Original Article

Impact of educational intervention and pedometer-based self-monitoring on physical activity levels in patients with pulmonary arterial hypertension

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Background: Appropriate levels of physical activity (PhA) provide health benefits to patients with chronic diseases, including patients with pulmonary arterial hypertension (PAH). In this study, we examined the effect of physicians' PhA recommendations on PhA, and the benefits and effectiveness of PhA self-monitoring using a pedometer for PAH patients.

Methods: A prospective clinical trial was performed from 22 April 2021, with consecutive PAH outpatients in stable condition at least three months prior to the study. Each patient was educated about the benefits of PhA in PAH during the initial visit. Patients wore pedometers (Omron HJ-321-E) for 2 weeks. After PhA assessment, the patients were contacted by a physician by phone. Patients who walked <5,000 steps per day (inactive group) were recommended to increase their PhA, and patients who walked ≥5,000 steps per day (active group) were recommended to maintain this level of PhA. Patients wore pedometers for 3 months. The primary endpoint was the number of steps taken after 12 weeks of the study. The secondary endpoints were the 6-minute walk distance (6MWD), quality of life (QoL) (36-Item Short-Form Health Survey), and anxiety and depression levels.

Results: The study included 41 PAH patients aged 45.9±11.9 years, with 32 (78%) of them women. Initially, 18 (44%) patients were in the inactive group (2-week mean: 3,318±1,185 steps/day) while 23 (56%) patients were in the active group (2-week mean: 7,647±1,991 steps/day). The entire study group showed an insignificant decrease in their PhA from 5,203 [interquartile range (IQR), 3,787–7,387] to 4,672 (IQR, 3,821–7,201) steps per day (P=0.57). Patients in the inactive group showed an insignificant increase in their PhA after 12 weeks [increase in the average number of steps per day by 104 (IQR, −244 to 1,007), P=0.52], while patients in the active group showed an insignificant trend towards PhA reduction [change in average daily steps: −815 (IQR, −1,400 to 580), P=0.37]. There were no differences at week 12 in the 6MWD, N-terminal-pro-B-type natriuretic peptide (NT-proBNP) level, QoL, or levels of anxiety and depression, all P values >0.05.

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Conclusions: Education, a simple recommendation about PhA, and self-monitoring with a pedometer are insufficient to achieve intervention in PAH patients. Additional methods of motivating and supervising these patients are necessary.

Keywords: Education; pulmonary arterial hypertension (PAH); physical activity (PhA); self-monitoring; step count

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Introduction

Exertional dyspnea and reduced exercise capacity are common symptoms of pulmonary arterial hypertension (PAH) (1-3). Clinical trials have shown that supervised exercise rehabilitation and training programs have many benefits for patients with PAH, including: improved exercise capacity, reduced disease symptoms, enhanced patients' quality of life (QoL), increase distance in the 6-minute walk test, and reduce N-terminal-pro-B-type natriuretic peptide (NT-proBNP) levels (4-8). Current PAH guidelines recommend supervised rehabilitation in stable, optimally pharmacologically treated patients (2,5). In real life, not all PAH patients have access to supervised rehabilitation, especially in rural areas and not all insurers reimburse supervised rehabilitation for PAH patients (8-10).

PAH patients might benefit from appropriate levels of physical activity (PhA) (11-13). One randomized trial in patients with PAH demonstrated the benefits of a supervised mobile health intervention (9). In the study, the group encouraged to be more physically active showed improvements in PAH patients' PhA levels (daily step count), QoL and reduced visceral fat volume (9).

In this study, we examined the effect of physicians' recommendations on PhA in patients with PAH, exploring whether the effect was dependent on the patient's baseline activity. Additionally, we checked whether the recommendation to increase PhA had an impact on the 6-minute walk distance (6MWD), NT-proBNP level, QoL, and psychological parameters. We present this article in accordance with the TREND reporting checklist (available at https://cdt.amegroups.com/article/view/10.21037/cdt-24-249/rc).

Highlight box

Key findings

- The study found that education, a simple recommendation about physical activity (PhA), and self-monitoring with a pedometer are insufficient to achieve intervention goals in pulmonary arterial hypertension (PAH) patients.

What is known and what is new?

- Supervised rehabilitation and supervised PhA may benefit patients with PAH.
- Compliance regarding wearing pedometers and counting steps was high in patients with PAH, but PhA targets were not met.
- Education about health benefits of PhA and self-monitoring with a pedometer are insufficient to achieve PhA goals in PAH patients.
- Additional methods of motivating and supervising PAH patients are essential to achieve the benefits of PhA.

What is the implication, and what should change now?

- Additional studies are warranted to examine the optimal methods of motivating and supervising PAH patients to increase PhA and effect of the intervention on clinical outcomes.

Methods

Trial design

A prospective, single, clinical study, involving simple recommendations and self-monitoring using a pedometer, was conducted between March 2021 and December 2022 in one PAH study center that is affiliated with the European Research Network. Each participant provided informed consent to participate in the study. This study was approved by the Bioethics Committee of the Centre of Postgraduate Medical Education (resolution 14/04/2021, register No. 62/2021). The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was registered in the ClinicalTrials.gov Registration and Results System Protocol 15/03/2024 (registration number NCT06312111).

The study was performed during the coronavirus disease 2019 (COVID-19) pandemic when restrictions had been relaxed. Patients wore masks at the hospital, but all walking tests were performed without masks. The examinations

were conducted during the patients' routine visits to the pulmonary hypertension (PH) care center.

Study participants

All study participants were adult (aged at least 18 years old) and had been diagnosed with PAH on the basis of right heart catheterization and additional exams described in the guidelines of both the European Society of Cardiology and the European Respiratory Society (2,14). Patients were optimally treated with pharmacological therapy, were receiving maximal targeted medication for PAH and were in stable condition with no progression or exacerbations of the disease at least 3 months prior to inclusion in the study. Exclusion criteria comprised mobility impairment due to musculoskeletal or neurological disease, cognitive impairment that could prevent completion of the questionnaire, and lack of consent to participate in the study. Ultimately, 41 patients were identified based on these criteria. In determining the sample size, we relied mainly on the study by Hemnes *et al.*, in which the study group size was similar, and on other studies assessing PhA and its effect on various PH severity that included 20 to 30 patients with PAH (9,13,15).

Study procedures/intervention

During the initial visit, patients were educated by a doctor about the documented health benefits of PhA in the general population, in chronic diseases, and in PAH. Various strategies to increase PhA were discussed. It was agreed with each patient that their usual PhA would first be measured, and then they would receive a recommendation regarding the number of steps per day to strive for. Each patient underwent a 6-minute walk test and had their blood sample taken to measure their NT-proBNP levels. The 36-Item Short Form Health Survey (SF-36) was used to measure the QoL, the Acceptance of the Illness Scale (AIS) was used to measure the disease acceptance, and the Hospital Anxiety and Depression Scale (HADS) was used to evaluate anxiety, depression, and anger levels. Over a period of 2 weeks, each patient measured their usual PhA with a pedometer and recorded their daily step counts in a diary. The first day was excluded from the analysis due to possible interference with the learning effect.

After 2 weeks, patients were asked to send data from their diaries to the study center, and within 24 hours of receiving the data, a doctor had analyzed the step counts and contacted each patient by phone. Patients who walked less than 5,000 steps per day were included in the inactive group and instructed by the doctor to increase their PhA to at least 5,000 steps a day. Strategies to increase PhA were discussed with each participant. The form of additional PhA was determined together with each patient, though for the majority of these inactive patients it an additional 30-minute walk of moderate intensity daily was suggested. Patients who averaged at least 5,000 steps per day were classified into the active group and asked to maintain their current level of PhA. The limit of 5,000 steps per day to separate active and inactive groups was chosen based on its frequent use in other studies including patients with chronic cardiac diseases and PAH, with this value distinguishing between inactive and active patients (12,16-19). Moreover, in the guidelines on PhA for mortality prevention in the general population, involving patients with chronic diseases, an estimate of 5,000 steps per day is obtained after converting the recommended PhA into steps (20).

Over the next 12 weeks, patients used pedometers to measure their PhA at homes and were tasked with independently achieving their goals without additional contact with a doctor or other staff member from the PH center.

At the end of these 12 weeks, patients were invited for a routine visit to the PH center. During the visit, they submitted records of their step counts, performed the 6-minute walk test, had their blood samples taken to measure their NT-proBNP levels, and again completed the SF-36, HADS and AIS questionnaires once more.

Device and step data

PhA was measured by a pedometer (Omron HJ-321-E), a small lightweight device weighing approximately about 20 g. This device was selected because it is widely available, affordable and easy to use. Additionally, it has a long battery life and can even be used in areas with poor internet access. The battery did not require replacement during the entire test. All participants were instructed to wear the pedometer correctly at all times, except when showering or sleeping. The pedometer could be attached to a belt or pants, or it could be put in a pocket. The pedometer has a 7-day memory so patients were instructed to write down their step results in a diary. Patients measured their steps over a period of 2 weeks. After that, they had teleconsultation with the doctor to discuss obtained results. The active phase of the study, during which patients constantly measured their

steps with a pedometer and recorded them in a diary, lasted another 12 weeks.

Primary and secondary outcomes

The primary outcome was step counts in patients with PAH. Secondary outcomes were changes in the 6MWD, NT-proBNP level, QoL, disease acceptance, and anxiety and depression levels after 12 weeks.

To assess QoL, a license number QM 057109 was obtained to utilize the 36-item Short Form (SF-36, v.2). SF-36 consists of 8 scales. The first four summarized components were used to evaluate the physical component of SF-36 (PCS); these components include physical functioning, role (physical), body pain and general health. The next four summarized components were used to evaluate the mental component of SF-36 (MCS); they include vitality, social functioning, role (emotional) and mental health (21). The scored items for each variable were coded and transformed on a scale of 0 (worst possible health state) to 100 (best possible health state). The higher the index, the better the QoL. The hospital anxiety and depression scale was used to assess anxiety and depression. It consists of 16 items divided into anxiety (seven questions), depression (seven questions), and anger (two questions). A cut-off value of eight or more in the HADS anxiety part (HADS-A) or HADS depression part (HADS-D) was used to determine whether patients were anxious or depressed (22,23). Acceptance of the disease was measured by the acceptance of illness scale (AIS) which contains eight questions. Answers were given on a scale of 1 (strongly agree) to 5 (strongly disagree). Patient could receive a minimum of 8 points and a maximum of 40 points. The higher the points, the higher the acceptance of the disease. A score of ≤18 denotes low illness acceptance, and a score of ≥30 denotes a high level of illness acceptance (24).

Statistical analysis

Statistical analysis was conducted using IBM SPSS Statistics software (IBM Corporation), version 28.0.1.0. Data distribution was tested using the Shapiro-Wilk test. Categorical variables are presented as numbers and percentages, while continuous variables are presented as medians and interquartile ranges (IQR) or as means and standard deviations. For group comparisons, χ^2, Fisher's, paired *t*-test or the Wilcoxon rank-sum test (Mann-Whitney *U* test) was used as appropriate. Missing step data in patients who did not achieve 100% compliance were completed with the average of the remaining days between visits one and two for each patient A linear regression model was used to identify predictors of PhA at follow up in patients with PAH. Differences in relationships were considered significant for P≤0.05.

Results

Compliance, safety and characteristics of the study group

Out of the 61 patients with PAH considered for inclusion in the study, 41 were included for further analysis (*Figure 1*). Two patients from the active group withdrew their consent to participate due to personal reasons after the initial phase of the study, and 2 patients were excluded from the analysis due to escalation of PH therapy during the study.

The initial phase of the study lasted two weeks. The mean follow-up for the entire study group during the active phase of the study was 101±24.8 days.

A physical method was used to assess compliance. The pedometer has a 7-day memory. Each patient was asked to write down the step counts given by the pedometer in a diary. Compliance was calculated by counting the number of days completed in the step diary during the study. Over the entire duration of the study, compliance with wearing the pedometer and counting steps in the whole study group was as high as 93.6% (range, 83.3–98.9%). There were no significant differences in compliance between the active and inactive groups. Compliance in the inactive group (<5,000 steps per day) was 93.3% (range, 84.1–96.5%), while compliance in the active group (≥5,000 steps per day) was 95% (range, 84.6–98.9%) (P=0.58). Patients willingly wore pedometers and counted their steps in the initial 2-week phase: compliance in both the inactive (range, 92.9–100) and active group (range, 100–100) was 100% (P=0.51). At follow-up, compliance remained high: 93.35% (range, 84.1–96.5%) for the inactive group and 95% (range, 84.6–98.95%) for the active group (P=0.58).

All of the pedometers remained in good working condition throughout the study, and none required battery replacement. No serious side effects were reported in any of the study groups.

Forty-one PAH patients aged 45.9±11.9 years were included in the study, 32 (78%) of whom were women. About 90% of all included patients were in the WHO functional class II. The initial characteristics of participants and differences between the active and inactive groups are presented in *Table 1*.

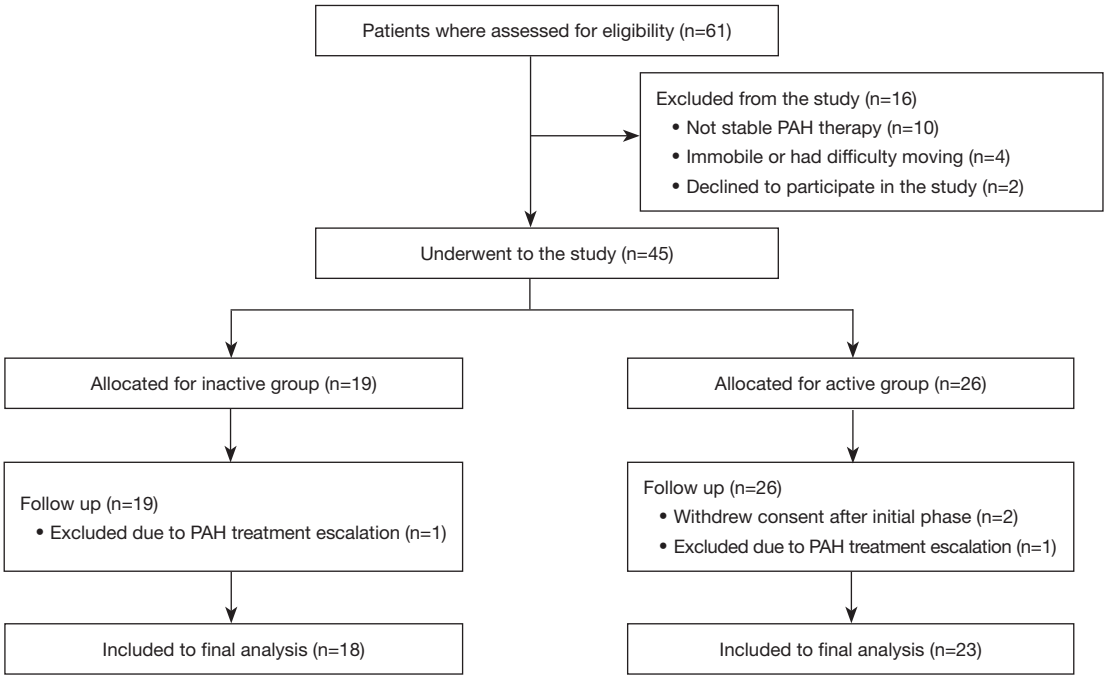

Figure 1 Flowchart of patient enrollment. PAH, pulmonary arterial hypertension.

Table 1 Clinical characteristics of the study participants

Parameter	All patients (N=41)	Inactive group (<5,000 steps/day) (N=18)	Active group (≥5,000 steps/day) (N=23)	Intergroup significance (P)
Sex (female)	32 (78.0)	11 (61.1)	21 (91.3)	0.02*
Age, years	45.9±11.9	46.3±13.5	45.7±10.9	0.85
Duration of PAH, years	6.0 (3.0–13.0)	5.9 (1.6–12.0)	6.0 (3.0–14.0)	0.71
Regular employment	26 (63.4)	7 (38.9)	19 (82.6)	0.004*
PAH subtype				0.43
CHD-PAH	25 (61.0)	12 (66.7)	13 (56.7)	
CTD-PAH	5 (12.2)	2 (11.1)	3 (13.0)	
HPAH	7 (17.1)	4 (22.2)	3 (13.0)	
IPAH	1 (2.4)	0	3 (13.0)	
Drugs for PAH				0.06
1 drug	10 (24.4)	2 (11.1)	8 (34.8)	
2 drugs	14 (34.1)	5 (27.8)	9 (39.1)	
3 drugs	17 (41.5)	11 (61.1)	6 (26.1)	
PAH medications				
PDE5/sGC	36 (87.8)	18 (100)	18 (78.3)	0.04*
ERA	32 (78.0)	14 (77.8)	18 (78.3)	0.97
Prostacyclin	21 (51.2)	13 (72.2)	8 (34.8)	0.02*

Table 1 (*continued*)

Table 1 (*continued*)

Parameter	All patients (N=41)	Inactive group (<5,000 steps/day) (N=18)	Active group (≥5,000 steps/day) (N=23)	Intergroup significance (P)
Parenteral prostacyclin	13 (31.7)	8 (44.4)	5 (21.7)	0.12
Calcium channel blocker, diltiazem	12 (29.3)	4 (22.2)	8 (34.8)	0.38
Anticoagulant	7 (17.1)	6 (33.3)	1 (4.3)	0.01*
Comorbidities				
HT	13 (31.7)	6 (33.3)	6 (26.1)	0.91
DB	1 (2.4)	0	1 (4.3)	0.84
CHD	0	0	0	0
COPD	2 (8.7)	2 (11.1)	2 (8.7)	0.79
Cancer	1 (2.4)	1 (5.6)	0	0.25
Obesity, BMI ≥30 kg/m^2	8 (19.6)	2 (11.1)	6 (26.1)	0.23
History of depression or antidepressants	4 (9.8)	3 (16.7)	1 (4.3)	0.19
WHO functional class				0.13
1	2 (4.9)	0	2 (8.7)	
2	37 (90.2)	16 (88.9)	21 (91.3)	
3	2 (4.9)	2 (11.1)	0	
6MWD, m	528±66	505±72	546±56	0.047*
NT-proBNP, pg/mL	149 [87–295]	264 [104–453]	112 [76–238]	0.05*
Saturation before 6MWT, %	95 [93–98]	94 [92.2–97.8]	96 [94–98.5]	0.25
Saturation after 6MWT, %	94 [85–96]	93.5 [82.7–96]	94 [89.5–96]	0.57
Desaturation†, %	3.5 [2–8.5]	3 [1–7]	4 [3-11]	0.27
Right heart catheterization‡				
RAP, mmHg	6 [5–8]	6 [3–6]	7.5 [6–8]	0.03*
PAP, mmHg	44 [36–52.5]	46 [37–53]	40 [36–51]	0.75
PVR, Woods Units	6.2 [5.1–8]	6.8 [5.4–9]	5.9 [4.6–7.3]	0.45
CI, L/min/m^2	2.9±0.7	2.9±0.8	2.8±0.6	0.79
Transthoracic echocardiography‡				
RAA, cm^2	21 [18–26]	22.5 [18–30]	20 [18–23.5]	0.23
TVPG, mmHg	54.6±22.1	59.6±19.5	50.7±23.6	0.21
TAPSE, mm	20.7±5.2	18.1±5.6	22.8±3.8	0.003*
Fluid in pericardium, yes	7 (17.1)	6 (33.3)	1 (4.3)	0.01*

Data are presented as median [interquartile range], number (percentage) or mean ± standard deviation. †, desaturation—the change in saturation before resting saturation before 6MWT and exercise saturation at the end of 6MWT; ‡, last right heart catheterization or transthoracic echocardiography before the study. *, P≤0.05. PAH, pulmonary arterial hypertension; CHD-PAH, pulmonary arterial hypertension due to congenital heart disease; CTD-PAH, pulmonary arterial hypertension associated with connective tissue disease; IPAH, idiopathic pulmonary arterial hypertension; HPAH, hereditary pulmonary arterial hypertension; PDE5/sGC, phosphodiesterase type 5/soluble guanylate cyclase; ERA, endothelin receptor antagonist; HT, arterial hypertension; DB, diabetes; CHD, coronary heart disease; COPD, chronic obstructive pulmonary disease; WHO, World Health Organization; 6MWD, six-minute walk distance; 6MWT, six-minute walk test; NT-proBNP, N-terminal-pro-B-type natriuretic peptide; RAP, right atrial pressure; PAP, pulmonary arterial pressure; PVR, pulmonary vascular resistance; CI, cardiac index; RAA, right atrial area; TVPG, transvalvular pressure gradient; TAPSE, tricuspid annular plane systolic excursion.

Table 2 Changes in steps and selected clinical parameters in the whole study group

Parameter	Whole study group		P
	Baseline (N=41)	Follow up (N=41)	
Steps per day	5,746.6±2,740.2; 5,203 [3,787–7,387]	5,659.7±2,923.6; 4,672 [3,821–7,201]	0.57‡
6MWTD, m	528±65.7	526±64.7	0.57†
NT-proBNP, pg/mL	149 [87–295]	171 [81–297]	0.33‡
PCS-SF-36, score	43.9±7.1	44.6±7.1	0.34†
MCS-SF-36, score	50.4±9.4	51.7±7.9	0.22†
AIS, score	29 [24–34]	31 [25–36]	0.02‡
HADS-A ≥8	8 (19.5)	10 (24.4)	0.06§
HADS-D ≥8	4 (9.76)	3 (7.3)	<0.01§
HADS-R	2 [1.0–4.0]	2 [1.0–4.0]	0.63‡

Data are presented as median [interquartile range], number (percentage) or mean ± standard deviation. †, Student's *t*-test for related variables; ‡, Wilcoxon; §, chi2. 6MWTD, 6-minute walk test distance; AIS, acceptance of illness score; HADS-A, Hospital Anxiety and Depression Scale (part assessing anxiety); HADS-D, Hospital Anxiety and Depression Scale (part assessing depression); HADS-R, Hospital Anxiety and Depression Scale (part assessing anger); NT-proBNP, N-terminal-pro-B-type natriuretic peptide; MCS-SF-36, mental component score of 36-Item Short-Form Health Survey; PCS-SF-36, physical component score of 36-Item Short-Form Health Survey.

Efficacy

The changes in the average number of steps per day during the active phase of the study were −174 (IQR, −758 to 1,043) for the entire group, 104 (IQR, −244 to 1,007) for the inactive group, and −815 (IQR, −1,400 to 580) for the active group. The changes in steps between baseline and end-point measures in both groups were not statistically significant.

Only 2 patients (11.1%) in the inactive group (initially <5,000 steps per day) achieved the intervention goal by increasing their number of steps to ≥5,000/day. Nine patients (50%) in the same group increased their average PhA compared to baseline.

Six patients (26.1%) reduced their PhA to <5,000 steps per day, and 17 patients (73.9%) from the active group maintained their PhA at the same level of ≥5,000 steps per day.

Clinical outcomes

The 6-minute walk test distance and the NT-proBNP concentration did not change significantly in either group. No significant changes were observed in the QoL nor in anxiety levels in both groups. However, the prevalence of depression significantly decreased in the whole study group. Acceptance of the disease significantly increased in the entire study group, and in the active group, but not in the inactive group. Changes in steps and selected clinical parameters in the whole study group are presented in *Table 2*, while changes in the active and inactive groups are shown in *Table 3*.

A linear regression model was used to check whether factors other than the recommended PhA affect the number of steps after the intervention. Gender, occupation, prostacyclin treatment and tricuspid annular plane systolic excursion (TAPSE) were included in the analysis. A multivariate linear regression model was built to predict 92.3% of the variable mean number of steps (R^2=0.92, P<0.001). The model was statistically significant.

Discussion

The main findings of this study can be summarized as follows: a simple doctor's recommendation about PhA is ineffective in PAH patients during a stable disease period, regardless of baseline PhA (I); wearing pedometers and counting steps are not uncomfortable for PAH patients (II).

The 2015 European Society of Cardiology/European Respiratory Society (ESC/ERS) Guidelines for the diagnosis and treatment of PH suggest encouraging PAH patients to be active within the limits of their symptoms (14). The current 2022 ESC/ERS Guidelines additionally recommend supervised rehabilitation in PAH (Class IA) (2). It has

Table 3 Changes in steps and selected clinical parameters in the active and inactive study groups

Parameter	Inactive group (<5,000 steps per day at baseline) (N=18)			Active group (≥5,000 steps per day at baseline) (N=23)		
	Baseline	Follow up	P	Baseline	Follow up	P
Steps per day	3,318±1,185; 3,532 [2,463–4,102]	3,504±1,170; 3,692 [2,625–4,210]	0.52†	7,647±1,991; 7,358 [6,026–9,232]	7,346±2,776; 7,008 [5,047–8,386]	0.37†
6MWTD, m	505±72	504±72	0.84‡	546±55	542±54	0.77‡
NT-proBNP, pg/mL	264 [104–453]	265 [120–503]	0.93‡	112 [76–238]	98 [72.5–197]	0.32‡
PCS-SF-36, score	42.5±6.1	43.5±7.4	0.24‡	45.0±7.7	45.6±7.0	0.60‡
MCS-SF-36, score	52.1±7.9	51.8±7.1	0.82†	49.1±10	51.7±8.6	0.46†
AIS, score	28.1±6.7	28.9±7.3	0.70†	29±6.6	31.7±6.7	0.03†
HADS-A ≥8	2 (11.1)	4 (22.2)	0.32§	6 (26.1)	6 (26.1)	0.12§
HADS-D ≥8	1 (5.55)	0	–	3 (13.0)	3 (13.0)	0.003§
HADS-R	2.3±1.6	2.3±1.6	>0.99†	2.8±1.5	2.6±1.4	0.60†

Data are presented as median [interquartile range], number (percentage) or mean ± standard deviation. †, Student's *t*-test for related variables; ‡, Wilcoxon; §, chi2. 6MWTD, 6-minute walk test distance; AIS, acceptance of illness score; HADS-A, Hospital Anxiety and Depression Scale (part assessing anxiety); HADS-D, Hospital Anxiety and Depression Scale (part assessing depression); HADS-R, Hospital Anxiety and Depression Scale (part assessing anger); NT-proBNP, N-terminal-pro-B-type natriuretic peptide; MCS-SF-36, mental component score of 36-Item Short-Form Health Survey; PCS-SF-36, physical component score of 36-Item Short-Form Health Survey.

been shown that in-hospital or outpatient rehabilitation programs can reduce clinical symptoms, anxiety and depression levels, as well as improve exercise capacity, the 6-minute walk test distance, QoL, skeletal muscle strength, and right ventricular function in PAH patients (4,7,8,10). In real life, especially in poor rural areas, patients with PAH still have little or no access to supervised rehabilitation or electronic equipment (9,25). Increased PhA will not replace rehabilitation for PAH patients but may provide additional benefits beyond those offered by standard treatment (11,26). In fact, education and medical recommendations to increase PhA remain the only tools available for some PAH patients in clinical practice.

The study showed that doctors recommendations for PhA to patients with PAH were ineffective. The negative results may be attributed to the fact that education and a one-time simple recommendation to increase PhA may not suffice to achieve a positive effect in inactive PAH patients and maintain PhA in active PAH patients. In both study groups at follow up, there were no changes in steps per day, 6MWD, WHO functional class, QoL, and anxiety levels compared to baseline. However, the prevalence of depression in the study group decreased, and the acceptance of the disease increased. The negative results of the study may indicate that greater supervision and motivation are needed to increase PhA among PAH patients. In a study assessing barriers to PhA in patients with PAH/CTEPH, the most frequently reported problems were lack of self-discipline, lack of energy, and lack of interest (27). Complex rehabilitation in PAH patients, which may be beneficial and effective, is always closely supervised (4,5,10). Hemnes *et al.* demonstrated the effectiveness of mobile health (mHealth) interventions in patients with PAH. Patients in the interventional group were supervised and received three automated text messages per day from the PH center showing their step counts and encouraging them to increase their PhA (9). The interventional PAH study group significantly increased their PhA by 1,250 steps per day (after adjusting for sex, age, baseline step count and functional class) compared to the control group, thus improving their QoL and reducing their visceral fat volume (9).

Another possible reason for negative study results could have been an inadequately selected or insufficiently intensive intervention. We set the goal of intervention to walking ≥5,000 steps per day for the inactive group and maintain PhA at a level ≥5,000 steps in the active group. We included PAH patients who were optimally treated pharmacologically, showed no signs of PH progression at least 3 months before the study, and had a low risk of death due to PH. It seemed reasonable for these patients to be given similar PhA goals as recommended for the general

population (20). In fact, there is no clearly defined data on the specific number of steps per day that benefit patients with PAH. One prospective observational study showed that PAH patients who needed hospitalization had less baseline step counts [median steps per day 3,899 (IQR, 2,425–4,463)] compared to patients who did not need hospitalization [median steps per day 5,367 (IQR, 3,700–6,548)] (28). Based on our experience, it was better to give patients one simple goal to strive for (e.g., 5,000 steps per day) in order to increase PhA, rather than recommending a range of steps.

Step counting and activity monitoring can be a valuable addition to existing indicators of PAH disease severity and QoL. Studies involving patients with PAH have demonstrated that the number of steps per day shows a correlation to the 6-minute walk test (13,17,29,30), NT-proBNP levels (30), right ventricle systolic function (15,30), and changes in QoL (13) can be used for additional assessment of the effectiveness of pharmacological treatment (16). Despite the negative results, our study may be helpful in improving the relationship between the PH treatment team and the patient. Most patients were enthusiastic to partake in the study. They were open to additional contact with the doctor and agreed to count their steps and undertake long-term self-monitoring of their PhA. Wearing pedometers and counting their steps were not inconvenient for the PAH patients, and this intervention was not associated with any serious side effects. Patients showed high compliance with wearing their pedometers and counting their steps throughout the study, amounting to 93% for the entire study group. Compliance did not decrease significantly in the active phase of the study despite reduced contact with the treatment team, confirming the positive attitude of patients towards such interventions and monitoring. This finding was consistent with those of closely supervised studies (9,16).

Limitations

This study has its limitations. It is a small single-center study. Thirty-nine (95%) of the 41 participants were in the WHO functional class I or II, stable, and at a low risk of death according to the four-strata model; these characteristics do not reflect the conditions of a usual population of PAH patients. We did not use a QoL questionnaire specifically dedicated to patients with PAH as it was not widely available in our center; instead, we used the more general SF-36 questionnaire, which has been validated for PAH patients and other populations such as patients with left heart failure. A higher limit of 5,000 steps per day was arbitrarily used as a goal of intervention and to separate the high and low PhA groups. This limit might have been too high and a major limitation of the study. There is no defined step value for PAH patients that reflects a good or bad prognosis or that may benefit PAH patients. In some meta-analyses of the general population associations between PhA and health outcomes are curvilinear, and people might benefit from small increases in PhA (11,31,32). It can be assumed that in patients with PAH this relationship may be similar. Our study was performed during the COVID-19 pandemic which may have affected the undertaken PhA and the patient's QoL. The study was conducted when the strictest restrictions had been relaxed and the same preventive rules against COVID-19 were applied for all participants throughout the entire study period. None of the study participants suffered from COVID-19 during the study.

Conclusions

This study demonstrates that education, a simple recommendation to increase PhA in physically inactive PAH patients, and self-monitoring with a pedometer are insufficient to achieve the intervention goal. The intervention is inexpensive, well tolerated and accepted by PAH patients. This study suggests that initially inactive PAH patients require additional methods of motivation and supervision to increase their PhA.

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Footnote

Reporting Checklist: The authors have complete the TREND reporting checklist. Available at https://cdt.amegroups.com/article/view/10.21037/cdt-24-249/rc

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://cdt.amegroups.com/article/view/10.21037/cdt-24-249/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was approved by the Bioethics Committee of the Centre of Postgraduate Medical Education (resolution 14/04/2021, register No. 62/2021), and written informed consent was obtained from each patient. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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