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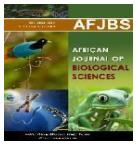

Effect of Cryolipolysis on Cardiovascular Risk Factors in Obese Hypertensive Postmenopausal Women

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Abstract

Background: Abdominal adiposity contributes to an elevated risk of cardiovascular disease (CVD) as well as morbidity in postmenopausal women. Although the diet-exercise program reduces the risk of CVD, the aim of this study was to determine how adding cryolipolysis to the diet-exercise program affected cardiovascular risk factors in obese hypertensive postmenopausal women in order to improve cardiometabolic health outcomes. **Subjects:** This study included 40 postmenopausal women with blood pressure (BP) ranging from 140/90 to 180/110 mmHg, ages ranging from 50 to 60 years, BMI of 30-35 kg/m2, and waist-hip ratio (WHR) of 0.81 to 1.0. They were selected at random to two groups of equal number. For 12 weeks, both the control and study groups received a DASH diet and aerobic exercise three sessions a week, The study group also received one session of cryolipolysis each week for 12 weeks. Weight, body mass index, waist hip ratio (WHR), waist circumference (WC), skin fold thickness, blood pressure (BP), and lipid profile (including cholesterol, LDL-C, HDL-C, and triglycerides) were evaluated before and after treatment. **Results:**After treatment, both the control and study groups detected significant reductions ($p<0.05$) of weight, BMI, WC, WHR, skin fold thickness, BP, cholesterol, LDL-C, HDL-C, and triglycerides. The study group significantly reduced weight, BMI, waist circumference, and skin fold thickness ($p<0.05$) compared to the control group.

Conclusion: Cryolipolysisis an effective adjunctive therapy added to a diet-aerobic exercise programfor reducingweight, WC,BMI,and abdominal fat in obese hypertensive postmenopausal women

Keywords: Hypertension, obesity, cryolipolysis, aerobic exercise, DASH diet, postmenopausal women

Introduction

Hypertension is defined as an arterial blood pressure of 140/90 mmHg or above. Postmenopausal women are more susceptible to hypertension than premenopausal women; around 41% of women suffer from hypertension after menopause. The prevalence is greater in females than males because of the higher age-related increases in females. [1,2].

Menopause is associated with a reduced estrogen level, and its effect on the blood vessels and cholesterol level may lead to restriction andhardness of the arteries due to deposits or plaques of cholesterol [3]. These functional and structural changes in the arteries promote cardiovascular disease (CVD) [4], which the major cause of mortality and morbidity in postmenopausal women [1].

Also, estrogen deficiency has a negative impact on metabolism and causes alterations in the distribution of body fat from gynoid to android patterns. The visceral fat depot increases to 15%-20% of total fat after menopause [5].Weight gain and central obesity have been linked to a statistically elevated risk of hypertension, coronary heart disease, type 2 diabetes and insulin resistance [6]. Menopausal transition is additionally accompanied by changes in the metabolism, dyslipidemia, elevated plasma levels of total cholesterol as well as low-density lipoprotein cholesterol (LDL-C), and lower levels of high-density lipoprotein cholesterol (HDL-C), the incidence of CVD risk increase, especially in women with central obesity, hypertension, or diabetes. [7,8].

According to the National Institute of Health (NIH), dietary modification alone reduces systolic BP from six to eleven mm Hg in both normotensive and hypertensive people. The DASH diet is recommended as a first- pharmacologic therapy in managing hypertension combined with lifestyle modifications. as it improvesanthropometric measurements, lowers BP, and improves blood lipid markers[9].A combination of exercise and diet isrecommended as the most effectiveapproach to achieve significant weight loss and decrease the risk and severity of obesity-associated problems like inflammation, dyslipidemia, hypertension, and CVDand hence improve the cardiometabolic health of individuals[10].

Cryolipolysis is a form of non-invasive therapy that uses freezing to destroy fat cells. Cooling lead to programmed cell death (apoptosis) of the subcutaneous fat tissue, but without damage to the overlying skin. [11].A previous study reported that adding cryolipolysis to the diet regime showed more improvement in waist circumference (WC), liver enzymeand lipid profile in women having central abdominal obesityenhancing the systematic effect [12].

To our knowledge, no previous studies were conducted to assess the influence of including cryolipolysis within a diet-exercise protocol on the CVD factors in hypertensive women. The aim of the study was to determine how adding cryolipolysis to a diet-exercise protocol affected anthropometric measures, blood pressure, and blood lipid levels in obese hypertensive postmenopausal women.seeking to provide better cardiometabolic health outcomes for this population.This study hypothesizedthat cryolipolysisplus diet-exercise program would produce more effects onanthropometric measurements, BP, and lipid profile than the diet-exercise program alone in obese hypertensive postmenopausal women.

Methods

I-Subjects:

The study used a two-group pre-and post-test design.50 obese postmenopausal women were recruited by a physician for the eligibility assessment of this study. They were diagnosed as having hypertension; BP ranged from 140/90 to 180/110 mmHg. Their age varied from 50 to 60 years old, with a BMI of 30-34.9 kg/m2, and WHR was 0.81-1.0 cm. They experienced menopause for at least 1 year. Exclusive criteria included women having scars, hernia, skin diseases in the abdominal area, vaginal bleeding, musculoskeletal problems, previous abdominal operations, or thosewho are on antidepressants, hormonal replacement treatment, or weight loss medications, as well as smokers, anemic, athletic, and diabetic women. Out of 50 women, five failed to meet our inclusion criteria, and five withdrew to join for personal and family reasons. (Fig. 1).

A blinded independent researcher used SPSS software to randomly assign 40 women to two groups of equal size (control and study) by opening sealed envelopes containing computer-generated randomization serially numbered index cards. Both groups received the same antihypertensive drug (Concor 5 mg once daily), a DASH diet, and three 45-minute aerobic activity sessions each week for 12 weeks. In addition, the participants in the study group received 45-minute cryolipolysis sessions in the abdominal region, once per week for 12 weeks. Each patient signed a form of informed consent as well as had the right to withdraw at any time during the study protocol. All women who joined the study completed the assessment and treatment procedures. The sample size was detected employing G*Power, version 3.1.9.7. A prior type of power analysis was utilized with an α error probability of 0.05 and power (1-β error probability) of 0.95. The the minimum sample size required was 32 patients. [13].

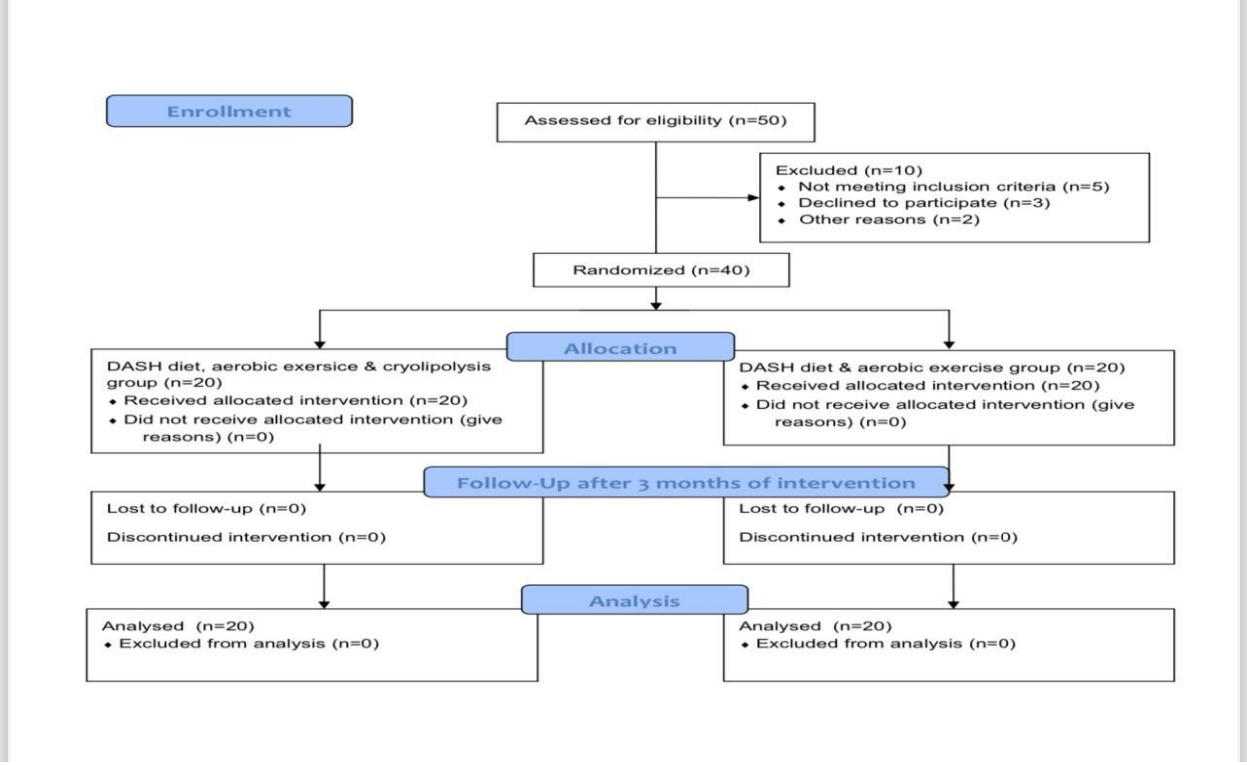

Fig. 1: Flow diagram of the participants included in the clinical trial

Outcomes

1-Anthropometric measures

All women's weight and height were measured using a standard weight and height scale, and BMI was calculated by dividing weight (kg) by height squared (m2). Waist and hip circumferences were measured using a traditional, stretch-resistant tape split into inches and centimeters up to 150 cm in length. A researcher who was blinded to group assignment assessed WC midway between the lower border of the last felt rib and the highest point of the iliac crest at the end of a typical expiration cycle. The hip circumference was measured by wrapping the tape around the widest part of the hips. Each measurement was performed twice, and an average was calculated.Then, WHR was calculated bydividing WCby hip circumference[14].

2-Assessment of skin fold thickness:

A skinfold caliperwas utilizedto assess body fat in the abdominal area. It was a quick, easy-to-use, and very affordable tool for estimating body fat providinginformation about the relative fatness and changes in body composition over time. A blinded researcher used a caliper to measure supra-iliac skinfold thickness in the most prominent part of abdominal fat. Women's skinfolds were pulled diagonally above the iliac crest along the anterior axillary line. At that moment, the skin and subcutaneous tissues were squeezed between the thumb and forefinger and gently pulled away from the underlying muscles. The caliper was then placed over the skin fold and held in place for three seconds while the grasp was maintained, then the value was recorded.The measurement was repeatedthree times, and the average was taken[15,16].

3-Measurement of blood pressure

Systolic and diastolic BP were measured using the auscultatory method. A blinded researcher measured BPfrom the woman's right arm while she was sitting at the same time of day, taking the reading three times and then calculating the mean. All women avoided toparticipate in practicingexercise 24 hoursbefore measuring BP[17].

4-Assessment of lipid profile

After a 9-12 hour overnight fast, postmenopausal women collected 5 ml of venous blood using sterile syringes and transferred it to clean tubes. The blood samples were centrifuged, and the plasma was isolated and refrigerated at -20 degrees Celsius till examination. Serum was then used for biochemical analysis of lipid profiles such as total cholesterol, HDL-C, LDL-C, and triglycerides levels using a spectrophotometer. All measurements were obtained at the beginning and end of the 12-week treatment course.

Intervention

1-Diet regime:

All postmenopausal women followed a DASH diet, which consisted of 20-25% of fat, 20-25% of protein, and 45-50% of carbohydrates. The diet included red meat, sweets, and sugary drinks and emphasized fish, nuts, fruits, vegetables, and whole grains. Diet was high in fiber, potassium, calcium, magnesium, and vitamins A, C, and E.Each woman received 4-5 meals each day, one meal every 3 hours, and drank at least 2 liters of water every day[18].

2-Aerobic exercise:

All postmenopausal women participated in theaerobic exercise program using an electronic treadmill (Pro Hanson), which had the following characteristics: length: 80 cm (204 cm), width: 34 cm (86 cm), weight: 186 kg, speed range: 1-20 miles/hour, incline range: 0-20%, motor:3 horsepower (hp).The warming-up phase started with ten minutes of walking on the treadmill at a speed of 3-4 km/h with zero incline at 40% of maximal heart rate (MHR), calculated as age-220. The actual phase consisted of 25 minutes of walking on the treadmill at moderate intensity (60-75% of MHR) at a speed of 4-5.5 km/h with zero incline. The treadmill's speed was gradually increased. The cool-down phase was walking on the treadmill for ten minutes at a speed of 3 km/h with zero incline and mild intensity (40% of MHR); the speed gradually decreased until it reached zero. The exercise program was performed three times per week for 12 weeks [19].

3- Cryolipolysis:

Postmenopausal women in the study group received cryolipolysissessions to decrease abdominal fat.A cryolipolysis machine with two handles was used; ithad the following characteristics: power output: 738 W, operation manner: continuous, power supply: 220-240 vac50hz, maximum power consumption: 803 VA, dimensions: 550x450x210 mm, weight: 40 kg, temperature range: -10°C to +2°C; power range: -200 to-60 mbar,vacuum modulation: 4% -18%, and work time: 20-80 minutes.

Each woman emptied her bladder to be relaxed throughout the session and assumed a supine lying position. The abdominal region was separated into right and left lower umbilical areas. A cold gel sheet was applied to the abdominal area to prevent skin-freezing complications including burn, bruising, and ecchymosis.A cryolipolysis vacuum was applied on both sides of the infra-umbilicus region, five cm below the umbilicus. The temperature was set to -5°C, and the vacuum was adjusted to the woman's tolerance, which eventually sucked in the treated fat roll. During this motion, the woman felt a strong pull sensation. After the cryolipolysis treatment, a 2-minute massage was applied to reduce discomfort and ecchymosis and to enable the temperature to return to normal. The application was performed for 45 minutes once a week for 12 weeks [20].

Statistical analysis

All of the statistical analyses were conducted utilizing SPSS version 22. Data were reviewed to ensure normal distribution and variance homogeneity. The Kolmogorov-Smirnov test was performed to determine if the data was normally distributed after removing outliers identified by box and whisker plots. In addition, utilizing Levene's test to examine variance homogeneity found no significant difference ($P>0.05$). The demographic features of all the participants in both groups were analyzed utilizing an independent sample t-test. Furthermore, MANOVA was used to determine the differences between both groups before and after intervention, and pairwise comparisons were conducted to detect the significant variations within groups.All statistical tests have a significance level of $P < 0.05$.

Results

According to Table 1, theunpaired t-test reportedno significant differences in the participants' baseline parameters including age ($p=0.078$), height ($p=0.061$),and weight ($p=0.379$).

Table 1. Comparison of baseline characteristics between both control and study groups

Variables	**Control group**	**Study group**	**T-value**	**P-value**
Age (years)	56.2±1.6	57.1±1.5	1.814	0.078^{NS}
Height (cm)	160.5±1.9	158.8±3.4	1.929	0.061 ^{NS}
Weight (kg)	84.6±4.5	83.4±3.9	0.891	0.379 ^{NS}

Data are provided as mean±standard deviation; with p-value: probability value; NS: indicating non-significant.

The control group reported a significant reduction ($p<0.05$) of weight, BMI, WC, WHR, and skin fold thickness, with percentage changes of 12.8%, 12.7%, 13.2%, 11.1%, and 16.9%. The study group reported a significant reduction ($p<0.05$) of weight, BMI, WC, WHR, and skin fold thickness, with percentage changes of 20.7%, 20.5%, 18.7%, 16.3%, and 23.2%. In comparison to the control group, the study group reported significant reduction ($p<0.05$) of weight, BMI, WC, and skin fold thickness, with no significant difference ($p>0.05$) in WHR. However, it revealed more percentage of improvements in all variables.(Table. 2).

Table 2. Comparison of anthropometric measurements and skin fold thickness between both control and study groups

Variables		Control Group	Study Group	F-value	P-value
Weight (kg)	Pre-treatment	84.6±4.5	83.4±3.9	0.794	0.379 NS
	Post-treatment	73.8±4.9	66.1±3.5	31.651	P<0.05 *
	Change %	12.8%	20.7%		
	P-value	P<0.05*	P<0.05*		
Body mass index (BMI) (kg/m^2)	Pre-treatment	32.9±1.4	33.1±1.2	0.349	0.558 NS
	Post-treatment	28.6±1.7	26.3±1.9	17.189	P<0.05 *
	Change %	12.7%	20.5%		
	P-value	P<0.05*	P<0.05*		
Waist Circumference (WC) (cm)	Pre-treatment	96.45±5.8	97.3±3.9	0.295	0.590^{NS}
	Post-treatment	83.6±6.4	79.1±5.9	5.535	0.024*
	Change %	13.2%	18.7%		
	P-value	P<0.05*	P<0.05*		
Waist hip ratio (WHR)	Pre-treatment	0.9±0.04	0.92±0.03	1.999	0.166 NS
	Post-Treatment	0.79±0.05	0.77±0.1	2.775	0.104 NS
	Change %	11.1%	16.3%		
	P-value	P<0.05*	P<0.05*		
Skin fold thickness (cm)	Pre-treatment	51.4±1.8	51.2±1.3	0.118	0.733 NS

	Post-treatment	42.6±3.6	39.3±4.4	6.485	0.015*
	Change %	16.9%	23.2%		
	P-value	P<0.05*	P<0.05*		

Data are provided as mean ± SD, with p-value (probability value), * (significant), and NS (not significant).

In Table 3, The control group reported a significant reduction ($p<0.05$) in systolic and diastolic blood pressure, cholesterol, LDL-C, HDL-C, and triglycerides, with a percentage change of 9.4%, 10.7%, 7.7%, 11.8%, 25.2%, and 21.9%, respectively. The study group reported a significant reduction ($p<0.05$) in systolic and diastolic blood pressure, cholesterol, LDL-C, HDL-C, and triglycerides, with a percentage change of 8.7%, 9.5%, 6.3%, 10.1%, 20.6%, and 22.1%, respectively. In comparison to the control group, the study group reported no significant difference ($p>0.05$) in both diastolic and systolic blood pressure cholesterol levels, LDL-C, HDL-C, as well as triglycerides.

Table 3. Comparison of blood pressure (BP)and lipid profile between both control and study groups.

Variables		Control Group	Study Group	F-value	P-value
Systolic BP (mm hg)	Pre-Treatment	153.3±4.4	152.2±3.9	0.634	0.431
	Post-Treatment	138.9±4.3	139.1±4	0.013	0.910
	Change %	9.4%	8.7%		
	P-value	P<0.05*	P<0.05*		
Diastolic BP (mm hg)	Pre-Treatment	97.8±4.6	98.1±3.4	0.055	0.815
	Post-Treatment	87.3±4.7	88.8±4.2	1.153	0.290
	Change %	10.7%	9.5%		
	p-value	P<0.05*	P<0.05*		
Cholesterol (mg/dl)	Pre-Treatment	227.4±15.3	227.5±15.5	0.101	0.984
	Post-Treatment	210.2±13.6	212.9±14.9	0.370	0.547
	Change %	7.7%	6.3%		
	P-value	P<0.05*	P<0.05*		
LDL-C (mg/dl)	Pre-Treatment	186.1±15.6	184.4±16.1	0.115	0.736
	Post-Treatment	164.3±13.6	165.8±14.8	0.112	0.740
	Change %	11.8%	10.1%		
	P-value	P<0.05*	P<0.05*		
HDL-C (mg/dl)	Pre-Treatment	41.3±5.1	42.7±5.9	0.650	0.425
	Post-Treatment	55.2±6.2	53.8±6.7	0.505	0.482
	Change %	25.2%	20.6%		
	P-value	P<0.05*	P<0.05*		
Triglycerides (mg/dl)	Pre-Treatment	188.9±11.2	185.8±17.4	0.436	0.513
	Post-Treatment	147.4±13.6	144.7±14.2	0.363	0.550
	Change %	21.9%	22.1%		
	P-value	P<0.05*	P<0.05*		

Data are provided as mean ± standard deviation. p-value = probability value; * = significant; NS = non-significant; LDL-C = low-density lipoprotein cholesterol; HDL-C = high-density lipoprotein cholesterol.

Discussion

Changes duringmenopauseincluding weight gain and estrogen deficiency areassociated with several comorbidities including dyslipidemia, hypertension, and insulin resistance, which negatively impact the cardiometabolic health of postmenopausal women.Weight gain that accumulates in the abdomen is associated with a higher incidence of CVD than inother parts of thebody [21].Therefore, this study evaluated the influence of adding cryolipolysisto a diet-exercise program oncardiovascular risk factors in obese hypertensive postmenopausal women.All postmenopausal women noticed substantial improvements of weight, waist circumference, body mass index (BMI), skin fold thickness, WHR, blood pressure, cholesterol, HDL-C, LDL-C, and triglycerides. Women who had cryolipolysis, on the other hand, showed greater improvement in weight, BMI, WC, and skin fold thickness while having no changes in WHR, BP, or lipid markers than their controls.

The findings of the investigation corresponded to a prior investigation, which reported the effective role of both the DASH diet and aerobic exercise in lowering blood pressure and lipid markers, including the amount of total cholesterol, the levels of LDL & HDL-C as well as TG in postmenopausal women[22]. Also, it was reported that dash diet plus exercise induced larger reductions in BP and greater improvement in vascular and autonomic functions than high-protein diet and exercise [23].Moreover, adding exercise to DASH was superior in reducing BP more than DASH diet alone or exercise alone [24]. The content ofthe DASH diet could explain its effect on decreasing the risk of CVD. Higher intakes of vitamin C, calcium, folate, soluble fiber, potassium, magnesium,and phytochemicals like(flavonoids, flavanones, carotenoids, and phytosterols) in the DASH diet can lead to reduction ofBP, increased antioxidant capacity, and benefits to lipid profile, insulin sensitivity, and oxidative stress [25].

Regular exercise is an excellent way to enhancephysical as well as mental well-being in postmenopausal women. Itimproves cardiac muscle function, reduces mild anxiety and tension, reduces arterial pressure, use of insulin and adjusts changes in resting BP [26].Although the process behindexercise-induced lipid alterations is still unclear, exercise enhancesthe consumption of plasma lipidsdecreasingtheir levels. Exercise increaseslipoprotein lipase (LPL) activity, the enzyme which causes chylomicrons and hydrolysis ofLDL-Cand triglyceride in granules. Also, increased expression of ATP-binding cassette transporter A-1 (ABCA1) in macrophages in response to exercise increases plasma HDL-C productionand protects against atherosclerosis[27].

Improvement in weight, BMI, WC, and skin fold thickness in women receiving cryolipolysiswas consistent with previous studies. A single cryolipolysis session for 60 minutes showed a reduction in WC and total body weightin female patients with localized abdominal fat [28]. Also, cryolipolysis for 8 weeks showed a significant reduction in abdominal subcutaneous adipose tissue and skin folds at supra iliac level in adolescents with abdominal adiposity [29]. Moreover, extra fat tissue in the belly, back, and extremitieswas reduced in Asian women and men after

performing cryolipolysis sessions for 12 weeks [30].In addition, cryolipolysis showed a significantly reduced in the amount of superficial fat layer and body contour with no changes in cholesterol and triglycerides in the pig model after three months of treatment [31]. However, cryolipolysis combined with diet reduced systolic and diastolic BP, weight, BMI, fat percentage, WC, fasting blood glucose, and triglycerides compared with a diet alone in postmenopausal women with metabolic syndrome after six months of treatment [32]. In the present study, non-significant differences found between groups in BP and lipid profile may be attributed to the difference in study duration, and design between studies.

Also, the findings agreed with those of theresrarchesthat investigated the influence of adding cryolipolysis to exercise. One study showed thatcryolipolysis plusaerobic exercise for 3 months improvedWC, skin fold thickness, and visceral fat in patients withatherosclerotic CVD[33]. Another study reportedthat cryolipolysis and abdominal exercise reducedbody weight, BMI, WC, WHR, and abdominal central subcutaneous fat in women with central obesity [11].Moreover, a recent study reported thatcryolipolysis and a diet-aerobic exercise program improved abdominal subcutaneous fat compared to diet-aerobic exercise alone in obese subjects [34].Cryolipolysis is a safe, comfortable, and non-invasive way of removing subcutaneous fat that does not cause skin damage or other adverse side effects. [35], which is consistent with our study results.

Limitations

The small sample size of this study limits future research; consequently, a larger sample size is necessary. In addition, the intermediate effects of the combination intervention were assessed only for 12 weeks. As a result, further study is required to examine the long-term effect and follow-up of the combination intervention on BP and lipid profile.In addition, the assessment of adipose thickness is limited to the use of the caliper, so more objective methods such as ultrasound, computerized tomography, and magnetic resonance imaging are required to assess abdominal fat and other body sites.

Conclusion

Accordingly, it could be concluded that adding cryolipolysis to the DASH diet and aerobic exercise was superiortothe diet-exercise programalone in improving weight, BMI, WC,and skinfold thickness. However, there was asimilar influence on BP and lipid profile after 12 weeks of treatment.

Ethical approval

The research was approved by the Ethical Committee for Human Research at Cairo University's Faculty of Physical Therapy (Reference number P.T.REC/012/00388). The study was registered with the Pan African Clinical Trials Registry (PACTR) under the registration number PACTR20235888250839. Women were asked to sign a written permission form before joining part in the study.

Author Contributions

We are four authors for this study, and we completed all of the requirements; no other researchers are involved in this research.

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Conflicts of interest
The authors have declared no conflicts of interest.

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