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RESEARCH ARTICLE

Efficacy and Safety of *Ayurveda* Compound Formulations in *Sthoulya* (Obesity) Management: A Multi-centric Clinical Trial

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Abstract

Background: *Ayurveda* offers a rich repository of medicinal formulations that have been traditionally used for various health conditions, including obesity. Scientific validation is essential to establish their efficacy and safety in contemporary healthcare. **Aim:** In this present study, it was aimed to evaluate the clinical efficacy and safety of *Navaka Guggulu* (NG) with *Brihat Manjishtadi Kwatha* (BMK) and *Tryushnadi Guggulu* (TG) with BMK for the treatment of *Sthoulya* (Obesity). **Methods:** A prospective, open-label, multi-centric clinical trial was conducted on 240 participants with 20% excess weight than desirable weight, age-adjusted BMI above the 85th percentile, and WHR >0.8 (females) and >0.95 (males). Participants were randomized into two groups: Group I received NG 1 gm twice daily and BMK 50 ml twice daily, while Group II received TG 1 gm twice daily and BMK 50 ml twice daily for 12 weeks. Outcomes were assessed through physical examination, BMI, WHR, EOSS (Edmonton Obesity Scoring System), and laboratory parameters. A paired *t*-test was used for statistical analysis. **Results:** Statistical analysis revealed a significant improvement in disease-specific parameters and chief complaints, including polyphagia, polydipsia, and excessive sweating. The mean values of BMI, waist circumference (WC), and WHR were found to be improved in both groups before and after the treatment, as well as during follow-up at the end of the 16th week. Statistical analysis of the EOSS score and laboratory parameters also revealed a significant upshot in both groups. All the interventions were useful in managing the clinical features and biomarkers; also, no clinically significant adverse event was observed. **Conclusion:** *Ayurveda* compound formulations NG, TG and BMK are remarkably useful and safe in managing obesity (*Sthaulya*) in the prescribed dose and comportment. Further, a double-masked, Randomized Controlled Trial (RCT) with an extended follow-up period is recommended to validate these findings.

Major Findings: The study showed significant reductions in BMI, waist circumference, and WHR in both intervention groups. Clinical symptoms like polyphagia, polydipsia, and excessive sweating improved notably, with better EOSS scores. No serious adverse effects were reported, indicating the safety and efficacy of the Ayurvedic formulations.

Keywords: *Ayurveda*, *Guggulu, Manjishtadi, Navaka*, Obesity, *Sthaulya, Trayodashanga*

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1. Introduction

Obesity is a chronic, non-communicable ailment that results from an interaction between an individual's genetic propensity to weight gain as well as environmental sway[1]. This disorder is also known as a chronic multisystemic and multidimensional set of symptoms characterized by an improper gain or distribution of adipose tissue, which is associated with an assortment of co-morbidities and impediments that lead to long-standing attenuation and management[2]. The prevalence of obesity and overweight is found to be rapidly increasing in India. A recent study reported that based on global trends, it is projected that nearly 27.8% of all Indians will be overweight, and 5% will be obese by the year 2030[3]. One more study estimated that approx. 20.0% of rural people in India will be either overweight or obese by the year 2030[4]. Numerous studies have established a strong association between obesity, overweight, and various non-communicable diseases[5]. The person with obesity is at high risk for a range of co-morbid conditions, as well as Cardiovascular Disease (CVD), Gastrointestinal (GI) disorders, type 2 Diabetes Mellitus (DM), muscular and joint disorders, respiratory disorders and psychological ailments, which may drastically influence their daily lives as well as enhancing the mortality risk[6,7].

Ayurvedic classics describe *Atisthaulya* (Obesity) as the excessive accumulation of *Medodhatu* (adipose tissue) and *Mamsadhatu* (muscle tissue), leading to increased bulkiness in the abdomen, breast, and hip regions. In *Ayurveda*, it is considered one of the *Santarpanottha Vikaras*, *i.e.*, the disorders occurring due to the consumption of excess calories. It is also opined that vitiation of *Medodhatu*, which is also interpreted as *Medodhatudusti, i.e.*, disorders of fat metabolism in the human body, is found to be one of the prime threats to cardiac ailments like ischemic heart disease. An unwholesome diet (*Asatmya ahara*) builds up fatty tissue in the body, resulting in weight gain and obesity. Therefore, a healthy diet comprising sufficient fibre, espousing an active lifestyle, and regular *Yoga* practice along with *Pranayam* meditation to manage stress and fatigue are highly suggested to put a stop to obesity[8-10].

There are many multi-ingredient formulations commonly practised in *Ayurveda* for the management of obesity, in the vein of *Tryushanahi Guggulu* (TG)[11] and *Navaka Guggulu* (NG)[12] mentioned in the *Sthoulyadhikara*. The digestive, appetitive, scrapping, lightness increaser, and *Vata-kapha* palliative properties of these drugs help in the reduction of symptoms. These drugs are well known to stop further Ama production, which can help break the basic pathology of obesity. A previous study has reported that NG can significantly ($p<0.001$) reduce the mean body weight, abdominal circumference, mid-thigh circumference, mid-arm circumference and mean BMI[13]. Another study reported that TG could treat dyslipidemia with a statistically significant reduction in triglycerides, LDL, VLDL, and total cholesterol levels[14]. *Brihat Manjishtadi Kwatha* (BMK) is also a well-known drug that is used widely in obesity; this decoction has *Rakta shodhak* (blood purifier) and *Sophahar* (anti-inflammatory) properties[15]. Based on these, this present study was planned to evaluate the clinical safety and efficacy of *Navaka Guggulu* (NG) with *Brihat Manjishtadi Kwatha* (BMK) and *Tryushnadi Guggulu* (TG) with *Brihat Manjishtadi Kwatha* (BMK) in the management of *Sthoulya* (Obesity).

2. Materials and Methods

2.1 Study Design and Settings

The present study was designed as an open-label, prospective, multi-centric, double-group study, which was performed at two different regional centres of the CCRAS. 120 participants from OPD. of Regional *Ayurveda* Research Institute (RARI), Vijayawada and 120 participants from the Central *Ayurveda* Research Institute (CARI), Kolkata, were enrolled for this clinical trial under the CCRAS Intra Mural Research (IMR) scheme. Each trial drug was given to the enrolled study participants during each visit as per the protocol schedule for 12 weeks, followed by routine observation, and the follow-up period was an additional four weeks (Figure 1).

2.2 Study Participants

The patients with the symptomatology of obesity were screened for eligibility to enrol in the trial. After getting written consent from the eligible participants, they were enrolled in the study after ascertaining the fulfilment of the inclusion criteria. A total of 238 participants

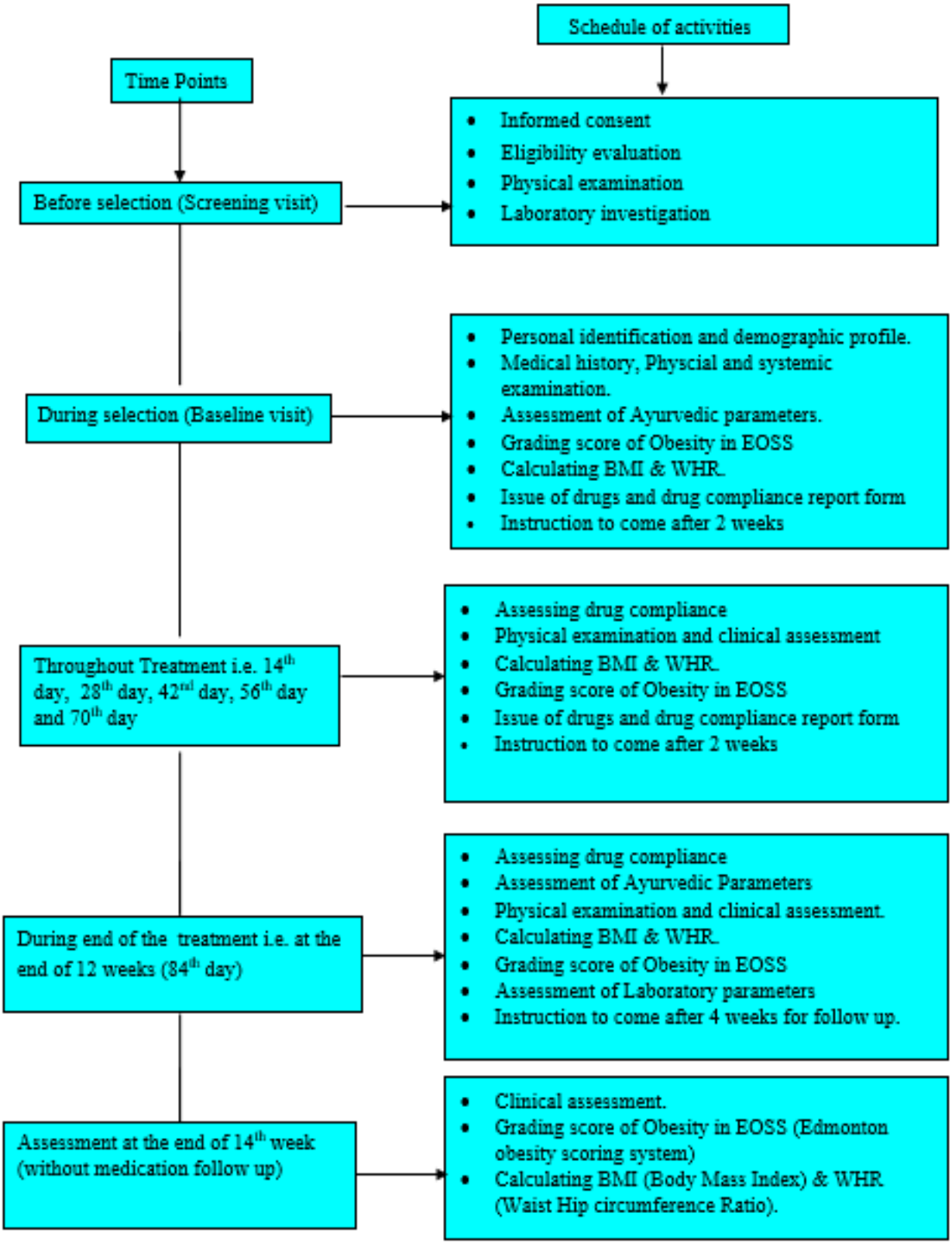


Figure 1. Study schedule.

completed the study, while two participants dropped out (Figure 2).

2.3 Ethical Consideration and Trial Registration

The present study was conducted according to ethical principles originating in the Declaration of Helsinki for biomedical research and ICMR ethical guidelines involving human participants (2006), consistent with Indian/ICH Good Clinical Practice (GCP) guidelines. The Institutional Ethical Committee's (IEC) approval was obtained in both study centres (RARISD, Vijayawada, dated 25th September 2014, and CARIDD, Kolkata, dated 5th July 2014). All the participants provided their written consent after receiving a detailed explanation of the study and the procedures they had to undergo during the trial. The clinical trial was prospectively registered in the Clinical Trial Registry of India (CTRI/2015/09/006150 Registered On: 03/09/2015, Last Modified On: 27/10/2017).

2.4 Inclusion Criteria

Participants of either sex with age above 25 years and below 60 years, having 20% excess weight than desirable weight according to height, sex and age/age-adjusted BMI above 85th percentile and male participants with Waist Hip circumference Ratio (WHR) > 0.95 and female participants with WHR > 0.8 were considered eligible to enrol as study participants in this trial.

2.5 Exclusion Criteria

Any participants diagnosed as obesity secondary to or associated with any other disease, hypertension (>160/100 mmHg), diabetes mellitus having Hb A1C of > 8, concurrent serious hepatic disorder ALT and/or AST, Total Bilirubin level (Bi) > 2 times than upper normal limit) or Kidney diseases (that is defined as Serum creatinine > 1.2 mg/dl), Severe lung disorders (that was defined as unrestrained COPD and or bronchial asthma), any pregnant or lactating women, history of smoking and alcohol/or any other addiction/drug abuser and the participants who have given the history of participation in any other clinical trial during the past 6 months or any other conditions that may make vulnerable the clinical trial were excluded.

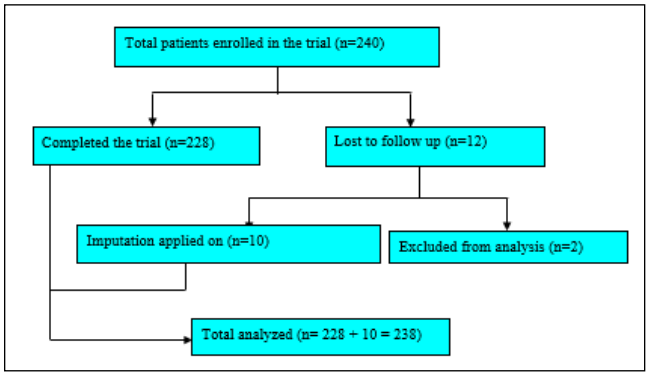


Figure 2. Outflow of the participants in the study.

2.6 Outcome Measures

The outcome was measured by the clinical and physical examination, disease-specific symptoms, and chief complaints, as well as by calculating BMI and WHR, grading score of obesity in EOSS and assessment of other laboratory parameters. Ayurvedic parameters were also assessed to evaluate the efficacy of the selected interventions.

2.7 Study Intervention

Tablet NG 1 gm was administered orally, two times daily with lukewarm water, after food intake. Similarly, BMK 50 ml decoction was administered orally two times daily after food intake. Tablet TG 1 gm was administered orally two times daily with lukewarm water after food. All the interventions were administered up to 12 weeks. All the formulations were manufactured following standard procedures in a GMP-certified pharmacy. Subsequent to the 12 weeks entire treatment period, the follow-up period of the participants was fixed for another two weeks, *i.e.*, 14 days.

2.8 Sample Size Calculation

The sample size was calculated based on the assumption of detecting a relevant change of 2 kg between the groups after the intervention with a standard deviation of 3.5 kg. The required sample size was calculated using the 95% confidence level and 80% power. Expecting an attrition rate of 20%, the desired number of participants to enrol in the present clinical trial was 120 (60 in each group).

2.9 Study Procedure

On the day of the enrolment at baseline, *i.e.* during Visit-1, the demographic profile of the participants, related medical history, family history and vital parameters were recorded. Followed by each subsequent visit was planned as per the protocol at an interval of 2 weeks, *i.e.*, during the 14th day - 2nd visit, 28th day - 3rd visit, 42nd day - 4th visit, 56th day - 5th visit, 70th day - 6th visit and finally in 84th day - 7th visit was performed. All the participants were assessed and provided the scheduled trial interventions at each successive appointment until the 84th day. Follow-up of the participants was done after two weeks, *i.e.*, on the 98th day. The information from the participants was documented in the pre-approved Case Record Forms (CRFs) and entered in e-formats designed in Microsoft Office Excel (MS 2010) with a rationale check ensuring the proper data entry at the study sites. The study centres periodically sent the e-CRFs of the enrolled participants to the central data management unit at the CCRAS headquarters, New Delhi, for verification (Figures 1 and 2).

2.10 Statistical Analysis

The results of the present clinical trial were evaluated by assessing the mean changes in the response from baseline to the 84th day. The statistical interpretations are presented as n (%) and mean ± Standard Deviation (SD). Paired t-tests were used to analyze the mean changes in the response from baseline to the 84th day of the trial period to evaluate the effect of the study intervention in the haematological and biochemical parameters, *i.e.*, serum urea, creatinine, uric acid and LFT. SPSS Inc. (released in 2006. SPSS for Windows, Version 15.0. Chicago, SPSS Inc.) was used to perform all the statistical analyses. All the statistical analysis was performed using SPSS Inc.

3. Results

The study was conducted in two peripheral institutes of CCRAS *viz.* RARI, Vijayawada and CARI, Kolkata. In each centre, 120 participants (240 participants in two centres) were enrolled and erratically alienated into two different groups. Group I was provided with NG and BMK, and Group II was provided with TG and BMK. The final report contains the statistical analysis of data obtained from 238 participants (Group I - 118 participants and Group II - 120 participants) as 2 participants withdrew themselves from the study at CARI, Kolkata, thereby being removed from the analysis (Table 1). Baseline data in both groups were comparable as observed under different parameters analyzed. The demographic profile of the participants (Table 2), Clinical and personal history (Table 3), and General physical examination (Table 4) were analyzed. Ayurvedic parameters in both Groups I and II show that the baseline data on the parameters *viz.* types of *Saara, Samhananna, Satmya, Satva, Ahara Shakti* and *Vyayama Shakti* were comparable in both Groups I and II. Also, there was no statistically significant alterations were observed in all these parameters in either Group I or Group II before and after the treatment (Table 5). Data of assessment of *Prakriti* shows 52.5% of participants in Group I and 49.2% of participants in Group II were *Vata-Kaphaja Prakriti,* while 47.5% of participants in Group I and 50.8% of participants in Group II were *Pitta-Kaphaja Prakriti* (Table 6).

The statistical analyses show different disease-specific parameters, *viz.*, *Maladhikyata* (Excess of excreta), *Hastapadadaha* (Burning sensation in the palm, sole and pectoral region while walking), *Tandra* (Stupor), *Deha chikkanata* (Greasiness of skin), *Alasya* (Lethargy), and *Dourgandya* (Bad odour) was found to be significantly improved in Groups I and II before and after the treatment at 84th day (Table 7). While evaluating the chief complaints, the data shows significant changes in the different parameters. Polyphagia, polydipsia, excess sweating, excessive sleepiness, body fatigue and history of loss of libido were improved in both groups from baseline to the 84th day of the treatment. The same was found unalleviated throughout the follow-up period at the end of the 16th week (Table 8). The mean value of BMI, Waist circumference and WHR were found to be improved in both Groups I and II before and after the treatment as well as at the end of the 16th week throughout follow-up. While improvements were observed, they were not statistically significant ($p>0.05$) (Table 9). Assessment of the EOSS score depicts that the parameter 'Patient has significant obesity-related end-organ damage' was markedly changed (43.3% to 1.7% in Group I) and (33.9% to 2.5% in Group II) before and after the treatment as well as at the end of 16th week

Table 1. Baseline profile of the participants

Participating Centre	Group	Total enrolled	Completed	Drop out	Withdrawn hence removed from analysis	Imputation applied on	Total cases analyzed
RARI, Vijayawada	Group I	60	56	4	0	4	60
	Group II	60	58	2	0	2	60
CARI, Kolkata	Group I	59	56	2	1	2	58
	Group II	61	58	2	1	2	60

Table 2. Demographic profile

Baseline Characteristics (n = 238)			Group I (118)	Group II (120)
Age			41.5±9.24 #	41.4±8.68 #
Gender	Male		23 (19.5%)	36 (30.0%)
	Female		95 (80.5%)	84 (70.0%)
Marital Status	Married		105 (89.0%)	107 (89.2%)
	Unmarried		7 (5.9%)	5 (4.2%)
	Widow(er)		6 (5.1%)	7 (5.8%)
	Divorcee		0 (0.0%)	1 (0.8%)
Educational Status	Illiterate		15 (12.7%)	14 (11.8%)
	Read and write		103 (87.3%)	106 (88.2%)
Past Occupation	Desk work		25 (21.2%)	35 (29.2%)
	Field work with physical labour		3 (2.5%)	5 (4.2%)
	Field work		9 (7.6%)	8 (6.7%)
	House wife		74 (62.7%)	67 (55.8%)
	Student		7 (5.9%)	5 (4.2%)
Present Occupation	Desk work		24 (20.3%)	35 (29.2%)
	Field work with physical labour		2 (1.7%)	4 (3.3%)
	Fieldwork		8 (6.8%)	9 (7.5%)
	Housewife		82 (69.5%)	71 (59.2%)
	Student		2 (1.7%)	1 (0.8%)
Socio-economic status	Above Poverty Line		105 (89.0%)	105 (87.5%)
	Below Poverty Line		13 (11.0%)	15 (12.5%)
Habitat	Urban		88 (74.6%)	99 (82.5%)
	Semi-Urban		18 (15.3%)	10 (8.3%)
	Rural		12 (10.2%)	11 (9.2%)
Religion	Hindu		101 (85.6%)	108 (90.0%)
	Muslim		8 (6.8%)	10 (8.3%)
	Christian		9 (7.6%)	11 (9.2%)
	Any Relieving Factors	Yes	43 (36.4%)	42 (35.0%)
		No	75 (63.6%)	78 (65.0%)
Values are reported as n (%) # Value is reported as mean ± standard deviation				

Table 3. Clinical profile

Personal History (n = 238)		Group I (118)	Group II (120)
Dietary Habits	Vegetarian	6 (5.1%)	12 (10.0%)
	Non-vegetarian	112 (94.9%)	108 (90.0%)
Addictions	Smoking	0 (0.0%)	1 (0.8%)
	Tobacco	12 (10.2%)	9 (7.5%)
	None	106 (89.8%)	110 (91.7%)
Smoking	Regular	0 (0.0%)	1 (0.8%)
	Occasional	1 (0.8%)	0 (0.0%)
	Never Smoked	117 (99.2%)	119 (99.2%)
Alcohol Intake	No	118 (100.0%)	120 (100.0%)
Sleep	Normal	94 (79.7%)	101 (84.2%)
	Disturbed	24 (20.3%)	19 (15.8%)
Bowel Habits	Regular	85 (72.0%)	77 (64.2%)
	Irregular	33 (28.0%)	43 (35.8%)
Stool Consistency	Normal	94 (79.7%)	96 (80.0%)
	Loose	7 (5.9%)	9 (7.5%)
	Constipated	17 (14.4%)	15 (12.5%)
Urine Output	Normal	74 (62.7%)	75 (62.5%)
	Frequent	3 (2.5%)	6 (5.0%)
	Urgency	41 (34.7%)	39 (32.5%)
Physical Exercise	Heavy Labour	2 (1.7%)	2 (1.7%)
	Moderate Labour	61 (51.7%)	52 (43.3%)
	Office Job	12 (10.2%)	15 (12.5%)
	Sedentary	43 (36.4%)	51 (42.5%)
Allergy to some material	Yes	94 (79.7%)	99 (82.5%)
	No	24 (20.3%)	21 (17.5%)
If yes, then nature of allergen	Dust	17 (70.8%)	13 (61.9%)
	Food	7 (29.2%)	8 (38.1%)
Values are reported as n (%)			

Table 4. General physical examination

General Physical Examination (n = 238)		Group I (118)	Group II (120)
Built	Severe Obese	91 (77.1%)	89 (74.2%)
	Morbidly Obese	25 (21.2%)	29 (24.2%)
	Super Obese	2 (1.7%)	2 (1.7%)
Nutrition	Nourished	64 (54.2%)	63 (52.5%)
	Malnourished	54 (45.8%)	57 (47.5%)
Pallor	Absent	118 (100.0%)	119 (99.2%)
	Present	0	1 (0.8%)
Lymphad enopathy	Absent	117 (99.2%)	118 (98.3%)
	Present	1 (0.8%)	2 (1.7%)
Edema	Absent	66 (55.9%)	74 (61.7%)
	Present	52 (44.1%)	46 (38.3%)
If present, then character	Pitting	47 (90.4%)	44 (95.7%)
	Non-Pitting	5 (9.6%)	2 (4.3%)
Skin Type	Dry	7 (5.9%)	2 (1.7%)
	Moist	78 (66.1%)	73 (60.8%)
	Thick	33 (28.0%)	44 (36.7%)
	Pinched	0 (0.0%)	1 (0.8%)
Colour	Pale	17 (14.4%)	7 (5.8%)
	Flushed	2 (1.7%)	1 (0.8%)
	Normal	99 (83.9%)	112 (93.3%)
Pigmentation	Hyper-pigmentation	4 (3.4%)	2 (1.7%)
	Normal	114 (96.6%)	118 (98.3%)
Hair	Normal	62 (52.5%)	63 (52.5%)
	Thin	29 (24.6%)	39 (32.5%)
	Alopecia	27 (22.9%)	18 (15.0%)
Nails	Normal	84 (71.2%)	85 (70.9%)
	Pallor	33 (28.0%)	34 (28.3%)
	Discoloration	1 (0.8%)	1 (0.8%)
Joints	Normal	73 (61.9%)	68 (56.7%)
	Abnormal	45 (38.1%)	52 (43.3%)
Values are reported as n (%)			

at the time of follow-up. No change in the parameter 'SEVERE (potential end stage) from obesity-related co-morbidities' was found in both groups before and after the treatment (Tables 10 and 11).

Further, the laboratory investigation report of routine blood tests shows that the mean TLC value was statistically significant ($p<0.05$) changed in Group I (Table 12), and Differential Leukocyte Count (DLC) test shows mean Neutrophil count was significantly ($p<0.05$) changed in both Group-I and Group II before and after the treatment. Similarly, the mean Lymphocyte was also significantly changed ($p<0.01$) in both Group I and Group II patients before and after the treatment (Table 13). Data of Laboratory

investigation report concerning lipid profile shows significant ($p<0.05$) changes in mean HDL value and S. Cholesterol/HDL Ratio in Group-I before and after the treatment. While in other parameters, *viz*. Serum Total Cholesterol, LDL, VLDL, Serum Triglycerides, Serum (S.) In Alkaline Phosphatase, no significant ($p>0.05$) alteration was found in either group prior to and subsequent to the treatment (Table 14).

Analysis of the laboratory investigation report concerning kidney and liver functions of the participants shows that there were significant changes in the mean value of Blood Urea ($p<0.01$), Serum Uric Acid ($p<0.05$), Total Protein ($p<0.05$), and S. Albumin (A) ($p<0.01$) in Group I before and after the treatment. No significant alterations ($p>0.05$) were observed in Serum Total Cholesterol, LDL, VLDL, Serum Triglycerides, and Serum Alkaline Phosphatase in either group before or after the treatment. (Table 15).

Table 5. Assessment of *Prakriti*

***Ayurvedic* Parameters (n = 238)**		**Group I (118)**	**Group II (120)**
Type of *Prakriti*	*Vata-Kaphaja*	62 (52.5%)	59 (49.2%)
	Pitta-Kaphaja	56 (47.5%)	61 (50.8%)
Values are reported as n (%)			

4. Discussion

Obesity and overweight represent a hastily rising intimidation to the health of the population in a more significant number of countries. Certainly, they are now so common that they are replacing more chronic problems, such as undernutrition and infectious disease, as the most significant cause of death[16]. This acquaintance has shown us that obesity is a chronic disease involving loads of inhabitants. The present study's result indicates that the participants' mean age was 41.5±9.24 in Group I participants and 41.4±8.68 in Group II participants. The data shows that the maximum number of participants was female in Group I, 80.5% of participants were female, whereas in Group II, 70.0% of participants were female (Table 2). In India, the prevalence of abdominal obesity was found to be far above the ground. The study reported that about 12.0%

Table 6. Assessment of *Ayurvedic* parameters in Group I and II before and after the treatment

***Ayurvedic* Parameters (n =238) Baseline**		**Group I**		**Group II**	
		84th day	**Baseline**	**84th day**	
Type of *Saara*	*MamsaSaara*	5 (4.2%)	4 (3.4%)	2 (1.7%)	4 (3.3%)
	MedoSaara	113 (95.8%)	114 (96.6%)	118 (98.3%)	116 (96.6%)
Type of *Samhananna*	*Pravara*	0	0	0	0
	Madhyama	0	6 (5.1%)	0	7 (5.8%)
	Avara	118 (100.0%)	112 (94.9%)	120 (100.0%)	113 (94.2%)
Type of *Satmya*	*PravaraSatmya*	23 (19.5%)	24 (20.3%)	19 (15.8%)	18 (15.0%)
	MadhyamaSatmya	94 (79.7%)	94 (79.7%)	95 (79.2%)	96 (80.0%)
	AvaraSatmya	1 (0.8%)	0	6 (5.0%)	6 (5.0%)
Type of *Satva*	*PravaraSatva*	51 (43.2%)	49 (41.5%)	37 (30.8%)	37 (30.8%)
	MadhyamaSatva	40 (33.9%)	41 (34.7%)	61 (50.8%)	62 (51.7%)
	AvaraSatva	27 (22.9%)	28 (23.7%)	22 (18.3%)	21 (17.5%)
Type of *Ahara Shakti*	*PravaraAhara Shakti*	43 (36.4%)	9 (7.6%)	50 (41.7%)	11 (9.2%)
	MadhyamaAhara Shakti	75 (63.6%)	54 (45.8%)	70 (58.3%)	51 (42.5%)
	AvaraAhara Shakti	0	55 (46.6%)	0	58 (48.3%)
Type of *Vyayama Shakti*	*PravaraVyayama Shakti*	2 (1.7%)	2 (1.7%)	3 (2.5%)	4 (3.3%)
	MadhyamaVyayama Shakti	74 (62.7%)	111 (94.1%)	62 (51.7%)	109 (90.8%)
	AvaraVyayama Shakti	42 (35.6%)	5 (4.2%)	55 (45.8%)	7 (5.8%)
Values are reported as n (%)					

Table 7. Disease specific *Ayurvedic* parameters

***Ayurvedic* Parameters (n =238)**		**Baseline**	**84th day**
Maladhikyata (Excess of excreta)	**Group I**	58 (49.2%)	11 (9.3%)
	Group II	63 (52.5%)	9 (7.5%)
Hastapadadaha (Burning sensation in the palm, sole) and pectoral region while walking)	**Group I**	76 (64.4%)	23 (19.5%)
	Group II	76 (63.3%)	17 (14.2%)
Hastapadasuptata (Numbness of palms and soles)	**Group I**	99 (83.9%)	37 (31.4%)
	Group II	107 (89.2%)	47 (39.2%)
Tandra (Stupor)	**Group I**	81 (68.6%)	6 (5.1%)
	Group II	97 (80.8%)	5 (4.2%)
Dehachikkanata (Greasiness of skin)	**Group I**	91 (77.1%)	36 (30.5%)
	Group II	93 (77.5%)	36 (30.0%)
Alasya (Lethargy)	**Group I**	116 (98.3%)	29 (24.6%)
	Group II	119 (99.2%)	18 (15.0%)
Dourgandya (Bad odour)	**Group I**	97 (82.2%)	44 (37.3%)
	Group II	106 (88.3%)	48 (40.0%)
Values are reported as n (%)			

of men and about 40.0% of women are considered to be abdominally obese in India. While approx. 49.3% of women belonging to the age group of 30-39 years and approx. 56.7% of women belonging to the age group of 40-49 crossed the cut-off mark. Considering the BMI, hardly 23% of the women traverse the marked limit for obesity[17]. As in this clinical trial, the maximum numeral of the active participants were female and housewives; the impact of data on occupational status on the disease is not significantly ascertained. However, to a great extent, participants were desk workers, which is found to be broadly associated with the disease obesity[18].

While analyzing the other demographic profile, it was found that most of the study participants in both groups belonged to Hinduism, were from urban areas, and belonged to the poverty line. The reason may be that both the study centres were in Urban and Hindu-majority areas. Data shows a maximum of 94.9% of study participants in Group I and 90% in Group II were non-vegetarian. The researcher has verified a strong association stuck between the intake of meat patterns and BMI. It also explains that animal food increases the risk of obesity through increased animal protein intake[19]. On the other hand, none of the participants in both groups were habituated to alcohol intake, and 99.2% of participants in both groups had a history of never smoking. Other parameters observed, *viz*. sleep, bowel habits, stool consistency, urine output, physical exercise, and allergy to some material in both the groups were comparable (Table 3).

This is a well-known fact that the clinical evaluation of obesity patients is a very complex phenomenon. The overall evaluation of obese individuals should also address their physical, psychological and social well-being. The clinical assessment of obese must comprise the investigator's assessment from end to end related patient history and evaluation, dietitian opinion for dietetic record in addition to measuring the body concerto, proper laboratory examination, assessment of sleep oximetry as well as psychologist inputs wherever suitable and appropriate[20]. Data from General physical examination shows 77.1% of study participants in Group I and 74.2% in Group II were severely obese; 21.2% in Group I and 24.2% in Group II were morbidly obese; while 1.7% of study participants in both Groups I and II were super obese (Table 4). 54.2% of participants in Group I and 52.5% in Group II were nourished, while 45.8% in Group I and 47.5% in Group II were malnourished. Clubbing, cytosis, and jaundice were absent among all the participants in both groups. Jugular venous pressure was not raised in all the participants in both groups. Neck Veins were normal in all the participants in both groups. Eruptions and Hemorrhage were absent in all the participants in both groups (Table 4).

Data of assessment of *Prakriti* shows 52.5% of participants in Group I and 49.2% in Group II were *Vata-Kaphaja Prakriti,* while 47.5% of participants in Group I and 50.8% in Group II were *Pitta-Kaphaja Prakriti* (Table 5). *Kapha* is one of the predominant factors of obesity; therefore, *Kapha* associated with *Vata* and *Pitta* is *Prakriti* quite common among the obese[21]. Further data of assessment of Ayurvedic parameters in both Groups I and II shows that the baseline data on the parameters, *viz*., types of *Saara, Samhananna, Satmya, Satva, Ahara Shakti* and *Vyayama Shakti* were comparable in both Groups I and II. Also, no statistically significant ($p>0.05$) alteration was found to be observed in all these constraints in both Groups I and II before and after the treatment (Table 6).

Table 8. Assessments of chief complaints

Parameters	Group	Assessment Stage							
		Baseline	14th day	28th day	42nd day	56th day	70th day	84th day	Follow up at the end of 16th week
Polyphagia	**Group I**	101 (85.6%)	104 (88.1%)	20 (16.9%)	8 (6.8%)	4 (3.4%)	3 (2.5%)	2 (1.7%)	2 (1.7%)
	Group II	110 (91.7%)	106 (88.3%)	22 (18.3%)	6 (5.0%)	2 (1.7%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
Polydipsia	**Group I**	108 (91.5%)	106 (89.8%)	57 (48.3%)	29 (24.6%)	11 (9.3%)	5 (4.2%)	3 (2.5%)	3 (2.5%)
	Group II	114 (95.0%)	110 (91.7%)	63 (52.5%)	34 (28.3%)	9 (7.5%)	7 (5.8%)	4 (3.3%)	3 (2.5%)
Excess Sweating	**Group I**	106 (89.8%)	97 (82.2%)	77 (65.3%)	32 (27.1%)	10 (8.5%)	4 (3.4%)	4 (3.4%)	4 (3.4%)
	Group II	112 (93.3%)	107 (89.2%)	76 (63.3%)	31 (25.8%)	13 (10.8%)	4 (3.3%)	0 (0.0%)	0 (0.0%)
Excess Sleep	**Group I**	81 (68.6%)	83 (70.3%)	60 (50.8%)	42 (35.6%)	30 (25.4%)	22 (18.6%)	19 (16.1%)	11 (9.3%)
	Group II	92 (76.7%)	88 (73.3%)	65 (54.2%)	44 (36.7%)	35 (29.2%)	29 (24.2%)	24 (20.0%)	13 (10.8%)
Body fatigue	**Group I**	114 (96.6%)	116 (98.3%)	114 **(96.6%)**	108 (91.5%)	87 (73.7%)	61 (51.7%)	30 (25.4%)	23 (19.5%)
	Group II	117 (97.5%)	118 (98.3%)	115 (95.8%)	102 (85.0%)	82 (68.3%)	46 (38.3%)	18 (15.0%)	11 (9.2%)
Loss of libido	**Group I**	35 (29.7%)	30 (25.4%)	34 (28.8%)	34 (28.8%)	33 (28.0%)	33 (28.0%)	32 (27.1%)	31 (26.3%)
	Group II	44 (36.7%)	23(19.2%)	44 (36.7%)	44 (36.7%)	44 (36.7%)	41 (34.2%)	39 (32.5%)	39 (32.5%)
Values are reported as n (%)									

The latest study on the association between obesity and functional GI disorders revealed that obesity has an epidemiologic association with diarrhoea, in particular. Still, it has inconsistent associations with other foregut symptoms (*e.g.*, nausea, bloating, upper abdominal pain) and hindgut symptoms (*e.g.*, constipation, lower abdominal pain). Moreover, it remains unclear whether these tenuous associations imply causations[22]. While analyzing the disease-specific parameters in this study, the data shows *Maladhikyata* (Excess of excreta) was markedly changed in both Groups I and II. During baseline analysis *Maladhikyata* (Excess of excreta) was 49.2% in Group I and 52.5% in Group II; after the treatment on the 84th day, it was observed at 9.3% in Group I and 7.5% in Group II (Table 7).

Hastapadadaha (Burning sensation in the palm, sole and pectoral region while walking) was also improved from 64.4% to 19.5% in Group I and 63.3% to 14.2% in Group II participants after the duration of treatment (Table 6). Recent research on the correlation between neuropathic pain and obesity found that pain arising not from musculoskeletal smash-ups was far above the ground in high-BMI patients. The study also opined that paroxysmal pain was further rigorous, signifying that obesity-associated inflammation may provoke neural injury[23].

The array of skin co-morbidities in obesity is well-heeled, and their indulgence is relatable for practitioners and dermatologists concerned with obesity management. The most proverbial unambiguous stigmata of the disorders of obesity involving the skin comprise plantar hyperkeratosis, skin tags which are also known as fibroma pendulum, as well as acanthosis nigricans. Therefore, it is considered relevant to be

Table 9. Assessment of physical parameters

Parameters	Group	Assessment Stage							
		Baseline	14th day	28th day	42nd day	56th day	70th day	84th day	Follow up at the end of 16th week
Palpation / dyspnea on exertion	Group I	76 (64.4%)	35 (29.7%)	75 (63.6%)	75 (63.6%)	72 (61.0%)	34 (28.8%)	21 (17.8%)	19 (16.1%)
	Group II	76 (63.3%)	32 (26.7%)	76 (63.3%)	74 (61.7%)	71 (59.2%)	22 (18.3%)	18 (15.0%)	18 (15.0%)
BMI>30	Group I	118 (100.0%)	118 (100.0%)	118 (100.0%)	118 (100.0%)	117 (99.2%)	114 (96.6%)	113 (95.8%)	111 (94.1%)
	Group II	120 (100.0%)	120 (100.0%)	120 (100.0%)	119 (99.2%)	118 (98.3%)	115 (95.8%)	114 (95.0%)	115 (95.8%)
B.M. I	Group I	37.04±4.455	36.56±4.237	36.12±4.196	35.61±4.191	35.24±4.213	34.79±4.246	34.34±4.236	34.22±4.143
	Group II	37.48±4.439	37.00±4.260	36.52±4.20	35.98±4.064	35.55±4.026	35.10±3.932	34.58±3.847	34.51±3.807
Waist Circumference	Group I	112.88± 12.775	111.97± 12.262	110.93± 11.778	109.50± 11.752	108.29± 11.503	107.14± 11.671	105.99± 11.537	105.46± 11.458
	Group II	114.63± 11.865	113.78± 11.589	112.72± 11.541	111.42± 11.554	110.23± 11.435	109.05± 11.240	107.83± 11.013	107.43± 10.937
Hip Circumference	Group I	111.25± 8.182	110.87± 8.385	110.40± 8.499	109.84± 8.616	109.41± 8.680	108.83± 8.734	108.27± 8.808	107.86± 8.819
	Group II	115.12±10.268	114.70± 10.450	114.31± 10.454	113.74± 10.320	113.31± 10.287	111.62± 14.310	112.23± 10.304	111.88± 10.476
Waist Hip Circumference ratio	Group I	1.01±0.140	1.01±0.143	1.00±0.142	0.99±0.147	0.99±0.142	0.98±0.143	0.98±0.142	0.98±0.141
	Group II	0.99±0.124	0.99±0.127	0.98±0.128	0.98±0.129	0.97±0.130	0.96±0.130	0.96±0.127	0.96±0.129
# Values are reported as mean ± standard deviation									

Table 10. Assessment of EOSS score in Group I

EOSS Score	Assessment Stage							
	Baseline	**14th day**	**28th day**	**42nd day**	**56th day**	**70th day**	**84th day**	**Follow up at the end of 16th week**
NO sign of obesity-related risk factors	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)
Patient has obesity-related SUBCLINICAL risk factors	29 (24.2%)	29 (24.2%)	29 (24.2%)	29 (24.2%)	32 (26.7%)	60 (50.0%)	78 (65.0%)	80 (66.7%)
Patient has ESTABLISHED obesity-related co-morbidities requiring medical intervention	38 (31.7%)	39 (32.5%)	54 (45.0%)	75 (62.5%)	78 (65.0%)	56 (46.7%)	39 (32.5%)	37 (30.8%)
Patient has significant obesity-related end-organ damage	52 (43.3%)	51 (42.5%)	36 (30.0%)	15 (12.5%)	9 (7.5%)	3 (2.5%)	2 (1.7%)	2 (1.7%)
SEVERE (potential end stage) from obesity-related co-morbidities	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)
Values are reported as n (%)								

Table 11. Assessment of EOSS Score in Group II

EOSS Score	Assessment Stage							
	Baseline	**14th day**	**28th day**	**42nd day**	**56th day**	**70th day**	**84th day**	**Follow up at the end of 16th week**
NO sign of obesity-related risk factors	0	0	0	0	0	0	0	2 (1.7%)
Patient has obesity-related SUBCLINICAL risk factors	22 (18.6%)	22 (18.6%)	23 (19.5%)	24 (20.3%)	26 (22.0%)	48 (40.7%)	64 (54.2%)	71 (60.2%)
Patient has ESTABLISHED obesity-related co-morbidities requiring medical intervention	55 (46.6%)	57 (48.3%)	67 (56.8%)	79 (66.9%)	83 (70.3%)	66 (55.9%)	50 (42.4%)	41 (34.7%)
Patient has significant obesity-related end-organ damage	40 (33.9%)	38 (32.2%)	27 (22.9%)	14 (11.9%)	8 (6.8%)	3 (2.5%)	3 (2.5%)	3 (2.5%)
SEVERE (potential end stage) from obesity-related co-morbidities	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)
Values are reported as n (%)								

screened in obese patients[24]. Similarly, *Deha chikkanata* (Greasiness of skin) was 77.1% in Group I and 77.5% In participants of Group II during baseline analysis, which was found to be improved by 30.5% in Group I and 30.0% in participants of Group II after the treatment at 84th day (Table 7).

In Group I participants *Tandra* (Stupor) was 68.6% during baseline analysis, which was improved to 5.1% after the treatment on the 84th day. Similarly,

Table 12. Routine blood investigation report

Parameter	Group	Baseline	84th day	p-value
Haemoglobin	**Group I**	12.45±1.634	12.44±1.674	0.878
	Group II	12.62±2.102	12.58±1.966	0.614
	p-value	0.477	0.529	
Total R.B.C. Count	**Group I**	4.54±0.454	4.57±0.510	0.499
	Group II	4.56±0.596	4.54±0.573	0.631
	p-value	0.816	0.702	
TLC	**Group I**	8223.73±2022.087	8700±2333.370	0.010(*)
	Group II	8170.00±2037.613	8455.83±2120.441	0.102
	p-value	0.838	0.399	
ESR	**Group I**	26.14±20.722	27.67±21.112	0.215
	Group II	27.33±20.539	28.00±21.060	0.644
	p-value	0.657	0.904	
Fasting Blood Sugar (F.B.S.)	**Group I**	99.70±19.730	102.86±21.874	0.018
	Group II	98.53±13.936	98.91±17.181	0.784
	p-value	0.597	0.122	
# Values are reported as mean ± standard deviation*$p< 0.05$				

Table 13. Blood test for Differential Leukocyte Count (DLC)

Parameter	Group	Baseline	84th day	p-value
Neutrophil	**Group I**	63.65± 6.613	65.16± 6.442	0.015(*)
	Group II	63.03± 6.265	64.47± 6.136	0.010(*)
	p-value	0.453	0.395	
Eosinophils	**Group I**	3.42± 2.170	3.47± 2.448	0.830
	Group II	3.57± 2.431	3.47± 2.033	0.574
	p-value	0.633	0.998	
Lymphocyte	**Group I**	29.75± 6.326	28.24± 5.905	0.006(*)
	Group II	30.28± 6.152	28.88± 6.169	0.005(*)
	p-value	0.514	0.416	
Monocytes	**Group I**	3.10± 1.263	3.12± 1.302	0.812
	Group II	3.10± 1.155	3.14± 1.252	0.486
	p-value	0.991	0.890	
# Values are reported as mean ± standard deviation *$p< 0.05$				

in Group II participants, it was improved from 80.8% to 4.2% after the duration of treatment (Table 7). Stupor coming up due to major psychiatric disorders is a crucial differential, a state of mutism and akinesis regardless of habitually apparent restiveness. Studies demonstrated that in individuals with obesity, there is always a considerable tendency to depression. Being deficient in substantial physical activity might affect endorphin levels in the body and initiate adaptation in the norepinephrine metabolism, which in turn can add to the advance of depression and anxiety symptoms[25,26]. It is tarnished that sleeping during the daytime and physical fatigue are associated mainly with metabolic and psychological phenomena, reduced sleep apnea, and sleep disruption. Several researchers also recommended that intent sleepiness is primarily related to metabolic aspects, while physical fatigue appears to be related to psychological distress. The degree of sleep and arousal within the 24 hours of the cycle depends on the interaction of the hypothalamic-pituitary-adrenal axis and pro-inflammatory cytokines. Consequently, hypercortisolemia with hypercytokinemia is linked with low sleep adeptness and physical fatigue, while eucortisolemia or hypercortisolemia is associated with high sleep competence and intent sleepiness[27]. *Alasya* (Lethargy) was 98.3% in Group I and 99.2% in Group

Table 14. Laboratory investigation report concerning lipid profile

Parameter	Group	Baseline	84th day	p-value
Serum Total Cholesterol	**Group I**	186.51± 32.728	184.50± 30.417	0.388
	Group II	183.53± 32.506	184.15± 32.237	0.809
	p-value	0.482	0.931	
HDL	**Group I**	43.31± 10.578	41.73± 10.446	0.034(*)
	Group II	43.60± 10.329	42.33± 10.032	0.062
	p-value	0.828	0.654	
LDL	**Group I**	118.94± 28.560	117.99± 26.872	0.662
	Group II	116.34± 27.878	116.95± 28.169	0.789
	p-value	0.477	0.771	
VLDL	**Group I**	24.18± 9.802	24.60± 11.268	0.636
	Group II	23.34± 9.747	24.87± 8.611	0.095
	p-value	0.509	0.831	
Serum Triglycerides	**Group I**	125.86± 48.339	131.94± 56.05	0.115
	Group II	125.73± 51.366	130.53± 46.981	0.240
	p-value	0.983	0.834	
Serum (S.) Alkaline Phosphatase	**Group I**	87.00± 21.918	89.06± 25.521	0.233
	Group II	86.33± 20.266	85.61± 22.880	0.581
	p-value	0.805	0.273	
S. Cholesterol/ HDL Ratio	**Group I**	4.47± 1.126	4.64± 1.170	0.045(*)
	Group II	4.40± 1.175	4.54± 1.194	0.117
	p-value	0.618	0.551	
# Values are reported as mean ± standard deviation*$p< 0.05$				

II participants during baseline analysis, which was found to be improved by 24.6% in Group I and 15.0% in Group II participants after the treatment on the 84th day (Table 7).

Data shows *Dourgandya* (Bad odour) was 82.2% in Group I participants as well as 88.3% in Group II participants during baseline analysis, which was

Table 15. Laboratory investigation report concerning kidney and liver functions

Parameter	Group	Baseline	84th day	p-value
Blood Urea	**Group I**	20.03± 5.856	18.60±5.280	0.006(*)
	Group II	18.60± 5.311	18.25±5.658	0.435
	p-value	0.050	0.621	
Serum Uric Acid	**Group I**	5.24± 1.438	5.01±1.159	0.014(*)
	Group II	5.22± 1.248	5.28±1.338	0.482
	p-value	0.901	0.095	
Serum Creatinine	**Group I**	0.72± 0.141	0.71±0.142	0.521
	Group II	0.74± 0.153	0.75±0.152	0.321
	p-value	0.269	0.053	
Serum Bilirubin	**Group I**	0.51± 0.307	0.49±0.246	0.346
	Group II	0.58± 0.319	0.57±0.263	0.616
	p-value	0.082	0.016(*)	
SGOT (A.S.T.)	**Group I**	22.77± 8.495	22.18±7.659	0.444
	Group II	23.08± 7.070	23.26±8.964	0.800
	p-value	0.756	0.319	
SGPT (ALT)	**Group I**	26.07± 13.020	26.29±14.545	0.858
	Group II	26.15± 11.651	26.95±12.790	0.459
	p-value	0.960	0.710	
Total Protein	**Group I**	7.70± 0.354	7.61±0.371	0.011(*)
	Group II	7.68± 0.404	7.61±0.463	0.070
	p-value	0.672	0.919	
S. Albumin (A)	**Group I**	4.21± 0.462	4.12±0.445	0.001(*)
	Group II	4.19± 0.478	4.18±0.524	0.668
	p-value	0.815	0.376	
S. Globulin (G)	**Group I**	3.49± 0.454	3.48±0.472	0.778
	Group II	3.50± 0.506	3.43±0.530	0.075
	p-value	0.892	0.439	
A/G Ratio	**Group I**	1.24± 0.292	1.21±0.276	0.203
	Group II	1.24± 0.295	1.26±0.324	0.204
	p-value	0.952	0.195	
# Values are reported as mean ± standard deviation*$p< 0.05$				

found to be improved by 37.3% in the participants of Group I and 40.0% participants of Group II after the treatment of the 84th day (Table 7). Obese are prone to hyperhidrosis, which leads to mal odour. This condition considerably affects the quality of life of the people, causing societal discomfiture and intricacy in school and professional milieu[28]. In the present study, both groups' results remarkably improved, indicating the interventions' efficacy. Excess sweating was improved in Group I, (89.8% to 3.4%) and Group II (93.3% to 0%) from baseline to the 84th day of the treatment and the same was found to be constant after the 16th week throughout follow-up in both groups (Table 8).

Obesity is a complex phenomenon involving multidimensional systems with pathophysiology and various etiological factors. A simple mechanism behind this is that extra calories are stored in the body fat. When someone consumes high amounts of energy, mainly in high-fat and high-sugar foods, and cannot use all the energy consumed due to insufficient or lack of physical activities, a large extent of extra calories is stored in the body as fat[29]. While assessing the chief complaints, the data shows polyphagia was improved in Group I (85.6% to 1.7%) and Group II (91.7% to 0 %) from baseline to the 84th day of the treatment, and the same was found to be unremitting during at the end of 16th week at the time of follow up (Table 8).

Many researchers have opined that dipsogenic polydipsia is seen among patients with hypothalamia and in hale and hearty persons who are captivating excessive amounts of fluids. Disproportionate water drinking might lead to symptomatic hyponatremia, being the most vital clinical materialization of this circumstance[30]. Polydipsia was improved in Group I (91.5% to 2.5%) and Group II (95.0% to 3.3%) from baseline to the 84th day of the treatment. The same was found unrelieved throughout the follow-up (Table 8).

Studies demonstrated that sleep and appetite boast a circadian rhythm with a diurnal beat. There is a reciprocal interface between sleep and obesity. Poor sleep, in whichever quantity or quality, is always connected with shadows in scheming appetite, followed by obesity. Individuals who are overweight might increase the threat of emergent sleep disorders such as obstructive sleep apnea, which might advance the decline of sleep quality[31]. Excess sleep was improved in Group I (68.6% to 16.1%) and in Group II (76.7% to 20.0%) from baseline to the 84th day of the treatment and the same was found to be further improved all at the end of the 16th week during follow-up in both groups (Group I 9.3% and Group II 10.8%) (Table 8).

Pshyconeurological conditions like stress and obesity are independently connected with decrements in neuromuscular functions. Fatigue is allied with high BMI, WC and insufficient recommended physical activity levels[32]. Studies pointed out that labour workers are more vulnerable to getting fatigued in high-stress job atmospheres, predominantly those with higher BMI, which might augment the threat of musculoskeletal injuries as well as heart diseases[33]. Body fatigue was improved in Group I, (96.6% to 25.4%) and in Group II, (97.5% to 15.0%) from baseline to the 84th day of the treatment and the same was found to be further improved at the end of the 16th week during follow-up in both groups. (Group I 19.5% and Group II 9.2%) (Table 8).

The circumstance of obesity is also associated with weakened sexual commotion concerning being short of sexual craving, complicatedness by means of sexual performance and evasion of the sexual meet. The latest study opined that sexual quality of life is mainly prejudiced for women having or diagnosed with Class III obesity[34]. Loss of libido was improved in Group I (29.7% to 27.1%) and in Group II (36.7% to 15.0%) from baseline to the 84th day of the treatment and the same was found to be unalleviated during follow-up at the end of 16th week in both groups (Table 8).

Obese individuals endure dyspnoea, which is related to a diminution in lung volumes and a high fraction of fat mass in the central body region[35]. The study evidenced that obesity grounds generous alteration to the mechanism of the lungs and chest wall that distress normal lung function. The most common anomaly linked with obesity is a decline in nature in expiratory reserve volume (ERV), which is exponentially interconnected with high BMI[36]. Palpation/dyspnea on exertion was improved from 64.4% to 17.8% in Group I before and after the treatment, and that was further found to be reduced to 16.1% during the scheduled period of follow-up. Likewise, in Group II, the same parameter was improved from 63.3% to 15.0% before and after the treatment as well as throughout the follow-up period.

The measurement of Body Mass Index (BMI) is crucial in determining potential future health issues. It is broadly used as a factor in the fortitude of assorted public health policies. This method utilizes an adult's height and weight to essentially consign them into malnourished/underweight, average body weight, overweight and obese groups[37]. These classifications help physicians to assess the risk for diabetes mellitus, hypertension, hypercholesterolemia, cancer and other chronic ailments. Further, BMI in childhood serves as a prediction method for health and disease in later life. It is also a vital tool for researchers in addition to its use in clinical practices. Besides BMI, researchers also study waist circumference and waist-to-hip ratio correlated with chronic diseases[38]. The study demonstrated the accuracy of BMI, WC and WHR as diagnostic tests for detecting adolescent fatness. They opined that BMI and WC performed well as diagnostic tests for detecting fatness compared to WHR[39] The mean value of BMI was found to be improved in both the groups before and after the treatment as well as during the follow-up (Table 9). There was also marked improvement observed in WC, which was found to be improved in both the groups before and after the treatment as well as at the time of follow-up. Similarly, the Hip Circumference and WHC ratios were improved in both groups before and after the treatment and at the 16th week during follow-up. However, such findings were statistically not significant (Table 9).

The EOSS, a tool that assigns patients a score of 0 to 4 according to their obesity-related co-morbidities and functional status, was used in the present study. Previous studies demonstrated that an increase in the EOSS score is associated with overall no-operative mortality risk[40]. EOSS is a simple, safe, and accurate screening tool for diagnostic criteria for clinically significant weight-related health complications that can potentially be applied in general practice[41]. This tool is recommended for assessing the existence of anonymous clinically important weight-related health complications for promising appliances in common health practices. Assessment of the EOSS score depicts that 'NO sign of obesity-related risk factors' was unchanged (0.8% in Group I) and (0% in Group II) before and after the treatment. The 'Patient has obesity-related SUBCLINICAL risk factors' altered (24.2% to 65.0% in Group I) and (18.6% to 54.2% in Group II) before and after the treatment. The result also found that 'Patient has ESTABLISHED obesity-related co-morbidities requiring medical intervention' was mild changed (31.7% to 32.5% in Group I) and (46.6% to 42.4% in Group II) before and after the treatment. While other parameters, 'Patient has significant obesity-related end-organ damage', were markedly changed (43.3% to 1.7% in Group I) and (33.9% to 2.5% in Group II) before and after the treatment and at the 16th week. There was no change in the parameter 'SEVERE (potential end stage) from obesity-related co-morbidities' found in both the groups before and after the treatment (Tables 10, 11).

Laboratory investigation report of routine blood tests shows that the mean TLC assessment was significantly ($p<0.05$) changed in Group I, while in Group II, no significant ($p>0.05$) changes were observed before and after the treatment. Although the FBS (Fasting Blood Sugar) value was also found to be changed in Group I clinically, the changed value was not imperative; at the same time as in Group II, no statistically significant ($p>0.05$) alteration was experiential during baseline and 84th day of the treatment (Table 12). Also, no statistically significant ($p>0.05$) changes were found in Hemoglobin, ESR and total RBC count (Table 12). Further, the laboratory investigation report of the Differential Leukocyte Count (DLC) test shows that the mean Neutrophil count was significantly ($p<0.05$) altered in both the groups before and after the treatment. Similarly, mean Lymphocyte was also significantly ($p<0.01$) altered in both Groups I and II before and after the treatment, whereas there were no significant ($p>0.05$) changes in Eosinophils and Monocyte count in both groups (Table 13).

Obesity is associated with the disturbance of lipid profile in the body, particularly by means of HDL-C diminution, in non-obese diabetic patients. The study demonstrated a positive correlation between WHR and TG/HDL-C ratio[42]. In the present study, the laboratory investigation report concerning lipid profile shows significant ($p<0.05$) changes in the mean value of HDL and S. Cholesterol/HDL Ratio in Group I before and after the treatment. While other parameters, *viz*. Serum Total Cholesterol, LDL, VLDL, Serum Triglycerides, Serum (S.) In Alkaline Phosphatase, no significant

(p>0.05) alterations were observed in both Groups I and II before and after the treatment (Table 14).

Analysis of the laboratory investigation report concerning kidney and liver functions of the participants confirmed that there were considerable changes in the mean value of Blood Urea (p<0.01), Serum Uric Acid (p<0.05), Total Protein (p<0.05), and Serum albumin (A) (p<0.01) in Group I before and after the treatment. While other parameters, *viz*. Serum Creatinine, SGOT (AST), SGPT (ALT), Serum Bilirubin, S. Globulin (G) and A/G Ratio no significant (p>0.05) changes were observed in both groups before and after the treatment (Table 15).

5. Conclusions

The present study found that *Ayurveda* compound formulations NG, TG and BMK are beneficial and safe in managing obesity (*Sthaulya*). Both groups were treated with the prescribed compound formulations, significantly improving the chief complaints, BMI, waist circumference, and WHR. Further significant improvements were observed in the EOSS score and laboratory parameters in both groups. Throughout the clinical trial, no participant required hospitalization or rescue medication or experienced any significant adverse events. However, advanced multi-centric, double-masked, and RCT studies can be designed with an additional absolute follow-up episode to support the outcomes of the present study regarding the effectiveness of these studied interventions along with safety concerns.

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7. Author Contribution

CMK, SKD, VS, KKR, and AK contributed to patient recruitment, clinical assessments, and data collection. TM, BSS, SK, and BM were responsible for study conceptualization, methodology, and manuscript drafting. AT and RR conducted statistical analysis and data interpretation. BCS and NS provided critical revisions and final manuscript approval. All authors have read and approved the final manuscript.

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