Shojaedin *et al.*
Innovations in Acupuncture and Medicine (2025) 18:8
https://doi.org/10.1186/s44424-025-00009-z

Innovations in Acupuncture and Medicine

RESEARCH

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Effectiveness of Acupuncture and Laser Acupuncture in Combination with Dietary Therapy and Exercise for Overweight and Obese Women: A Randomized Trial

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Abstract

Background Obesity presents serious health risks and is a leading cause of mortality, underscoring the need for effective interventions. Some studies have indicated that acupuncture could be beneficial for weight loss, whether used alone or in combination with lifestyle modification. Additionally, laser acupuncture has emerged as a complementary approach for weight loss. Hence, this study aims to compare the effectiveness of dietary therapy combined with exercise, acupuncture, and laser acupuncture for weight loss in overweight and obese women.

Methods A four-arm randomized trial was conducted to evaluate the efficacy of these interventions on weight loss. In this trial, 100 women among 120 participants, aged 18 to 50 with a BMI ranging from 25 to 39.9, were eligible for recruitment from the obesity clinic at Sina Hospital. Participants were randomly assigned to one of four groups: (1) diet therapy and exercise, (2) acupuncture with diet and exercise, (3) laser acupuncture with diet and exercise, and (4) a combined approach of acupuncture and laser acupuncture alongside diet and exercise. Laser treatments used a 980 nm wavelength at a power of 200 mW. Outcomes included changes in anthropometric measures, weight loss, and demographic data assessed before the intervention, after 12 sessions, and three months post-intervention.

Results All groups showed significant reductions in BMI and fat mass. The mixed treatment group had a greater reduction in fat mass compared to the diet-only group. However, fat mass reductions in the acupuncture and laser acupuncture groups were not significantly different from the diet group.

Conclusions Combining nutritional interventions with acupuncture therapies, especially laser acupuncture, appears effective for weight reduction and improving body composition. These findings support integrating acupuncture with dietary and lifestyle modifications for effective weight management.

Trial registration The study protocol was registered with the Iranian Registry of Clinical Trial (ID: IRCT20111121008146N42) and received ethical approval from Shahid Beheshti Medical Science University Authority Research Ethics Board (IR.SBMU.RETECH.REC.1401.544).

Keywords Laser acupuncture, Obesity, Overweight, Dietary therapy

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1 Introduction

Overweight and obesity are chronic health conditions defined as an increase in the size and amount of fat cells in the body. It should be considered as a disease and proper intervention should be done with timely diagnosis. Body mass index (BMI) is used to screen for overweight and obesity in adults. So that cut-off defined as overweight: BMI equal or more than 25 and obesity: BMI equal or more than 30. BMI is a measure of body fat based on height and weight and is defined as the body mass (in kilograms) divided by the square of the body height (in meters) and expressed in units of kg/m^2 [1].

Fat mass refers specifically to the total amount of fat tissue in the body. It includes both essential fat, which is necessary for normal physiological functions, and excess fat that may contribute to health risks. Measuring fat mass provides a clearer picture of an individual's obesity status than BMI alone, as it helps identify how much of the body is composed of fat versus lean tissue. Excess fat mass, particularly visceral fat (fat stored around internal organs), is associated with a higher risk of metabolic disorders such as type 2 diabetes, cardiovascular disease, and certain cancers [2].

Fat-Free Mass (FFM) represents the portion of the body that is not composed of fat. This includes muscle, bone, water, and other non-fat tissues. FFM is an important component in understanding overall body composition because it reflects the body's metabolic capacity. Higher levels of fat-free mass are generally associated with better health outcomes and increased physical performance. In contrast, low fat-free mass can indicate malnutrition or muscle wasting, which can also have negative health implications [2, 3].

In summary, while BMI provides a general classification of weight status, fat mass and fat-free mass offer more detailed insights into body composition and associated health risks.

Obesity is a more important risk factor for non-communicable disease including cardiovascular disease, Type 2 diabetes, metabolic syndrome, hypertension, sleep apnea, mental health conditions, musculoskeletal disorders, osteoarthritis, and a number of cancers, and also it is the leading cause of death. So that, it is an important topic in public health that requires effective intervention individually and at the community level [4, 5].

The worldwide prevalence of overweight and obesity in adult were 39% and 13%. According to the STEPs study, its prevalence in Iranian people was about 22.7% and 59.3%. And it was found that obesity is more common in women compared to men 15.3%, and 29.8%, respectively. Due to its increasing prevalence, it has become one of the major problems in public health.

In addition, abdominal obesity is known as an independent risk factor for no communicable disease and it can be seen in people with normal BMI [6].

Among the available methods for weight loss and size reduction, physical activity and diet are the most important strategies for reducing weight, but they are difficult to do in patients with musculoskeletal disorders such as osteoarthritis; also some several drugs and supplements are effective in weight loss, and in addition bariatric surgery used in cases due to BMI higher than 35 and comorbidities, but complications and adverse effect make us look for more effective and safer methods [7].

Laser acupuncture and acupuncture are two different methods used in weight loss through different mechanisms that occur via the secretion of chemical substances such as endorphins, and ACTH serotonin and decreases proinflammatory cytokines such as interleukin-6 (IL-6) and tumor necrosis factor–a (TNF-a) [8–10]. In acupuncture, fine needles are inserted in specific acupuncture points [8] (Fig. 1).

Meta-analysis results which included three RCTs in IRAN demonstrated that acupuncture can reduce waist size and around the hips it causes a decrease in the waist–hip ratio (WHR) and body mass index (BMI), but this probably depends on different methods and it may have some adverse events including infection. Laser acupuncture is a newer method based on acupuncture that does not use needles and uses lasers to stimulate acupuncture points [12–15]. It may be preferred according that many studies show it can be effective. According to the results, laser acupuncture led to weight loss, loss of appetite, and reduction of waist circumference [15]. On the other hand, the results of a review article showed that due to methodological problems, it is not possible to confidently comment on the effectiveness of laser acupuncture and clinical studies with a larger sample size and a more accurate and high-quality methodology with the control of confounding factors should be done to prove its effectiveness. Even in the studies whose results show the effectiveness of this method, it is recommended to increase the sample size and be multi-centered in subsequent studies. Considering the effectiveness of acupuncture and laser acupuncture in obesity, which has been mentioned in several articles, the question is whether the combination of these two methods is more effective than using one method alone or not. Different physiological pathways are involved in the mechanisms of action of acupuncture and laser acupuncture. However, due to their complementary effect on the nervous system and the secretion of chemical mediators, combining these methods may yield synergistic effects. Wu et al. [16] demonstrated that combining acupuncture methods,

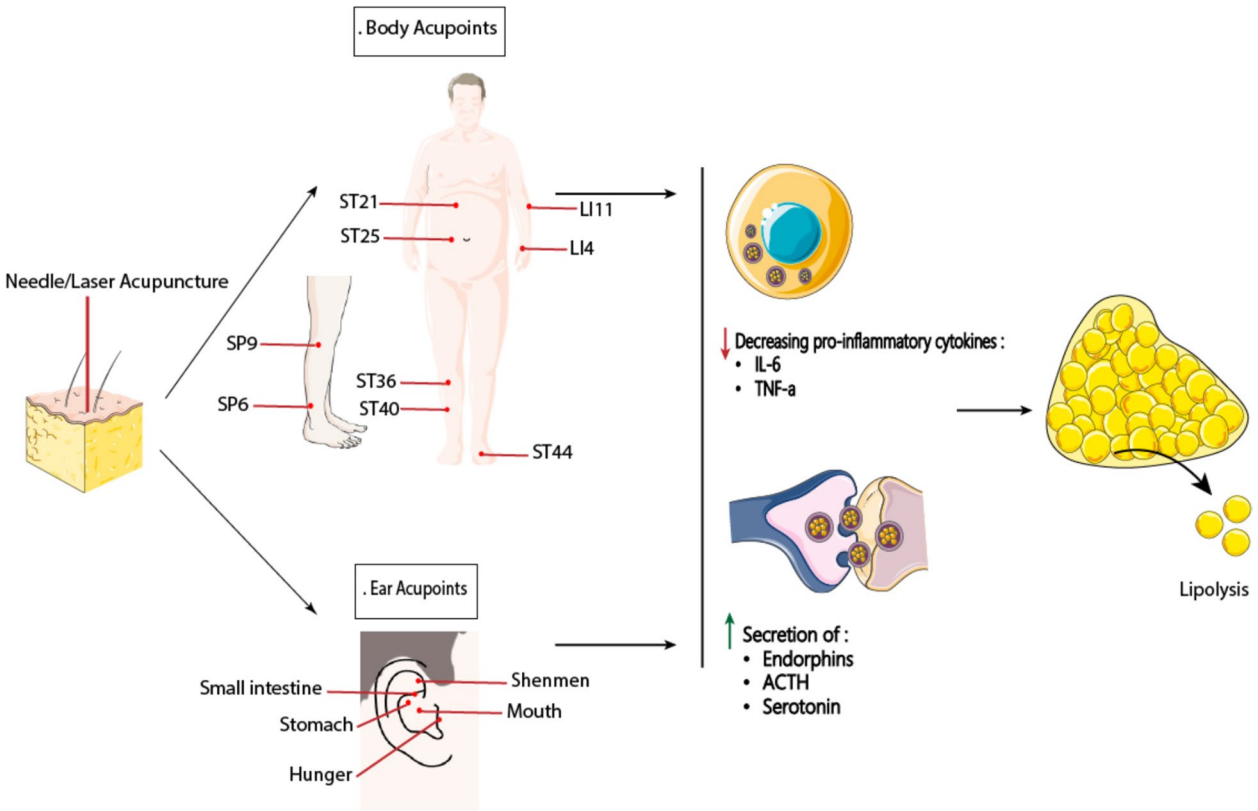

Fig. 1 Schematic representation of the pathways and acupoints involved in weight loss through needle/laser acupuncture. Shapes are adapted from Servier Medical Art, licensed under CC BY 4.0 [11]

such as laser acupuncture with electroacupuncture, can improve clinical outcomes in patients with osteoarthritis. This study mentioned that these modalities exert their synergistic effect by activating nervous system, promoting cell healing, inhibiting inflammation, and modulating pain signals. To date, no study has investigated the benefits of combining laser acupuncture with acupuncture in obese and overweight patients. However, some literature suggests that combination treatments methods targeting different physiological pathways could be more effective than monotherapy alone [17].

Hence, we decided to do this study to compare the effectiveness of three methods: acupuncture with diet and physical activity, laser acupuncture with diet and physical activity, and acupuncture with laser acupuncture together with diet and physical activity.

1.1 Method

1.1.1 Study Design

This trial used a randomized, four-arm group design to compare the efficacy of dietary therapy and exercise, acupuncture, and laser acupuncture therapy in weight loss of obese and overweight women.

1.1.2 Patients

Among 120 screened participants, 100 overweight and obese women with a BMI of 25–39.9 were enrolled in this study. We continued this study until 25 participants were enrolled in each group, and a total of 100 patients included in the analysis. As shown in Fig. 2, participants who dropped out or were lost to follow-up were not included.

The study population consists of those aged 18–50 referred to the obesity clinic of Sina Hospital. They were excluded if suffered from mood disorders, anxiety, psychotic disorders, and other psychiatric disorders in the last 6 months, also using psychotropic and hormonal drugs and steroid drugs or opioids in the last 6 months, uncontrolled hypertension or diabetes, cardiac and lung diseases, orthopedic disorders, or were dissatisfied to continue this study. Adherence to exercise and diet was monitored using a log book. Patients who missed 30% of their exercise sessions were excluded from this study.

The patients were divided into four equal arms (each group: 25 patients): group (1) group of diet therapy and exercise, group (2) acupuncture group with diet therapy and exercise, group (3) laser therapy group with diet therapy and exercise, and group (4) the combination

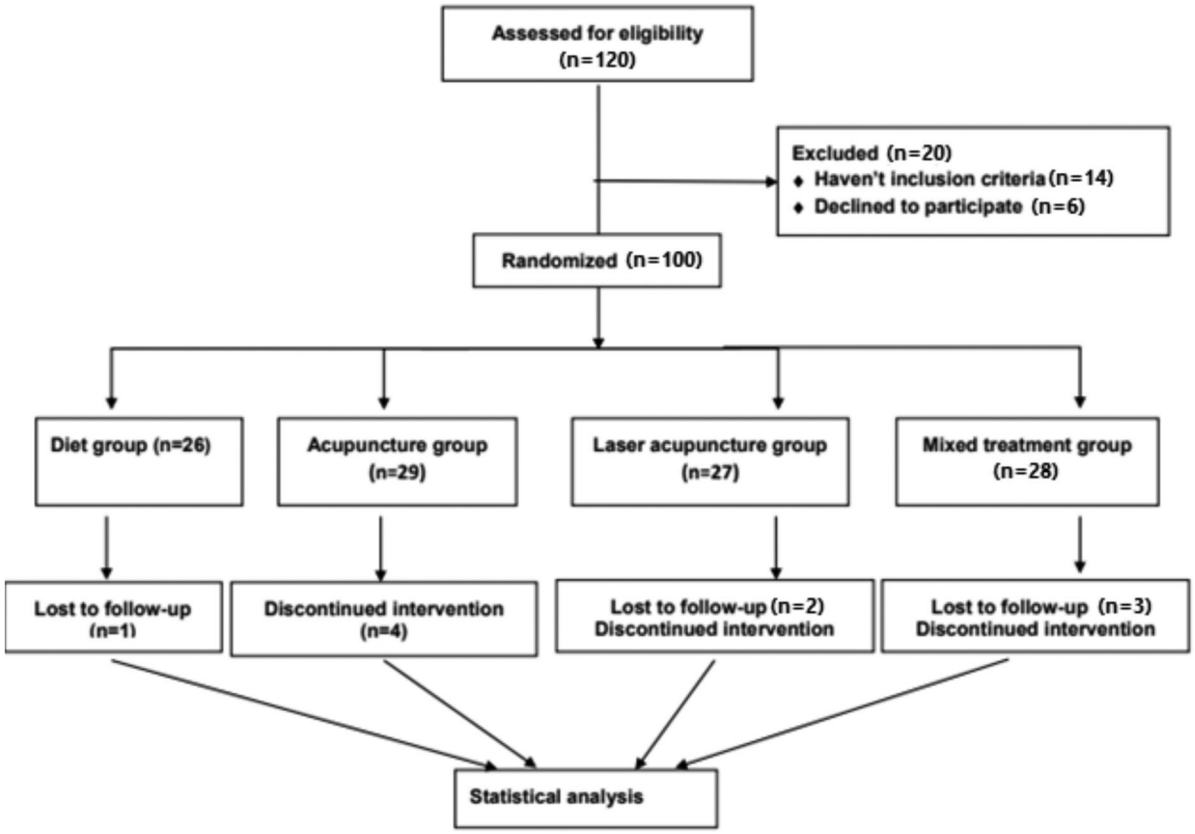

Fig. 2 Flowchart of dividing patients into groups and analyzed number

group of acupuncture and laser acupuncture along with diet therapy and exercise.

2 Randomization and Allocation

After obtaining consent, eligible participants were randomized into four groups using the block randomization technique. In order to randomize the sequence, block randomization was performed. All possible block size 8 patterns were listed and randomly selected, following that eight patients were allocated to each block, then 2 patients in each group was determined. This sequence continued until 100 patient allocate to groups.

Although blinding the therapist was not possible due to the obvious type of the treatments, the data analyst was blinded to the group assignments to prevent information bias.

3 Intervention Protocol

3.1 Laser Acupuncture Protocol

In the laser acupuncture intervention group, in addition to therapeutic regimens and physical therapy, laser acupuncture was performed by a trained therapist according to standard protocols applied 1 Joule of Gallium-Aluminum-Arsenide (GaAlAs) Laser with a wavelength of 980 nm and a device power of 200 mill watts for each of the following ear acupuncture points: shenmen, stomach, mouth, small intestine, and hunger (appetite control). Additionally, for the body acupuncture points including ST 21-25-36-40-44, LI 4-11, and SP6-9, a dose of 4 Joules with a wavelength of 980 nm and a device power of 200 mill watts was applied for each point. The treatment was administered in 12 laser acupuncture sessions, twice a week with a two-day interval between sessions.

4 Acupuncture Protocol

In intervention groups, in addition to therapeutic regimens and physical therapy, acupuncture therapy was performed by a trained therapist according to standard protocols in the ear points including shenmen, stomach, mouth, small intestine, and hunger (appetite control), as well as body acupuncture points including ST 21-25-36-40-44, LI 4-11, and SP 6-9 bilaterally according to Western medical style and STRICA 2010 [18, 19]. We used 28 needles per session for each subject. Depth of insertion of needles was on a particular tissue level. After straight insertion of needles we received

muscle twitch response. Needles were stimulated with manual rotation and remained for 20 min. We used needles with size 13×18 (mm in diameter and length, respectively) for ear, 30×60 18 (mm in diameter and length, respectively) for abdomen, and 25×25 (mm in diameter and length, respectively) for legs and other points (TONY manufacture, China). This was done for 12 sessions, twice a week with a two-day interval between sessions. We did not use any cupping, moxibustion, or herbal interventions. This protocol was conducted by a specialist in acupuncture. All subjects were instructed to have any strenuous exercises until 6 h after intervention.

In Table 1, we showed the acupuncture points used, the location, and the depth of the needles.

5 Exercises Protocol

The sports medicine specialist provided exercise. And the programs were personalized according to the needs of each person. Sports exercises were prescribed as a combination of 30 min of moderate-intensity walking, 5 days a week. The exercise's intensity was designed so that the performer could say at least three words in a row during the exercise. Three days a week, strength training with a green band of the "Tara band" brand, which had medium strength, was prescribed in three sets of 15 repetitions, focusing on the muscles of the upper and lower limbs and the abdomen. Exercise consistency was tracked with a logbook, and if 30 percent of the sessions were missed, they were excluded from this study.

6 Diet Protocol

The nutritionist provided the diet and the programs were personalized according to the needs of each person.

The diet plan was isocaloric based on the calculation of calories based on the Harris–Benedict formula; 500 cal were subtracted from the required calorie intake and based on the food pyramid, by calculating 55% to 60% carbohydrates, and 15% to 20% fat, and 20 to 25 percent protein and free vegetables in the food plan [20]. In addition, adherence to the dietary plan was monitored through weekly check-ins by nutritionist using diet logbooks. Participants who did not follow the diet were excluded.

7 Outcome Measures

The evaluations demographic information (age, education level, history of heart disease, medication information, and pregnancy history) was recorded. Anthropometric information before the intervention, after 12 sessions of interventions, and three months later, measured by the third therapist. Moreover, BMI was designated as the primary outcome of this study, as it is a validated anthropometric measure for weight status and it is also commonly used in obesity-related clinical trials. Therefore, the sample size calculation and statistical analyses were done to detect clinically meaningful changes in BMI.

Anthropometric measures of the patient using a height meter with a standard of one-tenth of a centimeter,

Table 1 Acupoints, locations, and depth of insertion in treatment of obesity

Acupoints	Locations	Depth of insertion
SP6	On the inner side of the calf, 3 cun above the tip of the medial malleolus, by the posterior border of the tibia	1.0–1.5 cun
SP9	On the inner side of the calf, in the depression between the inferior border of the medial condyle of the tibia and the medial border of the tibia	1.0–1.5 cun
ST40	Outside the calf, 8 cun above the tip of the lateral malleolus, the outer border of the tibialis anterior muscle	1.0–1.5 cun
ST36	On the anterior lateral side of the calf, 3 cun below Dubi (ST35)†, one horizontally placed finger distance lateral to the anterior border of the tibia (the middle finger)	1.0–1.5 cun
ST25	On the abdomen, horizontal to the umbilicus, 2 cun lateral to the anterior midline	1.0–1.5 cun
SP15	On the abdomen, 4 cun beside the navel	1.0–1.5 cun
ST21	On the upper abdomen, 4 cun above the center of the umbilicus, 2 cun lateral to the anterior median line	1.5–2 cun
ST44	Proximal to the web margin between 2nd and 3rd metatarsal bones, in a depression distal and lateral to the 2nd metatarsodigital joint	0.25 cun
Shenmen	On the lateral third of the triangular fossa at the branch between the superior crus and the inferior antihelix	2 mm
Stomach	At the end of helix crus	2 mm
Mouth	In the corner of the acoustic meatus and the ascending helix, but on the plain of the concha	2 mm
Small intestine	A continuation of the projection of the digestive tract in a ventral direction, adjacent to the duodenum zone, bordering caudally on the middle third of the crus of the helix	
Hunger	In the lower part of the tragus in the direction of the transitional fold toward the facial skin	2 mm
LI4	In the fleshy depression just beyond the meeting point where thumb and first finger bones meet, in a "V" shape	0.5 cun
LI11	At the lateral end of the transverse cubital crease midway between LU 5 and the lateral epicondyle of the humerus	1–1.5 cun

weight using a scale with a standard of one-tenth of a kilogram, and waist and hip circumference measured using a measuring tape.

BMI was determined based on the formula of weight divided by the square of height (kg/m2).

The amount of the body`s fat mass and fat-free was were measured by a body analyzer (Tanita Company).

Fat mass and fat-free mass are two components of body composition that play distinct roles in human physiology. Fat mass refers to the total amount of adipose tissue in the body, including both essential fat (necessary for normal physiological function) and storage fat (excess fat stores). It serves as an energy reserve, insulation, and protection for organs. On the other hand, fat-free mass, also known as lean body mass, comprises all non-fat tissues in the body, such as muscles, bones, organs, and water. It is metabolically active tissue and contributes to basal metabolic rate, overall strength, and physical functionality. In summary, fat mass represents the total fat content in the body, while fat-free mass encompasses all non-fat components. Understanding the distinction between these two components is crucial in assessing body composition and overall health status [2, 21].

Evaluations were done at baseline and three months later after 12 sessions of interventions. The applicants must follow the instructions before the body analysis:

- No drinking 4 h before the test.
- Not exercising 12 h before the test.
- Not taking diuretics before the test.
- Complete bladder emptying within 30 min of the test.

8 Sample Size Calculation

The required sample size to detect changes in BMI within each group was calculated considering a 95% confidence level ($\alpha = 0.05$) and 80% power ($\beta = 0.2$), using the following formula. Based on pairwise comparisons, the largest calculated sample size was chosen as the final sample size for each group, which was 25 participants per group. Thus, a total of 100 participants were enrolled across the four intervention arms.

$$n = \frac{(z_{1-\alpha/2} + z_{\beta})^2 (s_1^2 + s_2^2)}{(\bar{x}_1 - \bar{x}_2)^2}.$$

9 Statistical Analysis

Data analyses were performed with SPSS.ver26 for Windows (IBM Corp Released 2016, NY, and USA). Quantitative and qualitative variables are described with Mean ± SD and frequency (percent), respectively. The normality test was done with the Shapiro–Wilk test. ANOVA or Kruskal–Wallis test was performed for between-group comparison. The Tukey LSD test was performed for pairwise comparison.

Paired sample *t*-test or Wilcoxon matched paired was done for within-group evaluation. A marginal model and the generalized estimating equations (GEE) method with an unstructured covariance matrix were used for each outcome. The main effects of time, group, and group-by-time interaction were evaluated. In all models, the baseline values of the outcomes were included as the confounding factor (the group variable). The statistical significance level was set at 0.05.

10 Results

120 patients were included in this study, and after examining the inclusion and exclusion criteria, finally, 100 patients were eligible and were randomly divided into 4 groups. All 100 recruited participants completed this study thoroughly and had good adherence to the assigned diet and exercise protocols, as monitored with regular check-ins with the nutritionist and sport medicine specialists. No significant differences in adherence were observed between the groups. The baseline characteristics of these patients in each group are shown in Table 2.

The mean of weight, fat mass, and free-fat mass before and after this study is described in Table 3. The mean differences before and after treatment were calculated for all three outcomes. The between-group differences for BMI and fat-free mass across the groups were not statistically significant. However, for fat mass, significant mean differences were observed among the four groups. Pairwise comparisons showed that the mixed treatment group had significantly greater reductions in fat mass compared to the other groups.

The GEE analysis was performed in order to explore the effect of the time, group, and group-by-time interaction after intervention for three outcomes: BMI, fat mass, and fat-free mass. Table 4 summarizes the results of the GEE analysis. According to significant difference of baseline measure between groups, these values of the outcomes were included in model as the confounding factor.

The significant p-value for mixed treatment and laser acupuncture groups in three analysis show that these two groups had higher mean BMI, fat mass, and fat-free mass than diet group at baseline, but the patients in acupuncture group had non-significant lower mean fat-free mass compared with those in diet group.

There was no statistically significant group-by-time interaction effect estimated by GEE on the BMI, which means that the slope of BMI reduction in all three groups was not significantly different from the diet

Table 2 Baseline characteristics of patients in each group

	Diet group	Acupuncture group	Laser acupuncture group	Mixed treatment group	*p*-value*
Age (year)	38.40 ± 6.88	40.88 ± 5.92	39.48 ± 11.17	40.20 ± 9.38	0.767
Height (m)	1.58 ± 0.05	1.59 ± 0.07	1.61 ± 0.07	1.60 ± 0.08	0.769
Weight (kg)	76.34 ± 13.47	74.58 ± 13.04	87.16 ± 16.29	87.66 ± 14.73	0.001
BMI (kg/m^2)	30.28 ± 5.08	29.26 ± 4.11	33.78 ± 6.22	34.11 ± 4.70	0.001
History of smoking	25(100%)	25(100%)	20(80%)	12(48%)	0.0001
History of alcohol assumption	25(100%)	25(100%)	22(88%)	12(48%)	0.0001
DM *	0(0%)	0(0%)	1(4%)	0(0%)	0.387
HLP *	2(8%)	1(4%)	2(8%)	0(0%)	0.510
HTN *	0(0%)	0(0%)	1(4%)	0(0%)	0.387
CVD *	2(8%)	0(0%)	0(0%)	2(8%)	0.244
Lung disease	0(0%)	2(4%)	0(0%)	0(0%)	0.106
GI disease	0(0%)	1(4%)	4(16%)	1(4%)	0.094
Urogenital disease	0(0%)	0(0%)	2(8%)	3(12%)	0.129
Thyroid disease	2(8%)	5(20%)	4(16%)	0(0%)	0.110
Psychological disease	1(4%)	0(0%)	4(16%)	1(4%)	0.094
Neurologic disease	4(16%)	4(16%)	2(8%)	1(4%)	0.430
Cancer	4(16%)	4(16%)	3(12%)	1(4%)	0.518
Spinal disease	3(12%)	3(12%)	1(4%)	0(0%)	0.246
Hirsutism	1(4%)	3(12%)	0(0%)	0(0%)	0.100

P-value*: between-group comparison, ANOVA and chi-square test

DM* Diabetes Mellitus

HLP* Hyperlipidemia

HTN* Hypertension

CVD* Cardiovascular disease

Table 3 Comparing the mean outcomes before and after treatment in each group

		Diet group	Acupuncture group	Laser acupuncture group	Mixed treatment group	*p*-value*
BMI	Before	30.28 ± 5.08 CI: (28.18,32.38)	29.27 ± 4.11 CI: (27.60,30.94)	33.78 ± 6.22 CI: (31.27, 36.29)	34.11 ± 4.70 CI: (32.09, 36.13)	0.001
	After	28.02 ± 6.08 CI: (25.52,30.52)	26.47 ± 6.17 CI: (23.95,28.99)	32.17 ± 6.15 CI: (29.66, 34.68)	31.53 ± 5.11 CI: (29.41, 33.65)	0.003
	p-value**	0.0001	0.0001	0.0001	0.0001	
Fat mass	Before	30.32 ± 9.75 CI: (26.17,34.47)	28.36 ± 8.58 CI: (25.67,31.05)	36.01 ± 10.16 CI: (31.82, 40.21)	38.49 ± 9.06 CI: (35.75, 41.23)	0.0001
	After	27.47 ± 9.59 CI: (23.53,31.41)	25.43 ± 8.17 CI: (22.10,28.76)	32.76 ± 10.13 CI: (28.93, 36.59)	32.88 ± 9.19 CI: (29.98, 35.78)	0.009
	p-value**	0.0001	0.0001	0.0001	0.0001	
Fat-free mass	Before	46.01 ± 4.67 CI: (44.08,47.94)	46.22 ± 5.05 CI: (44.11,48.33)	51.14 ± 7.11 CI: (48.19, 54.09)	49.16 ± 9.00 CI: (46.43, 51.89)	0.011
	After	43.07 ± 10.22 CI: (39.82,46.32)	42.16 ± 12.55 CI: (36.98,47.34)	50.19 ± 7.24 CI: (47.21, 53.17)	48.16 ± 9.38 CI: (45.34, 50.98)	0.007
	p-value**	0.0001	0.0001	0.004	0.005	

P-value*: between-group comparison, ANOVA test

P-value**: within-group comparison, Paired sample *t*-test

Table 4 Result of GEE analysis for comparing different outcomes in treatment groups

	Parameter	Category	Estimate	SE	*p*-value
BMI	Group	Mixed treatment group	3.67	1.42	0.010
		Laser acupuncture group	3.83	1.60	0.017
		Acupuncture group	− 1.28	1.40	0.360
		Diet group	Ref		–
	Time	–	− 2.31	0.28	0.0001
Fat mass	Group	Mixed treatment group	8.17	2.61	0.002
		Laser acupuncture group	5.69	2.76	0.039
		Acupuncture group	− 1.96	2.54	0.441
		Diet group	Ref		
	Time	–	− 2.85	0.25	0.0001
		Mixed treatment group*Time	− 2.76	0.64	0.0001
		Laser acupuncture group*Time	− 0.40	0.43	0.346
		Acupuncture group*	− 0.08	0.46	0.861
		Diet group*Time	Ref		
Fat-free mass	Group	Mixed treatment group	4.12	2.19	0.061
		Laser acupuncture group	6.12	1.88	0.001
		Acupuncture group	− 0.35	2.01	0.861
		Diet group	Ref		–
	Time	–	− 2.24	0.71	0.002

Ref category: Diet group

GEE analysis was done

group. Therefore, we performed the analysis by removing interaction effects (Table 3). The coefficient of time was estimated as − 2.3, which shows in all groups BMI was reduced more than 2.3 units after the intervention compared to the baseline value (p-value = 0.0001).

For fat mass analysis, the negative significant estimate of the time variable ($b = -2.85$) tells us that the mean fat mass reduces about 2.8 unit after intervention compare to baseline in the diet group. In addition, the only significant p-value for the interaction variable belong to mixed treatment group, which means that patients in mixed treatment group experienced about − 2.76 unit lower mean fat mass than those in the diet group during this study (p-value < 0.0001). These analyses show no significant mean difference between patients in the diet group and those in laser acupuncture and acupuncture groups (p-value = 0.346, p-value = 0.861, respectively).

The group-by-time interaction effect estimated by GEE on the fat-free mass was not significant; therefore, GEE analysis was done without interaction effect. The time effect was − 2.24, which shows in all groups fat mass had the same changes equal to 2.24 as the diet group after intervention (p-value = 0.002).

The study results indicate that all interventions had significant within-group improvements; however, only the mixed treatment led to greater reduction in fat mass compared to diet alone (− 2.76 unit, $p < 0.0001$). No statistically significant differences were observed between the groups for changes in BMI or fat-free mass. Moreover, acupuncture and laser acupuncture groups did not differ significantly from diet group in terms of BMI reduction, fat mass, or fat-free mass (Fig. 3).

In terms of adverse events, patients were queried for experiencing any symptoms, such as nausea, dizziness, headache, and fatigue at each session. Furthermore, adverse events during and after the treatment were monitored by the therapist. There were no observed adverse events or reports during this study.

11 Discussion

11.1 Key Findings

This study encompassed a hundred women distributed across various treatment groups for weight reduction, with no significant difference in mean age or variations in the history of other diseases and lifestyle factors among the groups.

The GEE analysis revealed baseline differences in BMI, fat mass, and fat-free mass among the treatment groups, with higher mean values for the mixed treatment and laser acupuncture groups compared to the diet group. Although the slope of BMI reduction did not significantly differ among the groups, all groups displayed significant within-group reductions in BMI post-intervention, paralleled by similar trends for fat mass and fat-free mass.

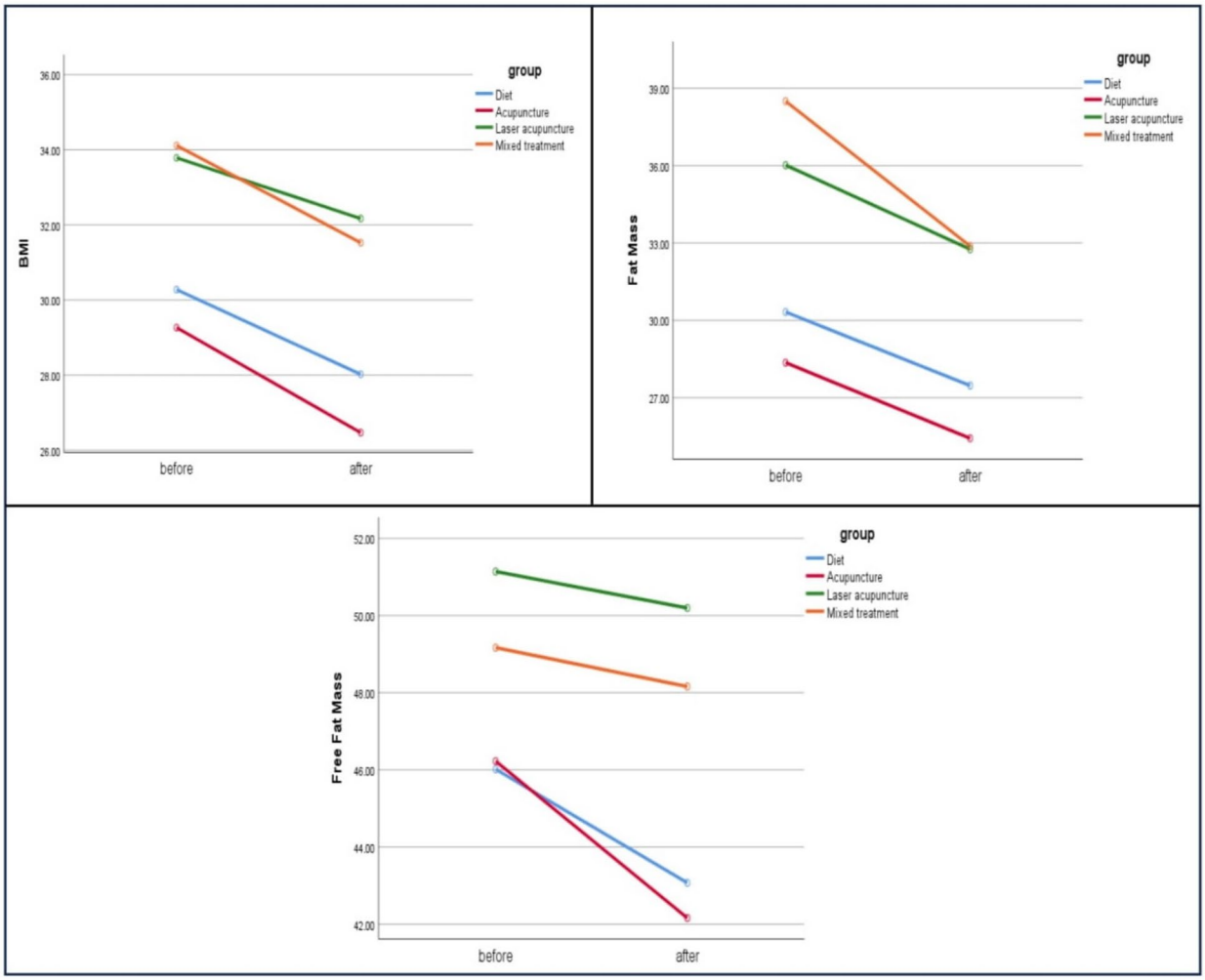

Fig. 3 Comparing trend of BMI, fat mass, and fat-free mass reduction in each group separately

Comparing mean outcomes before and after treatment within each group unveiled significant changes in weight, fat mass, and fat-free mass. Overall, the results of this study suggest that while significant improvements were observed within each group over time, between-group comparison showed that only the mixed treatment group had greater fat mass reduction compared to the diet group. Furthermore, BMI and fat-free mass did not change significantly across groups over time. Therefore, the different treatments had differential effects on BMI, fat mass, and fat-free mass (Fig. 4).

12 Comparison with Prior Works

Previous studies reported that the combination of nutritional intervention with acupuncture or laser acupuncture (LA) appears to be effective in reducing weight, improving lipid profiles, and positively impacting body anthropometry. Additionally, the use of acupuncture alongside lifestyle modification has shown to be more effective in subjects with overweight, rather than those with obesity. Furthermore, the positive effects of LA therapy on various body parameters, including weight, BMI, and appetite, have been consistently observed in several studies. The combination of laser acupuncture and dietary intervention has also demonstrated positive effects on waist: hip ratio, quality of life scores, BMI, and appetite scores in obese patients. These findings support the potential of integrating acupuncture and related therapies with nutritional and lifestyle interventions for weight management and improving overall health outcomes [8, 12–15, 22, 23]. The fat mass reduction observed in the mixed treatment group of our study is consistent with these studies.

It is worth mentioning that the within-group reductions observed in BMI and fat mass across different groups, ranging from 4.8 to 9.6% and 9 to 14.6%, were

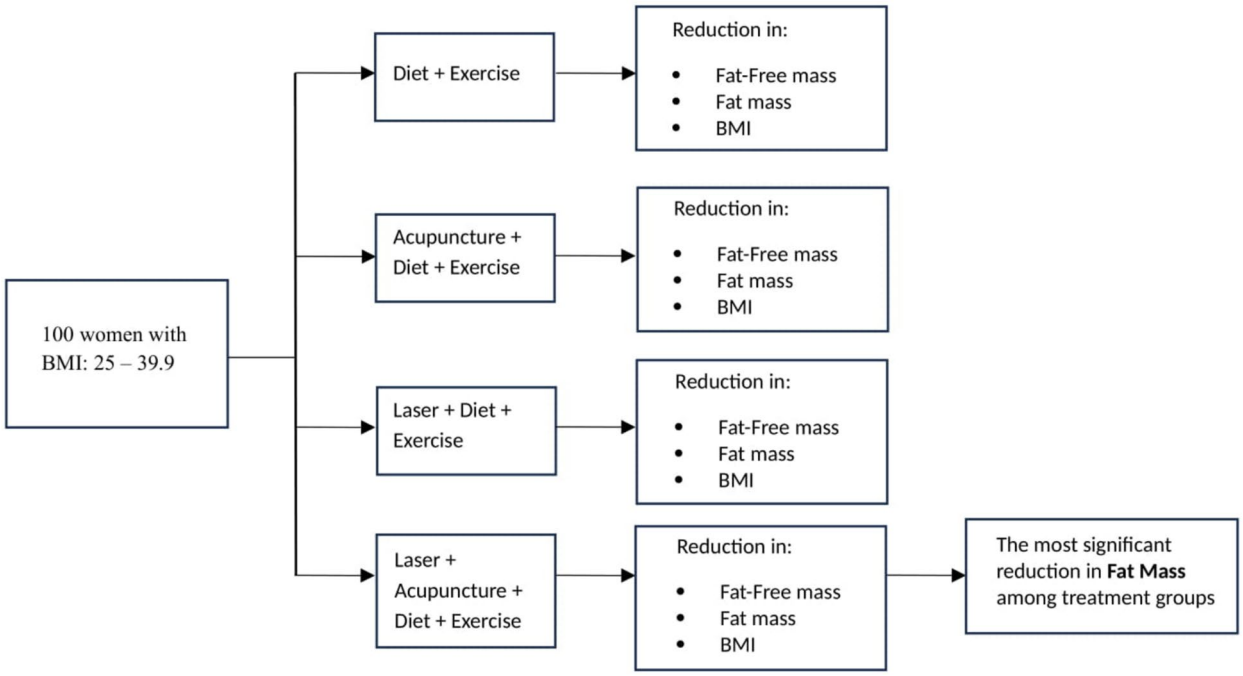

Fig. 4 Summary of the effects of different therapeutic interventions on BMI, fat mass, and fat-free mass

statistically significant and clinically meaningful. This is in line with previous studies which have shown that reducing weight even slightly (5–10%) improves health outcomes, including glycemic measures, lipid profiles, and cardiovascular risk factors [24]. Furthermore, Dhar et al. [25] reported that weight loss of less than 5% of body weight also would favorably impact obesity comorbidities, as well as cardiovascular, inflammatory, renal, and hepatic health. This review suggested that the minimum level of weight loss should not be rigidly set at 5% to be clinically meaningful, and even low-level weight loss can have positive impacts on health outcomes.

13 Mechanisms and Interpretation

Fat mass and fat-free mass are two components of body composition that play distinct roles in human physiology. Fat mass refers to the total amount of adipose tissue in the body, including both essential fat (necessary for normal physiological function) and storage fat (excess fat stores). It serves as an energy reserve, insulation, and protection for organs. On the other hand, fat-free mass, also known as lean body mass, comprises all non-fat tissues in the body, such as muscles, bones, organs, and water. It is metabolically active tissue and contributes to basal metabolic rate, overall strength, and physical functionality. In summary, fat mass represents the total fat content in the body, while fat-free mass encompasses all non-fat components. Understanding the distinction between these two components is crucial in assessing body composition and overall health status [2, 21].

Our results suggest that the mixed treatment approach primarily targeted the reduction or alteration of adipose tissue content, leading to a decrease in fat mass. However, acupuncture or laser acupuncture alone did not demonstrate significant changes in fat mass or other body composition measures compared to the diet group. Some potential reasons for these differences among other studies could be due to the differences in age, race, obesity degree, and fat distribution. Standardized acupuncture protocols, acupuncture techniques, treatment course, outcome measures, and even highly skilled acupuncturist are necessary.

Although previous studies have not investigated the effects of combining acupuncture and laser acupuncture on body compositions, the potential mechanisms of action for each modality have been examined separately.

It has been suggested that acupuncture may impact on FFM and fat mass positively through multiple pathways: regulation of hormonal functions, enhancement of metabolic rates, and modification of appetite. They also added that it can enhance insulin sensitivity and influence key appetite and energy expenditure-regulating hormones, such as leptin and ghrelin. Improved insulin sensitivity may itself enhance glucose metabolism and the mobilization of lipid stores, thereby reducing fat mass while maintaining or increasing fat-free mass

[26]. In addition, acupuncture has been reported to increase metabolic rates. Acupuncture, according to the systematic reviews, may increase resting energy expenditure, thus helping shed fat while preserving lean mass. Acupuncture can facilitate a favorable body composition through an improvement in metabolic functions, particularly the maintenance of FFM in weight loss interventions[27, 28]. Acupuncture may also favorably modulate appetite to promote weight loss. Some studies have reported that patients undergoing acupuncture exhibited reduced hunger and desire to eat, suggesting that this approach may help individuals manage their overall food intake more appropriately. Appetite regulation can result in a decrease in fat mass with the maintenance of lean tissue [29–31]. In summary, while further research is needed to fully elucidate the mechanisms by which acupuncture affects fat-free mass and fat mass, existing studies indicate that it may promote hormonal balance, enhance metabolism, and regulate appetite, leading to favorable changes in body composition by reducing fat mass while maintaining or increasing fat-free mass.

Furthermore, it has been shown that the laser acupuncture modality may modulate neuroendocrine pathways involved in fat metabolism, and also affect hormonal regulation, appetite control, and energy balance. Additionally, the potential anti-inflammatory effects of laser acupuncture and its impact on fat mass, and its role in mitigating chronic low-grade inflammation in adipose tissue, have been explored [32–34]. These inquiries encompass the exploration of potential effects on adipocyte metabolism, lipolysis, and adipokine regulation.

Another possible underlying mechanism for BMI and fat mass reduction is the activation of the autonomic nervous system. Some studies have suggested that acupuncture and laser acupuncture can modulate the autonomic nervous system, and increase sympathetic outflow [35, 36]. This activation can potentially raise the level of energy expenditure and stimulate lipolysis, and as a result facilitate the fat oxidation [37]. Moreover, laser acupuncture can increase skin temperature and microcirculation, which leads to indirect activation of the sympathetic system [38]. While there is some evidence suggesting that laser acupuncture can activate sympathetic system and facilitate the fat oxidation, further research is required to fully elucidate these pathways.

Moreover, research shows that using multimodal methods for weight loss can achieve better results, by targeting both physiological and behavioral pathways [39, 40]. According to a meta-analysis by Kim el al. (41), combining acupuncture, cognitive behavioral therapy, meal replacements, and exercise can cause a moderate weight loss. These results suggest that acupuncture along with cognitive behavioral therapy may yield a positive impact on emotional eating. Furthermore, the combination of acupuncture and pharmacotherapy can improve metabolic and neuroendocrine outcomes. Thus, future research should evaluate the efficacy of integrating these treatments for obesity management.

Lastly, this research considers the combined effects of laser acupuncture with traditional needle acupuncture on fat mass, aiming to investigate whether the integration of these modalities produces additive or synergistic effects on fat metabolism and distribution. These scientific etiologies provide a foundational basis for discussing the specific mechanisms and pathways through which laser acupuncture may exert its effects on fat mass, drawing from the articles and their findings.

The investigation into the effect of laser acupuncture on fat mass aims to elucidate the potential mechanisms underlying this therapeutic intervention. By delving into the physiological pathways influenced by laser acupuncture, researchers seek to uncover its impact on adipose tissue and fat metabolism. Understanding the neuroendocrine modulation and inflammatory pathways targeted by laser acupuncture can provide valuable insights into its role in reducing fat mass.

14 Limitations

This study had some limitations that should be mentioned. The nature of the intervention groups (diet, exercise, acupuncture, and laser acupuncture) made it impossible to blind both participants and therapist. Therefore, the data analyst was blinded to group assignments during the statistical analysis to reduce the bias. Furthermore, this study designated the diet-only group as the control group and no group received a sham intervention (sham acupuncture or sham laser). Since each group received a different type of intervention (acupuncture, laser acupuncture, and both), it was not possible to use a sham intervention in the control group. Also the use of sham interventions was not ethically justifiable in this study.

15 Implications and Future Directions

This study investigated the effects of needle and laser acupuncture on improving BMI, fat mass, and fat-free mass in obese patients. To draw more definitive conclusions and address the aforementioned limitations, future studies with larger sample sizes with a placebo-controlled arm (using a sham intervention) and a wider range of assessment tools are warranted. In addition, future studies could focus on integrating different modalities, such as behavioral therapy and

pharmacotherapy, to achieve better results in managing obesity and its related comorbidities.

16 Conclusion

The findings of our study showed that only the mixed treatment group had a significant reduction in fat mass, whereas laser acupuncture resulted in only a modest within-group reduction. The lack of significant changes in other outcomes highlights the need for further research to clarify the potential effects of laser acupuncture in managing adiposity. Furthermore, exploring the synergistic effects of laser acupuncture combined with traditional needle acupuncture may offer a comprehensive understanding of its implications for fat reduction.

Abbreviations

BMI	Body mass index
FFM	Fat-Free Mass
IL-6	Interleukin-6
TNF-a	Tumor necrosis factor–a
WHR	Waist-hip ratio
GaAlAs	Gallium-Aluminum-Arsenide Laser
GEE	Generalized estimating equations

Acknowledgements
We would like to thank all the patients who participated in our research project in the obesity department of Sina Hospital. We would also like to express our gratitude to Dr. Mahrokh Daemi, general surgery professor at Sina Hospital, for her valuable guidance, and we extend our gratitude to Dr. Somayeh Fatahi, nutrition specialist at Sina Hospital, for her effective collaboration.

Authors' Contribution
AS contributed to patient recruitment, data collection, supervision, and editing. FS and NL contributed to writing the original draft, reviewing, and editing. ZR and FZ contributed to formal analysis, data curation, and visualization. MA contributed to writing the original draft, patient recruitment, data collection, and editing.

Funding
Not applicable.

Declarations

Ethics Approval and Consents to Participate
The study protocol was registered with the Iranian Registry of Clinical Trial (ID: IRCT20111121008146N42) and approved by Shahid Beheshti Medical Science University Authority Research Ethics Board (IR.SBMU.RETECH.REC.1401.544).

Consent for Publication
Not applicable.

Availability of Data and Materials
No datasets were generated or analysed during the current study.

Competing Interests
The authors declare no competing interests.

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Received: 23 February 2025 Accepted: 11 June 2025
Published online: 03 July 2025

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