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PURE PRIME: implementing Pulmonary Rehabilitation in Primary care – a randomized-controlled feasibility trial

Jessica A. Walsh[1], Marita T. Dale[1], Zoe J. McKeough[1], Jennifer A. Alison[1,2], Sarah M. Dennis[1,3,4,*]

[1]Sydney School of Health Sciences, Faculty of Medicine and Health, The University of Sydney, Camperdown, NSW, Australia
[2]Allied Health, Sydney Local Health District, Camperdown, NSW, Australia
[3]South Western Sydney Local Health District, Liverpool, NSW, Australia
[4]Ingham Institute of Applied Medical Research, Liverpool, NSW, Australia
*Corresponding author: Sarah M. Dennis, Sydney School of Health Sciences, Faculty of Medicine and Health, The University of Sydney, Camperdown, NSW 2006, Australia (sarah.dennis@sydney.edu.au).

Abstract

Rationale: **Pulmonary rehabilitation (PR) is one of the most effective interventions for chronic respiratory disease, however access remains limited. Private physiotherapy and exercise physiology practices may be settings in which PR can be conducted to increase access and overcome some of the known barriers to PR uptake and completion.**

Objective: **The objective of this study was to investigate whether it is feasible to conduct PR in primary care, specifically in private practices. Secondary objectives were to assess whether PR conducted in primary care achieved the known clinical benefits of PR compared to usual care.**

Methods: **A randomized controlled feasibility trial was conducted. Participants with chronic respiratory disease were randomized to either a twice weekly, 8-week PR program conducted in private physiotherapy or exercise physiology practices or usual care. The primary outcome was proportion of randomized participants who completed the intervention. Clinical outcomes of exercise capacity, health status, and health-related quality of life (HRQoL) were collected at baseline and after 8 weeks. Safety data were collected.**

Results: **A total of 55 participants entered the study, with 52 (95%) randomized. Of participants who were randomized to the intervention group, 75% completed the intervention. Due to trial logistics, some participants who were allocated to the control group completed the intervention. In those who undertook the intervention, there were significant within-group changes in the incremental shuttle walk test (mean difference, 53.7; 95% CI, 37.8-69.6 meters), 1-minute sit-to-stand test (mean difference, 4.7; 95% CI, 3.3-6.0 repetitions), St George's Respiratory Questionnaire (mean difference, -7.38; 95% CI, -12.23 to -2.54), and chronic obstructive pulmonary disease (COPD) Assessment Test (mean difference, -3.1; 95% CI, -5.5 to -0.8). Only one minor study-related adverse event occurred.**

Conclusions: **An 8-week PR program is feasible and safe to conduct in private practices. Completion rates were high and changes in exercise capacity, health status, and HRQoL exceeded known minimum important differences.**

Clinical Trial Registration: **Australia and New Zealand Clinical Trials Registry ACTRN12622001501730.**

Keywords pulmonary rehabilitation, primary care, feasibility, chronic obstructive pulmonary disease, allied health

Introduction

Pulmonary rehabilitation (PR) is a highly effective intervention for chronic respiratory diseases.[1,2] Specifically, in chronic obstructive pulmonary disease (COPD) and interstitial lung disease (ILD), PR has been shown to improve breathlessness, exercise capacity, and health-related quality of life (HRQoL).[1,2] Pulmonary rehabilitation is also highly cost effective and leads to a reduction in hospital admissions, length of stay, and readmissions postexacerbation of disease.[3] National and international guidelines recommend people with both COPD and ILD be referred to PR.[4-6] Traditionally, PR is conducted face-to-face in small groups and normally runs for 6-8 weeks.[4] In Australia, PR is largely conducted in hospital-outpatient settings.[7]

Despite the health benefits of PR, it is estimated that only 5% of people who would benefit are ever referred.[8] Once referred, people encounter several barriers to both attendance and completing a PR program.[9] Barriers to PR attendance are complex and encompass intrapersonal, interpersonal, and structural factors.[10] In a systemic review, the most frequently represented barriers were environmental factors, which comprised issues related to travel, transport, waiting times, and health system infrastructure.[11] Completion rates vary depending on definition. An analysis of United Kingdom audit data found only 66% of people who commenced PR completed a discharge assessment.[12] These challenges underscore the importance and need for strategies to increase uptake and completion of PR.

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Research into alternative models of PR to overcome these barriers have been gaining traction,[13] with evidence showing mHealth,[14] telerehabilitation,[15] and home-based PR[16] achieve similar results as traditional center-based PR. However, many of these models use the existing trained PR workforce. In Australia, 60% of physiotherapists[17] and 57% of accredited exercise physiologists (AEPs)[18] work in primary care, mostly in private practices (PPs). The majority of private physiotherapy and exercise physiology practices have appropriate resources and infrastructure to conduct PR, and most clinicians working in these practices have an interest in delivering PR.[19] However, in Australia there are no subsidies to provide affordable PR in private practices. Compared to hospitals, PPs may be closer to patients' homes or workplaces, offer flexible class timing, and are often open outside normal business hours. With appropriate clinician training, the provision of PR in PPs may be able to overcome some of the environmental and workforce barriers to PR and increase access to this highly effective intervention.

In Australia, PPs are part of the primary health-care sector. Previous research evaluating PR in primary care has either not adhered to national guidelines[20-24] or not been conducted purely within primary care.[25,26] The largest of these studies, a randomized controlled trial, showed a statistically but not clinically significant improvement in HRQoL but no difference in exercise capacity.[20] Given the known barriers and limited availability of existing PR services, it is imperative to investigate whether an evidence-based PR program can be conducted wholly within primary care. None of these studies were conducted in Australia. Therefore, this study aims to investigate whether it is feasible for PP physiotherapists and AEPs to conduct PR in primary care in Australia. Secondary objectives were to assess, in participants with chronic respiratory diseases, whether PR conducted in primary care improves exercise capacity, HRQoL, and health status compared to usual medical care provided by a general practitioner (GP).

Methods

Study design and participants

This study was a 2-arm, randomized controlled feasibility trial. The inclusion/exclusion criteria are presented in Table 1. Screening was conducted within the hospital PR services to which patients had been referred, but all other study procedures, including all assessments and intervention sessions, were conducted in participating physiotherapy and exercise physiology practices. Participants were assessed at baseline and at follow-up after the 8-week intervention or usual care period. The study was approved by Sydney Local Health District (RPAH Zone) Human Research Ethics Committee (2022/ETH02324) and prospectively registered (ACTRN12622001501730). Informed consent was obtained from all participants. The trial protocol has been published.[27]

Randomization and blinding

Participants who were deemed suitable to undertake the intervention were randomized 1:1, using the randomization module of Research Electronic Data Capture, to either receive the intervention at their chosen private practice or the control group of usual care with no PR.[28,29] Randomization was stratified by exercise capacity (6-minute walk distance ≥350 m or <350 m, or incremental shuttle walk test [ISWT] distance ≥ 250 m or < 250 m) and level of breathlessness with activity (modified Medical Research Council [mMRC] dyspnea scale ≥3 or <3). Randomization occurred after baseline assessments, and therefore baseline assessments were blinded for group allocation. It was planned that follow-up assessments would be assessor blinded, but study logistics meant that this could not occur. However, the follow-up assessor did not conduct the baseline assessments or any intervention sessions.

Intervention

Participants allocated to the intervention arm undertook an 8-week PR program at their chosen PP. Pulmonary rehabilitation sessions were conducted face-to-face, twice a week in small groups. Participants were prescribed an individualized exercise training program based on their baseline exercise capacity assessment or symptom-based prescription that aligned with the current Australian and New Zealand PR guidelines.[4] This consisted of a minimum of 30 minutes of lower limb endurance training (eg, walking or stationary cycling), strength training, a home exercise program, and education.[30] Sessions were 1 hour in duration. The treating clinician used equipment available in their practice; no additional exercise equipment was provided. Basic monitoring equipment of an automatic blood pressure monitor and finger pulse oximeter was provided, if practices did not have them already. Clinicians followed their local safety protocol, and no additional safety equipment was provided. Clinicians were physiotherapists or AEPs who worked in the PP and had completed a training program aligned with the national PR guideline and were

Table 1 Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
• Age older than 18 years • Diagnosis of COPD or ILD (confirmed with spirometry[50] or diagnosis by medical doctor) • Referred to pulmonary rehabilitation at 1 of 3 metropolitan LHD hospitals and on the waitlist • Willing to attend twice weekly PR for 8 weeks in a private practice setting	• Exacerbation of respiratory disease within 4 weeks prior to recruitment • Completed PR in the past year • Prescribed home supplemental oxygen or requiring supplemental oxygen for exercise (desaturates <80% SpO_2 on field-walking test) • Medical conditions that contraindicate safe group exercise outside hospital setting (eg, unstable cardiac disease, severe musculoskeletal impairments) • Unable to provide informed consent

Abbreviations: COPD, chronic obstructive pulmonary disease; ILD, interstitial lung disease; LHD, local health district; PR, pulmonary rehabilitation; SpO_2, oxygen saturation measured by pulse oximetry.

required to meet competency thresholds before conducting the intervention. A detailed description of clinician training and the intervention can be found in the trial protocol, including the exercise training intensity, duration, and progression.[27] Practices were reimbursed per participant to an amount corresponding to the Australian government Medicare rebate at the time of the study. Participants allocated to the control group received usual GP care and did not commence any PR in the control period. Following this period, participants were able to commence PR at the hospital they had been referred to.

Outcomes

Feasibility outcomes

The primary feasibility outcome was adherence to the intervention, measured by the proportion of randomized participants who completed the intervention. Completion was defined as attending 12 of 16 (75%) allocated sessions.[31] Secondary outcomes included feasibility—the proportion of eligible participants randomized—and fidelity—the proportion of participants where exercise was prescribed at an appropriate intensity and duration at the first PR session . Number of adverse events (AEs) were recorded as a safety outcome measure.

Clinical outcomes

Although the study was not powered to detect change in the clinical outcome measures, changes in the following were assessed: exercise capacity, using a field-walking test (6-minute walk test [6MWT] or ISWT)[32] and the 1-minute sit-to-stand test (1mSTS);[33] dyspnea, using the mMRC dyspnea scale;[34] HRQoL, using the St George's Respiratory Questionnaire (SGRQ);[35] and health status, using the COPD Assessment Test (CAT).[36] Practices used the 6MWT as the field-walking test if it could be performed to technical standards.[32] If there was not a 30-meter straight track for the 6MWT, the ISWT was performed instead. Perception of change at follow-up was measured by a 5-point Global Rating of Change Questionnaire.

Sample size

As this was a feasibility trial with an aim to inform a future definitive trial, a formal sample size calculation was not appropriate. However, it is recommended that a minimum of 30 participants per arm is needed to estimate a parameter for any future sample size calculation.[37] Therefore, allowing for 20% attrition rate, 76 participants were needed. Despite attempts to meet the sample size, including adding an additional hospital for referrals, the sample size was not met.

Statistical analysis

Data were reported in accordance with the CONSORT extension for randomized pilot and feasibility trials guidelines.[38] The planned primary analysis was intention-to-treat (ITT). However, per-protocol and single-arm intervention analyses were also performed. Proportions and corresponding 95% confidence intervals or, for continuous variables means, standard deviations and ranges were calculated for feasibility outcomes. Clinical outcomes were summarized by descriptive statistics and effect sizes estimated. Mean differences and 95% confidence intervals pre- and postintervention, as well as between-group differences, were calculated. It was planned that change data for field-walking tests would be presented as percentage changes, however due to the small proportion of participants who performed 6MWT (majority performed ISWT), raw change data are presented. The proportion of participants who undertook the intervention and proportion who met the minimum important differences (MID) for each test were calculated. Missing data were not imputed.

Results

Between June 9, 2023, and May 14, 2025, a total of 236 participants were screened for eligibility; 181 were excluded based on eligibility or not responding to the invitation to participate, with 55 participants consenting to take part in the study. One was lost-to-follow up prior to the baseline visit, and the remainder ($n = 54$) completed a baseline assessment. Of these, 2 participants were withdrawn from the study prior to randomization, 25 allocated to the intervention arm, and 27 were allocated to the control arm. Full participant flow is reported in Figure 1. There were 6 PP sites, and within these PPs the intervention was delivered by 5 physiotherapists and 2 AEPs. Exercise equipment in each clinic is presented in Table 2. There was a mean group size of 3.2, ranging from 2 to 5 participants. Maximum group size was determined by practice size and equipment constraints but was also limited by recruitment rates.

Baseline characteristics are reported in Table 3. Most participants were diagnosed with COPD (89%), 52% were male, and 56% were aged between 70 and 79 years. Baseline mean (SD) field-walking test distances were 255 (150) meters for those who completed an ISWT and 408 (108) meters for those who completed a 6MWT.

Of the participants, 45 (87%) completed a follow-up assessment; reasons for dropouts are reported in Figure 1. Due to this being a pragmatic feasibility trial, we aimed to consider both robust research methodologies and the real-world practicalities of running a randomized controlled trial in 6 practices that were individual businesses. There were minimum numbers of participants that PPs needed for the intervention sessions to be financially viable as practices were paid per participant who attended each intervention session. This meant that during recruitment, if the number of participants randomized to the intervention group was not enough to form a group of adequate size, some participants were invited to switch to the intervention group. There were 2 reasons for this. First, we did not want to lose PPs conducting the intervention, and secondly, we did not want to have participants already recruited waiting excessive time before commencing either the intervention or control period. As the aim of the study was to test the feasibility of conducting PR in the PP setting, ultimately, we prioritized collecting data on participants who had undertaken the intervention, while retaining the PPs delivering the intervention. Thus, of the 27 participants allocated to the control arm, 14 complied with the control protocol and 13 crossed over to the intervention.

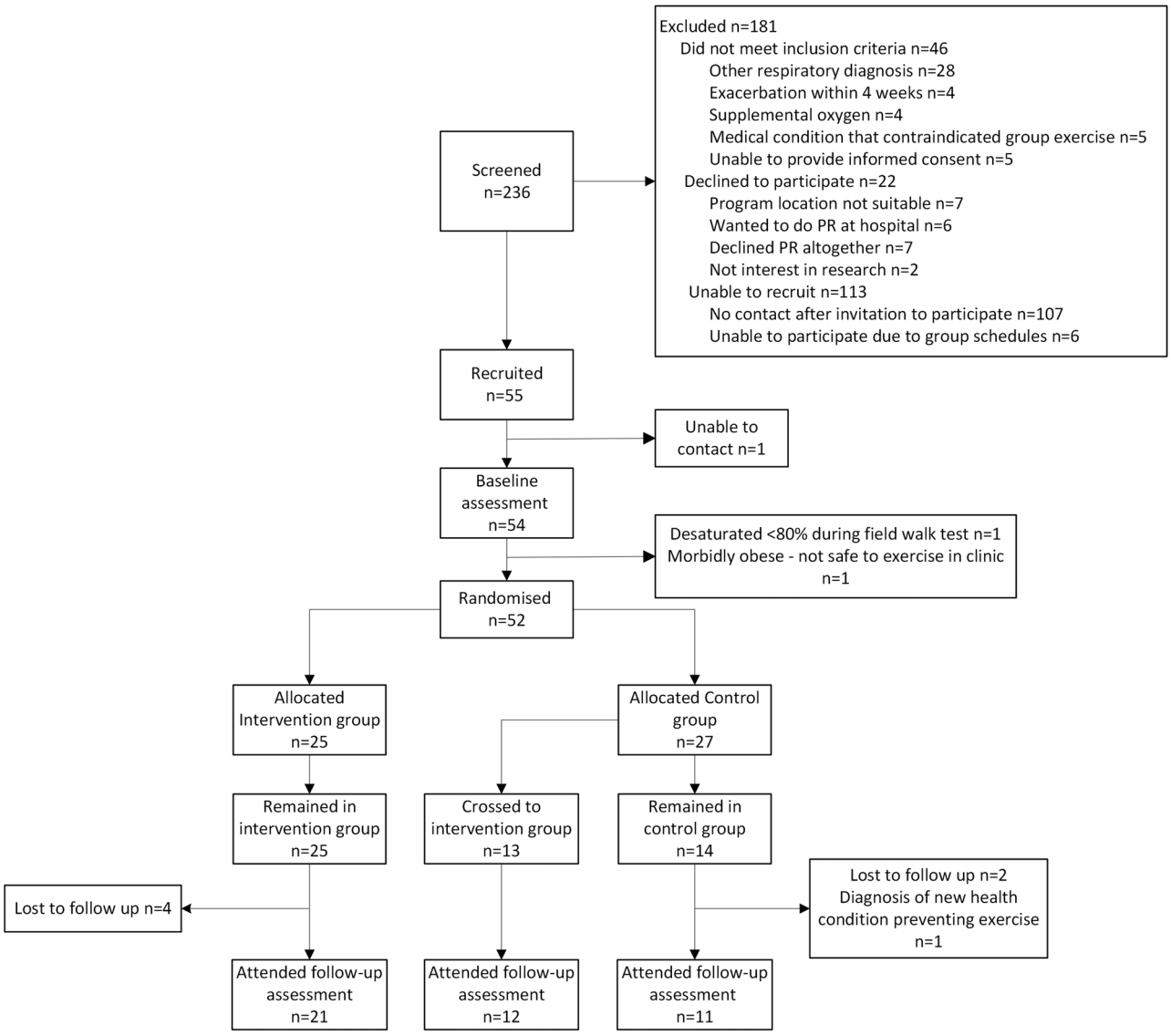


Figure 1 CONSORT diagram. Abbreviation: PR, pulmonary rehabilitation.

Table 2 Clinic exercise equipment.

Exercise modality	No. of clinics (%)
Ground walking track	6 (100)
Treadmill	3 (50)
Stationary cycle	5 (83)
Fixed weights	6 (100)
Free weights	6 (100)

Feasibility outcomes

Of the 55 participants recruited, 52 (95%) were randomized. Only 2 participants were withdrawn due to safety concerns. Of those randomized, 44 (85%) completed all study visits. Of the 25 participants randomized to the intervention group, 18 (72%; 95% CI, 52%-86%) achieved the primary outcome completion threshold of attending 12 of 16 (75%) PR sessions. Of all 38 participants who undertook the intervention, 28 (74%; 95% CI, 58%-85%) completed the intervention.

Regarding fidelity of the intervention, 1 participant was unable to perform ground walking and instead did marching on the spot for lower limb endurance training and, therefore, was excluded from the fidelity analysis. Of the 37 participants prescribed exercise based on a baseline field-walking test, clinicians prescribed the correct walking training intensity and duration, as per the study protocol, for 27 (73%; 95% CI, 57%-85%) participants. Only 2 (5%) participants were prescribed an intensity below the threshold indicated by their field-walking test, with 8 (22%) participants prescribed an intensity that was higher than that indicated by their test results. Strength training was prescribed in alignment with the protocol for all participants. Quantitative data around the delivery of education during the intervention was not collected, however this will be explored in planned qualitative interviews.

Clinical outcomes

Due to the protocol deviations, several sensitivity analyses were conducted. As per the original statistical analysis plan, an ITT

Table 3 Baseline characteristics.[a]

Variable	All ($n=52$)	Randomized participants		
		Intervention ($n=25$)	Control ($n=27$)	*P*-value
Disease				
COPD	46 (89%)	20 (80%)	26 (96%)	.07
ILD	6 (12%)	5 (20%)	1 (4%)	
Sex				
Female	25 (48%)	11 (44%)	14 (52%)	.57
Male	27 (52%)	14 (56%)	13 (48%)	
Age group, y				
50-59	4 (8%)	1 (4%)	3 (11.1%)	.18
60-69	10 (19%)	2 (8%)	8 (40.7%)	
70-79	29 (56%)	16 (64%)	13 (48.1%)	
80-89	8 (15%)	5 (20%)	3 (11.1%)	
90 and older	1 (2%)	1 (4%)	0 (0%)	
BMI, kg/m²	28.2 (7.1)	27.7 (7.7)	28.7 (6.6)	.64
Age-adjusted CCI	4.9 (1.9)	4.9 (1.6)	4.9 (2.1)	.90
FEV_1, L	1.56 (0.51)	1.53 (0.49)	1.59 (0.54)	.70
FEV_1 % predicted	67 (21)	66 (20)	67 (22)	.83
FVC, L	2.59 (0.71)	2.54 (0.59)	2.64 (0.81)	.65
FVC % predicted	85 (15)	84 (14)	86 (17)	.64
FEV_1/FVC	0.61 (0.14)	0.61 (0.15)	0.61 (0.14)	1.00
Smoking status				
Current smoker	14 (27%)	7 (28%)	7 (26%)	.84
Ex-smoker	31 (60%)	14 (56%)	17 (63%)	
Non-smoker	7 (14%)	3 (11%)	3 (11%)	
Pack years	36.2 (28.2)	37.5 (29.9)	34.9 (27.1)	.75
Exacerbations in last 12 months	1 (2)	1 (1)	1 (3)	.51
Respiratory hospitalizations in last 12 months	0 (0)	1 (1)	0 (1)	.01*
mMRC	2 (1)	2 (1)	2 (1)	1.00
ISWT ($n=45$), m	255.3 (150.4)	235.9 (151.4)	273.9 (150.4)	.40
6MWT ($n=7$), m	408.4 (107.6)	384.3 (151.4)	426.5 (75.2)	.70
1-minute STS, reps	17.9 (7.3)	16.7 (6.5)	19.0 (7.9)	.26
CAT**	19.3 (7.7)	18.4 (7.3)	20.1 (8.1)	.42
SGRQ				
Symptoms	55.3 (23.3)	51.4 (22.4)	58.9 (23.9)	.25
Activity	59.6 (21.7)	57.3 (20.4)	61.7 (23.0)	.47
Impacts	33.4 (17.1)	32.0 (18.0)	34.8 (16.5)	.57
Total***	45.0 (17.4)	42.9 (17.3)	46.9 (17.5)	.42

Abbreviations: 6MWT, 6-minute walk test; BMI, body mass index; CAT, COPD Assessment Test; CCI, Charlson Comorbidity Index; COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; ILD, interstitial lung disease; ISWT, incremental shuttle walk test; mMRC, modified Medical Research Council dyspnea score; reps, repetitions; SGRQ, St George's Respiratory Questionnaire; STS, sit-to-stand.
[a]Data reported as mean (SD) for continuous variables and No. (%) for categorical variables. *P*-value comparing intervention to control groups using independent *t*-test for continuous variables and chi-squared test for categorical variables.
*Indicates statistically significant difference $P<.05$.
**Scored 0-40 with higher scores indicating worse health status.
***Scored 0-100 with higher scores indicating worse HRQoL.

analysis was performed. There were no significant between-group differences, however 13 of the control participants completed the intervention so it is difficult to draw any conclusions. These results can be found in Supplementary Table A.

The per-protocol analysis included 39 participants, 25 in the intervention arm and 14 in the control arm. There were no significant differences in baseline measures between the 2 groups (Supplementary Table B). There were 21 participants from the intervention group and 11 participants from the control group who attended the follow-up assessment. Of these, there was a within-group mean difference in the intervention group that exceeded the known MID for ISWT, 1mSTS, CAT, and SGRQ total score. This difference was statistically significant for ISWT, 1mSTS, SGRQ impacts, and SGRQ total scores. There was a significant between-group difference for the ISWT and 1mSTS, also exceeding the MID for both outcomes (see Table 4).

A single-arm as-treated intervention group analysis was conducted for all participants who either were allocated to the intervention or who commenced the intervention despite being allocated to the control group. A total of 38 participants were included in the analysis, 34 of whom attended the follow-up assessment. There were statistically significant differences between baseline and follow-up for all measured outcomes except the SGRQ symptom domain. The mean differences in all

Table 4 Per-protocol analysis of participants who completed the follow-up assessment.[a]

Outcome	Baseline ($n=32$)		Study completion ($n=32$)		Within-group difference		Between-group difference MD (95% CI)
	Intervention ($n=21$) Mean (SD)	Control ($n=11$) Mean (SD)	Intervention ($n=21$) Mean (SD)	Control ($n=11$) Mean (SD)	Intervention ($n=21$) MD (95% CI)	Control ($n=11$) MD (95% CI)	
mMRC	2.0 (1.2)	2.0 (1.1)	1.6 (1.1)	1.9 (0.9)	−0.4 (−0.6 to −0.2)	−0.1 (−0.6 to 0.4)	−0.3 (−0.7 to 0.2)
ISWT, m	234.4 (162.40)	285.7 (135.5)	278.8 (161.7)	277.1 (130.5)	44.4* (20.7–68.0)	−8.6 (−32.1 to 15.0)	53.0 (15.3–90.6)*
6MWT, m	384.3 (157.2)	426.5 (75.2)	430.0 (171.1)	455.5 (73.7)	47.5 (−57.9 to 149.2)	19.0 (−67.8 to 105.8)	26.7 (−71.14to 124.5)
1-minute STS, reps	15.8 (6.6)	16.9 (6.6)	19.3 (7.7)	17.0 (6.6)	3.5* (2.0–4.9)	0.1 (−1.0 to 1.2)	3.4* (1.3 −5.4)
CAT	18.8 (7.6)	19.1 (10.1)	16.3 (7.8)	19.6 (11.9)	−2.8 (−5.6 to 0.1)	0.6 (−4.0 to 5.1)	−2.8 (−7.9 to 2.4)
SGRQ							
Symptoms	49.4 (21.0)	52.8 (27.7)	47.9 (21.0)	50.3 (31.0)	−1.5 (−8.2 to 5.3)	−2.5 (−9.8 to 4.8)	1.1 (−9.1 to 11.2)
Activity	59.3 (20.8)	50.2 (25.4)	54.5 (17.8)	51.7 (24.8)	−4.8 (−10.1 to 0.6)	1.4 (−6.7 to 9.6)	−6.2 (−15.5 to 3.1)
Impacts	32.2 (18.3)	30.7 (18.8)	24.5 (14.4)	29.8 (21.2)	−7.7 (−13.9 to −1.5)*	−1.0 (−7.9 to 5.9)	−6.7 (−16.1 to 2.7)
Total	43.3 (17.1)	40.5 (21.6)	37.6 (13.9)	39.9 (22.5)	−5.7 (−10.9 to −0.5)*	−0.4 (−6.5 to 5.8)	−5.3 (−13.3 to 2.7)
GRCQ							
Much better			9 (43%)	—[b]			
A little better			9 (43%)	1 (9%)			
No change			2 (10%)	9 (82%)			
A little worse			1 (5%)	1 (9%)			
Much worse			—	—			

Abbreviations: 6MWT, 6-minute walk test; CAT, COPD Assessment Test; GRCQ, global rating of change questionnaire; ISWT, incremental shuttle walk test; mMRC, modified Medical Research Council dyspnea score; SGRQ, St George's Respiratory Questionnaire; STS, sit-to-stand; reps, repetitions.
[a]Participants completed either an ISWT or a 6MWT, 23 participants completed an ISWT, and 7 participants completed a 6MWT.
[b]The empty cells with em dash indicate no responses for that item on the scale.
*Indicates statistically significant difference ($P<.05$).

outcomes exceeded the known MIDs.[32,33,39-42] Effect sizes, with Hedges' correction owing to the small sample size, were large for physical outcome measures and moderate for health status and HRQoL. Of those who completed a field-walking test at follow-up, 21 (68%) had a change that exceeded the known MID of the respective field-walking test.[32,39,40] The MID was met or exceeded by 75% for 1mSTS test,[33] 74% for CAT,[42] and 52% for SGRQ total score.[41] Supporting these findings, of those who attended the follow-up assessment, 88% reported feeling much better or a little better (47% and 41%, respectively). Detailed results are presented in Tables 5 and 6.

Safety outcomes

Over the course of the study there were 26 AEs. Of these, 4 were classed as serious AEs requiring hospital admission not related to the study. The remaining 22 AEs were not serious: 11 were exacerbations of respiratory disease, 7 were trips or falls unrelated to exercise, 2 participants had chest pain unrelated to the study, and another had cardiac issues that prevented exercise; the other 4 were miscellaneous (anemia, drainage of lip abscess, diverticulitis, and unknown illness under investigation). Only 1 AE was related to the intervention: shoulder pain after strength training. Although not AEs, 7 participants had their baseline field-walking test stopped due to desaturation below the threshold set out in the study protocol ($SpO_2<85\%$). On further assessment, only 1 participant was withdrawn from the study due to significant desaturation ($SpO_2<80\%$); the rest remained in the trial.

Discussion

The results of this study show that a PR program conducted entirely within a primary care physiotherapy or exercise physiology PP is feasible from a patient level, safe to conduct, and leads to improvements in exercise capacity, health status, and HRQoL. The primary feasibility outcome showed a high intervention completion rate, with 72% of randomized participants attending 75% or more of the intervention sessions. Although the study was underpowered for clinical measures, both the within-group and between-group mean differences exceed the known MIDs for ISWT, 6MWT, 1mSTS, CAT, and SGRQ in the per-protocol analysis and the same for the within-group differences in the single-arm intervention group analysis. Clinic level feasibility was not assessed, however, the need for protocol deviations suggest that

current funding levels limit the viability of the model. Our findings support advocacy for government-based funding reform,[7,43] as the primary barrier to further implementation of this model of PR is financial rather than clinical feasibility.

Table 5 Baseline characteristics of single-arm intervention cohort.

Variable	Baseline ($n = 38$)
Sex	
Female	19 (50%)
Male	19 (50%)
Age group, y	
Younger than 50-59	2 (5%)
60-69	7 (18%)
70-79	23 (61%)
80-89	5 (13%)
90 and older	1 (3%)
BMI, kg/m²	27.6 (7.3)
Age-adjusted CCI	5 (2)
FEV_1, L	1.58 (0.49)
FEV_1 % predicted	67 (20)
FVC, L	2.59 (0.60)
FVC % predicted	84 (14)
FEV_1/FVC	0.62 (0.15)
Smoking status	
Current smoker	10 (26%)
Ex-smoker	22 (58%)
Non-smoker	6 (16%)
Pack years	34.4 (26.4)
Exacerbations in last 12 months, median	0 (0, 1)
Respiratory hospitalizations in last 12 months, median	0 (0, 1)

Abbreviations: BMI, body mass index; CCI, Charlson Comorbidity index; FEV_1, forced expiratory volume (litres) in 1 second; FVC, forced vital capacity (litres).

Feasibility was also demonstrated by other metrics in addition to completion rates[44]: recruitment was strong with 91% of eligible participants enrolling (only 6% declined due to private practice setting factors), retention was high with only 2 participants removed between baseline and randomization and 85% of randomized participants completing all study visits. Lastly, provider engagement was sustained, with all active practices continuing intervention delivery and 3 of 6 clinics conducting multiple 8-week program iterations.

By conducting an evidence-based PR intervention, the results of this study exceeded the mean differences in exercise capacity from previous randomized controlled trials of PR in primary care.[20,23,24] The improvements in outcomes more align with studies of traditional center-based PR.[1] Given the pragmatic nature of this study, when compared to a national clinical benchmarking audit from the United Kingdom (UK), the proportion of participants meeting the MID for key outcome measures was higher in our study. In our cohort, 68% achieved the MID of a field-walking test compared to 57% in the UK audit, and 82% achieved the MID for at least 1 measure of HRQoL compared to 68% in the UK audit.[45]

We hypothesized that conducting PR in PPs would overcome some of the environmental barriers to center-based PR that patients experience and would increase compliance. The intervention completion rate in this study was 72% exceeding the completion rate commonly seen in hospital-based PR[12] and is more comparable to some of the newer models of PR such as telerehabilitation and home-based PR, which benefit from being delivered remotely.[15,46] These models of PR may suit some patients, however there are a subset of patients where face-to-face PR is safer and/or is preferred.[47] In the PP setting, the added benefit of peer support from smaller groups from the local community, clinician rapport, and the clinic environment may be facilitators in self-efficacy and behavior change. These factors could not be measured quantitively in this study, however they will be explored in an embedded qualitative study. Completion rates of

Table 6 Outcome measures single-arm intervention cohort.[a]

Outcome	Baseline ($n = 38$)	Follow-up ($n = 34$)	Mean difference (95% CI)	Effect size (95% CI)
mMRC	2.0 (1.1)	1.5 (1.0)	-0.4 (-0.6 to -0.3)*	-0.87 (-1.25 to -0.47)
ISWT, m	256.3 (157.2)	315.9 (176.3)	53.7 (37.8-69.6)*	1.32 (0.80-1.83)
6MWT, m	384.3 (157.2)	430.0 (171.1)	45.7 (-57.9 to 149.2)	0.87 (-0.37 to 2.03)
1-minute STS, reps	18.3 (7.7)	22.8 (10.5)	4.7 (3.3-6.0)*	1.20 (0.74-1.66)
CAT	19.5 (7.3)	16.5 (7.3)	-3.1 (-5.5 to -0.8)*	-0.52 (-0.87 to -0.16)
SGRQ				
Symptoms	56.4 (22.8)	49.1 (23.8)	-5.4 (-11.6 to 0.9)	-0.31 (-0.66 to 0.05)
Activity	61.5 (20.3)	55.3 (20.1)	-6.5 (-10.9 to -2.0)*	-0.53 (-0.90 to -0.15)
Impacts	34.5 (17.4)	24.9 (14.5)	-8.6 (-14.3 to -2.8)*	-0.54 (-0.91 to -0.16)
Total	46.3 (16.7)	38.2 (15.3)	-7.4 (-12.2 to -2.5)*	-0.55 (-0.92 to -0.17)
GRCQ				
Much better	—[b]	16 (47%)		
A little better	—	14 (41%)		
No change	—	3 (9%)		
A little worse	—	1 (3%)		
Much worse	—	—		

Abbreviations: 6MWT, 6-minute walk test; BMI, body mass index; CAT, COPD Assessment Test; GRCQ, global rating of change questionnaire ISWT, incremental shuttle walk test; mMRC, modified Medical Research Council dyspnea score; reps, repetitions; SGRQ, St George Respiratory Questionnaire; STS, sit-to-stand.
[a]Data reported as mean (SD) for continuous variables and No. (%) for categorical variables unless otherwise stated. Participants completed either an ISWT or a 6MWT, 35 participants completed an ISWT, and 3 participants completed a 6MWT.
[b]This item was only collected at follow-up hence the empty cells.
*Indicates statistically significant difference $P < .05$).

community-based PR programs are similar to our study,[48,49] however the added benefit of providing PR in PPs is that staff and infrastructure already exist.

While patient-level feasibility was demonstrated, practice-level feasibility remains uncertain. No staffing changes or workflow disruptions were required, and all participating practices had the necessary infrastructure, suggesting minimal operational burden. Practices were reimbursed at the current Medicare rebate rate, which was insufficient to cover the practice costs to provide small group programs. Future trials should explore reimbursement models that support practice viability and consider cost-effectiveness analyses to inform policy and funding decisions.

The safety of exercising patients outside a hospital setting is an important consideration, and without access to hospital emergency equipment that potentially only patients with milder disease should be included, or a lower intensity of exercise prescribed. Reassuringly, there was only 1 minor AE related to the study intervention. We acknowledge that we only included stable patients and excluded some patients on the basis of safety, however only 2 patients were withdrawn prior to randomization and 4 excluded during the screening process due to supplemental oxygen use or other safety concerns. Further, our cohort was similar to that in other PR trials, with moderate respiratory disability (mMRC dyspnea scale: mean, 2 [SD, 1]), exercise capacity (ISWT: mean, 255 [SD, 150] m), and disease severity (FEV_1 67% predicted). The fidelity results showed that clinicians prescribed exercise intensity mostly in line with the protocol, indicating that safety concerns did not impact exercise intensity. Once it is established whether this setting is safe for a stable population to undertake PR, further research will need to be conducted in people postexacerbation of their chronic respiratory disease.

Strengths

The pragmatic design of our study meant both assessment and exercise training were performed by PP clinicians upskilled in PR. Previous primary care or community-based studies have conducted the baseline assessment in a hospital setting, by hospital-based staff for safety precautions.[26,48] In total, 7 participants had their field-walking tests stopped due to oxygen desaturation < 85%. Unless there were reasons that would contraindicate another field-walking test outside of a hospital setting, the researcher would conduct a second field-walking test with a more sensitive oximeter (Masimo Rad5). After reassessment, only 1 participant was withdrawn from the study for desaturation < 80%. No other safety incidents occurred during assessment. This means that the model of PR delivered in this study could be standalone from the hospital in terms of workforce and infrastructure. However, given that more sensitive equipment was needed to assess safety for exercise of some patients, this equipment may be needed in PPs if this model of PR was to be scaled up.

Limitations

There are some limitations to this study. First, this was a feasibility study and was not powered to detect change in clinical outcomes. Further research is needed to examine the effectiveness of PR in the primary care setting powered for clinical outcomes. Second, there was a large proportion of control participants who undertook the intervention. This did not impact the primary outcome measure of the proportion of randomized participants who completed the intervention. However, our planned primary clinical outcome analysis of ITT was severely impacted. We therefore conducted sensitivity analyses to better understand the effect of the intervention on clinical outcome measures without cross-contamination of those who did not follow randomization. Despite these limitations, the study provides some important learnings for future studies that are conducted within PPs. The open communication between researchers and the PP, as well as the pragmatic way any protocol deviations were handled, meant that no PP ceased delivering the intervention during the study. Many PPs provided intervention sessions to multiple groups of participants. Although the results of this study show PR in PPs to be feasible at a patient level, we could not establish whether it was feasible from a practice level, a planned outcome measure of the study. However, this along with the acceptability of the intervention will be explored in the planned qualitative interviews with both patient and clinician participants.[27]

Further, we did not reach our planned sample size, meaning the results of the trial cannot be used to determine a sample size for a full-scale trial, a secondary aim of the study. We also aimed to maintain blinding of the assessor at follow-up assessments. However, blinding could not be maintained due to study logistics. Lastly, although the study was conducted encompassing areas with a broad socioeconomic range, they were all within metropolitan Sydney. Further research in regional and rural locations should be undertaken. This will also be the case for settings that have different health-care system structures and funding mechanisms, however the principles and learning from the trial will inform the design of interventions for different contexts.

Conclusion

In conclusion, a twice weekly, 8-week face-to-face PR program conducted in private physiotherapy and exercise physiology practices is feasible and leads to improvements in clinical outcomes that exceeded known MIDs. However, these results were underpowered, and the ITT analysis showed no significant between-group differences. Further research to test the clinical efficacy and longer-term effects of this model of PR are warranted given the positive results of this feasibility trial.

Author contributions

J.A.W.: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Writing - Original Draft; M.T.D.: Conceptualization, Methodology, Supervision, Writing - Review & Editing; Z.J.M.: Conceptualization, Methodology, Supervision, Writing - Review & Editing; J.A.A.: Conceptualization, Methodology, Supervision, Writing - Review & Editing; S.M.D.: Conceptualization, Methodology, Supervision, Writing - Review & Editing

Supplementary material

Supplementary material is available at *Annals of the American Thoracic Society* online.

Conflict of interest

Zoe J. McKeough is the managing director of Better Breathing Foundation. All other authors declare no conflicts of interest. Please see the ICMJE disclosure forms, which have been provided as supplementary material.

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Data availability

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

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