



Hybrid compared to conventional pulmonary rehabilitation: an equivalence analysis

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Shareable abstract (@ERSpublications)

A new, accessible PR implementation combining the outpatient centre and primary care was investigated. Compared to conventional PR, equivalence could not be confirmed on exercise capacity. Both programmes show statistical improvements in clinical outcomes. <https://bit.ly/4ascnwZ>

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Abstract

Background Pulmonary rehabilitation (PR) is a well-established intervention for patients with COPD, but access, uptake and completion are low. This retrospective propensity-matched study aimed to analyse equivalence from a hybrid PR modality against conventional PR.

Methods Between 2013 and 2019, 214 patients with COPD with valid baseline physical activity assessments enrolled in conventional PR for three times per week for 3 months. In 2021–2022, 44 patients with COPD enrolled in 3 months of hybrid PR, introducing two providers: once per week in the outpatient centre and two times per week in a primary care setting near the patient's home. All sessions were supervised. Propensity score matching (1:1) was performed. Equivalence between both programmes was analysed for exercise capacity with the equivalence margins of ± 30 m on the 6-min walk distance (6MWD). Clinical outcomes, accessibility and adherence were compared using t-tests.

Results 44 patients (mean \pm SD age 67 \pm 8 years; forced expiratory volume in 1 s (FEV₁) 47 \pm 15% predicted; 6MWD 355 \pm 122 m) in the hybrid PR group were matched to 44 patients (mean \pm SD age 66 \pm 8 years; FEV₁ 46 \pm 17% predicted; 6MWD 354 \pm 103 m) in the conventional PR group. Equivalence on the increase in 6MWD could not be confirmed; nevertheless, both groups improved their 6MWD clinically significantly (hybrid PR change 63 m (90% CI 43–83 m); conventional PR change 39 m (90% CI 26–52 m)). Changes in quality of life and symptoms were similar. Dropout in hybrid PR (23%) was comparable to conventional PR (27%) (p=0.24). Adherence in both groups was high and accessibility was better for patients following hybrid PR.

Conclusion Hybrid PR can be offered as an effective alternative to conventional PR, if patients are willing to take up the offer.

Introduction

Pulmonary rehabilitation (PR) is a very efficacious non-pharmacological intervention for patients with COPD and has become an established component of care [1–3]. Despite robust evidence supporting its benefits, uptake and completion rates remain low [4]. The number of patients accepting the offer to start PR ranges from 2% to 55% [4–7]. Additionally, dropout or non-completion rates range from 23% to 32% [8–10]. Patients describe the travel distance to the PR centre and disruption of their daily routine as important barriers affecting both uptake and completion [4, 10, 11].

It is unlikely that a single PR programme is adequate to serve all candidates. A recent workshop report by the American Thoracic Society emphasised the importance of innovating PR by exploring new settings that address current challenges [12]. Novel programmes that meet the minimum requirements for providing PR but with a setting tailored to the needs of patients may enhance uptake [12].



The traditional model of multidisciplinary PR is based in an outpatient centre, but different modalities of PR in various settings have already been explored. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic contributed to the popularity of these alternatives. Telerehabilitation and home-based rehabilitation have emerged as promising alternatives with similar results on exercise capacity and quality of life compared to centre-based PR [13, 14]. However, these programmes often include home visits by the providers, which might be of burden to the healthcare team. In addition such programmes may focus largely on exercise training, and face-to-face access to the multidisciplinary team may be challenging. A lot of heterogeneity concerning the content and structure of PR has been described in these studies, making it hard to formulate firm conclusions.

Our outpatient PR centre proposed a new modality of implementing PR when access to the outpatient centre was limited due to the SARS-CoV-2 pandemic. To allow for social distancing, a reduction in the number of patients participating in PR during one session was imposed, resulting in a waiting list. A form of hybrid PR was introduced in the usual care pathway combining the expertise of the outpatient centre with primary care physiotherapists. Primary care physiotherapy is typically available in the close neighbourhood of the patient, allowing more flexibility. Hybrid PR could be of relevance to increase access and completion of PR. This resulted in a unique model enabling remote but supervised PR while maintaining access to the multidisciplinary team.

The aims of this retrospective study were 1) to analyse equivalence of functional exercise capacity and compare clinical outcomes of the hybrid PR programme compared to conventional outpatient PR, and 2) to explore accessibility, adherence and completion in both programmes. Since both programmes aimed to deliver exercise training to the same standard and dose, an equivalence was hypothesised for the change in exercise capacity with no significant differences in other clinical outcomes. A lower dropout rate and higher accessibility in the hybrid PR group was hypothesised.

Methods

Participants

Baseline physical activity assessments by accelerometry, which is part of the clinical routine assessment, were available for 82% of patients with COPD starting conventional PR between 2013 and 2019. This database was used as the reference group. From February 2021 until November 2022, patients with COPD were included in the hybrid PR, except if their case was judged too complex for hybrid PR or if patients had a strong preference to follow the conventional centre-based PR programme. All patients participating in PR were recruited from the tertiary University Hospitals Leuven (Leuven, Belgium) and approval of the Ethics Committee Research UZ/KU Leuven was obtained for this retrospective study (S67725). The CONSORT statement extension on reporting non-inferiority and equivalence randomised trials was followed [15].

Conventional PR

At the University Hospitals Leuven, conventional PR is a centre-based multidisciplinary programme that has been running for over 20 years, adhering to the American Thoracic Society/European Respiratory Society guidelines [2]. Patients with COPD followed the conventional outpatient PR programme three times per week for 3 months. The programme consisted of exercise training, educational sessions and support from the multidisciplinary team, including physiotherapists, a nurse, a dietician, an occupational therapist, a psychologist, a social worker and a physician. Two hours of supervised group-based training consisting of whole-body exercises and strength training were performed, allowing a total training duration of 6 h per week. Approximately 25–30 patients exercised together in one session. Typically, the session consisted of the following exercises: stationary bike, treadmill, stair climbing, arm ergometry, leg press, vertical traction and chest press. Initial exercise intensity was determined as 60% of the maximum load from the cardiopulmonary exercise test (CPET) for the bike and 75% of the walking speed achieved during the 6-min walk test (6MWT) for walking. Resistance training started at 75% of the one repetition maximum, with three sets of eight repetitions. Progression was guided by Borg scores, aiming for a fatigue and dyspnoea rating of 4–6/10. Symptoms, heart rate, transcutaneous oxygen saturation and session content were documented in a logbook for monitoring purposes.

Hybrid PR

Hybrid PR comprised a combination of two settings: the outpatient PR centre and individual primary care physiotherapy. Before initiating hybrid PR, patients either selected a primary care physiotherapist based on their preference or received a recommendation from the centre, with the minimal requirement being access to a treadmill or stationary bike in the exercise room. The rehabilitation team contacted the chosen physiotherapist to outline the proposed programme, allowing for questions and initial session planning.

A primary care physiotherapist is typically available in close proximity to the patient's home, and according to the National Institute for Health and Disability Insurance in Belgium, patients are entitled to 30 min of individual therapy per session. The goal of the hybrid PR programme was to obtain a frequency of two sessions per week with the primary care physiotherapist and one session per week at the outpatient centre so that access to the multidisciplinary expertise team was ensured. A total training duration per week was aimed at 3 h. Sessions with the primary care physiotherapists were conducted individually, in contrast to group-based sessions at the centre. All sessions were supervised. Because of the shorter duration per session, typically the patient did the stationary bike or the treadmill, stair climbing and resistance training for the lower and upper limb based on the available equipment. Resistance training options included specialised equipment, elastic bands and free weights. The exercise intensity, based on symptoms or the repetition maximum estimation, and progression in primary care were aimed similar to the conventional PR, depending on session duration and available equipment. The logbook was provided to the patient who handled it between both settings, ensuring both settings were updated on the progress of the patient.

Outcome measures

All assessments took place at the outpatient centre 1 week prior to starting the PR programme and after 3 months of PR. Patients were considered to have completed the PR programme if they performed assessments at the 3-month mark. Adherence was defined as an attendance rate of >70% of the scheduled sessions. To evaluate functional exercise capacity, patients performed the 6MWT [16]. A CPET was performed on a cycle ergometer starting with unloaded cycling and increasing the work rate by $10 \text{ W} \cdot \text{min}^{-1}$ to assess the safety/physiological response of exercise and determine the peak oxygen uptake ($V_{\text{O}_2\text{peak}}$) and peak work rate (WR_{peak}) [17]. Isometric quadriceps force (QF) was measured with the Biodex dynamometer [18]. Quality of life was measured using the Chronic Respiratory Disease Questionnaire (CRDQ), and symptoms with the modified Medical Research Council (mMRC) dyspnoea scale [19, 20]. Physical activity was assessed with the validated DynaPort MoveMonitor (DAM; McRoberts, The Hague, The Netherlands). Following the recommendations from the international task force on physical activity in COPD, patients were asked to wear the DAM for 7 consecutive days during waking hours [21]. The mean amount of steps per day and movement intensity (MI) during walking measured on weekdays were included in the present analysis. A valid measurement was considered when data of at least 4 weekdays with >8 h of wear time were available [21]. Other assessments were lung function, anthropometrics, travel distance from the patient's home to the outpatient centre for all patients and travel distance from the patient's home to the physiotherapist for patients that followed the hybrid PR. Travel distances were determined using Google Maps as a proximation of accessibility. Fidelity of the PR programme was confirmed by evaluating progression of weekly training sessions carried out in the outpatient centre in both groups.

Propensity score matching

Propensity score matching was used as a method to balance the baseline characteristics of both groups using a propensity score model [22]. Based on the baseline 6-min walk distance (6MWD), forced expiratory volume in 1 s (FEV_1), age and body mass index (BMI), a propensity score was given to each patient. These covariates were chosen as variables used in other similar studies and their influence on the outcome of PR [23, 24]. An optimal 1:1 propensity score matching was performed with a calliper of 0.25 without replacement. Researchers performing matching were blinded to completion of PR. The balance of the baseline characteristics were assessed using independent t-tests between the hybrid PR group and the matched conventional PR group.

Statistical analysis

An equivalence analysis was performed between the hybrid PR group and the conventional PR group on functional exercise capacity. Equivalence margins were set using the minimal important difference (MID) of 30 m on the 6MWD [25]. If the confidence interval of the change in 6MWD between both groups fell within the predetermined margin of equivalence (−30 to 30 m), both programmes were considered equivalent. Based on a first experience in a pilot trial, we performed a sample size calculation for equivalence for the 6MWD. Based on the MID of 30 m, a between-group difference of 3 ± 41 m, an α -level at 0.05, a power of 0.80 and an expected dropout rate of 30%, 44 patients in each group were expected. The rehabilitation outcome measures of patients following the hybrid PR programme were compared to outcome measures of patients from the matched conventional PR programme. The clinical outcomes were the change in 6MWD, $V_{\text{O}_2\text{peak}}$, WR_{peak} , QF, CRDQ, mMRC and physical activity expressed as mean steps and MI during walking. Other outcomes were the difference in travel distance, number of responders on the 6MWD and number of dropouts in both groups. Qualitatively, the reasons for dropout were described. The within- and between-group differences were measured with dependent paired and independent unpaired t-tests, respectively. The analysis of daily steps was performed *via* a mixed model adjusted for

duration of daylight [21]. The difference in dropout and adherence was measured via a Chi-squared test. The p-value for all measures was set at $p < 0.05$. Statistical analysis was performed using SAS version 9.4 (SAS Institute, Cary, NC, USA).

Results

Patient population

Baseline data were available from 214 patients with COPD starting the conventional PR programme between 2013 and 2019. 76 patients were screened from February 2021 until November 2022 to start hybrid PR. Seven patients with COPD were excluded because the multidisciplinary team judged them as not eligible for referral to primary care professionals because of financial issues, language barrier, social issues or complex comorbidities. Six patients preferred to start conventional PR. The patient flowchart is shown in figure 1. 44 patients initiated hybrid PR. After propensity matching, no significant between-group differences were present between the hybrid PR group compared to the matched conventional PR group. Patient characteristics of the hybrid PR and the matched conventional PR group are shown in table 1.

Efficacy

The within- and between-group differences of patients in the hybrid PR group and the matched conventional PR group on the clinical outcomes are shown in table 1. The equivalence analysis for the change in the 6MWD was not significant, as shown in figure 2. The change in 6MWD between the hybrid PR group and the conventional PR group was 24 m (90% CI 1–48 m), where the upper limit of the CI exceeds the MID. Therefore, equivalence could not be confirmed. Patients improved their functional exercise capacity above the MID of 30 m in the conventional PR group and the hybrid PR group, with changes of 39 m (90% CI 26–52 m) and 63 m (90% CI 43–83 m), respectively. 66% of patients in the hybrid PR group responded on the 6MWD compared to 57% in the conventional PR group ($p=0.45$). The

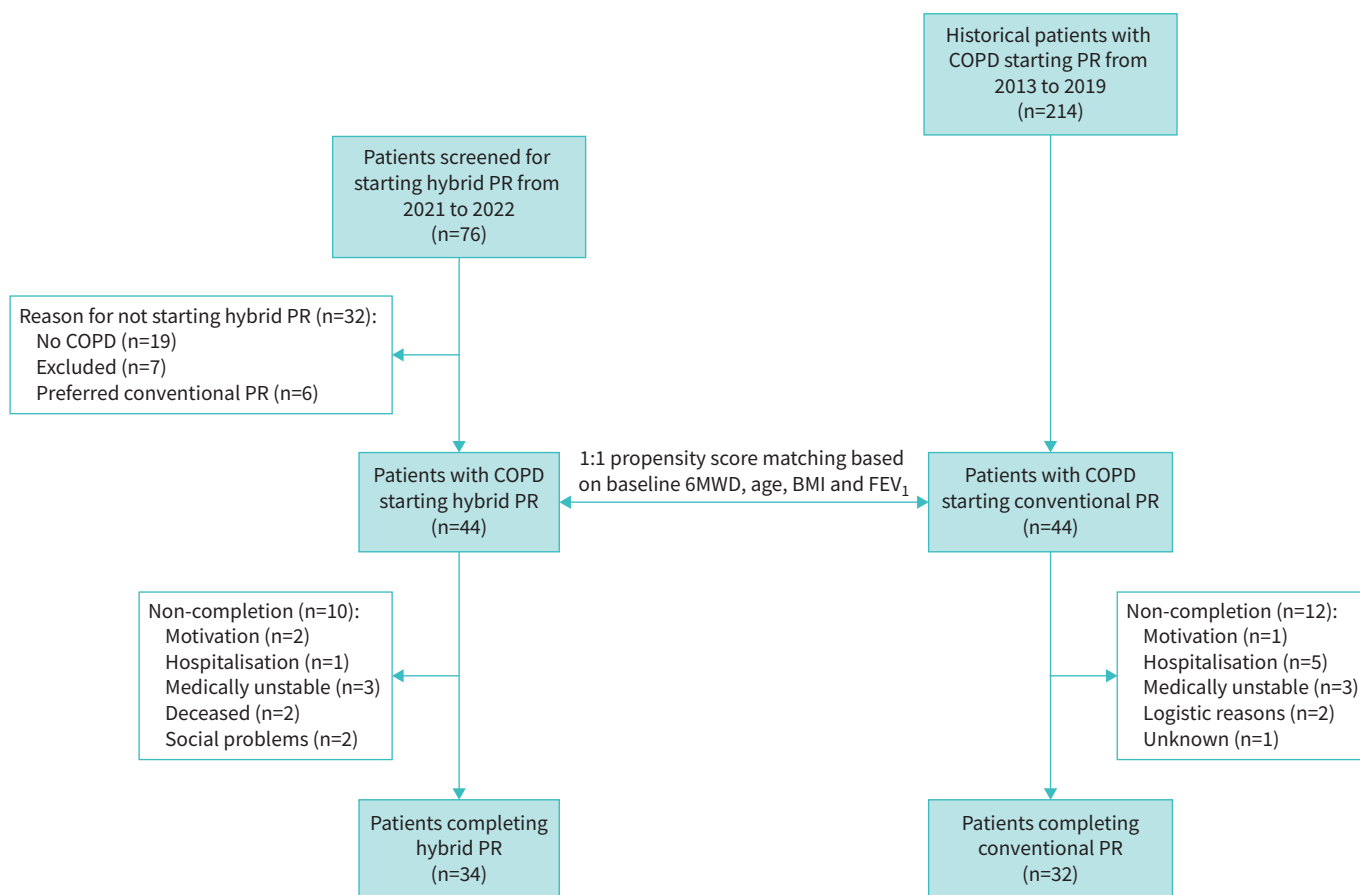


FIGURE 1 Flow of patients with COPD that followed conventional or hybrid pulmonary rehabilitation (PR). 6MWD: 6-min walk distance; BMI: body mass index; FEV₁: forced expiratory volume in 1 s.

TABLE 1 Baseline patient characteristics, and within- and between-group differences in clinical outcomes in the hybrid and matched conventional pulmonary rehabilitation (PR) groups

	Baseline characteristics		Within-group differences		Between-group differences	p-value (between-group difference)
	Hybrid PR (n=44)	Conventional PR (n=44)	Hybrid PR (n=34)	Conventional PR (n=32)		
Age, years	67±8	66±8				
Sex						
Male	28	28				
Female	16	16				
BMI, kg·m ⁻²	25.3±6.2	24.7±5.9				
FEV ₁ , L	1.17±0.44	1.21±0.49	0.05±0.25	-0.04±0.16	0.08±0.21	0.11
FEV ₁ , % pred	47±15	46±17	2.5±13	-1.8±6	4.3±9.4	0.09
6MWD, m	355±122	354±103	63±68*	39±42*	24±57	0.09
6MWD, % pred	57±18	56±17	10±10*	6±7*	4±9	0.09
QF, Nm	107±45	93±35	15±27*	12±17*	3±23	0.54
QF, % pred	82±32	72±20	14±18*	8±11*	5±15	0.16
CRDQ score						
Dyspnoea	14±4	16±5	5±4*	6±5*	-1±4	0.47
Fatigue	15±4	15±4	2±4*	4±3*	-2±4	0.21
Emotional function	29±7	27±6	3±7	5±5*	-1±6	0.59
Mastery	17±4	17±5	1±4	3±3*	-1±4	0.26
Total	73±15	75±16	11±15*	18±12*	-5±14	0.27
mMRC dyspnoea score	2±1	2±1	0±1	0±1	0±1	0.75
V _{O₂peak} , L	0.93±0.32	0.90±0.29	0.03±0.18	0.10±0.21*	-0.07±0.19	0.11
WR _{peak} , W	56±23	48±22	7±12*	10±14*	-3±13	0.37
Daily steps, n·day ⁻¹	3544±360	3031±338	222±127	1371±379*	-1016±447	0.03
MI during walking, m·s ⁻²	1.54±0.25	1.59±0.26	-0.001±0.11	0.007±0.094	-0.009±0.10	0.75

Data are presented as mean±SD, except for daily steps as mean±SEM. BMI: body mass index; FEV₁: forced expiratory volume in 1 s; 6MWD: 6-min walk distance; QF: quadriceps force; CRDQ: Chronic Respiratory Disease Questionnaire; mMRC: modified Medical Research Council; V_{O₂peak}: peak oxygen uptake; WR_{peak}: peak wattage; MI: movement intensity. *: p<0.05 for within-group differences.

hybrid PR group did not show significant changes after 3 months of rehabilitation on the CRDQ emotional function and mastery scores. These dimensions improved significantly in the conventional PR group; however, no between-group differences were present. The total CRDQ score improved significantly above the MID in both groups. The change in daily steps improved significantly more in the conventional PR group compared to the hybrid PR group (p=0.03). No other between-group differences were present.

Completion, adherence, fidelity and access

10 patients (23%) did not complete the hybrid PR compared to 12 patients (27%) in the conventional PR group (p=0.24). Two patients dropped out of conventional PR due to logistic reasons. Other reasons for dropout in the conventional and hybrid PR groups are described in figure 1. 97% of patients were adherent in the conventional PR group compared to 87% in the hybrid PR group (p=0.15). Fidelity in the content of the programme was confirmed by observing similar progression in exercise workload and duration in the hybrid PR and conventional PR groups, as shown in figure 3. Patients in the hybrid PR group

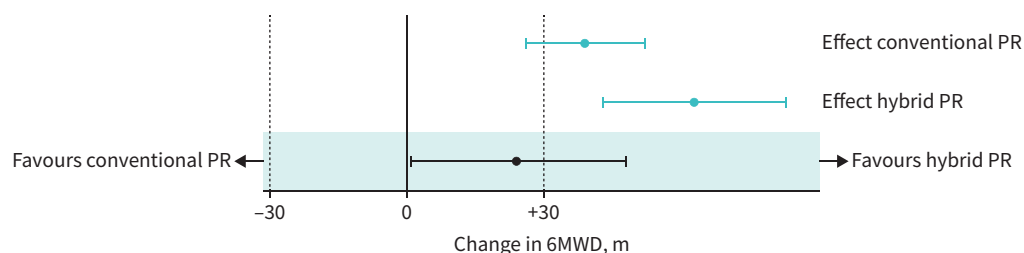


FIGURE 2 Change in 6-min walk distance (6MWD) for the conventional pulmonary rehabilitation (PR) group and the hybrid PR group, and the difference between both groups (shown in the shaded area). Data are presented as mean (90% CI).

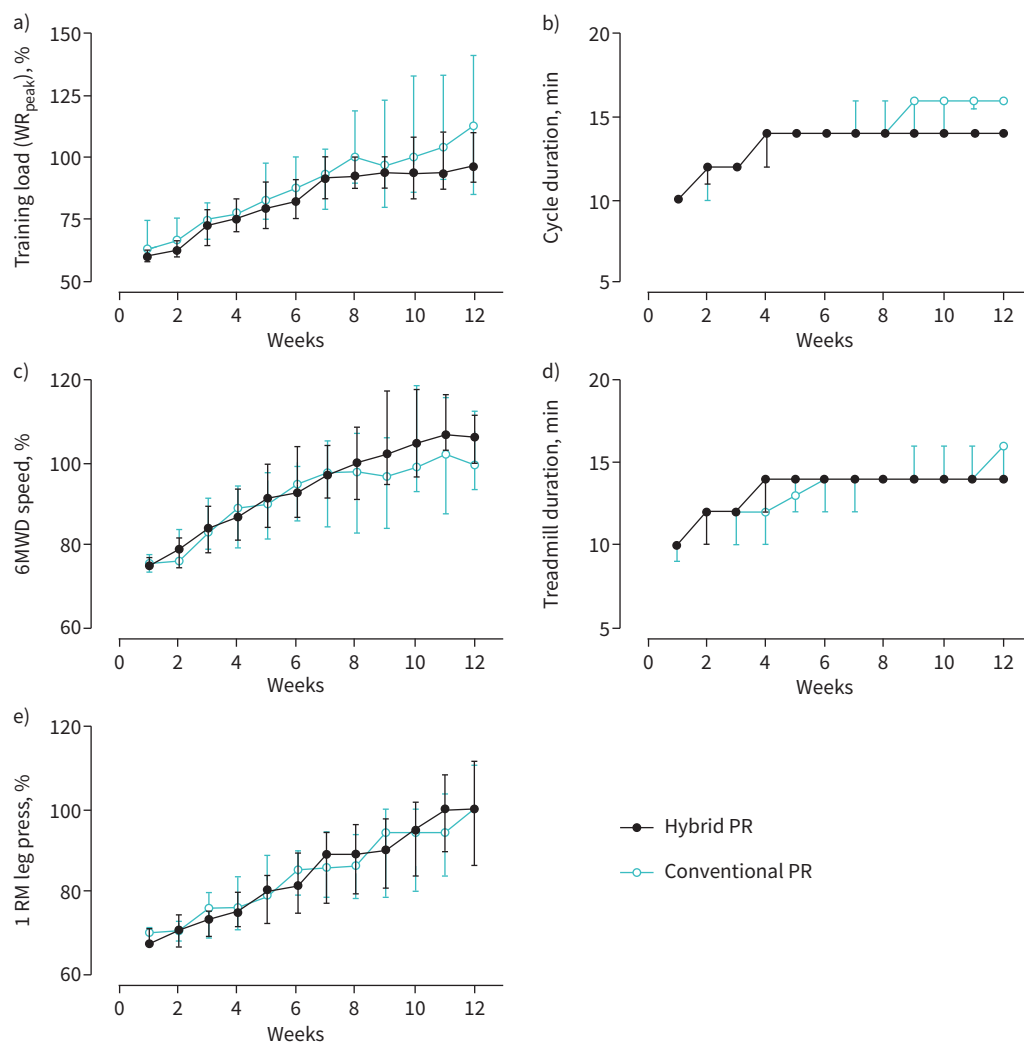


FIGURE 3 Weekly intensity progression of the exercise workload and duration of both the hybrid and conventional PR programmes. Data are presented as median with interquartile range. WR_{peak} : peak work rate; 6MWD: 6-min walk distance; 1 RM: one repetition maximum; PR: pulmonary rehabilitation.

increased their walking speed from week 1 to week 12 by $1.28 \pm 0.48 \text{ km} \cdot \text{h}^{-1}$, similar to patients in the conventional PR group, increasing by $1.15 \pm 0.48 \text{ km} \cdot \text{h}^{-1}$. The travelled distance as a measure of accessibility was $25 \pm 19 \text{ km}$ to the centre (three times per week) for patients following conventional PR, which was similar to patients in hybrid PR that travelled $20 \pm 15 \text{ km}$ to the centre (once per week). For patients following hybrid PR, the distance between the patient and their primary care physiotherapist was $4 \pm 5 \text{ km}$ (two times per week).

Discussion

This study compared a hybrid modality of PR to conventional centre-based PR. While both programmes improved exercise capacity, equivalence for improvement in exercise capacity could not be confirmed. Considering all end-points of this retrospective analysis, we cannot conclude that one programme is better than the other. Patients in both programmes improved clinically and statistically on exercise capacity, muscle force and quality of life.

In our conventional PR programme, the 6MWD improved 39 m. This improvement in functional exercise capacity aligns closely with the findings of the Cochrane review on PR for COPD, which reported a mean improvement of 43 m after PR [3]. Improvements in our hybrid PR group, however, were considerably higher, with a mean improvement of 63 m. A 4-month PR programme in primary care, consisting of two supervised sessions per week, also found improvements in 6MWD of 60 m [26].

New modalities of PR have been advocated for and investigated to tackle the current challenges in terms of access, uptake and completion [12]. Telerehabilitation and home-based PR have already been investigated as possible alternatives. Our findings from the hybrid PR group show outcomes that align or surpass the effects on exercise capacity and quality of life that were shown in telerehabilitation or home-based PR [13, 14].

In the present study, remarkably, patients in the conventional PR group improved their physical activity after 3 months of PR to a clinically relevant extent above 1000 steps, which was unexpected [27]. We can only speculate on possible reasons for this difference. First, our data were corrected for the mean duration of daylight, considering the change in daylight after 3 months of PR between both groups of 185 ± 265 min per day ($p=0.02$). Correcting for the change in daylight provided similar results. Second, data from the whole sample of patients prior to propensity matching ($n=214$) showed an increase of 724 ± 180 daily steps after 3 months of PR. Although our data were propensity matched, there remains a possibility that these groups were different based on unmeasured characteristics. Lastly, physical activity behaviour of patients in the hybrid PR may have been influenced by the SARS-CoV-2 pandemic and the regulatory measures of cultural, social and sport activities. However, based on a recently published review, exercise training alone does not show significant improvements in physical activity [28]. Still, patients that followed hybrid or conventional PR remained physically inactive after 3 months with an average daily step count below 5000. An additional behavioural programme focused on enhancing physical activity might be advised.

The travel distance to the PR centre is an important factor described by patients to limit uptake and completion [11]. This new modality can provide an alternative, ensuring better accessibility and flexibility by reducing travel distances significantly, although not entirely since this distance to the centre still had to be covered once weekly. This might explain that two patients dropped out of conventional PR due to logistics reasons, which was not found in the hybrid PR group. However, 10 patients still dropped out of the hybrid PR programme for various other reasons, so this programme gives a solution only for a few patients. Further reductions in travel distances could be obtained through telerehabilitation, but in that case access to the multidisciplinary team and a closer supervision by expert physiotherapists may be lost. Additionally, other trials show that patients often have a preference for a centre-based PR [29, 30]. Our study suggested that 12% of eligible patients preferred the centre-based PR. We could not ascertain the proportion of patients rejecting conventional PR but who would have chosen hybrid PR. This requires additional confirmation in a prospective study, such as the study protocol of Cox *et al.* [31] investigating the implementation of offering the choice between home-based or centre-based PR. For 10% of patients screened for hybrid PR, the multidisciplinary team judged conventional PR as the more suitable option. Typically, these patients had a very complex clinical or psychosocial presentation. Future implementation of hybrid PR should be a joint decision made by the multidisciplinary team and the patient taking into account possible contra-indications for referral to primary care.

A strength of this study is that it was powered for equivalence. Propensity score matching was used to reduce the impact of confounding bias to balance the baseline characteristics of these patients. However, we cannot exclude some unmeasured confounders that might imbalance both groups. Some additional limitations need to be addressed. First, this was a small sample size study looking into accessibility, uptake, adherence and efficacy. Additionally, in this retrospective study the SARS-CoV-2 pandemic occurred between both PR programmes. Second, occurrence of exacerbations was not collected and hence could not be investigated. Lastly, only short-term results were available, selection bias cannot be excluded and experiences were not assessed. Additionally, the implementation of this new modality should be evaluated in different healthcare systems.

We conclude that hybrid PR can be as effective as centre-based outpatient conventional PR, if patients are willing to accept the offer and the regional healthcare system provides for primary care physiotherapists nearby.

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Data availability: The aggregated data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics statement: This study was performed in accordance with the Declaration of Helsinki. This human study was approved by the Ethics Committee Research UZ/KU Leuven (approval S67725).

Conflicts of interest: The authors declare that they have no conflicts of interest.

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