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Krimighnadi Ghanavati with Honey versus Mustadi Ghanavati in Adults with Obesity (Sthaulya): A Randomised, Open-Label, Active-Controlled Clinical Trial

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ABSTRACT: **Purpose** Krimighnadi Kashaya is a classical polyherbal formulation indicated for obesity (Sthaulya) whose clinical efficacy has not been tested in a randomised trial. This trial compared a standardised tablet form of it, given with honey, against Mustadi Ghanavati, an established classical comparator.

Methods In this single-centre, open-label, parallel-group randomised trial, adults aged 16–60 years with BMI ≥ 25 kg/m² received Krimighnadi Ghanavati (Group A) or Mustadi Ghanavati (Group B), 1 g twice daily for 90 days, with common diet and activity advice, and were followed to day 120. Outcomes were body weight and BMI (primary), circumferences, abdominal skinfold, lipids, nine classical symptoms and safety indices.

Results Of 126 randomised participants, 102 (51 per group) completed the trial. Weight fell by 6.90 kg (8.0%) in Group A and 4.90 kg (6.0%) in Group B, and BMI by 3.64 and 2.61 kg/m² (both $p < 0.001$ within groups). Between-group differences in mean change favoured Group A but were not statistically significant for weight (2.0 kg, 95% CI −1.6 to 5.6) and borderline for BMI (1.03 kg/m², −0.00 to 2.06; $p = 0.051$); chest circumference differed significantly (3.5 cm, 0.8 to 6.2). All nine symptoms improved in both groups ($p < 0.001$); seven showed a significant advantage for Group A. Lipid fractions improved within Group A only. Marked improvement occurred in 35.3% versus 9.8% ($p = 0.002$). No adverse haematological, urinary or glycaemic change was recorded.

Conclusion Both formulations produced clinically meaningful (> 5%) weight loss over 90 days. Krimighnadi Ghanavati with honey gave greater symptomatic relief and a higher marked-response rate, but its advantage on weight was not established. A blinded, placebo-controlled trial is warranted.

1 INTRODUCTION

Obesity has become one of the defining chronic diseases of this century. The World Health Organization estimates that about 2.5 billion adults were overweight and 890 million were living with obesity in 2022 [1], and pooled data from 3663 population-based studies show that the prevalence of adult obesity has more than doubled since 1990 [2]. In India, the

ICMR-INDIAB study reported generalised obesity in 28.6% and abdominal obesity in 39.5% of adults [3], and the National Family Health Survey-5 documented a particularly high burden of central adiposity among women and urban residents [4]. Excess adiposity is now recognised as a disease state in its own right, with organ-level consequences [5], and every 5 kg/m² increase in BMI above 25 kg/m² is associated with about 30% higher all-cause mortality [6].

Lifestyle modification remains the foundation of treatment, and a sustained weight loss of 5% or more is regarded as clinically meaningful because it improves blood pressure, lipids and glycaemia [7]. Incretin-based drugs such as semaglutide and tirzepatide produce large reductions in weight [8, 9], but their cost, injectable route, gastrointestinal adverse effects and weight regain after discontinuation limit their use in low- and middle-income settings. There is therefore a continuing need for affordable, oral, well-tolerated options that can be combined with lifestyle change, and well-designed trials of traditional formulations can help to meet this need [10].

In Ayurveda, obesity is described as *Sthaulya* or *Medoroga*. Charaka places the excessively obese person (*Atisthula*) among the eight undesirable body types and lists eight defects: shortened life span, slowness of movement, difficulty in sexual activity, weakness, foul body odour, excessive sweating, excessive hunger and excessive thirst [11]. The pathogenesis (*Samprapti*) is explained as impaired tissue-level metabolism of fat (*Medo-dhatvagnimandya*), accumulation of *Kapha* and *Meda*, obstruction of the fat-carrying channels and an obstructed *Vata* that keeps central appetite high, a picture that closely parallels the modern understanding of obesity, insulin resistance and the metabolic syndrome [12, 13]. Treatment combines removal of causative factors with drugs that kindle digestion (*Deepana–Pachana*) and scrape accumulated fat (*Lekhana*).

Krimighnadi Kashaya is a decoction described in the Kerala compendium *Sahasrayogam*, where *Sthaulya* is among its stated indications [14]. Its ingredients (*Embelia ribes*, Triphala, *Trachyspermum ammi*, *Picrorhiza kurroa*, Trikatu and *Tinospora cordifolia*, with *Commiphora mukul* resin and honey as additives) are individually associated with anti-obesity, lipid-lowering or metabolic effects [15–21]. Mustadi Kwatha, described by Charaka for disorders of over-nutrition [22], has been tested as a tablet in hyperlipidaemia [23] and is used at the study centre as a standard therapy for *Sthaulya*. Ayurvedic obesity trials published to date have evaluated other formulations and procedures [24–28], but we could not identify any clinical trial of Krimighnadi Kashaya in any dosage form.

The present trial therefore addressed three gaps. First, it provides the first randomised evidence on Krimighnadi Kashaya, converted into a standardised, Guggulu-fortified tablet (*Ghanavati*) to improve compliance. Second, it compares the formulation against an active classical comparator rather than placebo, which reflects the decision clinicians actually face. Third, it evaluates outcomes on both the classical symptom framework of *Sthaulya* and conventional anthropometric, biochemical and safety measures, and reports between-group effect sizes with confidence intervals so that the size and certainty of any advantage can be judged.

2 METHODS

2.1 Trial design

This was a single-centre, prospective, randomised, open-label, active-controlled, parallel-group trial with 1:1 allocation, reported in accordance with the CONSORT 2010 statement [29]. Participants received treatment for 90 days and were followed for a further 30 days without treatment to assess the persistence of effect.

2.2 Setting and participants

Participants were recruited from the outpatient and inpatient departments of Kayachikitsa, Bharati Vidyapeeth (Deemed to be University) College of Ayurved and Hospital, Pune, India, a tertiary Ayurveda teaching hospital. Eligible participants were men and women aged 16–60 years with clinical features of *Sthaulya* and BMI ≥ 25 kg/m², who were willing to give written informed consent and to comply with the trial schedule. Exclusion criteria were secondary obesity (e.g. hypothyroidism, Cushing's syndrome or long-term corticosteroid use), polycystic ovarian syndrome, uncontrolled diabetes mellitus, significant cardiac, renal or hepatic disease, pregnancy or lactation, morbid obesity, concurrent use of anti-obesity medication and participation in another trial. Thyroid-stimulating hormone was measured where clinically indicated to exclude hypothyroidism.

2.3 Ethics and registration

The protocol was approved by the Institutional Ethics Committee of the college and registered prospectively with the Clinical Trials Registry – India. The trial was conducted in accordance with the Declaration of Helsinki [30] and the ICMR National Ethical Guidelines [31], and every participant gave written informed consent.

2.4 Interventions

Both formulations were prepared as aqueous-extract tablets (*Ghanavati*) in a GMP-certified pharmacy following the classical *Kwatha*-to-*Ghana* method [32]. For each, 27.5 kg of coarse powder of the ingredients was boiled in 16 parts of water, reduced, filtered and concentrated to about 5.5 kg of semi-solid extract (yield ≈ 5:1). In Krimighnadi Ghanavati, purified Guggulu (*Commiphora mukul*) was incorporated at about 10% of the extract weight; in Mustadi Ghanavati, about 10% fine powder of the same herbs was added for granulation. Both were compressed into 500 mg tablets. Raw materials were authenticated against the Ayurvedic Pharmacopoeia of India [33]; finished tablets were tested for weight uniformity, disintegration (< 15 min), microbial load and heavy metals, and thin-layer chromatographic fingerprints were recorded. The composition and regimen are shown in Table 1.

Table 1 Composition of the interventions and treatment regimen

Feature	Group A: Krimighnadi Ghanavati (trial)	Group B: Mustadi Ghanavati (comparator)
Classical source	Sahasrayogam, Kashaya Prakarana «sahasrayoga»	Charaka Samhita, Sutrasthana 23/12–14 «charaka23»
Herbal ingredients	*Embelia ribes*, *Emblica officinalis*, *Terminalia chebula*, *T. bellirica*, *Trachyspermum ammi*, *Picrorhiza kurroa*, *Zingiber officinale*, *Piper nigrum*, *P. longum*, *Tinospora cordifolia*	*Cyperus rotundus*, *Cassia fistula*, *Cissampelos pareira*, *E. officinalis*, *T. chebula*, *T. bellirica*, *Cedrus deodara*, *Tribulus terrestris*, *Acacia catechu*, *Azadirachta indica*, *Curcuma longa*, *Berberis aristata*, *Holarrhena antidysenterica*
Additive	Purified Guggulu (*Commiphora mukul*), ≈ 10% of extract	Fine powder of the same herbs, ≈ 10% of extract
Dose and timing	2 × 500 mg tablets twice daily after lunch and dinner (2 g/day)	Same
Vehicle (Anupana)	Honey 12 g, unheated, followed by a sip of lukewarm water	Lukewarm water 50–100 mL
Duration	90 days; drug-free follow-up to day 120	Same
Co-intervention	Common advice: low-fat, high-fibre diet at fixed times, no snacking, daily walking, no day-time sleep	Same

Both formulations were manufactured under the same standard operating procedure; tablets were dark brown and identical in size.

Compliance was monitored by tablet counts and a patient diary at every visit; adherence of at least 80% was required for the per-protocol analysis. Other weight-modifying drugs, steroids, appetite suppressants and diuretics were prohibited, and minor intercurrent illnesses were treated with medicines not affecting weight.

2.5 Outcomes

The primary outcomes were the changes in body weight (digital scale, to 0.1 kg) and BMI from day 0 to day 90. Secondary outcomes were: (i) chest, abdominal and hip circumferences (non-stretchable tape at the nipple line, the umbilicus and the

maximal protrusion of the buttocks); (ii) abdominal skinfold thickness (caliper, vertical fold 2.5 cm lateral to the umbilicus, mean of three readings); (iii) fasting serum total cholesterol, triglycerides, LDL, VLDL and HDL; (iv) nine classical symptoms of *Sthaulya*, namely excessive hunger (*Atikshudha*), excessive sleep (*Atinidra*), excessive sweating (*Atisweda*), malodorous sweat (*Swedadaurgandhya*), lethargy (*Alasya*), dyspnoea on exertion (*Shramashwasa*), excessive thirst (*Atipipasa*), body ache or malaise (*Angasada*) and diminished libido (*Alpa Vyavaya*), each graded on a predefined 0–4 ordinal scale (0–1 for *Angasada*), at days 0, 30, 60, 90 and 120; and (v) an overall response category. Safety was assessed through haemoglobin, total leucocyte and platelet counts, urine pH and specific gravity, fasting blood sugar and adverse-event reporting. Measurements were taken by the same trained assessor, and laboratory tests were performed in a NABL-accredited laboratory.

2.6 Sample size

The sample size was calculated for the difference between groups in BMI reduction, assuming a standard deviation of 0.9 kg/m², a minimum detectable difference of 0.5 kg/m², a two-sided α of 0.05 and 80% power [34]:

$$n = \left(\frac{Z_{1-\alpha/2}+Z_{1-\beta}}{d}\right)^2 \times 2\sigma^2 \quad (1)$$

which gives 51 participants per group. Enrolment continued beyond this number to allow for attrition, until 51 participants per group had completed the trial.

2.7 Randomisation, allocation concealment and blinding

A computer-generated simple random sequence (1:1) was prepared by a person not involved in recruitment, and allocation was concealed in sequentially numbered, opaque, sealed envelopes opened only after enrolment. Because the vehicles differed (honey versus water), participants and clinicians could not be blinded. The statistician was blinded to group identity.

2.8 Statistical analysis

Analyses were performed in SPSS 20.0 on the per-protocol population (participants completing 90 days of treatment). Continuous outcomes are summarised as mean ± standard deviation (SD) and compared within groups with paired t-tests; ordinal symptom grades were compared within groups with Wilcoxon signed-rank tests (day 0 versus day 90) and Friedman tests (all five visits), and between groups with Mann–Whitney U tests. Percentage effect was calculated as (mean before − mean after) / mean before × 100.

To quantify between-group differences with appropriate uncertainty, the standard deviation of within-participant change in each group was derived from the paired t statistic as $SD_\Delta = |\Delta|\sqrt{n} / |t|$, and the difference in mean change between groups was tested with Welch's t-test:

$$t = \frac{\overline{\Delta}_A - \overline{\Delta}_B}{\sqrt{\frac{SD_{\Delta,A}{}^2}{n_A} + \frac{SD_{\Delta,B}{}^2}{n_B}}} \quad (2)$$

with 95% confidence intervals and Hedges' g as the standardised effect size, interpreted as small (0.2), medium (0.5) or large (0.8) [35]. For Mann–Whitney comparisons, z was obtained from U by the normal approximation without correction for ties, which yields conservative (upper-bound) p-values. Baseline comparability was examined with Welch's t-test for continuous and χ^2 tests for categorical variables. The distribution of overall response was compared with the χ^2 test. A two-sided $p < 0.05$ was considered significant; no adjustment was made for multiple secondary outcomes, which are therefore interpreted as exploratory.

3 RESULTS

3.1 Participant flow

A total of 126 eligible participants were randomised: 64 to Group A and 62 to Group B. Thirteen participants in Group A and 11 in Group B discontinued or were lost to follow-up, so that 51 participants in each group completed the trial and were analysed (Fig. 1). Overall attrition was 19.0% (20.3% and 17.7%).

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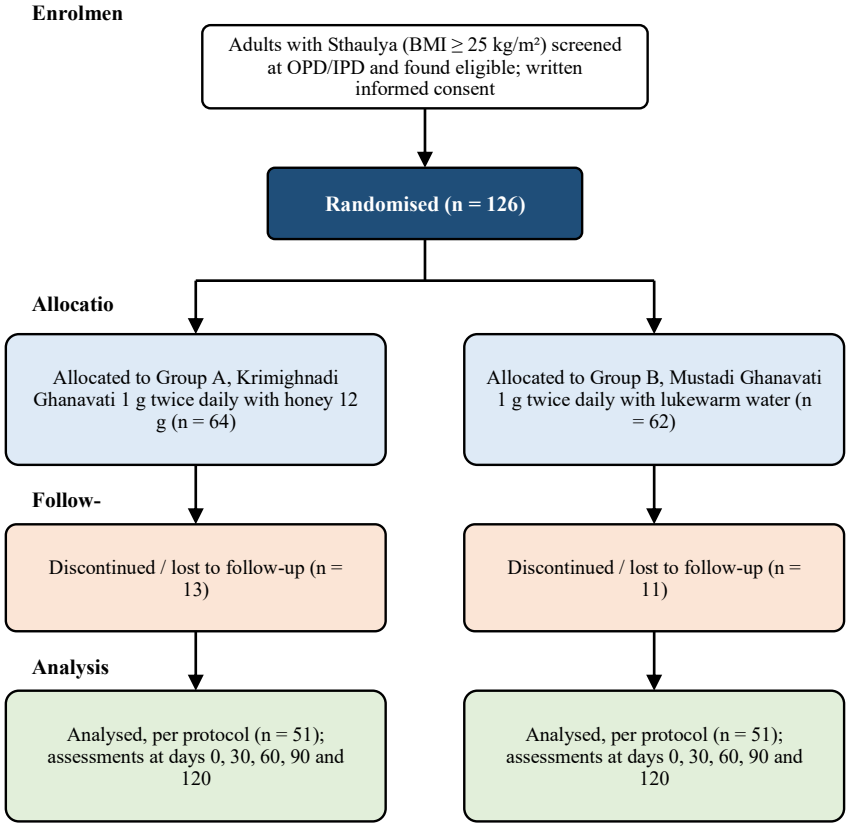


Fig. 1 CONSORT flow diagram of the trial

3.2 Baseline characteristics

Table 2 Baseline characteristics of the analysed participants

Characteristic	Group A (n = 51)	Group B (n = 51)	p
Age 31–50 years, n (%)	33 (64.7)	33 (64.7)	0.632
Female, n (%)	31 (60.8)	30 (58.8)	0.84
Married, n (%)	49 (96.1)	48 (94.1)	—
Service occupation, n (%)	39 (76.5)	24 (47.1)	<0.001
Urban residence, n (%)	30 (58.8)	32 (62.7)	0.685
Mixed diet, n (%)	39 (76.5)	37 (72.5)	0.65
Family history of obesity, n (%)	31 (60.8)	32 (62.7)	0.839
Duration > 5 years, n (%)	24 (47.1)	25 (49.0)	0.497
Kapha-dominant Prakruti (KV + KP), n (%)	21 (41.2)	22 (43.1)	0.879
Tikshna Agni, n (%)	29 (56.9)	32 (62.7)	0.826
Krura Koshtha, n (%)	29 (56.9)	27 (52.9)	0.898
Coated tongue (Sama Jivha), n (%)	18 (35.3)	40 (78.4)	<0.001
Body weight (kg), mean ± SD	86.19 ± 7.59	82.04 ± 6.85	0.005
BMI (kg/m²), mean ± SD	33.16 ± 2.38	32.58 ± 2.46	0.229
Abdominal skinfold (mm), mean ± SD	29.13 ± 3.79	31.82 ± 3.88	<0.001
Chest circumference (cm), mean ± SD	107.00 ± 4.68	102.00 ± 4.68	<0.001
Abdominal girth (cm), mean ± SD	115.00 ± 6.99	109.00 ± 5.51	<0.001

Hip circumference (cm), mean ± SD	108.00 ± 6.32	106.00 ± 6.94	0.131
Total cholesterol (mg/dL), mean ± SD	205.00 ± 16.78	185.00 ± 21.67	<0.001
Triglycerides (mg/dL), mean ± SD	147.00 ± 25.36	140.00 ± 20.73	0.13
LDL (mg/dL), mean ± SD	96.00 ± 11.21	101.00 ± 16.27	0.074
VLDL (mg/dL), mean ± SD	35.00 ± 5.47	32.00 ± 4.83	0.004
HDL (mg/dL), mean ± SD	51.00 ± 4.97	45.00 ± 3.85	<0.001

p values: χ^2 test for categorical variables (all categories of the variable), Welch's t-test for continuous variables. KV, Kapha-Vata; KP, Kapha-Pitta.

The groups were comparable in age, sex, residence, diet, family history, disease duration and constitutional characteristics (Table 2). However, Group A had a higher proportion of salaried workers, and Group B a markedly higher proportion of participants with a coated tongue, a classical sign of *Ama*. Despite randomisation, Group A also started with higher mean body weight, chest and abdominal circumferences, total cholesterol, VLDL and HDL and lower abdominal skinfold thickness; baseline BMI did not differ (33.16 versus 32.58 kg/m², p = 0.229).

3.3 Classical symptoms of Sthaulya

Table 3 Effect on the classical symptoms of *Sthaulya* (mean grade before and after 90 days)

Symptom	Group A BT → AT	Relief A (%)	Group B BT → AT	Relief B (%)	Mann–Whitney U	z	p
Excessive hunger (Atikshudha)	1.69 → 0.43	74.4	1.61 → 0.51	68.3	977.5	-2.16	0.031
Excessive sleep (Atinidra)	1.71 → 0.45	73.6	1.55 → 0.53	65.8	897.5	-2.70	0.007
Excessive sweating (Atisweda)	1.51 → 0.37	75.3	1.67 → 0.55	67.1	1054.0	-1.65	0.099
Malodorous sweat (Swedadaurgandhya)	1.71 → 0.45	73.6	1.73 → 0.61	64.8	983.5	-2.12	0.034
Lethargy (Alasya)	1.71 → 0.43	74.7	1.65 → 0.59	64.3	904.5	-2.65	0.008
Dyspnoea on exertion (Shramashwasa)	1.53 → 0.37	75.6	1.61 → 0.55	65.8	1037.0	-1.76	0.078
Excessive thirst (Atipipasa)	1.53 → 0.45	70.5	1.86 → 0.63	66.3	966.5	-2.24	0.025
Body ache / malaise (Angasada)	0.82 → 0.31	61.9	0.78 → 0.43	45.0	995.0	-2.04	0.041
Diminished libido (Alpa Vyavaya)	1.18 → 0.27	76.7	1.63 → 0.57	65.1	924.5	-2.52	0.012

BT, before treatment (day 0); AT, after treatment (day 90). All within-group changes were significant by the Wilcoxon signed-rank test (|Z| 5.55–6.50, p < 0.001). Between-group p values are from the normal approximation of U without tie correction and are therefore conservative.

Every symptom improved significantly within both groups (Wilcoxon p < 0.001; Table 3), and the Friedman tests showed a significant change across the five visits in every symptom in both groups (χ^2 132.2–160.3, df = 4, p < 0.001). Percentage relief

was higher in Group A for all nine symptoms, by 4.3 to 16.9 percentage points (Fig. 2), with the largest differences for body ache (61.9% versus 45.0%), lethargy (74.7% versus 64.3%) and diminished libido (76.7% versus 65.1%). Between-group differences were significant for seven of the nine symptoms even under the conservative approximation, with small effect sizes (r = 0.20–0.27); the differences for excessive sweating and exertional dyspnoea did not reach significance.

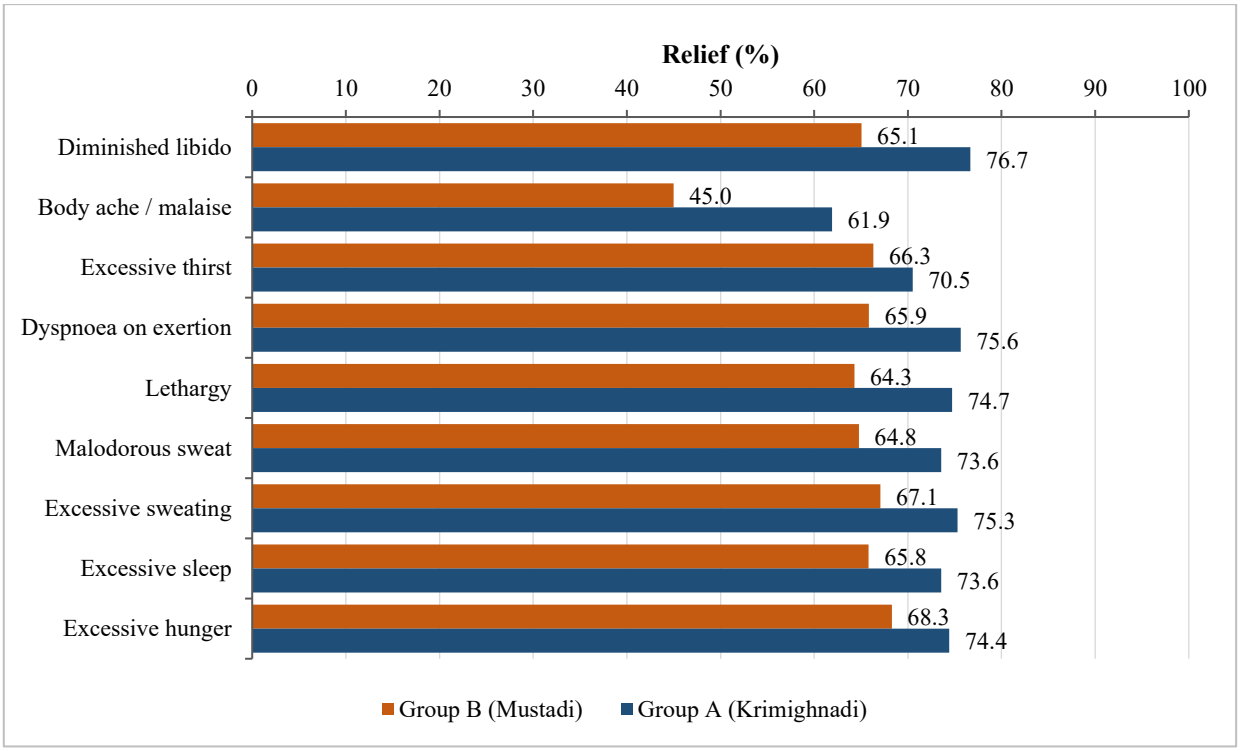


Fig. 2 Percentage relief in the nine classical symptoms of *Sthaulya* after 90 days of treatment

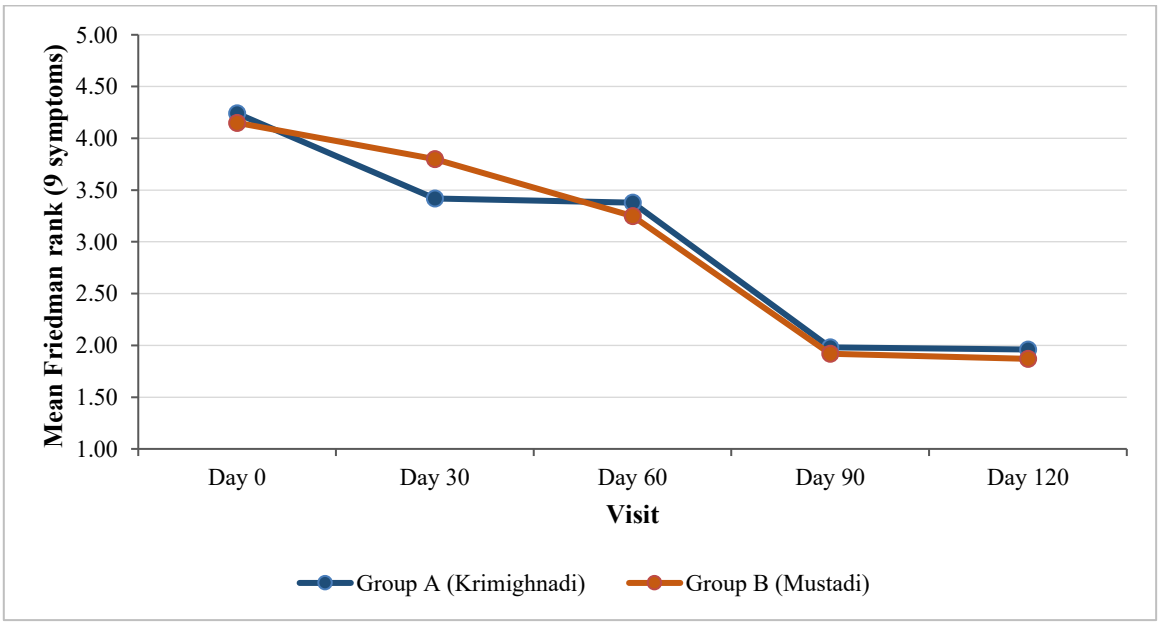


Fig. 3 Time course of symptom severity: mean Friedman rank averaged over the nine symptoms (lower rank indicates lower severity). Treatment was stopped at day 90

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The time course (Fig. 3) showed that improvement accumulated progressively over the 90 days of treatment, with the steepest change between days 60 and 90, and that the improvement was maintained at day 120, 30 days after treatment had stopped, in both groups.

3.4 Anthropometric and lipid outcomes

Table 4 Anthropometric and lipid outcomes within each group (mean ± SD; paired t-test)

Outcome	Group	Day 0	Day 90	Change (%)	t	p
Body weight (kg)	A	86.19 ± 7.59	79.29 ± 6.31	−8.0	5.22	<0.001
	B	82.04 ± 6.85	77.14 ± 6.46	−6.0	3.86	<0.001
BMI (kg/m²)	A	33.16 ± 2.38	29.52 ± 1.86	−11.0	9.76	<0.001
	B	32.58 ± 2.46	29.97 ± 1.82	−8.0	7.19	<0.001
Abdominal skinfold (mm)	A	29.13 ± 3.79	23.31 ± 4.46	−20.0	7.70	<0.001
	B	31.82 ± 3.88	27.64 ± 3.83	−13.1	4.93	<0.001
Chest circumference (cm)	A	107.00 ± 4.68	100.00 ± 5.97	−6.5	7.11	<0.001
	B	102.00 ± 4.68	98.50 ± 5.61	−3.4	3.77	<0.001
Abdominal girth (cm)	A	115.00 ± 6.99	106.00 ± 9.25	−7.8	4.95	<0.001
	B	109.00 ± 5.51	103.00 ± 6.16	−5.5	5.99	<0.001
Hip circumference (cm)	A	108.00 ± 6.32	102.00 ± 6.19	−5.6	4.40	<0.001
	B	106.00 ± 6.94	103.00 ± 5.54	−2.8	2.92	0.005
Total cholesterol (mg/dL)	A	205.00 ± 16.78	190.00 ± 15.03	−7.3	4.30	<0.001
	B	185.00 ± 21.67	178.00 ± 15.84	−3.8	1.82	0.075
Triglycerides (mg/dL)	A	147.00 ± 25.36	136.00 ± 22.70	−7.5	2.83	0.007
	B	140.00 ± 20.73	133.00 ± 24.54	−5.0	1.40	0.168
LDL (mg/dL)	A	96.00 ± 11.21	88.00 ± 15.59	−8.3	3.31	0.002
	B	101.00 ± 16.27	96.00 ± 15.02	−5.0	1.84	0.072
VLDL (mg/dL)	A	35.00 ± 5.47	31.00 ± 5.24	−11.4	4.06	<0.001
	B	32.00 ± 4.83	30.00 ± 5.29	−6.2	1.87	0.067
HDL (mg/dL)	A	51.00 ± 4.97	55.00 ± 5.10	+7.8	4.74	<0.001
	B	45.00 ± 3.85	47.00 ± 4.92	+4.4	2.08	0.043

Percentage change = (day 0 − day 90) / day 0 × 100; + indicates an increase (HDL).

Both treatments produced significant reductions in weight, BMI, abdominal skinfold and all three circumferences (Table 4). In Group A, mean BMI moved from the class I obesity range (33.16 kg/m²) into the overweight range (29.52 kg/m²), and mean weight loss (8.0%) exceeded the 5% threshold of clinical relevance, as did the 6.0% loss in Group B. The largest relative change in both groups was in abdominal skinfold thickness (20.0% and 13.1%). All five lipid fractions improved significantly within Group A, whereas in Group B only HDL changed significantly ($p = 0.042$).

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3.5 Between-group comparison

Table 5 Between-group comparison of mean change from day 0 to day 90 (Welch's t-test)

Outcome	Mean change A	Mean change B	Difference (95% CI)	t	p	Hedges g
Body weight	6.90	4.90	2.00 (-1.64 to 5.64)	1.09	0.278	0.21
BMI	3.64	2.61	1.03 (-0.00 to 2.06)	1.98	0.051	0.39
Abdominal skinfold	5.82	4.18	1.64 (-0.61 to 3.89)	1.44	0.152	0.28
Chest circumference	7.00	3.50	3.50 (0.82 to 6.18)	2.59	0.011	0.51
Abdominal girth	9.00	6.00	3.00 (-1.13 to 7.13)	1.45	0.152	0.28
Hip circumference	6.00	3.00	3.00 (-0.39 to 6.39)	1.76	0.082	0.35
Total cholesterol	15.00	7.00	8.00 (-2.30 to 18.30)	1.54	0.127	0.30
Triglycerides	11.00	7.00	4.00 (-8.57 to 16.57)	0.63	0.529	0.12
LDL	8.00	5.00	3.00 (-4.22 to 10.22)	0.82	0.411	0.16
VLDL	4.00	2.00	2.00 (-0.89 to 4.89)	1.38	0.172	0.27
HDL	-4.00	-2.00	-2.00 (-4.54 to 0.54)	-1.56	0.121	0.31

Change is expressed as day 0 minus day 90, so positive values indicate reduction (HDL: negative values indicate an increase). Positive differences and g favour Group A.

The mean change was larger in Group A for every anthropometric and lipid outcome (Table 5; Fig. 4), but the confidence intervals were wide. The difference was statistically significant only for chest circumference (3.5 cm, 95% CI 0.8 to 6.2; g = 0.51). The difference in BMI reduction (1.03 kg/m²; g = 0.39) was of borderline significance (p = 0.051), and the difference in weight loss (2.0 kg; g = 0.21) was not significant (p = 0.278). For the lipid fractions, the between-group differences were small to moderate (g = 0.12–0.31) and not significant.

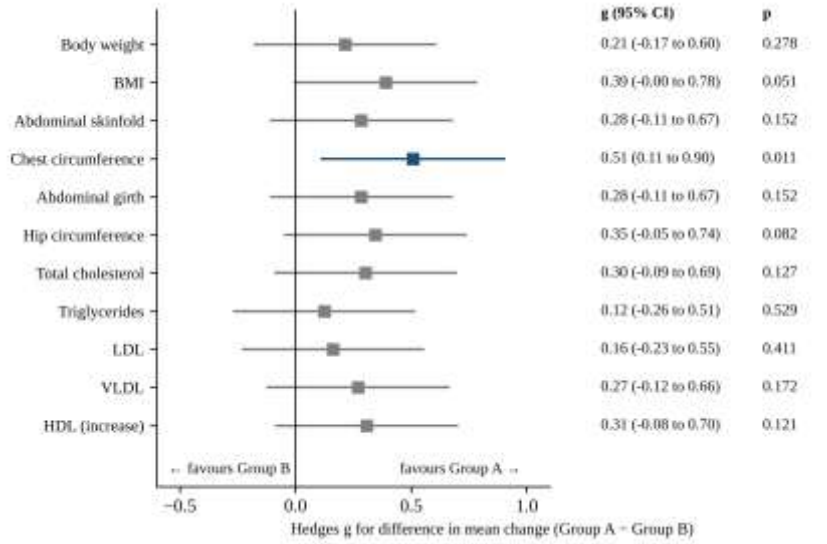


Fig. 4 Forest plot of standardised between-group differences (Hedges g with 95% CI) in mean change from day 0 to day 90. The filled blue marker indicates p < 0.05

3.6 Overall response

Marked improvement was recorded in 18 participants (35.3%) in Group A and 5 (9.8%) in Group B, moderate improvement in 30 (58.8%) and 41 (80.4%), and mild improvement in 3 (5.9%) and 5 (9.8%); no participant was unimproved (Fig. 5). The

distribution differed significantly between groups (χ^2 = 9.55, df = 2, p = 0.008), and the proportion with marked improvement was higher in Group A (risk difference 25.5 percentage points; odds ratio 5.02; Fisher's exact p = 0.004).

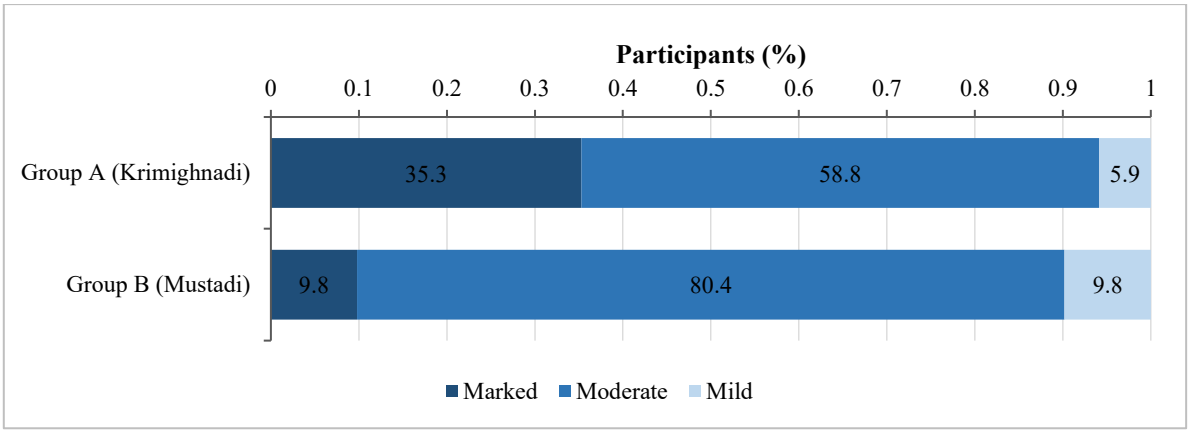


Fig. 5 Distribution of overall response at day 90 (χ^2 = 9.55, p = 0.008)

3.7 Safety

Table 6 Safety parameters (mean ± SD; paired t-test)

Parameter	Group A day 0	Group A day 90	p	Group B day 0	Group B day 90	p
Haemoglobin (g/dL)	14.01 ± 1.67	13.97 ± 1.69	0.051	13.61 ± 1.38	13.59 ± 1.41	0.274
Total leucocyte count (/mm³)	7783 ± 2169	7778 ± 2164	0.683	7695 ± 1987	7693 ± 1978	0.876
Platelets (lakh/mm³)	2.88 ± 0.81	2.89 ± 0.81	0.219	2.91 ± 0.92	2.89 ± 0.91	0.074
Urine pH	6.53 ± 0.79	6.53 ± 0.81	0.616	6.59 ± 0.81	6.61 ± 0.84	0.165
Urine specific gravity	1.02 ± 0.01	1.02 ± 0.01	0.583	1.02 ± 0.01	1.02 ± 0.01	0.103
Fasting blood sugar (mg/dL)	111.08 ± 16.18	111.12 ± 16.27	0.864	113.50 ± 15.56	113.68 ± 15.63	0.497

No safety parameter changed significantly within either group (Table 6), and all values remained within reference ranges. Fasting blood sugar was unchanged despite the daily intake of 24 g of honey in Group A. No serious adverse event was recorded, and no participant required dose modification or withdrawal because of an adverse effect.

4 DISCUSSION

4.1 Principal findings

In this first randomised trial of Krimighnadi Kashaya, a standardised tablet form of the formulation, given with honey together with simple diet and activity advice, reduced body weight by 8.0% and BMI by 3.6 kg/m² over 90 days in adults with obesity. The active comparator, Mustadi Ghanavati, reduced weight by 6.0%. Both reductions exceed the 5% threshold associated with cardiometabolic benefit [7]. Krimighnadi Ghanavati produced greater relief in all nine classical symptoms, a significantly greater reduction in chest circumference and a markedly higher proportion of marked responders (35% versus 10%), and it was the only treatment associated with within-group improvement of all lipid fractions. However, its advantage over the comparator for the primary outcomes was modest and not statistically established for weight (g = 0.21) and borderline for BMI (g = 0.39).

4.2 Comparison with previous studies

The magnitude of weight loss in both groups is comparable to or larger than that reported in earlier Ayurvedic obesity trials with multi-herbal formulations and procedures, which have generally reported reductions of 2–6 kg over 6–12 weeks [24–27],

and to the results of a placebo-controlled trial of a Guggulu-based formulation [28]. It is also within the range reported for other traditional multi-herbal preparations tested in randomised trials [36]. The findings with Mustadi Ghanavati are consistent with its earlier use in hyperlipidaemia [23] and support its role as an active comparator.

The within-group lipid changes in Group A should be interpreted cautiously. Guggulsterones antagonise the farnesoid X receptor and lower cholesterol in experimental models [20], but a randomised trial of standardised guggulipid in hypercholesterolaemia did not show LDL reduction [37]. In the present trial, baseline lipid values were mostly within the normal range, the between-group differences were not significant, and Group A started with higher total cholesterol and VLDL, so that part of its larger fall may reflect regression towards the mean. A dedicated trial in dyslipidaemic patients is needed before any lipid-lowering claim can be made.

4.3 Probable mode of action

Both formulations combine ingredients that are pungent, bitter and astringent, light and drying, properties that classical theory opposes to the heavy, oily and cold qualities of *Kapha* and *Meda*. The additional elements in Group A are Guggulu, the classical fat-scraping (*Lekhana*) agent, honey, described as fat-reducing and as a vehicle that carries drugs into the minute channels, and the strong digestive stimulants Trikatu and *Embelia ribes* (Fig. 6). Experimental and clinical evidence supports anti-obesity or metabolic effects of embelin [15], piperine [17], ginger [18], Triphala [16, 38], *Tinospora cordifolia* [19] and honey [21], and for the comparator of *Cyperus rotundus* [39], curcumin [40], berberine [41] and *Emblica officinalis* [42]. Modulation of the gut microbiota is a plausible common pathway for polyherbal preparations [43]. The greater relief of hunger, thirst and lethargy in Group A is consistent with the classical description of obstructed *Vata* stimulating appetite in *Sthaulya* [11, 13].

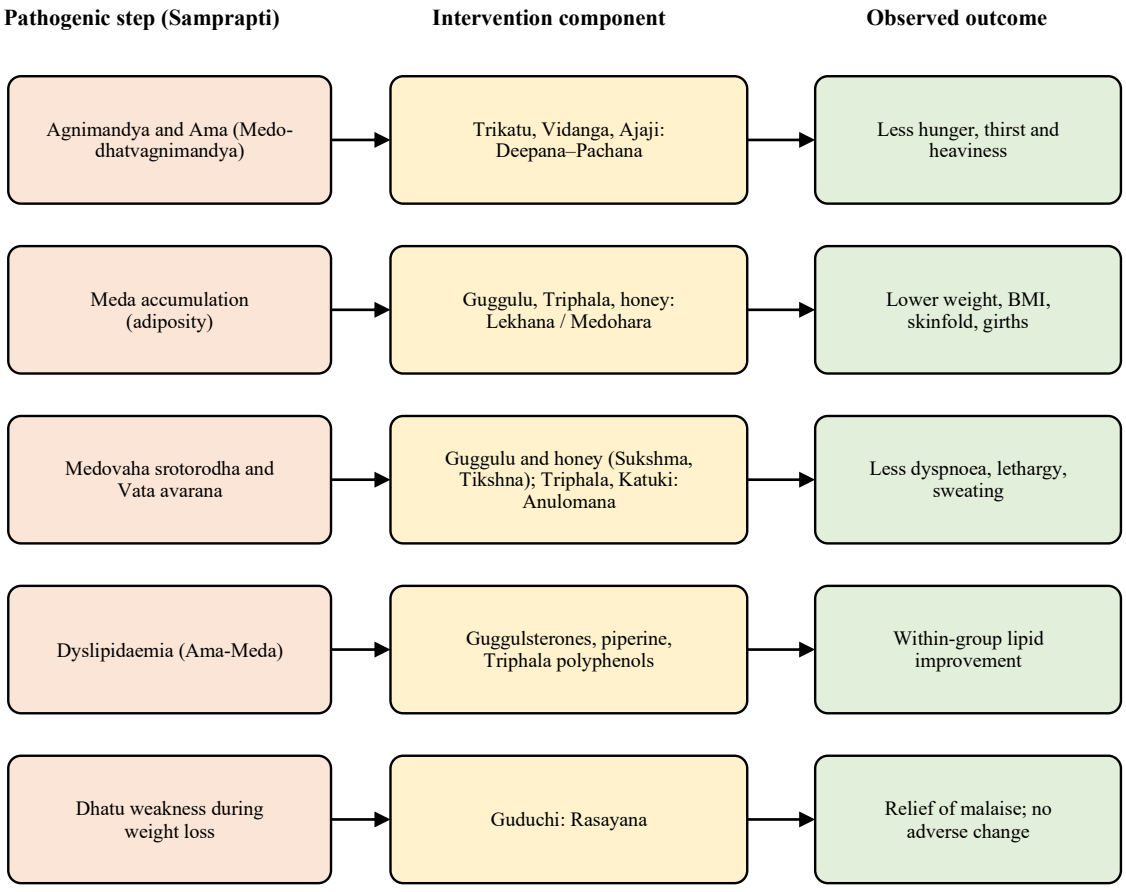


Fig. 6 Proposed mode of action of Krimighnadi Ghanavati with honey, linking the classical pathogenesis (*Samprapti*) of *Sthaulya* to the components of the formulation and to the outcomes observed in the trial

4.4 Novelty and implications

The trial contributes (i) the first clinical evidence on Krimighnadi Kashaya, (ii) a reproducible, Guggulu-fortified tablet with documented manufacturing and quality-control steps, (iii) a head-to-head comparison against an active classical standard, (iv) integrated measurement of classical symptoms, anthropometry, lipids and safety with a drug-free follow-up, and (v) transparent reporting of between-group effect sizes with confidence intervals, which shows clearly where the evidence is strong (within-group efficacy, symptom relief, responder rate) and where it is not yet conclusive (comparative effect on weight and lipids). For practice, both formulations, combined with diet and activity advice, can be considered for adults with obesity, with Krimighnadi Ghanavati preferred where symptom burden is high. For research, the estimated standardised difference in BMI change ($g \approx 0.4$) indicates that about 100 participants per group would be needed to confirm superiority with 80% power.

4.5 Limitations

The trial has several limitations. First, it was open-label, because the vehicles differed; symptom grades are therefore susceptible to expectation bias, although anthropometric and laboratory outcomes are less so. Second, the vehicle itself differed, so the contribution of honey cannot be separated from that of the formulation. Third, the analysis was per protocol, with 19% attrition, and an intention-to-treat analysis could not be performed. Fourth, despite randomisation, several baseline variables differed between groups, including weight, circumferences, lipids and tongue coating, and adjustment by analysis of covariance was not possible from the available data; residual confounding and regression to the mean cannot be excluded. Fifth, dietary intake and physical activity were advised but not quantified. Sixth, the trial was conducted at a single centre over a relatively short period, without imaging of body composition, insulin-resistance markers or validated quality-of-life instruments, and the post-treatment follow-up was limited to 30 days. Finally, multiple secondary outcomes were tested without adjustment.

5 CONCLUSIONS

In adults with obesity, 90 days of Krimighnadi Ghanavati with honey or Mustadi Ghanavati, each combined with diet and activity advice, produced clinically meaningful reductions in weight, BMI, girths and skinfold thickness and relieved the classical symptoms of *Sthaulya*, without adverse changes in safety indices. Krimighnadi Ghanavati gave greater symptomatic relief, a greater reduction in chest circumference and a higher rate of marked response, but its superiority for weight and BMI was not established. A multicentre, blinded, placebo-controlled trial with intention-to-treat analysis, a matched vehicle and longer follow-up is warranted.

Declarations

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Author contributions MSS: conceptualisation, investigation, data curation, formal analysis, writing of the original draft. SAD: conceptualisation, methodology, supervision, writing – review and editing. Both authors read and approved the final manuscript.

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Data availability The data supporting the findings of this study are available from the corresponding author on reasonable request.

Ethics approval The study was approved by the Institutional Ethics Committee of Bharati Vidyapeeth (Deemed to be University) College of Ayurved, Pune (approval no. BVDUCOA/EC/-103(1)/2022-23) and registered with CTRI no - 2023/12/060602).

Consent to participate Written informed consent was obtained from all participants.

Consent for publication Not applicable; no identifiable individual data are reported.

Competing interests The authors declare no competing interests.

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