Patient with or without hypothyroidism were enrolled in the study. Patients with hypothyroidism who were stable on medication and had normal TSH levels were included in the study. Patients with or without comorbidities, if comorbidity existed, were on stable prescription and met the following criteria: Hypertension (≤140/90 mmHg on prescription) and Type 2 DM (HbA1C ≤ 7.5 on prescription) were enrolled in the study. Patients willing to provide consent and those willing for follow up visits were included in the study.

Exclusion criteria

Patients with any acute illness requiring immediate medical care were excluded from the study. Patients with PCOS, PCOD, infertility disorder, or any other hormonal disorder were not included in the study. Patients with Type I

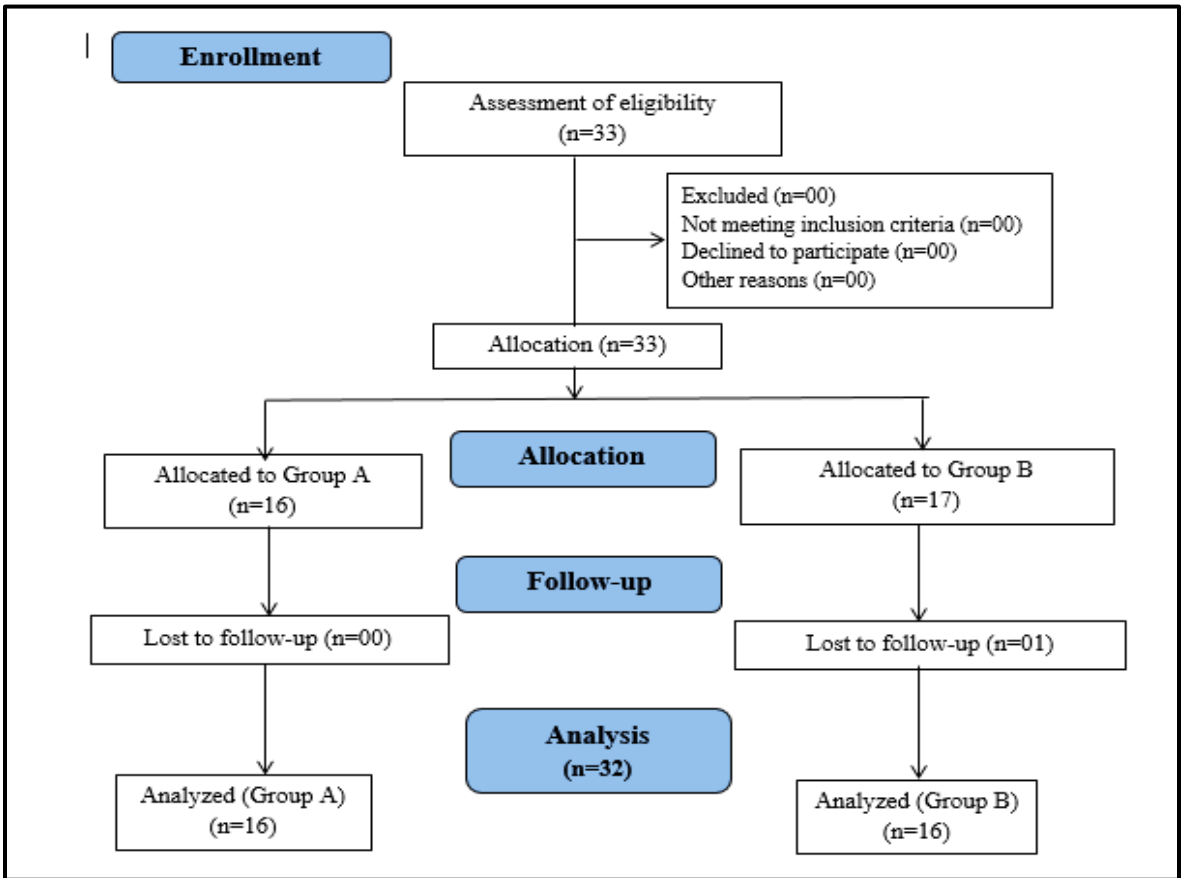

Figure 1. CONSORT diagram for the study.

DM/Complicated cardiovascular diseases / HbA1C ≥ 7.5/ history of TIA, cerebrovascular accident, stroke or any revascularization, hepatic failure/renal impairment were not included in the study. Patients who were pregnant, breastfeeding or planning to become pregnant during the study were not considered for the study. Any other condition that proved the patient unfit for participation were also excluded from the study.

The deposition of patients is expressed in the consort chart.

Composition of the Kapiva Get Slim Juice

Daru Haldi (*Berberis aristatsa*), Gurmar (*Gymnema sylvestre*), Haldi (*Curcuma longa*), Haritaki (*Terminalia chebula*): Kutki (*Picrorrhiza kurroa*), Musta (*Cyperus rotundus*), Chitrak Mool (*Plumbago zeylanica*), Fenugreek (*Trigonella foenum graecum*), Bibhitaki (*Terminalia bellirica*), Giloy (*Tinospora cordifolia*), Ginger (*Zingiber officinale*), Garcinia Extract (*Garcinia cambogia*), Amla Juice (*Emblica officinalis*), Cinnamon (*Cinnamomum zeylanicum*), Black Pepper (*Piper nigrum*), Cumin (*Cuminum cyminum*), Calcium propionate, Potassium sorbate.

Dosage and duration of the treatment

30 ml Kapiva Get Slim Juice mixed with 200 ml of normal or lukewarm water twice a day, one hour before meals, in the afternoon and evening for both groups. The treatment duration was of 90 days.

Both study groups received individualized diet and exercise consultations for 90 days, with separate consultations provided for patients following a vegetarian diet and those following a non-vegetarian diet.

Methodology

After receiving the approval from the ethics committee study was conducted in accordance with Ayush/ ICH-GCP guidelines. On screening visit, voluntary written informed consent from patients for their participation in the study was obtained. Overweight to obese male and female patients with or without hypothyroidism between 20-45 years of age were screened for eligibility criteria.

On the screening visit, written informed consent was obtained from the patient for participation in the study. On the screening visit patient's demographic details were recorded. Patient underwent clinical examination (general and systemic examination including cardiac, respiratory, gastrointestinal, genitourinary and nervous system. Blood samples of all eligible patients were collected for biochemical and hematological investigations. After confirming that the patient met all the inclusion criteria and did not exhibit any exclusion criteria, they were enrolled in the study.

On baseline visit (day 1), 33 patients were enrolled in either Group A: Overweight to obese patients or Group B: Overweight to obese with hypothyroidism patients in a 1:1 ratio. Both groups provided consultation on diet and exercise. Patients were asked about the occurrence of any adverse event during the screening period. Patients were screened for other allergies for the ingredients of the investigational product.

The treatment duration was of 90 days. The efficacy of Kapiva Get Slim Juice in the management of weight was determined by comparing pre-and post-treatment status of the patients from the same group.

Drug compliance was assessed by the investigator on every follow-up visit. If any patient continuously missed dosing for >6 consecutive or divided days during the 30 days period, patient was treated as drop out. The patient was advised to continue the diet and exercise regimen as suggested by the investigator during the entire study period. Patients were assessed for any adverse events during study period.

The patients were asked to follow up on every two weeks from baseline i.e. Day 15, Day 30, Day 45, Day 60, Day 75 and Day 90. Assessment of body weight, BMI, digestive behavior and general complaint assessment based on VAS was done from screening to end of the study. Anthropometric assessment, quality of life, energy assessment was done on screening, visit 3 (day 30), visit 5 (day 60) and visit 7 (day 90). Assessment of complete blood count, random plasma blood sugar, lipid profile, LFT, RFT, and TSH levels of patients with hypothyroidism was done at screening and end of the study. Treatment compliance, safety and tolerability of the study intervention in terms of adverse events (AEs), serious adverse events (SAEs) were assessed from baseline to end of the study.

The patients were asked to contact investigator for any adverse event between the visits. After completion of 90 days, the patients were asked to stop the study medication. The patients were advised to follow the investigator instructions for further treatment.

This proof-of-concept study targeted individuals ranging from overweight to Class 1 obesity (BMI between 25-35 kg/m^2). The study aimed to explore the efficacy of an Ayurvedic juice formulation for weight management in this specific population. Given the elevated health risks associated with overweight & obesity, intervening at an early stage holds significant potential for beneficial outcomes. It is acknowledged that clinical trials involving individuals with Class 2 and 3 obesity are warranted in the future.

Statistical analysis

Statistical analysis has been done by using SPSS version 10.0. The weight, BMI, waist circumference, hip circumference, waist/hip ratio, mid-upper arm circumference, body fat percentage, visceral fat level percentage, IWQOL-lite score, energy events, lipid profile, thyroid function test, complete blood count, glycemic profile, renal function test, and liver function test and general complaints were analyzed by dependent student t test.

For assessing digestive behavior, a chi-square test was employed.

Result

Demographic characteristics

There were 33 male and female patients enrolled into study and 32 patients completed the study and data is depicted in Figure 1. There were 16 evaluable patients in each group. The average age in Group A was 29.25± 6.75 years and in Group B was 34.56 ± 7.34 years. The details are presented in table 1. All study patients were from the middle socioeconomic status, among both groups. Patients in the study were following either a vegetarian or non-vegetarian diet, with corresponding diet charts provided to each individual. Throughout the study duration, none of the subjects reported alcohol consumption, and none of them engaged in intense physical activity.

Table 1. Demographic details.

Parameters	Group A	Group B
Total number of patients	16	16
Male	13	01
Female	03	15
Average age (years)	29.25 ± 6.75	34.56± 7.34

Anthropometric assessment

Weight, Height and BMI

In the present study, the initial body weight of the group A patients (overweight to obese) was 82.81 kg and BMI was 27.95 kg/m^2, after treatment with Kapiva Get Slim Juice, at day 90 there was around 7.05 kg of reduction of body weight to average of 75.76 kg with BMI of 25.57. The reduction in body weight observed in the study was statistically significant ($p<0.001$). A significant reduction was seen in just 15 days and the trend continued till day 90. (Table 2 & Figure 2)

While the initial body weight of the group B patients (overweight to obese with hypothyroidism) were 81.13 kg and BMI was 30.36 kg/m^2, after treatment with Kapiva Get Slim Juice, at day 90 there was around 5.67 kg of reduction of body weight to average 75.46 kg with BMI of 28.23 kg/m^2. The reduction in body weight and BMI observed in the study was statistically significant ($p<0.001$). The significant reduction was seen in just 15 days and the trend continued till day 90 (Table 2 & Figure 2).

Table 2. Anthropometric assessment of group A and group B patients.

Groups	Parameters	Screening	Day 15	Day 30	Day 45	Day 60	Day 75	Day 90	P value
Group A	Weight (Kg)	82.81± 4.72	81.01± 4.89	79.72± 4.68	78.85± 4.72	76.89± 4.57	76.27± 4.62	75.76± 4.71	<0.001
	Height (cm)	172.50± 7.69	172.50± 7.69	172.50± 7.69	172.50± 7.69	172.50± 7.69	172.50± 7.69	172.50± 7.69	1
	BMI (kg/m²)	27.95± 2.54	27.34± 2.56	26.91± 2.51	26.61± 2.46	25.95± 2.38	25.74± 2.38	25.57± 2.38	<0.001
Group B	Weight (kg)	81.13± 5.22	80.16± 5.36	78.76± 5.41	77.81± 5.32	76.22± 5.32	75.83± 5.20	75.46± 5.20	< 0.001
	Height (cm)	163.69± 6.48	163.69± 6.48	163.69± 6.48	163.69± 6.48	163.69± 6.48	163.69± 6.48	163.69± 6.48	1
	BMI (kg/m²)	30.36± 2.44	29.99± 2.45	29.46± 2.41	29.11± 2.37	28.52± 2.39	28.37± 2.33	28.23± 2.32	< 0.001

Data between screening and day 90 analyzed by dependent student t test. Significant at p<0.05. Values represent mean± SD.

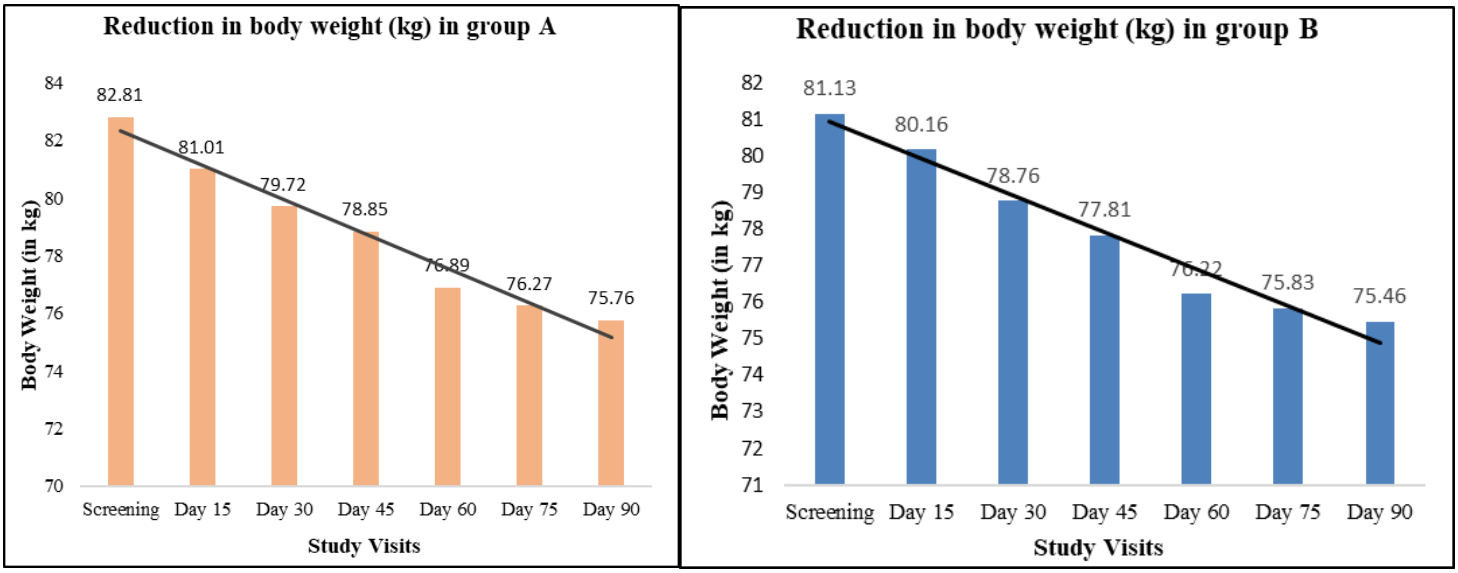

Figure 2. Depiction of the reducing trend in body weight after treatment with Kapiva Get Slim Juice in group A and group B.

Other anthropometric parameters

In group A patient, after 90 days of treatment with the Kapiva Get Slim Juice, there was a gradual yet significant reduction in anthropometric parameters such as waist (3.87 cm), hip (3.18 cm), and mid-upper arm circumference (1.82 cm) along with the waist/hip ratio, body fat and visceral fat % measured through the impedance technique bioelectrical impedance analysis (BIA) (Table 3).

In group B patients, after treatment with the Kapiva Get Slim Juice, there was a significant reduction in anthropometric parameters such as waist (2.32 cm), hip (2.13), and mid-arm circumference (1.49 cm) along with the body fat and visceral fat % through the impedance technique (Table 3).

Assessment of modified impact of weight on quality of LIFE-LITE (IWQOL- Lite) in overweight to obese patients

Modified impact of weight on quality of life questionnaire was used to assess the weight related physical and emotional functioning of study patients. Questionnaire was designed in way that each question in each domain was scored from 0 to 10 where 0 means no and 10 means severe.

After 90 days of treatment with Kapiva Get Slim Juice, clinically meaningful and statistically significant reduction in physical function, self-esteem, sexual life, public distress and work domain score was observed in study patients indicating improved quality of life (Table 4).

Assessment of energy audit diary in patients

The energy audit was performed by calculating frequencies of low, moderate and high energy events reported by patients in their diaries for each 30 days till 90 days.

In Group A it was evident from data that number of events in very high category were increased significantly. No. of high energy events were also increased as compared to screening. There were significantly decreased number of neutral and moderate energy events observed at day 30, day 60 and day 90. It indicated that the effectiveness of treatment was seen on improved energy levels in 30 days' time (Table 5).

While in group B it was evident from data that number of high, moderate, and neutral energy events significantly

increased over the 90-day treatment. Gradual and significant reduction in low energy events were also observed over 90 days of treatment with Kapiva Get Slim Juice (Table 5).

Table 3. Other anthropometric assessment.

Groups	Parameter	Screening	Day 30	Day 60	Day 90	*P* value
Group A	Waist (cm)	97.06±4.91	95.63±4.85	94.19±4.81	93.19±4.37	<0.001
	Hip	118.81±5.96	118.81±5.96	116.69±5.88	115.63±5.77	<0.001
	Waist /Hip Ratio	0.82±0.04	0.81±0.04	0.81±0.04	0.81±0.04	<0.001
	Mid-upper arm circumference (cm)	29.50±1.60	29.02±1.73	28.38±1.61	27.68±1.53	<0.001
	Body fat%	26.81±1.75	26.18±1.77	25.53±1.75	25.21±1.85	<0.001
	Visceral fat level (%)	23.56±5.92	23.19±5.54	22.94±4.93	22.52±4.90	<0.001
Group B	Waist (cm)	88.13±5.41	86.81±5.66	86.38±5.66	85.81±5.67	< 0.001
	Hip	115.69± 4.85	115.31± 4.87	114.63± 4.62	113.56± 4.37	< 0.001
	Mid-upper arm circumference (cm)	28.94±1.68	28.49±1.69	27.86±1.67	27.45±1.59	< 0.001
	Body fat %	29.29±1.59	28.67±1.54	28.01±1.57	27.68±1.57	< 0.001
	Visceral fat level (%)	23.56±4.24	23.03±3.92	22.47±3.61	22.06±3.61	< 0.001
	Waist (cm)	88.13±5.41	86.81±5.66	86.38±5.66	85.81±5.67	< 0.001

Data between screening and day 90 was analyzed by dependent student t-test. Significant at p<0.05 Values represent mean± SD.

Table 4. Assessment of modified impact of weight on quality of LIFE-LITE (IWQOL- Lite) questionnaire.

Groups	Parameter	Screening	Day 30	Day 60	Day 90
Group A	Physical Function	53.13±2.16	51.69±1.96	36.31±1.78	25.06±1.39**
	Self-esteem	22.56±1.86	21.75±1.91	16.69±1.20	6.94±0.93**
	Sexual life	21.69±1.74	20.63±1.78	18.13±1.20	12.63±1.02**
	Public distress	5.38±0.50	5.38±0.50	4.38±0.50	2.44±0.51**
	Work	11.06±0.85	10.63±0.96	8.44±0.63	5.00±0.73**
Group B	Physical Function	51.38±1.93	51.25±2.02	36.94±1.88	24.19±2.20**
	Self-esteem	22.31±1.82	22.19±1.91	16.63±1.09	7.44±0.96**
	Sexual life	23.94±3.40	23.31±2.94	18.63±1.93	12.31±1.66**
	Public distress	5.44±0.51	5.19±0.54	4.44±0.51	2.44±0.51**
	Work	10.88±0.62	10.50±0.89	8.63±0.72	5.19±0.83**

Data between screening and day 90 were analyzed by dependent student t-test. Significant at p<0.05. Values represent mean score ± SD.

Table 5. Assessment of energy audit diary for patients.

Groups	Energy Events	Day 30	Day 60	Day 90	P value
Group A	Very High	7.63±5.46	13.56±7.11	18.63±8.06	0.00001
	High	42.75±5.13	46.63±5.45	46.13±7.19	0.215
	Moderate	41.81±3.76	35.38±8.07	38.25±7.52	0.090
	Neutral	27.75±6.43	23.88±7.22	17.00±4.38	0.00005
	Low	00	0.56±2.25	00	1
	Very Low	00	00	00	1
Group B	Very High	00	00	00	1
	High	25.88±2.16	44.31±3.66	47.81±2.46	<0.00001
	Moderate	22.44±2.68	30.56±2.68	32.50±2.19	<0.00001
	Neutral	21.94±3.73	31.00±3.01	32.19±2.79	<0.00001
	Low	49.69±3.57	14.13±3.48	7.50±1.51	<0.00001
	Very Low	00	00	00	1

Data between screening and day 90 was analyzed by dependent student t-test. Significant at p<0.05. Values represent event mean± SD.

Table 6. Assessment of digestive behavior scores for patients.

Group	Study Visits	Score			
		0-None	1-Mild	2-Moderate	3-Severe
Bloating					
Group A	**Screening**	5	3	8	0
	Day 30	8	6	2	0
	Day 60	11	5	0	0
	Day 90	14*	2	0	0
Group B	**Screening**	3	5	5	3
	Day 30	4	11	1	0
	Day 60	11	5	0	0
	Day 90	12*	4	0	0
Heartburn					
Group A	**Screening**	0	5	7	4
	Day 30	0	12	4	0
	Day 60	8	7	1	1
	Day 90	9	7	0	0
Group B	**Screening**	1	6	6	3
	Day 30	1	10	5	0
	Day 60	7	9	0	0
	Day 90	12*	4	0	0
Flatulence					
Group A	**Screening**	0	8	8	0
	Day 30	0	12	4	0
	Day 60	9	7	0	0
	Day 90	9	7	0	0
Group B	**Screening**	0	9	7	0
	Day 30	0	13	3	0
	Day 60	6	10	0	0
	Day 90	9	7	0	0
Constipation					
Group A	**Screening**	3	6	4	3
	Day 30	3	12	1	0
	Day 60	12	4	0	0
	Day 90	14*	2	0	0
Group B	**Screening**	8	2	6	0
	Day 30	9	6	1	0
	Day 60	12	4	0	0
	Day 90	13	3	0	0
Post Prandial Fullness					
Group A	**Screening**	5	1	8	2
	Day 30	6	9	1	0
	Day 60	10	6	0	0
	Day 90	13*	3	0	0
Group B	**Screening**	4	5	6	1
	Day 30	6	9	1	0
	Day 60	12	4	0	0
	Day 90	13*	3	0	0

Data between screening and day 90 were analyzed by Chi Square test. Significant at $p<0.05$. Values represent number of patients.

Table 7. Assessment of general complaints of patients.

Groups	Parameter	Screening	Day 15	Day 30	Day 45	Day 60	Day 75	Day 90
Group A	**Profuse Sweating**	3.06±2.49	2.69±2.18	2.13±1.75**	1.63±1.36	1.44±1.21**	0.81±1.11	0.50±0.82**
	Irregular Thirst	3.38±2.78	2.88±2.39	2.50±2.10**	2.25±1.88	1.94±1.65**	1.44±1.26	1.00±1.03**
	Dyspnea	3.06±2.21	2.88±2.06	2.44±1.75**	2.06±1.48	1.81±1.33**	1.25±1.13	0.75±0.77**
	Craving	6.00±0.82	5.19±0.66	4.56±0.51**	4.00±0.52	3.63±0.62**	3.31±0.60	3.31±0.60**
Group B	**Profuse Sweating**	4.75±1.98	4.06±1.73	3.56±1.55**	2.75±1.39	2.31±1.01**	1.44± 0.89	1.06±0.77**
	Irregular Thirst	4.19±2.17	3.56±1.82	3.06±1.65**	2.75±1.44	2.38±1.26**	1.81±1.17	1.44±1.03**
	Dyspnea	2.75±2.24	2.63±2.19	2.19±1.80**	1.81±1.52	1.56±1.31**	1.13±1.09	0.75±0.77**
	Craving	6.00±0.73	5.13±0.81	4.75±0.58**	4.19±0.66	3.56±0.63**	3.31±0.60	3.25±0.58**

Data between screening and day 90 were analyzed by dependent student t-test. Significant at $p<0.05$. Values represent mean± SD.

Assessment of digestive behavior in patients

Digestive behavior based on symptoms such as bloating, heartburn, flatulence, constipation and post prandial fullness was assessed on a 4-point ordinal scale where, 0-None, 1-Mild symptoms- not interfering with daily activities, 2-Moderate symptoms- interfering with daily activities, 3-Severe symptoms-interfering with daily activities severely.

In group A patient, 87.5% of patients reported no bloating and constipation after 90 days of the treatment. 56.20% of patients reported complete resolution and 43.25% of patients reported mild hurt burn and flatulence after 90 days of the treatment. 81.25% of patients reported complete resolution of post-prandial fullness after 90 days of treatment (Table 6).

In group B at screening, complaints of bloating, heartburn, flatulence, constipation, and postprandial fullness were reported by 81.25%, 93.75%, 100%, 50%, and 75% of the patients, respectively. After 90 days of treatment with Kapiva Get Slim Juice, the proportion of patients with no complaints of bloating, heartburn, flatulence, constipation, and postprandial fullness increased to 75%, 75%, 56.25%, 81.25%, and 81.25%, respectively (Table 6).

Assessment of general complaints of patients

The present study assessed various general complaints such as sweating, irregular thirst, dyspnea and craving in overweight to obese patients using a 0-10 visual analogue scale, where 0 represented no symptom and 10 indicated a very severe symptom.

The results showed a significant improvement in general complaints of group A over the course of the study. In terms of profuse sweating score, there was a progressive and significant decrease in symptoms from screening (3.06±2.49) to day 90 (0.50±0.82) observed. Similarly, irregular thirst exhibited a significantly decreasing trend from screening (3.38±2.78) to day 90 (1.00±1.03). Dyspnea, or difficulty in breathing, also showed significant improvement from screening (3.06±2.21) to day 90 (0.75±0.77). Furthermore, craving, which represents the desire for food, decreased significantly throughout the study. From screening (6.00±0.82), there was a significant and consistent reduction in craving score up to day 60 (3.63±0.62), after which it plateaued (Table 7).

While group B patients demonstrated a noteworthy enhancement in general complaints. Notably, there was a progressive and significant decrease in profuse sweating symptoms, with a score declining from 4.75 at screening to 1.06 at day 90. Similarly, irregular thirst displayed a significant decreasing trend, with scores decreasing from 4.19 at screening to 1.44 at day 90. Dyspnea also exhibited significant improvement, as the average score decreased from 2.75 to 0.75 between screening and day 90. Moreover, throughout the study, craving experienced by study patients decreased gradually yet significantly with scores reducing from 6.00 at screening to 3.25 at day 90 (Table 7).

Assessment of laboratory examination of patients

There were no clinically as well as statistically significant ($p<0.05$) changes observed after 90 days' treatment in TSH level, lipid profile, complete blood count, glycemic profile, renal function test, liver function test in both group of the patients (Table 8).

Assessment of tolerability and treatment compliance in overweight to obese patients

The group A and B patient's demonstrated excellent tolerability and a remarkably high treatment compliance rate of 99.13% and 99.30% respectively, when using Kapiva Get Slim Juice.

There were no adverse events were reported throughout the study in either group. Throughout the study, vital signs such as heart rate, respiratory rate, and body temperature consistently remained within the normal range, and no significant alterations were detected

Table 8. Assessment of blood parameters in overweight to obese patients.

Parameter / Duration	Group A		Group B	
	Screening	Day 90	Screening	Day 90
TSH (uIU/ml)	-	-	2.84±0.99	2.89±1.23
Total Cholesterol (mg/dl)	168.89±37.56	160.37±33.19	173.27±34.95	169.88±36.05
Low-Density Lipoprotein (LDL) (mg/dl)	94.34±31.55	91.05±19.47	100.87±29.64	91.59±33.05
High-Density Lipoprotein (HDL) (mg/dl)	48.81±10.13	46.07±6.68	44.09±5.38	50.64±9.76
Very low-density lipoprotein (VLDL) (mg/dl)	25.75±15.68	27.86±20.15	28.31±9.38	27.65±7.42
Triglycerides (mg/dl)	128.74±78.39	143.91±100.21	141.57±46.87	138.27±37.11
TG/LDL ratio	1.49±1.10	1.69±1.44	1.46±0.50	1.79±0.96
Total Leukocyte Count (cell/cu.mm)	6800.00±1353.02	6381.25±1065.34	7864.29±2142.11	7678.57±1709.33
Neutrophils (%)	52.94±8.31	51.25±6.47	57.64±6.96	53.57±7.87
Lymphocytes (%)	37.69±7.69	38.75±6.47	32.64±7.10	36.43±7.87
Monocytes (%)	6.31±0.60	6.38±0.72	6.14±0.77	6.43±0.85
Eosinophil (%)	3.69±0.60	3.63±0.81	3.57±0.65	3.57±0.85
Basophils (%)	0	0	0	0
Total RBC Count (mil/cu.mm)	4.95±0.62	4.73±0.58	4.41±0.42	4.38±0.47
Hemoglobin (g/dl)	14.53±1.47	14.17±1.29	12.08±1.72	11.89±1.55
Hematocrit (%)	43.05±4.31	42.56±4.30	36.01±4.47	36.69±4.01
Platelets (*10^3/ul)	250.13±77.57	250.25±69.78	355.00±76.91	337.00±72.28
Random Blood Sugar Level (mg/dl)	100.31±27.82	98.17±23.28	99.04±17.22	98.81±16.08
Blood Urea Nitrogen (mg/dl)	10.59±1.69	10.53±1.72	10.78±2.78	9.43±2.54
Blood Urea (mg/dl)	22.68±3.62	22.36±3.81	23.09±5.96	20.63±5.53
Serum Creatinine (mg/dl)	1.06±0.28	0.98±0.20	0.99±0.21	0.84±0.15
Uric Acid (mg/dl)	4.49±1.49	4.85±1.15	4.87±1.64	4.65±1.70
Total Bilirubin (mg/dl)	0.73±0.30	0.68±0.22	0.71±0.32	0.60±0.24
Direct Bilirubin (mg/dl)	0.36±0.14	0.25±0.07	0.30±0.18	0.26±0.08
Indirect Bilirubin (mg/dl)	0.37±0.23	0.42±0.20	0.41±0.19	0.34±0.18
SGOT/ AST (U/L)	50.76±17.07	39.19±13.00	40.66±19.51	33.02±13.32
SGPT/ ALT (U/L)	34.58±13.66	33.68±8.88	26.65±13.80	32.13±12.35
Total Protein (g/dl)	6.74±0.49	6.65±0.40	6.95±0.65	7.63±0.63
Albumin (g/dl)	4.23±0.25	4.60±0.30	4.41±0.53	4.55±0.40
Globulin (g/dl)	2.51±0.36	3.05±0.26	2.55±0.58	3.08±0.37

Data between screening and day 90 were analyzed by student t-test. Non- Significant at p>0.05. Values represent mean± SD.

Discussion

Kapiva Get Slim Juice is a proprietary product created with strong Ayurveda rationales for reducing obesity. It has been conceptualized on the basis of Ayurvedic principles of treating obesity. Herbs in the formulation are *Medohara* and *Lekhana.* It is being manufactured using the authentic Ayurvedic process of making *Swarasa* and *Kashaya.* Ingredients in the juice help in addressing obesity, while targeting regulating the appetite, improving metabolism, reducing hunger cravings and burning fat effectively.

The purpose of the research is an attempt to evaluate the safety and efficacy of Kapiva Get Slim Juice for management of weight, anthropometry and thereby improvement in QOL. Kapiva Get Slim Juice, is herbal decoction which has ingredients such as *Daru haldi, Gurmar, Haldi, Haritaki, Kutki, Musta, Chitrakmool, Bibhitaki, Giloy, Garcinia, Amla, Ginger, Fenugreek, Cinnamon, Black pepper, Cumin* known to reduce the appetite,

improving metabolism, reducing hunger cravings and burning fat effectively which consequently help in the process of weight management.

In this study, the effectiveness of Kapiva Get Slim Juice in reducing various anthropometric parameters was investigated in two groups: overweight to obese patients and overweight to obese patients with hypothyroidism. After a 90-day treatment period, significant and clinically meaningful reductions were observed in weight, BMI, waist circumference, hip circumference, waist/hip ratio, mid-upper arm circumference, body fat percentage, and visceral fat level in both groups. Moreover, the study found that the treatment with Kapiva Get Slim Juice had a positive impact on the quality of life of the patients. Physical function, self-esteem, sexual life, public distress, and work domain scores significantly improved, indicating an overall enhancement in their well-being. Additionally, the patients reported a greater number of higher energy events, suggesting increased vitality. Furthermore, the study demonstrated that the Kapiva Get Slim Juice effectively alleviated general complaints and digestive issues commonly experienced by overweight to obese individuals. Symptoms such as profuse sweating, irregular thirst, dyspnea, and cravings were reduced, along with improvements in digestive complaints such as bloating, heartburn, flatulence, constipation, and postprandial fullness. This indicates an overall improvement in their well-being and digestive health. Importantly, no clinically or statistically significant changes were observed in laboratory parameters, and no adverse events were reported throughout the study in either group, highlighting the safety of Kapiva Get Slim Juice.

Kapiva Get Slim Juice is an exclusive product developed with a robust foundation in Ayurvedic principles to combat obesity. Its formulation is rooted in the Ayurvedic concepts of treating obesity, with a focus on specific herbs known as *Medohara* and *Lekhana*. By leveraging the power of carefully selected ingredients, this juice aims to address obesity by regulating appetite, enhancing metabolism, curbing hunger cravings, and promoting efficient fat burning. In essence, investigational product combines ancient Ayurvedic wisdom with modern understanding to provide an effective solution for weight management and promoting a healthier lifestyle.

Following clinical trials provide valuable insights into the efficacy of the individual ingredients used in Kapiva Get Slim Juice.

Berberine in *Daruhaldi* helps in appetite suppression and the central obesity related pathway to prevent obesity by down regulating expression of genes that promote the proliferation and differentiation of adipocytes. Moreover, it could alleviate the growth of adipose tissue by inducing the enzymes that activate the glucose and fatty acids uptake. In addition, *Berberine* regulates the levels of gut hormones, subsequently, treating obesity and insulin resistance. Several studies have been conducted on the role of *Berberine* in obesity management. In a meta review of these trials, it was concluded that *Berberine* helps in reducing the waist hip ratio significantly [15, 16].

Gymnemic acid an active component isolated from *Gymnema sylvestre*, has anti-obesity and anti-diabetic properties by decreasing body weight and inhibition of glucose absorption. Several components extracted from *Gymnema*, prevent the accumulation of triglycerides in the muscle and liver and also decrease fatty acids accumulation in the circulation [17]. In a study conducted in India on overweight individuals, the efficacy of a formulation containing *Terminalia chebula, Emblica officinalis, Terminalia belerica, Cyperus rotundus, Embelia ribes, Plumbago zeylanica, Guggul,* and *Garcinia cambogia* was examined. The results showed a reduction in waist and hip circumference, while other parameters such as weight and BMI were not significantly affected [18]. Comparatively, the decrease observed in our study for all the mentioned parameters was greater than what was reported in the aforementioned study. This could be attributed to the fact that Kapiva Get Slim Juice formulation contained additional ingredients that might have positively influenced the overall effectiveness of the treatment.

Haritaki, when administered with honey twice a day, resulted in a significant reduction in BMI and body fat percentage in a study involving 70 patients with *Sthaulya* [19]. Similarly, the effect of *Lekhaniya mahakashaya*, containing *Kutki,* on obesity showed a significant difference in BMI and waist/hip ratio before and after treatment [20], which aligns with the findings of the present study. *Cyperus rotundus* was shown to prevent the conversion of pre adipocyte cells to adipocytes in a pilot study involving obese individuals. Treatment with *Cyperus rotundus* extract resulted in a statistically significant reduction in body weight, BMI, and waist circumference compared to the placebo group [21], which corresponds to the outcomes observed in the present study.

Chitraka & turmeric were both found to be effective in reducing body fat percentage, BMI, and skinfold thickness in a clinical trial involving obese individuals. *Chitraka* showed statistically more significant results in comparison [22]. Fenugreek seeds, known for their fiber content and ability to induce a feeling of fullness, have been demonstrated to reduce appetite. A meta-analysis of randomized controlled trials (RCTs) indicated that fenugreek supplementation significantly reduced fasting plasma glucose, triglyceride levels, waist circumference, and systolic blood pressure, while increasing high-density lipoprotein (HDL) levels [23]. Interestingly, our study patients did not exhibit changes in lipid profile or glycemic profile, which were within normal ranges.

Terminalia bellirica (Bibhitaki) and *Tinospora cordifolia* (Giloy) have shown potential in regulating adiponectin expression, enhancing fatty acid binding protein-4 activity, and improving lipid metabolism [24-26]. However, our interventional product did not demonstrate similar activity. The administration of *Emblica officinalis* (Amla) fruit juice

to obese subjects resulted in significant changes in weight, waist circumference, body mass index, and lipid profile levels in a study where 20 ml of fresh fruit juice was consumed twice a day for 45 days. In an another study *Emblica officinalis* has been shown to decrease serum concentrations of both T3 and T4 [27, 28]. It is noteworthy that our investigational product contains *Emblica officinalis* as one of its ingredients, which could potentially contribute to the management of TSH levels observed in our study.

Hydroxycitric acid (HCA) found in Vrikshamla (*Garcinia cambogia*) has been associated with weight loss by competitively inhibiting the enzyme adenosine triphosphatase-citrate-lyase. HCA may also increase the release or availability of serotonin in the brain, leading to appetite suppression. Furthermore, it is postulated that HCA inhibits pancreatic alpha amylase and intestinal alpha glucosidase, resulting in reduced carbohydrate metabolism [29]. It is likely that a similar mechanism contributed to the weight loss observed in our study.

A comprehensive meta-analysis investigating the impact of cinnamon supplementation on anthropometric indices revealed significant reductions in BMI and body weight [30]. Ginger have been associated with anti-obesity effects, including weight reduction and appetite suppression [31]. Black pepper (*Piper nigrum*) has been suggested to inhibit the interaction between GHSR and Ghrelin, potentially leading to appetite reduction and weight loss in obesity [32]. Moreover, a randomized clinical trial involving overweight/obese women revealed that cumin powder significantly reduced weight, BMI, waist circumference, fat mass, cholesterol, triglyceride, and LDL levels while increasing HDL levels [33]. Similar results have been observed in the present study.

Furthermore, the Kapiva Get Slim Juice also exhibited effectiveness in addressing various digestive health issues frequently observed in individuals with overweight to obese patients and in hypothyroidism patient, including constipation, postprandial fullness, bloating, and heartburn. The observed alleviation of symptoms related to both hypothyroidism and digestive health issues indicates the comprehensive nature of the investigational product in targeting multiple aspects of the condition. By addressing these symptoms, the product may contribute to overall well-being and enhanced quality of life in individuals with hypothyroidism who are overweight or obese.

In group B of our study, there were no significant alterations observed in serum TSH values, and they remained within the normal range before and after the study. It is noteworthy that hypothyroidism and obesity commonly coexist as comorbid conditions, and research has indicated that managing obesity can help control hypothyroidism. Therefore, the development of a product targeting weight reduction in individuals with hypothyroidism is not only crucial but also beneficial for a wider population. The findings of our study indicate that Kapiva Get Slim Juice was equally effective in promoting weight reduction in both overweight-to-obese patients and overweight-to-obese with hypothyroidism. Furthermore, the study provides evidence of the product's safety, as there were no adverse events reported and no significant changes in laboratory investigations were observed.

Overall, the findings from these clinical trials support the potential effectiveness of the individual ingredients present in Kapiva Get Slim Juice for weight management and improving various parameters associated with obesity. The combination of these ingredients in the formulation may synergistically enhance the product's efficacy, as observed in our study.

Conclusion

It is concluded that obesity and overweight, along with hypothyroidism, have become major health concerns affecting millions of people worldwide. In Group A, the consumption of Kapiva Get Slim Juice resulted in an average weight reduction of 1.8 kg in 15 days, 3.09 kg in 30 days, 5.83 kg in 60 days, and 7.05 kg in 90 days. In Group B, Kapiva Get Slim Juice led to an average weight reduction of 0.97 kg in 15 days, 2.37 kg in 30 days, 4.91 kg in 60 days, and 5.67 kg in 90 days. Remarkably, significant weight reduction was observed within just 15 days in both groups, which included individuals with and without hypothyroidism. Additionally, both overweight and obese patients, including those with hypothyroidism, experienced significant improvements in various health metrics. This included reductions in BMI, waist circumference, hip circumference, mid-upper arm circumference, waist/hip ratio, body fat percentage, and visceral fat percentage. Participants also reported enhancements in their quality of life, both in terms of physical and emotional well-being, and a reduction in various symptoms. Importantly, no adverse events were observed in any of the study's participants throughout the duration of the study. Furthermore, there were no clinically or statistically significant changes observed after 90 days of treatment, indicating the safety of the product. In conclusion, Kapiva Get Slim Juice offers a promising solution for individuals seeking effective weight management and an overall improvement in well-being. Its demonstrated efficacy, safety profile, and potential to alleviate symptoms associated with obesity and hypothyroidism make it a valuable addition to the weight management products in the market.

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Abbreviations

Table 9. List of Abbreviations

WHO	World Health Organization
QOL	Quality Of Life
BMI	Body Mass Index
CONSORT	Consolidated Standards of Reporting Trials
TSH	Thyroid Stimulating Hormone
DM	Diabetes Mellitus
HbA1C	Glycated Haemoglobin
PCOS	Polycystic Ovary Syndrome
PCOD	Polycystic Ovarian Disease
TIA	Transient Ischemic Attack
LFT	Liver Function Test
RFT	Renal Function Test
AE	Adverse Events
SAE	Serious Adverse Events
SPSS	Statistical Package For The Social Sciences
IWQOL-lite	Impact Of Weight On Quality Of Life-Lite
Kg	Kilogram
SD	Standard Deviation
cm	Centimeter
SGOT/ AST	Serum Glutamic Oxaloacetic Transaminase/ Aspartate Aminotransferase
SGPT/ ALT	Serum Glutamic Pyruvic Transaminase/ Alanine Aminotransferase
RCT	Randomized Controlled Trials
HDL	High-Density Lipoprotein
HCA	Hydroxycitric Acid
GHSR	Growth Hormone Secretagogue Receptor
LDL	Low Density Lipoprotein
BIA	Bioelectrical Impedance Analysis

Conflict of interests

Dr. Kriti Soni is part of R&D team at Adret Retail Pvt Ltd (Kapiva Ayurveda). Another author declares no conflict of interest.

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Author contribution

Conceptualization: Dr. Kriti Soni, Dr. Ninad Naik; Methodology: Dr. Ninad Naik and Dr. Gayatri Ganu; Data curation and Formal analysis: Dr. Ninad Naik and Dr. Gayatri Ganu; Funding acquisition: Dr. Kriti Soni; Investigation: Dr. Ninad Naik; Validation, visualization: Dr. Ninad Naik, Dr. Kriti Soni; Writing - original draft preparation: Dr. Ninad Naik and Dr. Gayatri Ganu; Writing-Reviewing and Editing: Dr. Kriti Soni and Dr. Gayatri Ganu.

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