

ORIGINAL ARTICLE

# Effects of Supervised Aerobic Exercise Training on Weight Loss, Functional Capacity, Quality of Life and Depression Level in Patients With Essential Hypertension: A Non-Randomized Controlled Trial

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## Abstract

**Background:** Hypertension is a major risk factor for cardiovascular disease, and aerobic exercise is recommended as complementary therapy for its management. This study aimed to evaluate the effects of a supervised aerobic exercise program on weight loss, functional capacity, quality of life (QoL), and depression level in patients with essential hypertension.

**Methods:** A non-randomized controlled trial with patient preference allocation was conducted. The participants were assigned to either a supervised aerobic exercise group (n = 91) or a control group (n = 47). The exercise group underwent a six-week supervised aerobic training program (five sessions per week), while the control group maintained their usual lifestyle. Outcome measures, including resting blood pressure, weight, body mass index (BMI), lipid profile, functional capacity (6-minute walk test, 6 MWT), QoL (SF-36), and depression level (Beck Depression Inventory, BDI), were assessed at baseline and after six weeks.

**Results:** The supervised aerobic exercise group showed significant improvements in the 6 MWT distance, SF-36 subscales (physical function, role physical, vitality, role emotional, and mental health), and reductions in resting systolic blood pressure, weight, BMI, and BDI scores compared to the control group ( $p < 0.05$ ). Within-group comparisons further confirmed significant improvements in physical and mental health measures post-intervention ( $p < 0.01$ ).

**Conclusion:** A 6-week supervised aerobic exercise program significantly enhanced functional capacity, QoL, and mental health in patients with hypertension. These findings support supervised aerobic exercise as an effective complementary therapy for hypertension, promoting both physical and mental well-being with no reported adverse effects.

**Keywords:** Supervised aerobic exercise, functional capacity, quality of life, depression level, essential hypertension.

## INTRODUCTION

Hypertension is the most common and modifiable cardiovascular disease (CVD) risk factor for cardiovascular disease due to stroke, myocardial infarction, and sudden death (1). Despite the availability of effective pharmacological treatments and guideline-based management strategies, a sizable portion of the hypertensive population still fails to achieve optimal blood pressure control (2). However, this underscores the need to explore complementary and alternative therapeutic approaches rather than relying solely on traditional methods. While pharmacological interventions remain a cornerstone of hypertension management, incorporating alternative strategies such as supervised aerobic exercise training may offer additional benefits and help address the persistent challenges in achieving satisfactory blood pressure control (2). In contrast, sedentary behavior is positively associated with higher blood pressure levels (3).

Sedentary lifestyles pose significant health risks across all age groups (4, 5). Low physical activity is a strong predictor of future cardiovascular morbidity and mortality in patients with hypertension (6, 7). Many researchers have shown that a single episode of exercise can reduce blood pressure (BP), and physically active individuals have a lower risk of becoming hypertensive than sedentary individuals (8, 9). Physical activity has a positive effect on hypertension by activating the sympathetic nervous system, endothelial function, insulin sensitivity, and renin-angiotensin system (10). Regular exercise, mainly aerobic exercise, is a critical modifiable behavioral determinant of hypertension and is recommended as a complementary therapy for the prevention and treatment of hypertension (1).

A meta-analysis of 26 randomized controlled studies (RCS) concluded that aerobic exercise is effective in reducing clinical BP in hypertensive subjects (-8.3 mmHg, systolic blood pressure (SBP), and -5.2 mmHg diastolic blood pressure (DBP)) with training sessions conducted 2–3 times per week, lasting 30–45 min, and with moderate intensity (11). Therefore, aerobic exercise is recommended by current American and European hypertension guidelines to reduce BP (12). Previous studies have reported that patients with hypertension have low long-term compliance with exercise programs (13). Poor adherence to exercise as an antihypertensive therapy underscores the need for supervised aerobic exercise training to increase motivation to exercise, which may

favorably impact adherence among patients with hypertension (13).

Other benefits of aerobic exercise training in patients with hypertension include positive effects on cardiovascular health, including functional capacity, weight loss, quality of life (QoL), and depression level. A significant factor in the effectiveness of aerobic exercise is its positive effect on functional capacity, which results in improved prognosis and survival after a diagnosis of hypertension (14). Functional capacity following a cardiovascular event is a strong independent predictor of mortality (15). Aerobic training includes interventions specifically addressing weight loss, such as high-calorie energy expenditure exercise training (16–18). A few studies examining the effect of aerobic exercise training on weight and QoL have shown that decreases in body mass index (BMI) also resulted in significant improvements in QoL (17, 19). According to a meta-analysis of 33 studies, the QoL of hypertensive patients is worse than that of normotensive individuals (20). Previous studies have indicated that psychological distress is a significant risk factor for CVD, such as hypertension, and adversely affects recovery after hypertension (17, 21). Many studies have shown that aerobic exercise has potentially positive effects on some psychiatric conditions such as anxiety and depression (19, 22). Although important, the effect of a supervised aerobic exercise training program on weight loss, functional capacity, QoL, and depression level in hypertensive subjects has been poorly investigated (17, 19, 23), and none of the studies have examined all these parameters collectively in the same patient group (24, 25).

The present trial aimed to evaluate the effects of a supervised aerobic exercise training program on weight loss, functional capacity, QoL, and depression level in patients with essential hypertension.

## MATERIALS AND METHODS

### *Study Population*

The study included 155 patients who had been diagnosed with controlled arterial hypertension (essential hypertension) more than one year prior and had been taking the same anti-hypertensive medication for a minimum of three months. Essential hypertension was diagnosed according to the criteria outlined (BP  $\geq$ 140/90) in the Association for the Advancement of Medical Instru-

mentation/European Society of Hypertension/International Organization for Standardization Guidelines (26). The inclusion criteria were as follows: age > 18 years and the absence of concomitant metabolic and cardiovascular diseases. Exclusion criteria were: having suffered an event of ischaemic heart disease (<6 months), secondary hypertension, hypertrophic obstructive cardiomyopathy, congestive heart failure, uncontrolled cardiac arrhythmia, thyroid dysfunction, diabetes mellitus, symptomatic peripheral arterial occlusive disease, aortic insufficiency or stenosis, pulmonary or heart disease with dyspnoea at small or moderate effort, an outbreak of orthopedic problems on hip, knee or ankles, such as arthroplasty, contracture or severe osteoarthritis, using of antidepressant or anxiolytic drugs, pregnancy, cognitive dysfunction. The patients signed an informed consent form before inclusion in the study.

The study was approved by the local ethics committee (No.2016/196), and the Helsinki Declaration was taken into consideration. Written informed consent was obtained from each patient before participation in the study. The study protocol was registered and made public at ClinicalTrials.gov (NCT05987436).

### **Procedure and Intervention**

The participants were followed up for routine management of diet, weight, and BP. No antihypertensive medication changes were made during the study period of 6 weeks. There was no randomization of the type of treatment or of the patients to be chosen. A supervised aerobic exercise training program was administered to patients who were accepted for inpatient treatment for six weeks. Patients who chose the treatment type according to personal preferences were divided into two groups:

1. The supervised aerobic exercise group (Group 1) exercised for six weeks, involving once per day, five sessions per week, under the supervision of a medical doctor and a nurse in the aerobic exercise laboratory. The aerobic exercise training program lasted six weeks, and the patients lived in the hospital for the entire period. Aerobic exercise training was performed on cycle ergometers (Ergoline, Ergoselect II 100/200/Reha, Germany) equipped with a computed ergometer and developed to monitor electrocardiography (ECG), heart rhythm, and BP. Each session consisted of a 5-minute warm-up, followed by 50 min of aerobic exercise with an intensity of 50–70% of heart rate reserve, calculated using the

Karvonen formula, and ended with a 5-minute cool-down period (27).

2. The participants assigned to the control group (Group 2) were advised to maintain their dietary habits and physical activity levels, and an aerobic exercise program was provided to them after completing the study. No aerobic exercise program was administered in the control group.

### **Blood Pressure**

After ten minutes of resting in a supine position, office BP was measured from the brachial artery using a mercury sphygmomanometer (ERKA D-83646 Bad Tolz, Kallmeyer Medizintechnik GmbH Co. KG, Germany) by the same physician. Exercise Stress Test All patients in Group 1 performed the exercise test on a treadmill following the Bruce Protocol with continuous 12-lead electrocardiograph recording (Cambridge Heart, Inc. Exercise System CH 2000, GB) before initiating the aerobic training program (28). For each patient, test readings were recorded with 12-derivated ECG at the beginning, every 3 min during the test, and at the 2nd minute of the resting period.

### **Outcome Measures**

A detailed history and physical examination were obtained, including that of the patients in the study. All participants completed the questionnaire, which gathered demographic data (age, sex, marital status, education level, and occupation). Baseline body weight (using calibrated electronic digital scales [Oncomed; SC-105, California, America]) was measured at the pre-treatment period and after post-treatment 6th week for all participants by the same physician.

Serum total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, very-low-density lipoprotein (VLDL) cholesterol, and triglycerides were measured using standard enzymatic kits during the pre-treatment and post-treatment periods for all participants. Twelve-hour fasting blood samples were collected between 6.00 am and 10.00 am at baseline and at week 6.

The functional capacity, QoL, and depression level of all the participants were evaluated by the six-minute walk test (6MWT), Short Form-36 (SF-36), and Beck Depres-

sion Inventory (BDI), respectively from face-to-face interviews at the pre-treatment and the post-treatment. These instruments were recorded by the same physician who was blinded to the type of treatment for each patient.

### ***Assessment Of Functional Capacity***

The 6 MWT and estimated metabolic equivalents (METs) were performed to evaluate functional capacity. The 6 MWTs were performed along a flat, 30-meter-long hospital corridor with marks at 3 m intervals for all participants. The 6 MWT was supervised by a medical practitioner.

### ***Assessment Of QoL***

The SF-36, which was used to evaluate QoL, consists of 36 questions and two components. The physical component summary comprises four domains (physical function, physical role, bodily pain, and general health), and the other four comprise the mental component summary (vitality, emotional role, social function, and mental health). Scores range from 0 to 100, with higher scores indicating a better QoL (29).

### ***Assessment Of Depression Level***

The BDI was used to assess participants' depression levels. The BDI is a 21-item self-reporting questionnaire. The questionnaire consisted of four statements. These statements were graded on a scale of 0 to 3 (30). A score higher than 17 indicated the presence of depression.

### ***Statistical Analyses***

Kolmogorov-Smirnov normality tests were conducted for all continuous data. Comparisons between pre- and post-treatment values were evaluated using the Student's dependent samples t-test. Nonparametric Mann-Whitney or Chi-square tests ( $\chi^2$ ) were performed to compare sociodemographic and clinical measures between the two groups. All categorical variables were described as percentages, whereas means and standard deviations were reported for continuous variables. The level of significance was set at  $p < 0.05$ . All analyses were conducted using IBM SPSS 23.

## **RESULTS**

None of the patients received any treatment other than that described earlier, and no complications were observed. This study included 138 patients (Figure 1). There were 91 patients in group 1 and 47 patients in group 2. There were no statistically significant differences between the two groups in terms of age, sex, marital status, educational level, or occupation. The demographic and clinical characteristics of the patients are presented in Table 1.

### ***Between-Groups***

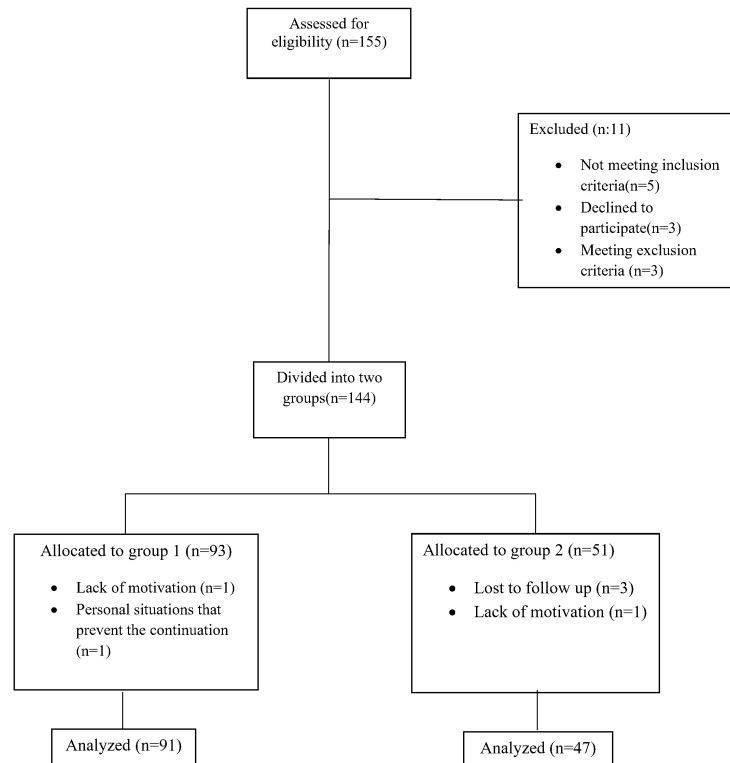
There was a significant difference in total cholesterol, LDL levels, and role physical scores during pre-treatment between the two groups ( $p=0.01$ ,  $p=0.002$ , and  $p=0.007$ , respectively). A comparison of resting SBP, resting DBP, resting heart rate, weight, body mass index (BMI), total cholesterol, HDL, LDL, VLDL, triglycerides, and 6 MWT scores between the two groups before and after treatment is shown in Table 2. When the two groups were compared, a significant increase in the 6 MWT distance and SF-36 subscales, including physical function, role physical, physical component summary, vitality, role emotional, mental health, and mental component summary, was found in Group 1 after the post-treatment ( $p < 0.05$ ).

### ***Within-Groups***

Resting SBP, resting DBP, resting heart rate, weight, BMI, total cholesterol, HDL, LDL, VLDL, triglycerides, and 6MWT scores between pre-treatment and post-treatment sixth week in both groups are shown in Table 2.

There was a significant reduction in resting SBP, weight, BMI, and BDI scores between the pre-treatment and post-treatment groups in Group 1 ( $p < 0.05$ ). There was a significant increase in the 6 MWT and SF-36 subscales of physical function, physical role, physical component summary, vitality, emotional role, and mental component summary scores between pre-treatment and post-treatment in Group 1 ( $p < 0.05$ ). There was a significant increase in the SF-36 subscales of role physical and mental health scores between pre- and post-treatment in Group 2 ( $p < 0.05$ ).

Figure 1, Flow chart of the study



**Figure 1:** In the flow chart, under the heading ‘Excluded’, the 3rd premise is incomplete. it should be ‘ - Meeting exclusion criteria (n=3)’.

## DISCUSSION

This study has shown that supervised aerobic exercise training for 6 weeks can reduce resting SBP, weight, and depression levels, and increase functional capacity and QoL in patients with essential hypertension. The supervised aerobic exercise training group showed better functional capacity and QoL than the control group among patients with essential hypertension. Collectively, our findings indicate that supervised aerobic exercise should be recommended for its benefits in patients with essential hypertension.

Aerobic exercise is the cornerstone of lifestyle recommendations in current hypertension guidelines (31). A meta-analysis of 28 RCTs concluded a mean reduction in SBP of 12 mmHg, thus supporting the antihypertensive effects of aerobic exercise (32). Tabara et al. (33) found that aerobic exercise could lower the resting SBP by 5–15 mmHg and resting DBP by 4–9 mmHg in patients with essential hypertension. In the present study, we found that the supervised aerobic exercise training of 6 weeks duration reduced resting SBP by  $4.4 \pm 12.8$

Table 1. Demographic characteristics of Group 1 and Group 2

	Group 1 (n=91)	Group 2 (n=47)	P value
Age (years)	59.36±6.22	59.14±7.75	0.861
Gender			0.783
Female	79 (86.8%)	40 (85.1%)	
Male	12 (13.2%)	7 (14.9%)	
Marital status			0.926
Married	73 (80.2%)	37 (78.8%)	
Single	1 (1.1%)	1 (2.1%)	
Widower	16 (17.6%)	8 (17%)	
Divorced	1 (1.1%)	1 (2.1%)	
Education level			0.651
No formal education	17 (18.7%)	9 (19.2%)	
Primary school	67 (73.6%)	34 (72.3%)	
Secondary school	1 (1.1%)	0	
High school	2 (2.2%)	0	
University	4 (4.4%)	4 (8.5%)	
Occupation			0.622
Housewife	83 (91.2%)	45 (95.8%)	
Officer	4 (4.4%)	1 (2.1%)	
Work requiring physical effort	4 (4.4%)	1 (2.1%)	

mmHg and resting DBP  $2\pm 12.8$  mmHg in patients with hypertension. There was no reduction in resting BP in the control group.

Obesity predisposes all age groups to CVD by increasing blood pressure, plasma lipid levels, and causing a sedentary lifestyle (17, 34). According to previous studies, obese patients may acquire significant health benefits from improvements in physical activity levels and weight changes (17, 35). Weight reduction with aerobic exercise

training has significant effects on increasing functional capacity, QoL, and psychological health (17, 19). There is strong evidence in the general population that physical activity is a determining factor for the decrease and maintenance of healthy weight (19). A RCT with a physical activity program of 165-220 min/week with hypertensive patients reported a significant reduction in body weight (-1,8 kg) and BMI (-0,6 kg/m<sup>2</sup>), results for the present study (-3,2 kg and -1,2 kg/m<sup>2</sup>, respectively) were better



Table 2. Clinical and functional outcomes after treatments and changes from baseline values

Group 1 (Aerobic exercise) (n=91)				Group 2 (Control) (n=47)		
	Pre-treat- ment	Post-treat- ment	Change	Pre-treat- ment	Post-treat- ment	Change
Resting SBP (mm Hg)	119.7±11.9	115.2±6.7	-4.4±12.8 <sup>a</sup>	116.3±5.2	117±5	0.6±3.8
Resting DBP (mm Hg)	74.1±11.6	72±6.8	-2±12.8	71±2	71.6±3	0.6±3
Resting heart rate (beats/min)	78.5±9.8	77.1±8.4	-1.3±8.9	76.5±7.8	76.4±7	0±2.2
Weight	87.3±13.9	84.1±13	-3.2±2.1 <sup>c</sup>	84.5±11.9	84±11.6	-0.51±1.1
BMI	34.8±5.2	33.5±4.9	-1.2±0.8 <sup>c</sup>	32.9±4.8	32.5±4.6	-0.4±0.4
Total cholesterol (mg/dl)	196.5±37.6	192.3±44.5	-4.1±39	213.7±36.3	210.8±37.5	-2.9±21.1
HDL (mg/dl)	44.5±9.8	45.1±9.9	0.6±6.6	44.4±11.2	43.4±9.8	-1±4.2
LDL (mg/dl)	118.8±29.6	117.5±33.6	-1.3±31.8	135.7±33	133.9±33.7	-1.8±16.1
VLDL (mg/dl)	34±18.8	31.3±12.1	-2.7±16.4	33.4±15	31.4±14.1	-2±9.6
Triglycerides (mg/dl)	168.8±95.8	156.3±60.7	-12.5±83.3	162.7±68.8	160.2±72.2	-2.5±43.7
6MWT (m)	376.1±53.4	424.9±76.3	48.7±53.3 <sup>c,f</sup>	365.2±57.1	354.5±87.3	-10.7±3.6
SF-36						
Physical function	37.3±21.9	53.4±22.1	16±18.5 <sup>c,e</sup>	40.3±21.9	42.6±24.1	2.3±12
Role physical	26.3±37.7	57.6±44.5	31.3±40.4 <sup>c,f</sup>	9.5±26.8	19.1±38.3	9.5±26.8 <sup>a</sup>
Bodily pain	47.6±21.1	45.9±19.1	-1.7±24.4	45.5±18.7	41.4±13	-4.1±13.1
General health	52.5±15.3	54.1±14.1	1.5±11.8	57.3±9	56.4±10.1	0.8±5.2
Physical component summary	40.9±15.4	52.4±16.6	11.4±12.2 <sup>c,f</sup>	40.7±9	42.3±11.5	1.6±6.6
Vitality	46.7±14	51.2±15.4	4.5±13.3 <sup>b,d</sup>	45.1±13.3	45.2±12.4	0.1±4.1
Social function	54.5±22.7	56.5±22.2	2±17.7	51±22.2	49.2±18.3	-1.8±8.2
Role emotional	27.4±36.7	59±43.5	31.5±44.2 <sup>c,f</sup>	17.7±33.9	19.8±39.1	2.1±37
Mental health	56.7±14.6	58.8±15.1	2±12.2 <sup>e</sup>	51.4±10.1	53.5±10.2	1.1±3.1 <sup>a</sup>
Mental component summary	46.3±13.4	55.9±16.9	9.5±13 <sup>c,f</sup>	43.7±8.5	42.6±12	-1.1±9
BDI	14.9±9.3	10.7±8.2	-4.2±5.2 <sup>c</sup>	13.6±10	13.1±9.9	-0.4±1.9

**SBP:** Systolic blood pressure, **DBP:** Diastolic blood pressure, **BMI:** Body mass index, **HDL:** High-density lipoprotein, **LDL:** Low density lipoprotein, **VLDL:** Very-low-density lipoprotein, **6MWT:** Six-minute walk test, **SF-36:** Short Form-36, **BDI:** Beck Depression Inventory.

Within-group differences: <sup>a</sup> P < 0.05; <sup>b</sup> P < 0.01; <sup>c</sup> P < 0.001. Between-group differences (As compared to the pre-treatment and the post-treatment 6th week): <sup>d</sup> P < 0.05; <sup>e</sup> P < 0.01; <sup>f</sup> P < 0.001.

than in that study (33). In this study, while weight reduction in the supervised aerobic exercise training group was 3.6%, there was a 0.6% reduction in body weight in the control group over six weeks. Based on the results of this study, we consider that supervised aerobic exercise training as a physical activity can be more successful in weight loss in patients with hypertension.

Exercise training has also been shown to reduce triglyceride and LDL cholesterol levels and increase HDL cholesterol levels (36, 37). It has not yet been established how much aerobic exercise is required in order to improve lipid levels (38). According to previous studies, the duration of aerobic exercise for improvement of serum lipid levels is mostly eight weeks or more (39). In the present study, we found that supervised aerobic exercise training increased HDL cholesterol by 0,6 mg/dl, and reduced LDL cholesterol and triglycerides by 1,3 mg/dl and 12,5 mg/dl, respectively after 6 weeks. However, these differences were not statistically significant. If the aerobic exercise duration is longer than six weeks, lipid levels can be more positively affected.

Previous studies have shown that an improvement in functional capacity is an important predictive marker of survival in cardiovascular diseases (15, 17). Using the 6 MWT, there was an increase of 48 months (12.8%) in the supervised group at the end of 6 weeks, while there was an increase of 10 months (2.7%) in the control group. According to these results, functional capacity improved approximately five times in the supervised aerobic exercise training group compared to the control group for hypertensive patients. In view of the considerable impact that an increase in functional capacity has on the health of hypertensive patients, supervised aerobic exercise training should be recommended.

Two RCTs with hypertensive patients reported that there is a positive effect of physical activity on QoL (24, 25). Specific designs of physical activity programs aimed at improving QoL and adherence to exercise have been reported, such as counseling, supervision, and group interventions (19). In this study, when the two groups were compared, the benefits of supervised aerobic exercise training on QoL were observed in some domains, such as physical function, role physical, physical component summary, vitality, role emotional, mental health, and mental component summary after six weeks for hypertensive patients. It seems that supervised aerobic exercise training, such as in the present study, has had

favorable effects on the QoL of hypertensive patients.

Previous studies show that psychological distress plays an essential role in the pathogenesis and prognosis of CVD (17, 21). Physical activity such as aerobic exercise has potentially beneficial effects on psychological status (19, 22). The sense of well-being associated with aerobic exercise training may be related to the release of neurotransmitters, which act at the brain level and increase the feeling of well-being (19). Weight loss due to aerobic exercise training may contribute to these reduced levels (17). In this study, during 6 weeks, while the reduction in BDI score in the supervised aerobic exercise training group was  $4.2 \pm 5.2$ , there was a  $0.4 \pm 1.9$  reduction in the BDI score in the control group in patients with hypertension. Although there was no significant difference between the two groups in terms of depression levels, a noticeable improvement was observed in the supervised aerobic exercise group compared to pre-treatment.

Several potentially important limitations of this study deserve attention. First, there was no randomization of the type of treatment or the patients to be chosen. All patients were allocated to the experimental group according to their desire to participate in the supervised aerobic exercise or control group. This situation has the potential for self-selection bias, as patients choose their treatment groups based on personal preferences. This may have influenced the outcomes and limited the generalizability of our findings. Second, the present study had no long-term follow-up assessments, making it impossible to determine if the observed short-term improvements were maintained in the long term. Third, the comparison groups were subjected to different conditions. Hospitalized patients had a controlled lifestyle, with regular hospital meals and monitored BP. Randomized studies and long-term follow-up assessments may better demonstrate the effectiveness of supervised aerobic exercise training in patients with hypertension.

The findings of this study demonstrate that a 6-week supervised aerobic exercise program provides significant benefits to patients with essential hypertension. Participants in the exercise group experienced a 12.8% increase in the 6-minute walk test distance, substantial improvements in multiple SF-36 subscales related to quality of life, a mean reduction of 4.4 mmHg in resting systolic blood pressure, an average weight loss of 3.2 kg, and a notable decrease in Beck Depression Inventory scores. These results highlight the positive impact



of supervised aerobic exercise on functional capacity, cardiovascular health, weight management, and mental wellbeing. The structured and supervised nature of the program may have contributed to better adherence and improved outcomes than unsupervised interventions. Given the absence of adverse events and their beneficial effects on metabolic outcomes, functional capacity, and overall well-being, supervised aerobic exercise should be recommended as an effective complementary lifestyle therapy for hypertensive patients. These findings also have important implications for the design of exercise programs tailored to patients with hypertension, emphasizing the role of structured exercise interventions in managing the condition.

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#### Abbreviations list

**6-MWT:** 6-minute walk test  
**BDI:** Beck Depression Inventory  
**BMI:** Body Mass Index  
**BP:** Blood pressure  
**CVD:** Cardiovascular disease  
**DBP:** Diastolic Blood Pressure  
**ECG:** Electrocardiography

**HDL:** High-density lipoprotein

**LDL:** Low-density lipoprotein

**QoL:** Quality of life

**RCS:** Randomized Controlled Study

**SBP:** Systolic Blood Pressure

**SF-36:** Short form 36

**VLDL:** Very-low-density lipoprotein

#### Ethics approval and consent to participate

This study was approved by Selcuk University Faculty of Medicine local ethics committee (No.2016/196). The research protocol adhered to the principles of the Helsinki Declaration. The study protocol was registered on ClinicalTrials.gov (NCT05987436). As this study did not involve animal subjects, no statement on ethical approval for animal research is required.

#### Consent for publication

Written informed consent was obtained from all participants prior to enrollment.

#### Availability of data and materials

The physical data collected in the study are securely stored in physical form. Access to the data is provided in accordance with research ethics guidelines and legal regulations concerning the protection of personal data. Data sharing is possible under the condition that the requesting researcher complies with ethical standards and obtains the necessary institutional approvals. Requests for access should be made by contacting the corresponding author.

#### Competing interests

All of the authors had no conflict of interest.

#### Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

#### Authors' contributions

Idea/Concept: IA, FL. Design: IA, FL. Control/Supervision: IA, EBB, FL. Data Collection And/Or Processing: HK, IK, AG. Analysis And/Or Interpretation: IA, EBB. Literature Review: IA, HK. Writing The Article: IA, HK. Critical Review: FL. References And Fundings: IA. Materials: EF. Other: IK, AG, EBB.

#### Acknowledgements

None.