Safety, feasibility and effectiveness of the remotely delivered Pulmonary Hypertension and Home-Based (PHAHB) physical activity intervention

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Shareable abstract (@ERSpublications)
The PHAHB exercise trial demonstrates that an entirely remotely delivered physical activity intervention is safe and feasible, and displays preliminary effectiveness for improving physical function, physical activity levels and QoL in adults with PH https://bit.ly/3M5Jj4d

Cite this article as: McCormack C, Kehoe B, Cullivan S, *et al*. Safety, feasibility and effectiveness of the remotely delivered Pulmonary Hypertension and Home-Based (PHAHB) physical activity intervention. *ERJ Open Res* 2024; 10: 00608-2023 [DOI: 10.1183/23120541.00608-2023].

Received: 21 Aug 2023
Accepted: 9 Oct 2023

Abstract

Background Pulmonary hypertension (PH) is a heterogeneous condition, associated with a high symptom burden and a substantial loss of exercise capacity. Despite prior safety concerns regarding physical exertion, exercise training as a supportive therapy is now recommended for PH patients. Currently, most programmes are hospital-based, which limits accessibility. There is a need to provide alternative approaches for physical activity engagement for PH patients. The aim of this research was to develop, implement and evaluate the safety, feasibility and effectiveness of home-based physical activity intervention for PH.

Methods An entirely remotely delivered home-based physical activity intervention underpinned by behaviour change theory and informed by end-users, was assessed using a single-arm feasibility study design. Participants (n=19; 80% female) with a mean±SD age of 49.9±15.9 years with a diagnosis of PH undertook a 10-week, home-based physical activity intervention with induction training, support materials, telecommunication support, health coaching, exercise training and assessments, all remotely delivered. Training involved respiratory training along with a combination of aerobic and resistance exercises.

Results The intervention was deemed safe as no adverse events were reported. A high level of feasibility was demonstrated as the protocol was implemented as intended, sustained a high level of engagement and adherence and was well accepted by participants in terms of enjoyment and utility. There was a significant improvement in functional capacity, physical activity, exercise self-efficacy and quality of life, between baseline and post-training.

Conclusion The study demonstrates that an entirely remotely delivered home-based physical activity programme is safe, feasible and effective in improving functional capacity, physical activity and quality of life in PH patients.

Introduction

Pulmonary hypertension (PH) affects ∼1% of the global population and is characterised by progressive dyspnoea and fatigue leading to a reduction in functional capacity and quality of life (QoL). Insufficient physical activity in patients with PH further compromises aerobic capacity, haemodynamic function and the odds of survival [1, 2]. In contrast, exercise training improves exercise capacity and QoL [3–5].

To date, most PH exercise training studies have utilised the Heidelberg model [6] which involves an intensive 3-week inpatient induction phase, with a continued multimodality, monitored outpatient period

for 12 weeks. Exercise involving a combination of aerobic and resistance training along with respiratory training is undertaken ⩾5 days a week. Despite demonstrating significant improvements in exercise capacity, muscle function, QoL and pulmonary haemodynamics, the Heidelberg model is resource intensive and unlikely to be scalable [7]. Furthermore, most PH units are located in large urban centres and are not necessarily accessible to patients living in remote, rural areas.

An alternative and pragmatic approach, found to be as effective as a supervised exercise programme in cardiac rehabilitation, is a home-based model of delivery [8]. Home-based exercise interventions have the potential to mitigate commonly reported barriers to participation in centre-based programmes, such as time constraints, access to facilities, transportation issues, parking and cost [9]. A recent study reported a preference among PH patients for home-based physical activity programmes, with appropriate support and monitoring [10, 11]. The few studies that have examined the beneficial effects of home-based programmes in PH have found them to be safe and effective in improving functional capacity and QoL [12–14].

The use of telehealth in conjunction with wearable technology, and evidence-based behavioural change techniques, provides a low-cost and scalable solution to exercise training promotion in PH, that is likely to be sustainable and foster long-term behaviour change. Research of remote programmes in other chronic respiratory diseases appears to be largely beneficial in improving clinical outcomes [15]. To our knowledge, no previous research has examined the feasibility and effectiveness of a home-based physical activity intervention that is delivered entirely remotely in PH patients.

The Pulmonary Hypertension and Home-Based (PHAHB) intervention is a novel patient-centred, theoretically informed and remotely delivered physical activity programme for PH patients. The primary aim of the PHAHB trial was to assess the safety and feasibility of the intervention. The secondary aim was to assess the effects of PHAHB on physical function, physical activity, sedentary behaviour, fatigue, QoL and exercise self-efficacy.

Methods

This study employed a single group, pre-/post-intervention design. Participants were recruited from the National Pulmonary Hypertension Unit at the Mater Misericordiae University Hospital (Dublin, Ireland). Eligible participants were invited to participate during their routine 3-/6-month clinic visit commencing in February 2020. The study adhered to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting template [16] and Template for Intervention Description and Replication (TIDieR) [17]. Ethical approval was obtained from the Mater Misericordiae institutional review board (ref:1/378/2032) and Dublin City University research ethics committee (DCUREC/2018/246). The trial was registered at www.isrctn.com (identifier ISRCTN83783446).

Eligibility criteria included adults aged ⩾18 years with formal diagnosis of PH (World Health Organization groups I and IV) by right heart catheterisation with mean pulmonary arterial pressure ⩾25 mmHg and resting pulmonary capillary wedge pressure ⩽15 mmHg, on optimised conventional PH therapy and clinically stable with no medication changes in the 2 months prior to enrolment. A detailed list of exclusion criteria has been published previously [18]. Written informed consent was obtained prior to participation.

To date, exercise training interventions for PH have not been underpinned by behavioural change theory despite calls for the use of theory in the implementation of interventions [19]. The PHAHB intervention was underpinned by social cognitive theory [20] and associated behavioural change techniques found to be effective for increasing physical activity including instruction on how to perform behaviour, setting graded tasks, goal-setting, self-monitoring and adding objects to the environment [21, 22]. In addition, the intervention was end-user-informed through qualitative research exploring patients' attitudes towards physical activity, exercise preferences and desired support needs [10, 11].

Intervention

The full study protocol for the PHAHB intervention has been described previously [18]. Briefly, participants completed a 10-week patient-centred, home-based physical activity intervention. All assessments and components of the study intervention were completed remotely. Participants were in regular contact with the researcher *via* telecommunication technologies. The multicomponent physical activity intervention included three 1:1 60–90-min induction sessions, five 30-min health coaching sessions (with a focus on goal setting, action planning, feedback on performance, review of goals, and problem solving) and an individualised exercise training programme. Participants were provided with a stationary bike (NordicTrack GX 2.7U), exercise videos, a specifically designed physical activity manual and log-book and Fitbit Charge 3 fitness tracker for self-monitoring. In addition, participants were provided

with an automatic blood pressure monitor (Beurer BM44), finger pulse oximeter (Safe Heart peripheral oxygen saturation (S_{pO_2}) monitor) and real-time single lead electrocardiography/heart rate/respiratory rate monitor (Frontier X, UK) for assessment purposes.

The exercise training involved a combination of aerobic, resistance and respiratory training. Individualised exercise plans were agreed based on a shared decision-making process between the clinical exercise physiologist and the participant during bi-weekly individual health-coaching sessions. The modified 10-point Borg rating of perceived exertion (RPE) scale [23] was used to regulate exercise intensity. Participants aimed to achieve an initial RPE of 3 (moderate), with progression to an RPE of 4 (somewhat hard), if manageable.

Safety and feasibility

Safety was assessed by documentation of serious adverse events, which were defined as unintended physical injury resulting from or contributed to by study participation, that required additional monitoring, treatment or hospitalisation or resulted in death. The feasibility of the intervention was assessed in accordance with guidelines by Bowen *et al*. [24], and included the following domains: implementation, demand, acceptability and practicality. Feasibility outcomes were captured through trial monitoring, researcher field notes and participant exit questionnaires. Secondary outcomes were assessed remotely at baseline and after the 10-week intervention (post-training) and included exercise capacity (6-min walk test (6MWT)), lower body strength (30-s sit-to-stand test (STS)), physical activity levels and sedentary behaviour (using an ActivPAL3 micro accelerometer). In addition, overall level of fatigue (fatigue severity scale), QoL (Cambridge Pulmonary Hypertension Outcome Review (CAMPHOR)) and indices of exercise self-efficacy (including outcome, task, scheduling, recovery and self-regulatory self-efficacy) were also assessed using validated questionnaires as described previously [18].

The 6MWT was administered at home (n=3) or a local community centre (n=17) according to standard guidelines [25] using detailed step-by-step video and written instructions and supervised remotely by the clinical exercise physiologist *via* telecommunications. Real-time heart rate and a single-lead ECG were monitored continuously using telemetry (Frontier X). Timing, distance covered, RPE, blood pressure and S_{pO_2} were measured with the assistance of a family member/friend. The 30-s STS test was also supervised remotely by the clinical exercise physiologist, who provided a demonstration prior to the test. Each participant performed two trials separated by 5 min, with the best score being recorded. ActivPAL micro activity monitors (PAL Technologies, Glasgow, UK) were placed on the right thigh and used to assess sedentary behaviour and levels of light, moderate and vigorous intensity physical activity over a 7-day period. The accelerometer, along with the questionnaires used to measure fatigue, QoL and indices of exercise self-efficacy were mailed to participants and include a pre-paid postage envelope for return.

Statistical analysis

Statistical analysis was performed using SPSS v27 (IBM, New York, NY, USA). The mean difference between baseline and post-training on efficacy outcomes was compared using a paired-samples t-test or a Wilcoxon signed-rank test. A two-way repeated-measures ANOVA was used to compare within group differences in RPE, palpitations, chest pain, fatigue and breathlessness during the 6MWT at baseline and post-training. Significant main effects and interactions were examined using the Bonferroni test. To assess temporal changes in outcome measures, exercise training was divided into three blocks of 3 weeks each, starting from week 2. Mean differences in outcome measures across the three blocks were compared using a one-way repeated-measures ANOVA. Significant main effects were probed using the Tukey test. The significant level was set at α-value of $p<0.05$.

Results

Participant enrolment

The study recruitment process is shown in figure 1. 103 patients were screened, of whom 45 met the study inclusion criteria and 20 were enrolled. A recent change in disease-targeted therapy or being scheduled to begin a new drug therapy during the intervention period were the primary reasons for ineligibility (figure 1). One participant dropped out of the study due to hospitalisation for an illness unrelated to PH or the intervention.

Participants baseline characteristics are summarised in table 1. The sample population was 80% female, with a mean±SD age of 49.9±15.9 years. Participants resided at an average distance of 105 km from the National Pulmonary Hypertension Unit. Participants were diagnosed with pulmonary arterial hypertension (PAH) (n=17) or chronic thromboembolic pulmonary hypertension (n=3). The majority of PAH was idiopathic.

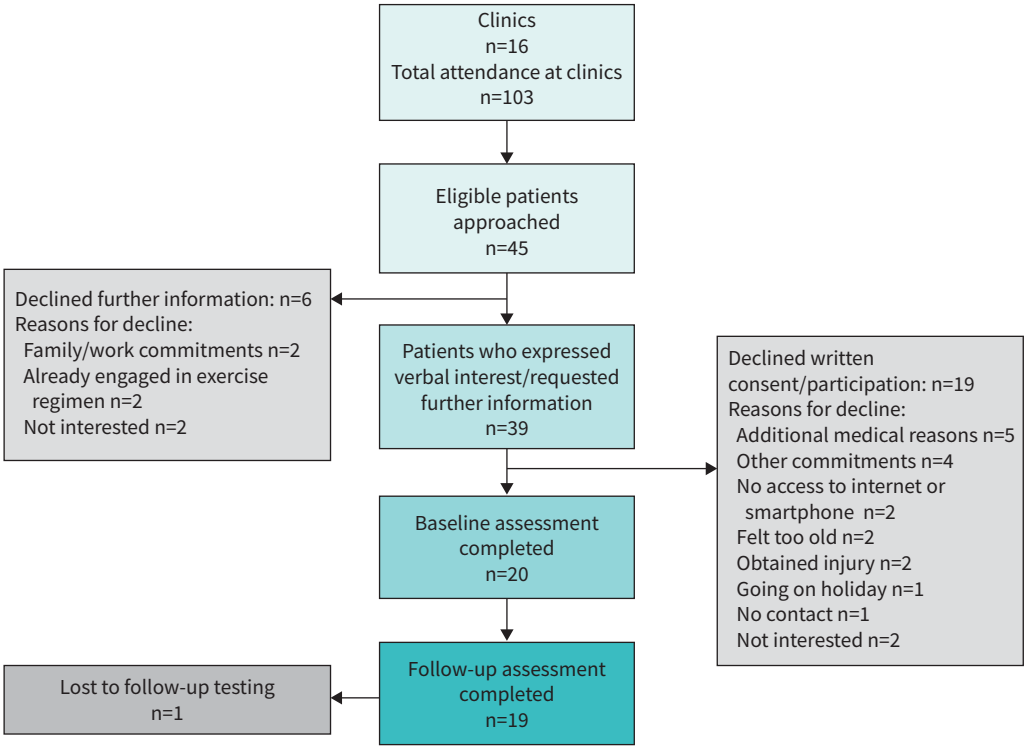

FIGURE 1 Flow diagram summarising the study recruitment process.

Primary outcomes

The intervention was deemed safe as there were no serious or minor adverse events reported during the study. One participant reported a knee injury unrelated to participation in the study. Engagement was high, with all participants (n=20) attending the three online induction sessions. The mean±SD duration of the induction and health coaching sessions were 58±14 min and 28±8 min, respectively. A high proportion (85%) of participants attended the five health-coaching sessions and 5% each attended four, three and two sessions. Mean self-reported adherence to the individually prescribed/agreed resistance training, respiratory training and aerobic training was 91%, 94% and 95%, respectively. Fitbit uptake was high with 85% of participants appropriately syncing their Fitbit data to the Fitbit Health Solutions Dashboard. The Fitbit tracker was the most frequently used support tool, with 84% reporting daily use. Participant compliance to recording their daily exercise was 100%. Almost two-thirds (63%) of participants indicated that they referred to the physical activity manual and 47.3% indicated viewing the exercise videos (*via* WhatsApp) almost daily.

Researcher field notes provided a detailed account of the feasibility of the intervention from the perspective of the clinical exercise physiologist. With regards to fidelity, each component of the intervention was delivered as per protocol. A quarter of participants required one additional follow-up call (mean±SD 17±8 min) to assist with Fitbit setup or to address questions related to the exercise programme.

The remote-based nature of the intervention delivery presented a number of technical challenges including insufficient internet connectivity and smartphone storage capacity along with synchronisation issues. A series of pre-recorded "how-to" videos produced to assist with Zoom, Fitbit and accelerometer set-up along with instructions for assessment procedures, activity monitoring, 6MWT and questionnaire completion were identified as valued resources.

The induction sessions were deemed feasible by the researcher. They were identified as a key component of the intervention and provided an opportunity for rapport-building with the participants. Topics related to safety, the acute effects of exercise, the benefits of exercise, breathing techniques and managing exercise intensity were well received by participants. Discussions with participants regarding potential barriers to programme engagement and programme goals allowed the researcher to become familiar with their individual support needs and circumstances.

TABLE 1 Participants' baseline clinical characteristics

Male:female	4:16
Age (years)	49.90±15.87
Height (m)	166.56±10.40
Weight (kg)	79.14±21.97
BMI (kg·m^{-2})	28.31±6.42
Distance from NPHU (km)	104.69±109.15
PH specific diagnosis	
IPAH	10 (50)
CTD-PAH	4 (20)
IPAH-CCB	2 (10)
CTEPH	3 (15)
Other	1 (5)
Duration of diagnosis (years)	6±4.40
NYHA functional class	
1	3 (15)
2	12 (60)
3	5 (25)
Risk stratification	
Low	10 (50)
Intermediate	10 (50)
Comorbidities	
Yes	19 (95)
No	1 (5)
Medication combination treatment	
None	2 (10)
Monotherapy	2 (10)
Double combination	8 (40)
Triple combination	8 (40)
PH targeted drugs	
Phosphodiesterase-5 inhibitors	18 (90)
Endothelin-receptor antagonists	16 (80)
Prostaglandin-12	10 (50)
Pre-syncope	
None	14 (70)
Syncope	6 (30)
Unknown	1 (5)
Clinical signs of RHF	
Yes	1 (5)
No	19 (95)
Respiratory rate (beats·min^{-1})	17.50±1.05
Blood profile	
Hb (g·dL^{-1})	14.01±1.86
BNP (ng·L^{-1})	138.58±161.94

Data are presented as n, mean±SD or n (%). BMI: body mass index; NPHU: National Pulmonary Hypertension Unit; PH: pulmonary hypertension; IPAH: idiopathic pulmonary arterial hypertension; CTD-PAH: connective tissue disease associated PAH; IPAH-CCB: IPAH calcium channel blocker responder; CTEPH: chronic thromboembolic pulmonary hypertension; NYHA: New York Heart Association; RHF: right heart failure; Hb: haemoglobin; BNP: brain natriuretic peptide.

Most participants (79%) found the PHAHB intervention to be "extremely" enjoyable or "quite a bit" (21%) enjoyable. Health coaching sessions were deemed to be the most helpful (84.2%) component of the intervention, followed by induction sessions and the Fitbit tracker (both 78.9%).

Secondary outcomes

There was a significant increase in the average number of steps taken per day and time spent in light intensity physical activity and moderate-to-vigorous intensity physical activity (table 2). Self-reported engagement in aerobic training and resistance training during each exercise block (B) is summarised in table 3. There was a significant increase in the weekly number and duration of cycle ergometer session and the mean duration of the walking sessions between B1 and B3. The number of aerobic training sessions (sum of cycle ergometer and walking training) per week and the time per session increased significantly

TABLE 2 Self-reported exercise training

	Exercise blocks			p-values		
	B1 (weeks 2–4)	B2 (weeks 5–7)	B3 (weeks 8–10)	B1 *versus* B2	B1 *versus* B3	B2 *versus* B3
Cycle ergometer						
Sessions per week (n)	1.72±1.07	2.42±0.99	2.56±1.10	0.063	**0.014***	0.992
Time per week (min)	21.98±17.29	40.29±26.91	33.87±33.87	**0.014***	**0.002***	**0.010***
Walking						
Sessions per week (n)	1.82±1.17	1.98±1.38	2.00±1.24	1.00	1.00	1.00
Time per week (min)	42.91±34.88	54.66±44.51	66.98±51.28	0.102	0.01	0.220
Aerobic training#						
Sessions per week (n)	3.56±1.24	4.40±1.88	4.56±1.55	**0.043***	**0.004***	1.00
Time per week (min)	64.89±37.13	94.96±60.32	117.40±65.23	**0.002***	**0.000***	**0.002***
RPE	3.73±0.47	3.85±0.52	4.03±0.44	0.555	**0.017***	0.318
Resistance training						
Sessions per week (n)	2.14±0.64	2.43±0.83	2.56±0.68	0.092	**0.017***	0.092
Sets per session (n)	2.43±0.47	2.75±0.38	2.94±0.22	**0.053***	**0.001***	0.070
Sets per week (n)	5.42±1.97	7.05±2.66	7.59±2.20	**0.002***	**0.000***	**0.002***
Reps per session	9.61±1.71	10.98±2.07	12.29±1.45	**0.002***	**0.000***	**0.008***
Reps per week (n)	55.36±24.54	82.45±36.66	95.28±33.98	**0.000***	**0.000***	**0.004***
Exercises per session (n)	4.21±0.53	4.92±0.97	5.71±0.98	**0.004***	**0.000***	**0.000***

Data are presented as mean±SD, unless otherwise stated. Bold font represents statistical significance. B: blocks; RPE: rate of perceived exertion. #: sum of number of cycle ergometer and walking sessions. *: p<0.05.

between all three blocks. The mean±SD RPE of the aerobic training sessions increased from 3.73±0.47 during B1 to 4.03±0.44 during B3 (p=0.017). The mean number of resistance training sessions and the mean number of sets and repetitions per session increased significantly between B1 and B3. There was no significant difference in the number of respiratory sessions undertaken between any of the 3-week blocks.

TABLE 3 Secondary outcome measures at baseline and post-training

	Baseline	Post-training	p-value
Outcomes			
6MWD (m)	380.34±65.72	451.05±76.55	**0.001**
30 STS (reps)	10.05±2.89	18.32±3.95	**0.001**
Sleep duration (h)	9.43± 1.58	9.92±1.57	**0.004**
Fatigue	44.89±17.68	42.26±15.30	0.089
Physical activity and sedentary behaviour			
Sedentary waking (h)	10.14±1.84	9.10±1.56	**0.001**
Standing (h)	3.21±1.18	3.54±1.38	0.078
Stepping (h)	1.18±0.60	1.58±0.72	**<0.001**
LIPA (h)	1.02±0.46	1.18±0.50	**0.008**
MVPA (h)	0.15±0.16	0.39±0.30	**<0.001**
QoL			
CAMPHOR total score	30.26±16.64	25.89±18.51	**0.019**
CAMPHOR QoL	10.21±7.50	8.79±7.547	**0.032**
CAMPHOR activity	7.68±4.110	8.32±4.85	0.259
CAMPHOR symptoms	12.37±6.80	8.79±7.08	**<0.001**
Exercise self-efficacy			
Outcome self-efficacy	4.68±0.52	4.89±0.47	**0.034**
Task self-efficacy	7.63±1.53	8.46±1.19	**<0.001**
Scheduling self-efficacy	7.81±1.65	8.69±1.28	**0.001**
Recovery/coping self-efficacy	7.10±1.91	8.52±1.37	**<0.001**
Self-regulatory exercise self-efficacy	7.72±1.55	8.57±1.21	**0.001**

Data are presented as mean±SD, unless otherwise stated. Bold font represents statistical significance. 6MWD: 6-min walk distance; STS: sit-to-stand test; LIPA: light-intensity physical activity; MVPA: moderate-to-vigorous physical activity; QoL: quality of life; CAMPHOR: Cambridge Pulmonary Hypertension Outcome Review.

Performance in the 6MWT improved significantly (p<0.001) between baseline and post-training (figure 2), with a mean increase of 72 m (range 34–115 m). None of the participants reported chest pain or palpitations pre- or post-6MWT at baseline or post-training and the mean S_{pO_2} value remained constant at 94–95%. Perception of breathlessness and fatigue increased significantly from pre- to post-6MWT at both baseline and post-training. There was no interaction effect for perception of breathless and fatigue between baseline and post-training.

There was a significant improvement in the 30-s STS score (p<0.001) between baseline and post-training (figure 2). The mean±SD increase was 8.32±3.95 reps (range 12–25 reps). The difference in the STS and 6MWT performance scores between baseline and post-training were calculated and were found to be positively correlated (r=0.75). Each 1-rep increase in STS was associated with a 10.5-m improvement in 6-min walk distance (6MWD).

Compared to baseline, there was a significant improvement in total CAMPHOR score (p=0.019) and symptoms (p<0.001) at post-training (table 3). Although the fatigue severity score (table 3) was 6% lower at post-training than baseline, it failed to reach statistical significance (p=0.089). All measures of self-efficacy improved significantly between baseline and post-training (table 3).

Discussion

The present study found that a novel and entirely remotely delivered physical activity intervention is safe, feasible and effective in medically stable PH patients. A high safety profile has been reported previously in inpatient [6, 26–28] and hybrid models of exercise training [12, 29, 30]. Participants perceived the programme to be practical and reported a high level of satisfaction and enthusiasm, as evidenced by the high engagement rates. The study provides preliminary evidence of effectiveness through improvements in physical function, physical activity and QoL.

The extensive design process of the PHAHB intervention is likely to have positively influenced adherence rates. A novel aspect of the PHAHB intervention was the focus on physical activity behaviour change and the utilisation of evidence-based behaviour change techniques to enhance intervention effectiveness. It has been shown that physical activity interventions that combine behaviour change techniques such as self-monitoring, goal setting, providing feedback on performance, adding object to the environment and review of behaviour goals [31] elicit greater effectiveness. The individualised approach to exercise training planning and progression using shared decision-making guided by a clinical exercise physiologist has not been reported in previous PH studies. Empowering individuals to engage in the decision-making process

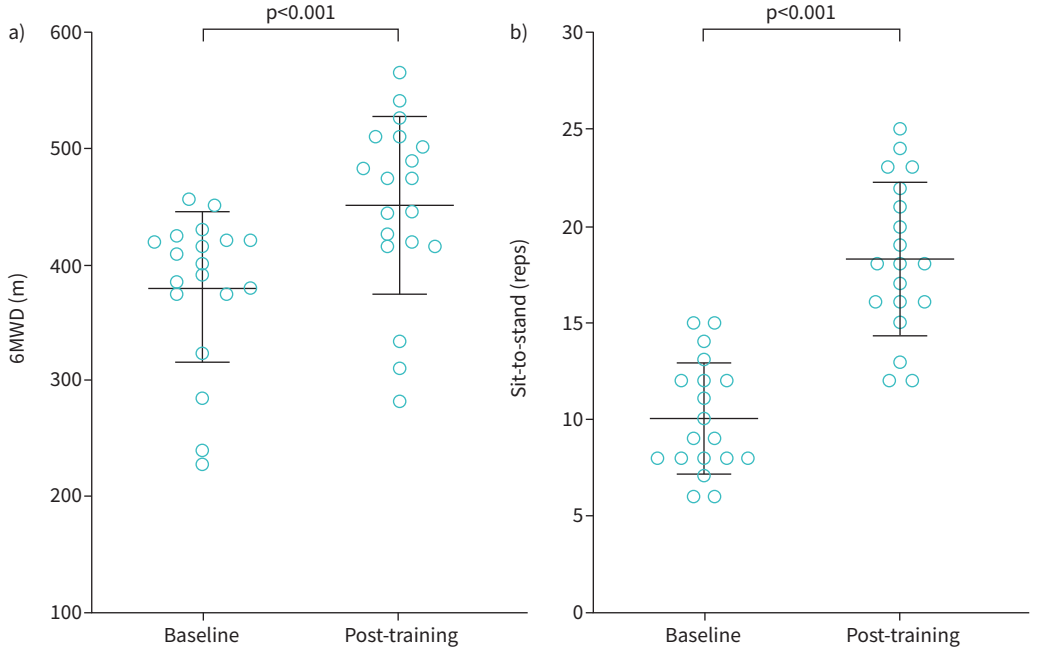

FIGURE 2 a) 6-min walk distance (6MWD) and b) 30-s sit-to-stand performance at baseline and post-training.

and to self-regulate their physical activity is likely to foster the development of more autonomous forms of motivation, a central element in increasing participation and enjoyment levels [32] and promoting adherence to exercise [33].

Performance in the 6MWT has previously been shown to strongly correlate with daily physical activity levels, right atrial pressure and prognosis in PH [34]. All participants in the current study improved their 6MWD. The average improvement in 6MWD of 72 m is similar to a recent 6-month home-based intervention which included 17 PH participants who engaged in an aerobic training and respiratory training rehabilitation programme [14] and is at the upper end of the range reported for PH patients following participation in centre-based exercise training programmes (53–72 m) [4, 35, 36]. 10 of the participants who achieved a 6MWD <440 m at baseline achieved a score ⩾440 m post-training, as recommended by the European Society of Cardiology/European Respiratory Society risk stratification as a treatment goal for PH patients [37].

Our study contributes to the literature in terms of physical activity outcomes in PH. To our knowledge, no previous work has focused on physical activity behaviour change as an important outcome in physical activity interventions despite preliminary evidence indicating that physical activity and sedentary behaviour may have unique influences on survival in this cohort [2, 38]. The PHAHB intervention increased moderate-to-vigorous physical activity by 154% and reduced sedentary behaviour by 11%. Given the recent evidence indicating that physical activity needs to be of at least moderate intensity to significantly improve 6MWD and QoL in individuals with PH [38], the present findings are encouraging from a clinical perspective. The 17% increase in light intensity physical activity (1.5–2.9 METs), which primarily involves activities of daily living, may also provide an important therapeutic target, particularly for sedentary/insufficiently active populations [39].

The improvements in QoL were similar to those recently reported in PH patients following 1 year of medical treatment [40]. The significant change in CAMPHOR symptoms domain may potentially influence patients' ability to engage in physical activity and activities of daily living. It is encouraging that the majority of participants were close to attaining the recommended minimal important clinical difference values [40] following the relatively brief PHAHB intervention.

The manner in which the intervention was remotely monitored and assessed has potential implications for the broader feasibility and scalability of this pragmatic approach. Importantly, participants did not incur any financial cost during the programme, and no travel was involved. The unit cost for the intervention equipment (wearable trackers, cycle ergometer, print material) was approximately EUR 270. Participants safely completed baseline and follow-up assessments remotely, with no major issues reported. The adoption of remote assessment/monitoring in clinical practice may help to improve patient care.

Strengths and limitations

A major strength of this study was the systematic, iterative approach taken to develop the intervention, which was evidence-based, underpinned by behaviour change techniques and informed by end-users. The study included a national sample of PH patients with a broad range of ages. However, only three men participated in the study, which may limit the generalisability of the study findings in terms of gender. Other study limitations included the absence of a control group and the small sample size. However, this was planned as a pilot study with the primary aim of establishing the safety and feasibility of the intervention to inform a larger-scale evaluation using a randomised controlled trial (RCT). Finally, remote monitoring is open to potential bias that could affect the accuracy and reliability of the data.

Conclusion

The PHAHB trial demonstrates that a novel remotely delivered physical activity intervention is safe and feasible, and has preliminary effectiveness for improving physical function, physical activity levels and QoL in PH. The PHAHB model holds promise for the adoption of home-based delivery models among the wider PH population. Further research in the form of larger scale RCTs is needed to confirm these findings.

Provenance: Submitted article, peer reviewed.

Acknowledgements: We would like to acknowledge the pulmonary hypertension (PH) nurse specialists and secretary in the PH Unit in the Mater Hospital (Dublin, Ireland) for their support with this trial. We would like to thank all PH patients involved in this study and their family members, carers and friends for their engagement and support.

Conflict of interest: B. Kehoe's institution has received grant funding for the submitted research from Actelion Pharmaceuticals. B. Kehoe has received grant funding from the National Cancer Control Programme and Irish Research Council, outside the work submitted. S. Gaine's institution has received grant funding for the submitted research from Actelion Pharmaceuticals. S. Gaine has received honoraria and speaker's fees from MSD and Janssen Pharmaceuticals, outside the submitted work; received travel support from MSD and Janssen Pharmaceuticals, outside the submitted work; participated in a data safety monitoring board for United Therapeutics and Janssen Pharmaceuticals; and has received consulting fees from or Altavant, Gossamer Bio, Janssen and MSD outside the submitted work. B. McCullagh has received honoraria, speaker's fees and travel support from Janssen Pharmaceuticals, outside the submitted work. N.M. Moyna's institution has received grant funding for the submitted research from Actelion Pharmaceuticals. N.M. Moyna has received grants from Enterprise Ireland and Health Service Executive, outside the submitted work; and received consulting fees from Irish Health Life, outside of the submitted work. All other authors have nothing to disclose.

Support statement: This study was supported by Janssen Ireland Science UC grant NOPRODPAH4014. Funding information for this article has been deposited with the Crossref Funder Registry.

Ethics statement: Ethical approval was obtained from the Mater Misericordiae institutional review board (ref. 1/378/2032) and Dublin City University research ethics (DCUREC/2018/246).

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