Hüzmeli *et al.*
BMC Sports Science, Medicine and Rehabilitation (2025) 17:29
https://doi.org/10.1186/s13102-025-01082-w

BMC Sports Science,
Medicine and Rehabilitation

RESEARCH **Open Access**

The effectiveness of functional inspiratory muscle training on exercise capacity and peripheral muscle strength in patients with essential hypertension: a three-arm randomized controlled trial

İrem Hüzmeli[1*], Nihan Katayıfçı[1], Büşra Abay[2], Oğuz Akkuş[3] and Aysel Yıldız Özer[4]

Abstract

Background The effect of inspiratory muscle training (IMT) applied along with function in Hypertension (HT) patients is uncertain. In this study, it was to determine the effectiveness of functional IMT (F-IMT) on functional lower and upper exercise capacity, mobility, peripheral and respiratory muscle strength, blood pressure, fatigue, physical activity, and quality of life (HRQoL) in HT patients.

Methods Prospective, randomized controlled, assessor-blinded, parallel three-armed trial. Forty-five patients with HT were divided into F-IMT group (IMT with 50% maximal inspiratory pressure (MIP)/4 weeks + exercise and IMT with 50% MIP/4 weeks, $n = 15$), IMT group (MIP 50%, $n = 15$) and control group (CG, breathing exercises, $n = 15$). 6-min walking test (6-MWT), 6-min pegboard ring test (6PBRT), 1-min sit to stand test (1STS), mobility, peripheral muscle strength, MIP, maximal expiratory pressure (MEP), systolic& diastolic blood pressure (SBP, DBP), fatigue, physical activity, and HRQoL were evaluated before and after 8 weeks of training.

Results Increases in 6-MWT were higher in F-IMT ($p < 0.001$). 6PBRT, 1STS, quadriceps femoris strength were improved and SBP reduced in F-IMT and IMT than CG ($p < 0.001$). Mobility, handgrip, HRQoL, and physical activity level increased within groups ($p < 0.05$). MIP increased within F-IMT and IMT; MEP, fatigue, DBP improved only within F-IMT ($p < 0.05$).

Conclusions F-IMT is more effective in enhancing exercise capacity, reducing fatigue and DBP, and improving MEP. Both IMT and F-IMT show similar benefits for upper extremity exercise capacity, quadriceps femoris strength, SBP, and MIP. Mobility, HRQoL, and physical activity levels are increased with F-IMT, IMT, and breathing exercises.

Trial registration ClinicalTrials.gov Identifier: NCT06343246 (03/29/2024).

Keywords Arterial blood pressure, Respiratory muscle training, Exercise test, Physical activity, Quality of life

*Correspondence:
İrem Hüzmeli
fztirem@gmail.com
Full list of author information is available at the end of the article

Introduction

Hypertension (HT) is the leading modifiable risk factor worldwide, affecting approximately one-third of the world's population [1]. HT can cause structural and functional changes in target organs, causing many problems such as low exercise capacity, lack of movement, impaired postural balance and peripheral muscle weakness [2–4]. Treating HT is imperative given its widespread occurrence; lifestyle changes are crucial for both the prevention and treatment of HT [1]. These changes not only help to control blood pressure but also improve cardiovascular and overall health problems that occur due to HT [1].

Non-pharmacologic interventions have proven effective in lowering blood pressure levels among patients with HT; the main ones are healthy eating, positive behavioural changes, and training programs covering various breathing and exercise techniques [5]. Exercise is an important treatment method for reducing the risk of cardiovascular disease (CVD) and for preventing, treating, and controlling HT [4–6]. Although eight weeks of moderate-intensity aerobic exercise is recommended in the non-pharmacological treatment of hypertension (HT), exercises of different intensities are still being investigated [7]. A meta-analysis by Zheng et al. found that incorporating exercise into standard care improved functional capacity in individuals with HT. Specifically, dynamic aerobic and resistance exercises showed consistent improvements, and further research is needed to explore the potential benefits of body-mind therapies and inspiratory muscle training on VO_{2max} and the 6-min walk test [8]. Besides the exercises, it is recommended to implementing stress management strategies like meditation, deep-breathing exercises, yoga, and ensuring adequate sleep, is vital for arterial health [9]. The same situation also applies to respiratory exercise studies performed with and without load [10]. The respiratory muscles play a crucial role beyond driving respiration and, essential for postural control and core stabilization, which are key to performance and injury prevention. However, the dual roles of these muscles can conflict, leading to dyspnoea disproportionate to the ventilatory demand and compromising their effectiveness in core stabilization. Inspiratory muscle training (IMT) has emerged as a vital element in HT rehabilitation that serves as an innovative approach to physical activity. The mechanism underlying IMT's blood pressure-lowering effect may involve the central respiratory network, potentially through influencing sympathetic nerve drive and vagus nerve activity. Increased inspiratory muscle strength, facilitated by IMT, most likely enhances cardiopulmonary coupling, thus contributing to its efficacy [8]. Individuals with essential hypertension and patients with isolated systolic hypertension who have high resting blood pressure may benefit from IMT with 30% MIP [11]. Studies have demonstrated that IMT lowers blood pressure when comparing an intervention group with a control group. Combination of exercise and IMT have benefits effects on exercise capacity, HRQoL and respiratory muscle in cardiovascular disease [12, 13]. On the other hand, functional inspiratory muscle training (F-IMT), which involves performing IMT in body positions and movements that mimic the actual activity, has demonstrated greater ergogenic effects for running exercises compared to traditional IMT [14, 15]. Functional inspiratory muscle training characterized by performing inspiratory muscle training (IMT) while adopting body positions and movements that replicate the target performance, has shown an ergogenic effect superior to that of traditional IMT in a previous study [14]. This training method simultaneously stimulates both the ventilatory and core muscles, which play roles in respiration and posture control during exercise [16]. By performing inspiratory muscle training (IMT) in positions that challenge core stability, both respiratory and non-respiratory functions of these muscles can be optimized, leading to improved core stability. Consequently, FIMT may surpass traditional IMT methods in enhancing load carriage performance by specifically targeting the dual functions of the respiratory muscles, namely sustaining ventilation and providing spinal stability. Similar gains in respiratory muscle strength, exercise capacity, and quality of life were observed as a result of IMT and F-IMT in geriatric individuals with and without COPD [17]. F-IMT simultaneously stimulates both the ventilator and core muscles, which play roles in respiration and posture control during exercise [15]. Although different types of breathing exercises (with load, without load, or guided with a device) cause positive effects by lowering blood pressure in HT [8, 18, 19], no study has been found that comprehensively investigates their effectiveness in changing physical and mental parameters in these patients. Accordingly, the aim of this study is to compare different types of interventions in patients with HT, primarily by examining functional exercise capacity, and also to determine their effectiveness in changing important physical and mental parameters such as mobility, peripheral and respiratory muscle strength, blood pressure, respiratory functions, dyspnoea, fatigue, physical activity, and quality of life.

Methods

Study design and participants

This study was planned as a prospective randomised-controlled, assessor-blinded, parallel three-armed trial.

Forty-five patients with HT were randomly allocated to one of two intervention groups (IMT group, $n=15$; F-IMT group, $n=15$) or to a control group (CG, breathing group, $n=15$). Randomisation was performed using a secure, web-based randomisation system (MedCalc statistical software version 17.6) with a 1:1:1 allocation ratio. The allocation order was generated using computer-generated random numbers by a person not involved in this study.

Eligible participants diagnosed with essential HT who applied to University, Research and Practice Hospital, Department of Cardiology, between August 2023 and January 2024 were included. Additional inclusion criteria comprised being at least 18 years old, having previously been diagnosed with essential HT (systolic blood pressure (SBP) is 130 mm Hg or more and/or diastolic blood pressure (DBP) is 80 mm Hg or more [5], and receiving either no pharmacological treatment or only thiazide diuretics.

Exclusion criteria for patients comprised having any of the following: severe shortness of breath; diabetes; orthopaedic, musculoskeletal, or neurological limitations; significant cognitive impairment; BMI > 30 kg/m^2, a current or past history of deep vein thrombosis, myocardial infarction, or stroke within 6 months; congestive heart failure; unstable angina; lung disease of any aetiology (including asthma and chronic obstructive pulmonary disease); malignancy; or previously received IMT.

Study protocol

All patients within the groups received instructions on how to sustain diaphragmatic breathing and how to endeavour to achieve 8–15 breaths with intervals of 5–10 s of rest after each set. The groups adhered to the

	CG	IMT	FIMT
Frequency	2 times daily/morning, evening	2 times daily/morning, evening	2 times daily/morning, evening
Intensity	Active breathing with no load	50% MIP	50% MIP
Time	30 min/day	30 min/day	30 min/day
Duration	Diaphragmatic breath 8 week	Basic IMT with 50% MIP/8 week	IMT with 50% MIP/4 week + exercise and IMT with 50% MIP/4 week
Repetition	10–15 breaths with intervals of 5–10 seconds of rest	10–15 breaths with intervals of 5–10 seconds of rest	10–15 breaths with intervals of 5–10 seconds of rest
Workload	Constant	The intensity of the IMT was modified based on weekly Maximum Inspiratory Pressure (MIP) measurements	The intensity of the IMT was modified based on weekly Maximum Inspiratory Pressure (MIP) measurements.

Fig. 1 Study protocol

training program outlined in the study protocol section (Fig. 1).

In the CG, patients performed diaphragmatic exercises without any device and load, completing 3 sets of 10–15 repetitions every day per week for 8 weeks.

Within the IMT group, the patients underwent IMT interventions every day per week for 8 weeks. One session was supervised, and the other six sessions were performed at home. The training employed a pressure threshold-loading device, specifically the POWER Breathe VR Classic Low Resistance (IMT Technologies Ltd., Birmingham, UK). This device enables users to consistently inhale against a uniform pressure load during each breath, primarily targeting the strengthening of the diaphragm and rib cage muscles. The intensity of training was set at 50% of MIP. After 10–15 consecutive breathing cycles with the IMT device, participants were asked to perform 3–4 normal breaths without device. As patients' tolerance increased, the number of consecutive breathing cycles was increased (Rated Perceived Exertion = 11–13 on a 6–20 scale). IMT intensity was adjusted using weekly MIP measurements.

Regarding the F-IMT group, optimal muscle training involves starting with foundational IMT to strengthen respiratory muscles before introducing F-IMT [15]. It is recommended to combine IMT with the function(s) after ensuring that the participant has learned the intervention correctly [15, 17, 20]. Therefore, after completing the initial four-week IMT program at 50% of MIP using the POWER Breathe VR device, all participants in the F-IMT group underwent 4 weeks of IMT with functions. In F-IMT protocol, a general set of exercises according to American College of Sports Medicine's (ACSM) exercise prescription for hypertension was used, which included the extremities, in order to provide holistic benefits. The exercises contained shoulder flexion, shoulder abduction, sit-stand, and step-up-down. We selected upper extremity exercises that we thought would be particularly challenging for HT patients, as well as exercises that they frequently use in their daily lives and that change the core stability. HT individuals performed these exercises using their own body weight, with exercise intensity and repetitions determined according to ACSM's guidelines (perceived exertion level, RPE 11–13). In this group, all the exercises were performed with an IMT device, 8–12 repetitions, 2 sets, 4 weeks [15].

During sessions, patients' vital signs were consistently monitored. Daily record charts were maintained and reviewed to ensure proper training control. Regular calibration, follow-up, and device management were conducted at specified intervals, with patients advised not to alter their pressure loads.

Outcome measures

Patient demographic, physical, and physiological traits were documented through patient verbal statements and examination of their files. Pre- and post-test assessments were administered to all groups at the start and the end of the 8-week period.

Primary outcomes: Exercise capacity

i. The Six-Minute Walk Test (6MWT) was used to assess the exercise capacity and was administered following the guidelines set by the American Thoracic Society (ATS) [21]. It took place along a continuous 30-m stretch of flat ground. Following the completion of the test, the total distance walked by the participant was recorded in meters [21]. Reference values were utilized for comparisons [22].
ii. The Six-minute Pegboard Ring Test (6PBRT) was used to assess upper-extremity exercise capacity. Participants sit on an adjustable chair and use both arms to quickly attach and remove 20 rings from iron bars positioned at shoulder level over six minutes. The total score was based on the number of rings handled [23]. Predicted 6PBRT values were calculated [24].
iii. The 1-min sit-to-stand test (1STS) is an effective tool used to assess individuals' exercise capacity. During the 1STS, participants used a standard 48 cm chair without armrests, positioned against a wall. Sitting with knees at a 90° angle, feet flat on the floor, and arms crossed over their chest, participants were instructed to stand up fully and sit back down as many times as possible within one minute, without using their hands. The pace was self-determined, and while it was not necessary to fully sit back on the chair, participants had to reach a vertical position with their back. A 15-s warning was given, but no encouragement was provided. The number of complete repetitions within the minute was recorded [25].

Secondary outcomes: Mobility

The Timed Up and Go test (TUG) measures the time required for a patient to rise from a chair, walk a distance of 3 m, turn around, and then return to a seated position in the same chair. This test is a straightforward assessment that is utilised to gauge an individual's mobility, as established by Podsiadlo et al. in 1991 [26].

Secondary outcomes: Peripheral muscle strength

Quadriceps femoris isometric muscle strength was assessed bilaterally, while participants were seated, using a hand-held dynamometer (J-Tech Power Track Commander, Baltimore, MD, USA). Each measurement was repeated three times using a digital muscle meter, and the best score was recorded [27, 28]. Hand-grip strength was evaluated using a hand-grip dynamometer (Baseline, Hydraulic Hand Dynamometer, White Plains, NY). Measurements were conducted in three repetitions for both the right and left sides, with the participant's shoulder positioned in a seated stance, the elbow flexed at 90 degrees, and the forearm in a neutral position. The highest values obtained for both the right and left sides were recorded in kgF [29].

Secondary outcomes: Blood pressure

Blood pressure was measured with an aneroid sphygmomanometer (215 004 02, Erka Perfect, Germany). Casual SBP and diastolic BP (DBP) were measured by brachial auscultation in the subject's non-dominant arm after at least 5 min of quiet rest by a single trained health profession, according to American College of Cardiology/American Heart Association guidelines [30].

Secondary outcomes: Respiratory parameters

The level of dyspnoea were recorded at rest and/or during exercise using a subjective measure known as the Modified Borg Scale (MBS), which spans from 0 to 10. A score of 0 signifies "none" whereas a score of 10 represents "very severe" dyspnoea [31]. In addition to this, The Modified Medical Research Council (MMRC) dyspnoea scale was utilised to assess dyspnoea, with levels graded accordingly [32].

In this study, the strength of respiratory muscles, measured as MIP and maximal expiratory pressures (MEP), was evaluated using a portable electronic mouth-pressure device (MicroRPM, CareFusion, Kent, UK) following ATS/ERS criteria [33]. Reference values were used for comparison [34]. The minimal clinically important difference (MCID) for inspiratory muscle strength was determined to be 11 cmH_2O [35].

Pulmonary function tests were conducted using a portable spirometer (SPIROBANK IIVR Maggiolino, Roma, Italy). Parameters measured included FEV_1/FVC, which was expressed as percentages of predicted values. The tests were performed while seated, and the best of three technically acceptable manoeuvres, with a 95% match between them, were selected and recorded for statistical analysis [36].

Secondary outcomes: Fatigue

Fatigue was assessed using the Fatigue Severity Scale (FSS), which is a reliable measure consisting of nine self-administered items scored from 0 to 7. A score exceeding 36 indicates severe fatigue [37].

Secondary outcomes: Physical activity

Physical activity levels were measured using the International Physical Activity Questionnaire (IPAQ) short form, which is a reliable and valid tool for assessing physical activity. Scores falling below 600 MET-minutes/week were categorised as inactive, scores ranging from 600 to 3000 MET-minutes/week were categorised as minimally active, and scores exceeding 3000 MET-minutes/week were categorised as sufficiently active [38].

Secondary outcomes: Health related quality of life (HRQoL)

This study utilised the Short Form-36 (SF-36) which comprises sub-parameters assessing physical functionality, pain, general health perception, physical and emotional role limitations, social functionality, mental health, and energy/fatigue. Scores range from 0 to 100, with higher scores indicating better function. Overall physical and mental health components were computed using subscales [39].

Statistical analysis

A minimum required sample size of 45 (15 per group) was calculated by following the 6MWT analyses from a previous study [40] and using G*Power (Statistical Power Analyses for Windows, Version 3.1.9.7, University of Dusseldorf, Dusseldorf, Germany). This calculation was based on an alpha error probability of 0.05, an effect size of 0.716, and a power of 80%, while accounting for a 10% drop-out rate.

Statistical analyses were completed using IBM SPSS 20.0, a statistical analysis software by SPSS Inc., USA. The assessment of data normality was performed using the Saphiro-Wilks, and continuous variables were described either as mean ± standard deviation (SD) or as median and interquartile range (IQR) depending upon data normality. A comparison of baseline characteristics among the three groups was conducted through one-way ANOVA and the Kruskal–Wallis test. Categorical data were evaluated using the chi-square test and presented as count and frequency. ANCOVA was conducted to assess changes in exercise capacity, mobility, performance, respiratory muscle strength, pulmonary function, peripheral muscle strength, dyspnoea, fatigue, physical activity, and quality of life across the three groups while adjusting for baseline variables. All necessary assumptions for ANCOVA (normal distribution, homogeneity, homogeneity of the regression slope, random independent samples, and linearity) were met. The baseline values for each outcome measure served as covariates. Post-hoc comparisons were performed using the Bonferroni test. Secondary analysis focused on between-group effects and pairwise comparisons among the remaining study groups. Intention-to-treat analysis was employed for handling missing data, and a significance level of $p < 0.05$ was utilised throughout the statistical analyses. Effect size (ES) was determined using the partial eta squared (η^2) test and was categorised as follows: 0.01 represented a small effect, 0.06 represented a medium effect, and 0.14 or higher represented a large effect [41].

Results

Out of 59 patients with HT who were screened for eligibility, 45 were randomised into the three study groups and 14 patients were excluded from the study. Among the participants in the study, three from the F-IMT group, one from the CG, and two from the IMT group were lost to follow-up; withdrawal reasons are detailed in Fig. 2.

Table 1 displays the demographic and baseline clinical characteristics of the groups. No significant differences

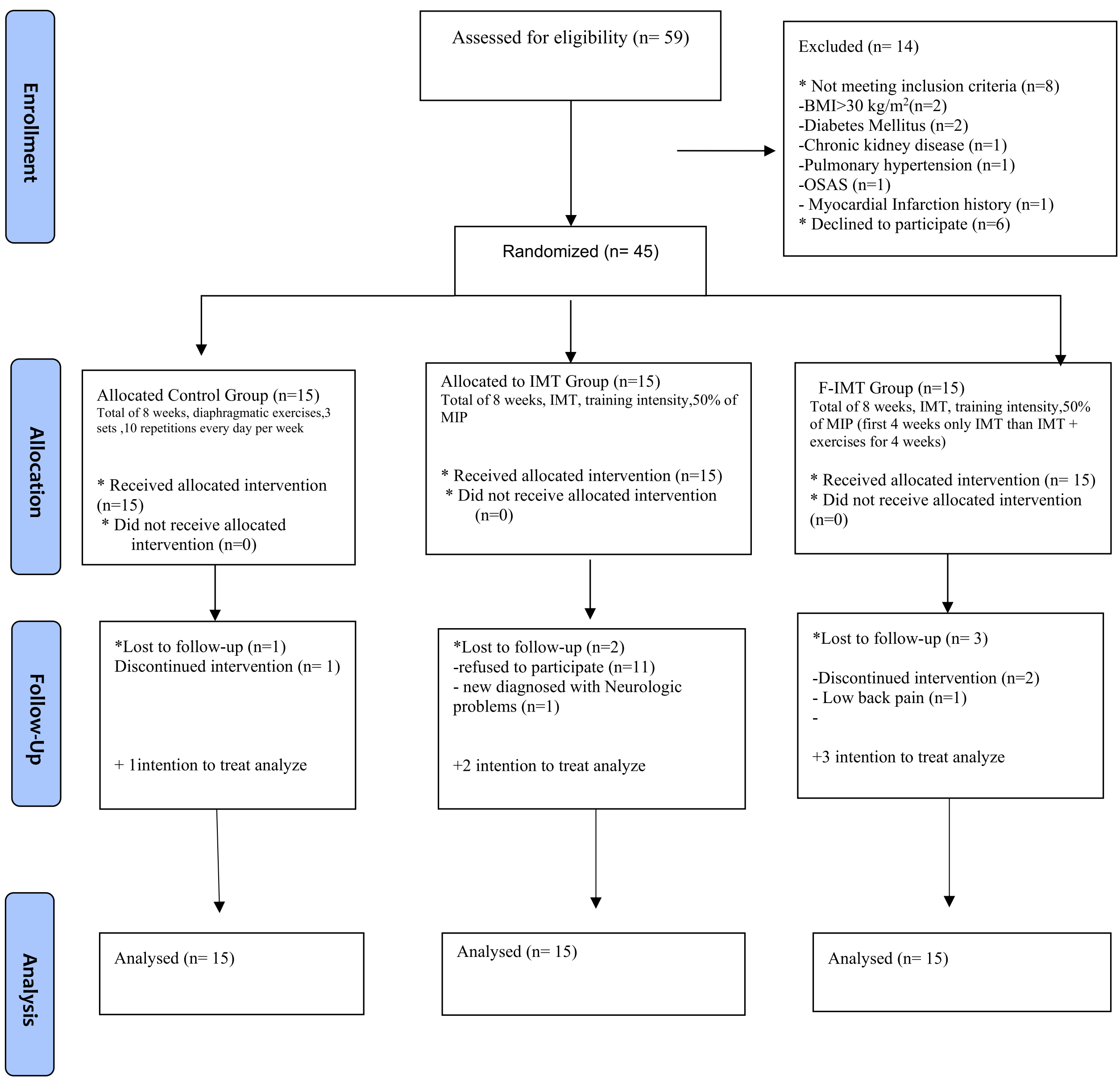

Fig. 2 CONSORT Flow diagram

Table 1 Demographic and baseline clinical characteristics of the groups

	CG	IMT	F-IMT	P
AGE (YEARS)	54.60 ± 7.12	59.93 ± 7.86	55.93 ± 9.12	0.183
SEX N (%)				
FEMALE	3(20)	2 (13.3)	4(26.7)	0.659
MALE	12(80)	13(86.7)	11(73.3)	
BMI (KG/M2)	28.31 ± 3.81	29.40 ± 2.37	31.15 ± 4.24	0.103
BMI CATEGORY				
18.6–24.9 KG/M^2	1(6.7)	1(6.7)	0(0)	0.893
25–29.9 KG/M^2	6(40)	6(40)	7(46.7)	
30 < KG/M2	8(53.3)	8(53.3)	8(53.3)	
OCCUPATION N(%)				
HOUSEWIFE	3(20)	2(13.3)	5(33.3)	0.774
EMPLOYEE	3(20)	1(6.7)	1(6.7)	
FREE WORKER	3(20)	3(20)	3(20)	
OFFICER	1(6.7)	0(0)	0(0)	
RETIRED	5(33.7)	6(40)	6(40)	
MARITAL STATUS				
MARRIED	15(100)	13(86.7)	14(93.3)	0.189
SINGLE	0(0)	0(0)	1(6.7)	
DIVORCED	0(0)	2(13.3)	0(0)	
FAMILY HISTORY (HT) N, (%)				
YES	7(46.7)	5(33.3)	4(26.7)	0.507
NO	8(53.3)	10(66.7)	11(73.3)	
PACK X YEARS	20(5–29)	42.5(2.625–54.37)	25(14.37–36.25)	0.348
SMOKING (CURRENT/EX/NON-SMOKER), N (%)	3(20)/7(46.7)/5(33.3)	2(13.3)/6(40)/5(33.3)	4(26.7)/6(40)/5(33.3)	0.660
ALCOHOL EXPOSURE (YES/NO/EX-DRINKER)	1(6.7)/13(86.7)/1(6.7)	4(26.7)/10(66.7)1(6.7)	1(6.7)/12(80)/2(13.3)	0.231
MMRC (0–4)	2(1–2)	1(1–2)	2(1–2)	0.436
EXERCISE HABIT YES/NO	5(33.3)/10(66.7)	6(40)/9(60)	5(33.3)/10(66.7)	0.650
RESTING DYSPNEA N(%) YES NO	1(6.7)/14(93.3)	3(20)/12(80)	2(13.3)/13(86.7)	0.440
ACTIVITY DYSPNEA N(%) YES NO	8(53.3)/7(46.7)	12(80)/3(20)	13(86.7)/2(13.3)	0.092

BMI Body mass index, *MMRC* Medical research council, Kruskal–Wallis Test, Chi-Square Tests, one-way ANOVA, * $p < 0.05$

were observed between the groups in terms of age, sex, body mass index (BMI), education status, participation in physical activity, medication usage, comorbidity index, smoking status, alcohol consumption, or perception of dyspnoea ($p > 0.05$).

Baseline characteristics were similar between the groups ($p > 0.05$), except for TUG ($p = 0.001$) and 6MWT distance ($p = 0.016$) (Tables 2 and 3).

The 6MWT, 6MWT%, TUG, hand-grip strength, SF-36 mental health, and IPAQ total scores were statistically different after the intervention within the CG, IMT and F- IMT groups ($p < 0.05$). Differences in 6MWT, TUG, peripheral muscle strength, and blood pressure results within and between groups are shown in Table 2.

Exercise capacity

Following the intervention, there was a statistically significant improvement in 6MWT, 6MWT%, 6PBRT, 6PBRT%, and 1STS within the IMT and F-IMT groups ($p < 0.001$, Fig. 3). Treatment effects were found in 6MWT (m), 6MWT%, 6PBRT, 6PBRT% and 1STS results between the groups ($p < 0.05$). The increase in 6MWT distance and 6MWT% was significantly higher in F-IMT than IMT ($p < 0.001$) and CG ($p < 0.001$). In addition, the increases in 6MWT distance and 6MWT% were significantly higher in the IMT groups than in the CG ($p < 0.001$). When comparing the three groups after training, the ES was large for the 6MWT

Table 2 Differences in Exercise capacity, mobility, peripheral muscle strength within-group and between-groups

	CG (*n*: 15)				IMT (*n*: 15)				F-IMT (*n*: 15)				
	Baseline mean ± SD	After mean ± SD	Mean Difference (95% CI)	Within group p	Baseline mean ± SD	After mean ± SD	Mean Difference (95% CI)	Within group p	Baseline mean ± SD	After mean ± SD	Mean Difference (95% CI)	Within group p	Treatment effect p
6-MWT (m)	520.97 ± 72.53	528.66 ± 70.03	8.67(−14.65–2.68)	**0.006**	446.03 ± 108.18	476.71 ± 104.57	30.33(24.68–35.98)	**< 0.001**	429.50 ± 80.32	482.37 ± 84.25	52.24(−58.00–46.47)	**< 0.001**	**< 0.001**[a,b,c]
6-MWT%	85.63 ± 15.15	86.85 ± 14.72	1.20(−2.27–0.13)	**0.028**	78.45 ± 19.66	83.84 ± 19.05	5.39(−6.44–4.34)	**< 0.001**	74.79 ± 18.23	84.13 ± 19.60	9.17(−10.23–8.11)	**< 0.001**	**< 0.001** [a],[b,c]
6 PBRT (rings)	307.60 ± 46.47	309.66 ± 48.13	1.42(−3.90–1.10)	0.262	257.47 ± 69.25	272.73 ± 71.42	**15.78(−18.26–13.30)**	**< 0.001**	274.13 ± 39.81	291.20 ± 55.65	**17.19(19.60–14.78)**	**< 0.001**	**< 0.001,**[a,c]
6 PBRT%	69.45 ± 12.22	69.92 ± 12.57	0.35(−0.93–0.22)	0.223	60.59 ± 14.88	64.21 ± 15.38	**3.70(−4.27–3.13)**	**< 0.001**	62.62 ± 10.15	66.51 ± 10.21	**3.92(−4.49–3.36)**	**< 0.001**	**< 0.001**[a,c]
1 STS (repetition)	22.53 ± 5.86	23.46 ± 6.95	0.98(−2.30–0.32)	0.137	21.80 ± 4.52	27.86 ± 5.55	**6.19(−7.52–4.86)**	**< 0.001**	24.86 ± 4.10	33 ± 5.12	**7.95(−9.29–6.60)**	**< 0001**	**< 0.001**[a,c]
TUG (sec)	7.98 ± 1.03	7.62 ± 0.93	1.35(0.63–2.07)	**< 0.001**	15.28 ± 3.21	11.78 ± 2.65	**2.17(1.35–2.98)**	**< 0.001**	10.02 ± 2.65	8.11 ± 2.05	**2.25(1.60–2.84)**	**< 0.001**	0.119
QF R (N)	177.46 ± 44.28	181.20 ± 44.21	3.54 (−7.34–0.25)	0.067	178.40 ± 38.06	192.33 ± 44.34	13.70(−7.34–0.25)	**< 0.001**	163.13 ± 44.67	181.35 ± 45.88	18.63(−22.47–14.80)	**< 0.001**	**< 0.001**[a,c]
QF L (N)	164.73 ± 35.29	167.46 ± 34.87	2.60(−7.48–2.27)	0.287	162.78 ± 53.59	174.05 ± 57.26	**11.18(−16.05–6.32)**	**< 0.001**	151.53 ± 36.98	168.99 ± 39.08	**17.67(−22.56–12.77)**	**< 0.001**	**< 0.001**[a,c]
HG R (Pound)	82.46 ± 20.42	85.14 ± 20.20	2.58(−4.85–0.31)	**0.027**	74.86 ± 18.91	80.32 ± 20.67	**5.44(3.25–7.63)**	**< 0.001**	62.73 ± 19.72	67.94 ± 20.07	−5.32(−7.62–7.62)	**< 0.001**	0.146
HG L (Pound)	86.20 ± 18.57	87.93 ± 17.64	1.80(−3.93–0.22)	**0.026**	73.73 ± 18.53	78.51 ± 20.25	4.77(−6.27–3.28)	**< 0.001**	64.73 ± 20.08	68.87 ± 19.51	**4.07(−5.64–2.50)**	**< 0.001**	**0.028**[c]
SBP mmHg	135.06 ± 30.11	133.28 ± 27.63	1.54(1.91–5)	0.372	142.26 ± 16.03	135.58 ± 11.36	4.98(1.44–8.52)	**0.007**	124.33 ± 18.54	117.44 ± 13.90	**8.82(5.26–12.93)**	**< 0.001**	**0.019**[a]
DBP mmHg	80.06 ± 14.44	79.50 ± 13.55	0.41(−1.92–2.74)	0.723	82.60 ± 12.52	79.90 ± 13.21	2.25(−4.62–0.11)	0.062	73.40 ± 10.23	70.66 ± 8.42	**3.32(0.92–5.72)**	**0.008**	0.218

CG Control group, *IMT* Inspiratory muscle training, *F-IMT* Functional Inspiratory Muscle Training Group, *SD* Standard deviation, *CI* confidence interval, *6MWT* Six minute walking test, *6PBRT* 6-min pegboard ring test, *SBP* systolic blood pressure, *DBP* diastolic blood pressure, *1STS* 1-min sit to stand test, *QF* Quadriceps Femoris strength, *HG R* Hand grip strength right, *HG L* Hang grip strength left, *TUG* Time up and go test

Bonferroni corrected ANCOVA test, * $p < 0.05$

[a] statistically significant difference in comparison with FIMT and CG

[b] statistically significant difference in comparison in FIMT and IMT

[c] statistically significant difference in comparison in IMT and CG

Table 3 Changes in Pulmonary function, respiratory muscle strength, fatigue, physical activity, HrQoL within and between the groups

	CG (*n*: 15)				IMT (*n*: 15)				F-IMT (*n*: 15)				
	Baseline mean ± SD	After mean ± SD	Mean Difference (95% CI	Within group p	Baseline mean ± SD	After mean ± SD	Mean Difference (95% CI	Within group p	Baseline mean ± SD	After mean ± SD	Mean Difference (95% CI	Within group p	Treatment effect p
FEV_1/FVC %	86.24 ± 9.47	86.35 ± 9.11	−0.18(−1.29-.0.92)	0.734	85.18 ± 8.57	85.91 ± 7.38	−0.74(−1.85–0.36)	0.181	82.85 ± 14.21	84.03 ± 14.29	−1.08(−2.19–0.29)	0.056	0.517
MIP cmH_2O	93.26 ± 24.77	96.86 ± 25.39	−3.99(−12.50–4.52)	0.350	89.26 ± 25.88	104.58 ± 28.30	−10.33(−18.82–1.84)	**0.018**	87.26 ± 24.65	100.37 ± 26.95	−17.01(−25.51–8.50)	**< 0.001**	0.106
MIP %	100.39 ± 26.06	103.96 ± 25.17	−3.71(−13.27–5.85)	0.438	96.04 ± 23.86	107.73 ± 26.97	−11.60(−21.15–2.05)	**0.018**	96.64 ± 28.13	117.53 ± 38.14	−20.83 (−30.38–11.28)	**< 0.001**	**0.048**[a]
MEP cmH_2O	104.60 ± 25.35	105.00 ± 24.54	−1.26(−8.49–5.97)	0.817	96.93 ± 34.33	99.01 ± 35.63	−2.22(−9.34–4.89)	0.532	81.60 ± 32.77	94.80 ± 28.44	−12.19(−19.46–4.91)	**0.002**	0.075
MEP %	88.26 ± 21.47	88.28 ± 18.92	−0.75(−7.73–6.23)	0.829	81.27 ± 24.87	84.16 ± 28.75	−2.86(−9.78–4.05)	0.408	75.11 ± 38.35	87.10 ± 36.73	−11.27(−18.25–4.29)	**0.002**	0.090
SF-36 Mental Health	70.05 ± 23.26	79.48 ± 19.91	−9.77(−14.35–5.19)	< 0.001	66.35 ± 20.71	76.40 ± 19.08	−9.73(−14.16–5.31)	< 0.001	68.05 ± 17.00	75.17 ± 17.25	−7.10(−11.52–2.68)	**0.002**	0.620
SF-36 Physical Health	70.04 ± 17.87	71.23 ± 17.88	−1.65(−6.65–3.34)	0.508	63.79 ± 21.00	66.67 ± 21.71	−2.70(−2.08–7.49)	0.260	63.13 ± 15.14	65.94 ± 15.76	−2.56(−7.35–2.23)	0.286	0.054
FSS (0–63)	24.66 ± 19.97	23.27 ± 15.83	2.13(−0.64–4.90)	0.128	39.06 ± 18.24	36.17 ± 17.63	1.88(−0.94–4.71)	0.186	28.46 ± 12.79	22.53 ± 11.09	6.21(3.49–8.92)	**< 0.001**	**0.049**[a,b]
IPAQ total (MET- min/week)	1604.90 ± 1878.56	1741.24 ± 1844.97	−146.51(257.09–35.93)	**0.011**	394.66 ± 334.13	683.97 ± 539.74	280.02(−419.18–140.86**)**	**< 0.001**	665.42 ± 553.45	1030.83 ± 549.40	−360.48(−470.40–250.55)	**< 0.001**	**0.035**
IPAQ vigorous (MET-min/week)	304.00 ± 693.61	432.00 ± 1264	1.83(−160.98–164.65)	0.982	0.00 ± 0.00	0.00 ± 00	−75.73(−234.55–83.07)	0.341	32.00 ± 123.39	64.00 ± 247.87	−86.09(−243.88–71.68)	0.277	0.688
IPAQ moderate (MET-min./week)	270.40 ± 515.01	1393.68 ± 3879.07	−1235.31(−2457.0–13.61)	0.050	84.00 ± 325.33	249.41 ± 381.30	131.34(−1322.68–1059.99)	0.825	28.00 ± 108.44	157.23 ± 177.45	−51.27(−1255.81–1153.26)	0.932	0.323
IPAQ walking (MET-min./week)	875.13 ± 633.74	878.41 ± 682.52	−17.19(−173.66—139.27)	0.825	544.80 ± 563.26	723.14 ± 607.59	**−170.60(−324.29–16.91)**	**0.030**	568.66 ± 422.89	823.16 ± 446.24	**−248.32(−401.55–95.08)**	**0.002**	0.116
IPAQ sitting (MET-min./week)	410.0 ± 224.97	385.20 ± 223.18	41.37(−21.07–103.81)	0.188	509.00 ± 384.45	384.05 ± 149.17	**84.92(21.89–147.94)**	**0.010**	398.00 ± 184.04	322.58 ± 111.21	**98.85(36.29–161.42)**	**0.03**	0.398

FEV1 forced expiratory volume in 1 s, *FVC* forced vital capacity, *MIP* maximal inspiratory pressure, *MEP* maximal expiratory pressure, *FSS* Fatigue severity scale, *SF-36* Short Form, *IPAQ* International physical activity questionnaire, Bonferroni corrected ANCOVA test

* $p < 0.05$

[a] statistically significant difference in comparison with FIMT and CG

[b] statistically significant difference in comparison in FIMT and IMT

[c] statistically significant difference in comparison in IMT and CG

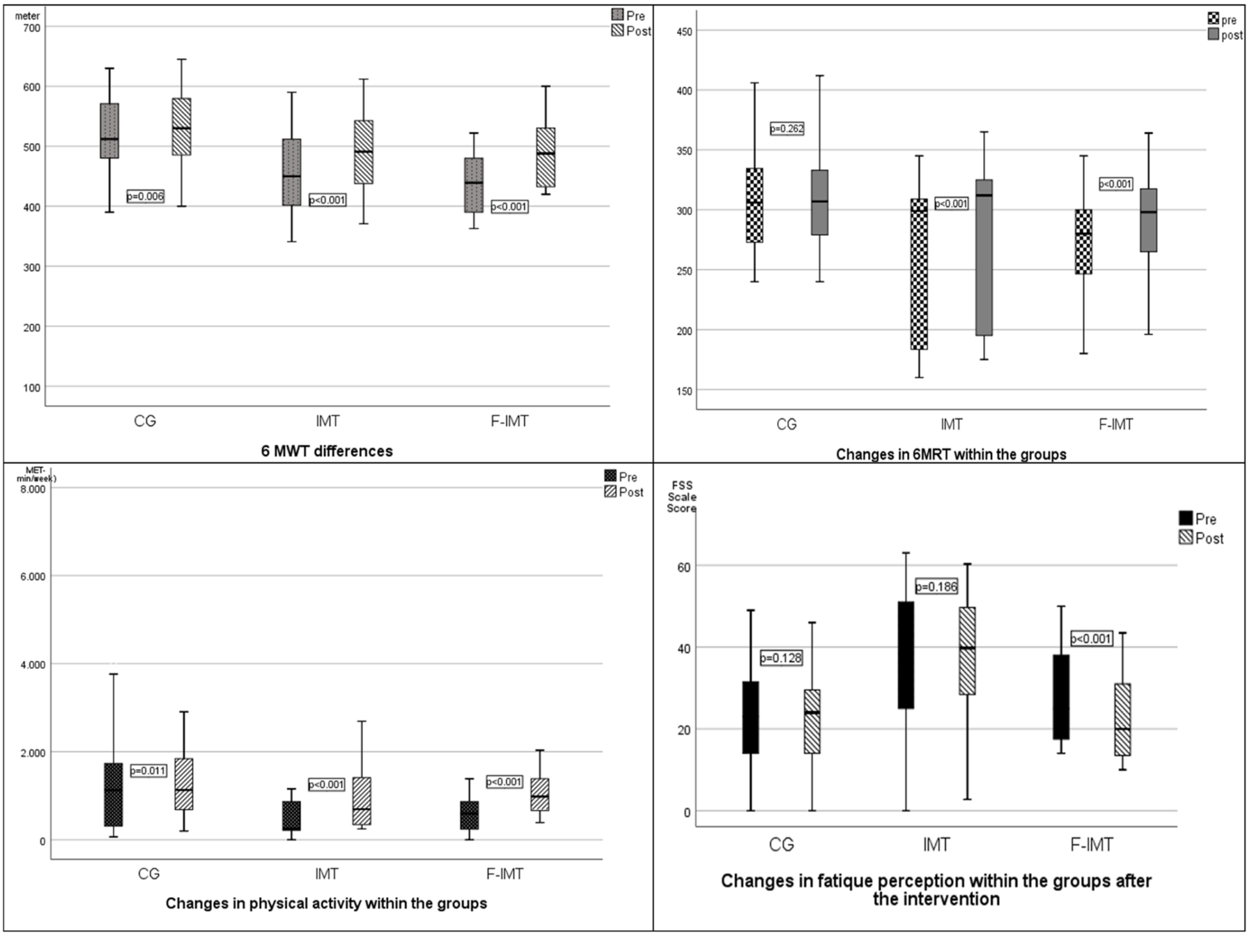

Fig. 3 6-min walking test, 6-min ring test, physical activity and fatigue scores before and after the interventions

distance ($\eta^2 = 0.717$), 6MWT% ($\eta^2 = 0.730$), 6PBRT ($\eta^2 = 0.698$), 6PBRT% ($\eta^2 = 0.697$), 1STS ($\eta^2 = 0.598$).

Mobility

Mobility increased in all groups ($p < 0.05$); no differences were found between the groups ($p > 0.05$).

Peripheral muscle strength

Following the program, there was a statistically significant improvement in bilateral quadriceps muscle strength and hand grips. The increase in quadriceps muscle strength was significantly higher in the F-IMT ($p < 0.001$) and IMT groups ($p < 0.001$) than in the CG. Results showed a large treatment effect on QF strength [R ($\eta^2 = 0.446$), L ($\eta^2 = 0.321$)]. The R-L hand grip measures increased in the F-IMT ($p < 0.001$) and IMT groups ($p < 0.001$). The improvement in left HG strength was significantly higher in the IMT groups than in the CG groups ($p = 0.009$). A large treatment effect was observed in the left HG strength results ($\eta^2 = 0.159$).

Blood pressure

A significant difference was found in the SBP results between the groups after the treatments ($\eta^2 = 0.175$, large; $p = 0.019$). The decrease in SBP was statistically higher in the F-IMT group compared to the CG (Δ SBP = 7.28 mmHg 95% CI = 1.12–13.44; $p = 0.016$) and the IMT group (Δ SBP = 3.84 mmHg 95% CI = 10.21–2.53); $p = 0.42$). Similar decreases were found in CG and IMT (Δ SBP = 3.44 mmHg 95% CI = 2.65–9.53; $p = 0.499$). Although diastolic blood pressure (DBP) decrease was higher in F-IMT (Δ DBP = 1.45 mmHg 95% CI = 0.73–2.57; $p = 0.0.267$) than CG and IMT (Δ DBP = 0.53 mmHg 95% CI = 2.25–1.19; $p = 0.535$), there was no statistically significant decrease between the groups ($p = 0.218$).

Table 3 shows the changes in pulmonary function, respiratory muscle strength, fatigue, physical activity, and HrQoL within and between the groups.

Pulmonary function and respiratory muscle strength

FEV1/FVC% were similar between all groups. While the F-IMT group's MIP, MIP% ($p < 0.001$), MEP ($p = 0.002$), and MEP% ($p = 0.002$) rose significantly, the IMT group showed improvement only in MIP and MIP% ($p = 0.018$). A large treatment effect was observed between the groups in MIP ($\eta^2 = 0.138$).

Physical activity, fatigue and HrQoL

The IPAQ total score increased after the intervention within the F-IMT, IMT, and CG groups ($p < 0.05$, Fig. 3). IPAQ walking and IPAQ sitting scores improved after the intervention within the IMT and F-IMT groups. The decrease in FSS was significantly higher (Fig. 3) in F-IMT compared to IMT ($p = 0.033$) and CG ($p = 0.038$). The treatment effect was found between the groups in FSS ($\eta^2 = 0.887$, large effect) and IPAQ total ($\eta^2 = 0.017$, medium effect) results ($p < 0.05$).

SF-36 mental health scores were statistically different after the intervention within the CG ($p < 0.001$), IMT ($p < 0.001$) and F-IMT groups ($p = 0.002$).

Discussion

The unique aspect of this study is the comprehensive investigation into the effect of F-IMT on measures of physical and mental status, such as exercise capacity, mobility, respiratory function, and psychosocial functions, in patients with essential HT. This study's key findings are as follows: 1) IMT, F-IMT, or breathing exercises (without a device) increased the scores of 6MWT distance, mobility, hand-grip strength, and physical activity. 2) An eight-week inspiratory muscle strength intervention was particularly effective in improving upper- and lower-extremity exercise capacity, mobility, peripheral muscle strength, inspiratory muscle strength, fatigue perception, and physical activity. 3) F-IMT was statistically more effective than the other methods in improving the 6MWT, 6MWT%, fatigue perception, and decreased SBP.

Exercise intolerance is an important symptom of cardiopulmonary diseases [42]. Exercise tests often help clinicians to assess a patient's prognosis and response to treatment. Performing a distance less than 350 m as a result of 6MWT is associated with increased mortality in chronic obstructive pulmonary disease, chronic heart failure and pulmonary arterial hypertension [43]. The progression of prehypertension to HT has been found to be associated with a decrease in exercise capacity [43]. Physical exercise causes a significant improvement in the remodelling of large and small vessels, which significantly reduces blood pressure in arterial HT patients and can be used as an important non-pharmacological treatment [44]. In a previous study performed with HT patients, the increased risk of mortality imposed by low functional capacity and additional cardiovascular risk factors was eliminated by relatively small increases in exercise capacity [45]. The benefits of the antihypertensive effects of different exercise methods include improving traditional cardiovascular risk factors; increasing cardiorespiratory capacity, myocardial perfusion, and peripheral perfusion; and improving autonomic function [46, 47]. Therefore, the present study aimed to investigate the effects of three different respiratory exercise modalities on exercise capacity, physical activity, and psychosocial status. Both two inspiratory muscle training programs improved exercise capacity, physical activity, mental health status, peripheral and respiratory muscle strengths, and reduced blood pressure in the current study. This decrease in SBP and the increase in exercise capacity are consistent with the literature [43–45].

Deep breathing exercises have been shown to be beneficial to HT patients by lowering blood pressure. These exercises prolong the contraction time of the diaphragm, minimise the respiratory rate, increase the volumes of inhalation and exhalation, and maximise the amount of oxygen entering the blood circulation [48]. Regulation of blood pressure responses during exercise is also controlled by the autonomic nervous system, and the cardiovascular fitness of individuals is directly related to BP dynamics during exercise [49]. There are a limited number of studies that have investigated the effect of respiratory muscle training on exercise capacity in HT patients. In a previous study, an increase in exercise capacity was also observed in HT patients who underwent inspiratory muscle training; A difference in the 6-min walk test (6MWT) distance was noted: 21.68 m between the control group and the low load inspiratory muscle training (IMT) group, and 23.17 m between the control group and the high load IMT group [40]. Similar to the previous study, IMT increased exercise capacity in our study, in which the highest increase was in the F-IMT group, with a difference of 52.24 m. Additionally, upper-extremity functional exercise capacity and 1-min sit-to-stand test results improved after interventions in both the IMT and F-IMT groups. F-IMT might affect venous filling, stroke volume, cardiac output, and peripheral blood flow (respiratory pump) through parasympathetic activation and baroreflex activation. This may lead to increased peripheral muscle strength, decreased fatigue, and increased physical activity. In our study, the improvement in FSS results of the F-IMT group supports this scenario. Another previous study with F-IMT demonstrated an improvement in performance during the exercise with thoracic loads [20]. Notably, the increase in exercise capacity was greater in the F-IMT group than IMT and CG in the current study. Upper-extremity physical exercise may decrease sympathetic tone; in particular, it has been found that forearm endurance training can lower the response of sympathetic nerves [50]. Sympathetic tone plays a crucial role in regulating peripheral resistance, particularly by controlling the constriction and dilation of tiny arteries and arterioles. A decrease in sympathetic tone may result in a decrease in peripheral vasoconstriction, arterial distension pressure, and ultimately an enhancement in small-artery compliance [51, 52] showed that engaging in regular aerobic training for the arms results in a significant decrease in blood pressure as well as an enhancement in the flexibility of tiny arteries. This study is also the first to demonstrate the effectiveness of IMT on upper-extremity functional exercise capacity in HT patients. It is recommended that future studies investigate the effectiveness of IMT with different types of upper-extremity exercise training in HT patients.

The secondary effects of HT on postural control and balance have been highlighted in the literature. HT can impair balance through artery damage and reduced blood flow in functional areas [53]. Loss of peripheral muscle strength may be associated with a lack of postural control and with mobility and balance problems in HT patients [53, 54]. Another study demonstrated similar gains after F-IMT and IMT in balance and postural control in geriatric individuals with and without COPD [17]. Both IMT interventions similarly improved physical performance, and it is additionally one of the limited studies to demonstrate the effectiveness of IMT on upper-extremity functional capacity in our study. These results may be related to the improvement in the mechanism indicated by Hausdorff et al. [53] and the decrease in resting blood pressure mediated by the metoboreflex activation of breathing exercise.

Peripheral muscle strength, pulmonary function, and respiratory muscle strength are effective parameters for determining physical fitness levels and overall health. In order to ensure the necessary oxygenation due to the increase in strength required due to workload during exercise, lung functions and respiratory muscles may develop in parallel and support each other [55]. Both F-IMT and IMT with 50% MIP were effective in improving QF strength R ($\eta^2 = 0.446$, large effect), L ($\eta^2 = 0.321$, large effect), and left HG strength ($\eta^2 = 0.159$, large effect) in HT patients in the current study. IMT led to an increase in respiratory muscle strength and mitigated the respiratory muscle metaboreflex, as evidenced by reduced heart rate and blood pressure [56]. We used a resistive pressure threshold loading device with 50% MIP intensity in this study. Trunk and upper extremity exercises, along with the POWER Breathe VR device, placed an extra load on respiratory muscles in the F-IMT program. Similarly, the decreases in SBP and DBP were statistically significant in the F-IMT and IMT groups in our study. IMT may reduce blood flow competition between respiratory muscles and other working limb muscles during strenuous exercise [57]. There is also evidence that respiratory muscle training reduces fatigue in other exercising locomotor muscles in chronic heart failure patients by improving vascular conductance and blood flow in these muscles [56]. Chang et al., 2021 found IMT with 50% MIP improved peripheral muscle strength and decreased locomotor muscle fatigue. IMT applied for 4 weeks in recreational athletes at an intensity of 50% to 80% could increase the vertical movement of the diaphragm and reduce the metoboreflex phenomenon by increasing the blood flow to the limbs according to in this previous study [58]. Katayama et al. reported the effect of increased inspiratory muscle work on blood flow to both active and inactive limbs during light dynamic leg exercise. Brachial artery blood flow increased compared to resting levels during exercise without inspiratory resistance, whereas it decreased with inspiratory resistance. Femoral artery blood flow increased at the onset of exercise and continued throughout exercise without inspiratory resistance, and did not change when inspiratory resistance was added. These results suggest that sympathetic control of blood redistribution to the active limbs is facilitated in part by the respiratory muscle-mediated metaboreflex [59]. High-resistance inspiratory muscle strength training reduced SBP, improved peripheral vascular function, and saved time in middle-aged and elderly adults with SBP above normal [60]. Vilaça et al. showed that a six-week IMT protocol increased inspiratory muscle strength; this effect was noted following the improvement in MIP observed in the trained group compared to the control group [61]. According to this previous statement, the decrease in SBP and the improvement in MIP was attributed to increased motor unit recruitment during the muscle-training period. It is clear that for healthy older adults, IMT, if performed regularly, contributes to increasing the strength of the inspiratory muscles in addition to being associated with peripheral muscle strength, thereby contributing to quality of life improvement. Similarly, the effects of F-IMT or IMT protocols on muscle strength and quality of life likewise improved the quality of life and physical activity level in our study. We believe that IMT at appropriate intensity, as in our study, will cause positive changes in muscle strength, endurance, and exercise performance and will positively affect peripheral oxygenation by increasing the resistance of the diaphragm to fatigue. Different IMT protocols can cause positive effects on patients' lifestyles.

IMT mostly perform with about 5 min daily, totalling 30 min weekly, making it a time-efficient strategy that may promote higher adherence rates than more time-intensive protocols [62–64]. With rising cardiovascular disease (CVD) among middle-aged and older adults, effective and adherent interventions are crucial. Despite aerobic exercise reducing CVD risk, adherence is low. Therefore, New lifestyle interventions are needed. IMT is a promising non-pharmacological approach that lowers blood pressure, improves adherence, and enhances vascular function [62–64]. Similarly, F-IMT that is a respiratory training combined with activity, has shown effectiveness on blood pressure, muscle strength, fatigue, mental health status, and physical activity.

The proposal to include IMT in cardiac rehabilitation programs is gaining increasing attention. The core strategy of typical CR programs is exercise-based therapy combining aerobic and resistance exercises [65]. A previous study has shown that combined exercise programs are more beneficial than aerobic exercise programs alone in improving physical function during coronary artery disease rehabilitation [66]. In our study, the effectiveness of IMT combined with functional activities was observed in HT. Therefore, it is recommended that IMT be added to the current guidelines alongside aerobic exercise.

Study strengths and limitations

This is the first study to show the effectiveness of combined IMT and functional exercise in HT patients and the effects of IMT on upper-extremity functional capacity. This treatment protocol can be performed in a short time with an easy-to-apply device. The limitations of this study were that physical activity could not be measured with the help of a device, and no long-term follow-up. It was not possible to conduct cardiopulmonary exercise testing due to technical difficulties. Pulmonary function was assessed with spirometry, but to fully comprehend the impact of IMT on pulmonary function, static lung volumes and diffusing capacity should also be measured. Despite using a computer-based program to randomize patients, the baseline 6MWT distance and TUG results varied between groups. In this situation, it is possible that the control group's higher physical activity level may have limited program-related development. We performed covariant analyses to account for this baseline difference. We also designed the study to be assessor blind. Still, this is one of our study's limitations. We recommend considering this situation in larger-scale studies.

Conclusions

F-IMT improved upper- and lower-extremity functional capacity, mobility, peripheral and respiratory muscle strengths, blood pressure, fatigue, physical activity, and quality of life in patients with HT. It is recommended that future studies evaluate the long-term effects of F-IMT, the results of different upper-extremity training protocols added to F-IMT, and the cost effectiveness of such protocols.

Abbreviations

Δ	Difference
1STS	1-Minute sit to stand test
6-MWT	6-Min walking test
6PBRT	6-Min pegboard ring test
ACSM	American College of Sports Medicine
ATS	American Thoracic Society
BMI	Body mass index
CG	Control group
COPD	Chronic obstructive pulmonary disease
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
ES	Effect size
FEV_1/FVC	FEV1: forced expiratory volume in 1 s/ FVC: forced vital capacity
F-IMT	Functional inspiratory muscle training
FSS	Fatigue Severity Scale
HRQoL	Health Related Quality of Life
HT	Hypertension
IMT	Inspiratory muscle training
IPAQ	International Physical Activity Questionnaire
MBS	Modified Borg Scale
MCID	Minimal clinically important difference
MEP	Maximal expiratory pressure
MIP	Maximal inspiratory pressure
MMRC	Modified Medical Research Council
SDP	Systolic, diastolic blood pressure
SF-36	Short Form-36
TUG	The Timed Up and Go test
VO2 max	Maximal oxygen consumption
η^2	Partial eta squared

Acknowledgements

Not applicable.

Authors' contributions

İH, NK, and OA conceived and designed the study. İH and BA collected the data. İH and NK performed the data analysis. İH, NK, and AYÖ wrote and revised the manuscript. All authors approved the submitted version.

Funding

This study was supported by the Hatay Mustafa Kemal University Scientific Research Project Coordinatorship (21.GAP.034). The funding source did not play a part in the design of this study, the collection and analysis of data, the decision-making process for publication, or the preparation of the manuscript.

Data availability

The data supporting the findings of this study are available from the corresponding author, (İH), upon reasonable request.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the The Hatay Mustafa Kemal University Clinical Research Ethics Committee (Approval No:20.01.2022–25). This study carried out according to the Helsinki Declaration (NCT06343246, 03/29/2024) and adhered to CONSORT guidelines. Patients were provided with both written and oral information, and they subsequently signed an informed consent form.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Hatay Mustafa Kemal University, Hatay 31000, Turkey. [2]Department of Physiotherapy and Rehabilitation, Institute of Health Sciences, Hatay Mustafa Kemal University, Hatay, Turkey. [3]Department of Cardiology, Tayfur Ata Sökmen Faculty of Medicine, Hatay Mustafa Kemal University, Hatay, Turkey. [4]Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, Marmara University, Istanbul, Turkey.

Received: 13 June 2024 Accepted: 14 February 2025
Published online: 28 February 2025

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