Original research

Telerehabilitation for chronic respiratory disease: a randomised controlled equivalence trial

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ABSTRACT

Rationale Pulmonary rehabilitation is an effective treatment for people with chronic respiratory disease but is delivered to <5% of eligible individuals. This study investigated whether home-based telerehabilitation was equivalent to centre-based pulmonary rehabilitation in people with chronic respiratory disease.

Methods A multicentre randomised controlled trial with assessor blinding, powered for equivalence was undertaken. Individuals with a chronic respiratory disease referred to pulmonary rehabilitation at four participating sites (one rural) were eligible and randomised using concealed allocation to pulmonary rehabilitation or telerehabilitation. Both programmes were two times per week for 8 weeks. The primary outcome was change in Chronic Respiratory Disease Questionnaire Dyspnoea (CRQ-D) domain at end-rehabilitation, with a prespecified equivalence margin of 2.5 points. Follow-up was at 12 months. Secondary outcomes included exercise capacity, health-related quality of life, symptoms, self-efficacy and psychological well-being.

Results 142 participants were randomised to pulmonary rehabilitation or telerehabilitation with 96% and 97% included in the intention-to-treat analysis, respectively. There were no significant differences between groups for any outcome at either time point. Both groups achieved meaningful improvement in dyspnoea and exercise capacity at end-rehabilitation. However, we were unable to confirm equivalence of telerehabilitation for the primary outcome ΔCRQ-D at end-rehabilitation (mean difference (MD) (95% CI) −1 point (−3 to 1)), and inferiority of telerehabilitation could not be excluded at either time point (12-month follow-up: MD −1 point (95% CI −4 to 1)). At end-rehabilitation, telerehabilitation demonstrated equivalence for 6-minute walk distance (MD −6 m, 95% CI −26 to 15) with possibly superiority of telerehabilitation at 12 months (MD 14 m, 95% CI −10 to 38).

Conclusion telerehabilitation may not be equivalent to centre-based pulmonary rehabilitation for all outcomes, but is safe and achieves clinically meaningful benefits. When centre-based pulmonary rehabilitation is not available, telerehabilitation may provide an alternative programme model.

Trial registration number ACtelerehabilitationN12616000360415.

Key messages

What is the key question?

⇒ Is supervised telerehabilitation, delivered into the home, equivalent to centre-based pulmonary rehabilitation for clinical outcomes and completion rates?

What is the bottom line?

⇒ Pulmonary telerehabilitation for chronic respiratory disease is safe and achieves clinically meaningful outcomes; however may not be equivalent to centre-based pulmonary rehabilitation for all outcomes.

Why read on?

⇒ Access to centre-based pulmonary rehabilitation is limited globally, exacerbated by restrictions related to COVID-19; when centre-based pulmonary rehabilitation is not available, home-based telerehabilitation, with readily available equipment and direct supervision of exercise training, may provide an alternative programme model.

INTRODUCTION

Pulmonary rehabilitation is an effective and recommended treatment strategy for people with chronic respiratory disease.[1] Yet despite improvements in exercise capacity and symptoms, and reduced healthcare utilisation achieved with pulmonary rehabilitation,[2] fewer than half of all people referred complete a programme.[3] This problem is compounded by poor referral rates[3] and a lack of available programmes, with sufficient pulmonary rehabilitation programmes globally to serve <2% of the population who would benefit.[4]

Chronic respiratory diseases, including chronic obstructive pulmonary disease (COPD), bronchiectasis, asthma and interstitial lung disease (ILD) constitute nearly 10% of the global burden of disease.[5] For people with stable chronic respiratory disease, being able to complete a programme of pulmonary rehabilitation reduces the likelihood of being admitted to hospital (HR 0.439, p=0.02).[6] However, there are well documented health-system

and patient-related barriers to attending and completing pulmonary rehabilitation including issues of travel and transport to a rehabilitation centre, symptoms and disability and a failure to understand or identify potential benefits.[7] Consequently, exploration of alternative modes of delivering pulmonary rehabilitation to improve equity of access and patient-related outcomes is a research priority.[8]

Telerehabilitation is the use of information and communication technology to provide rehabilitation services at a distance. Telerehabilitation has the potential to improve healthcare access and pulmonary rehabilitation service delivery options, particularly to individuals who are geographically or socially isolated, who work or who find travel difficult. Previous studies suggest telerehabilitation is safe for people with chronic respiratory disease,[9] however existing trials have often required participants to attend a centre to access telerehabilitation equipment[10]; have not included supervised exercise training[11 12]; or used bespoke telerehabilitation equipment that may be difficult to source or replicate outside the initial trial.[13] To be considered as an alternative to the gold standard of centre-based pulmonary rehabilitation, a telerehabilitation model should include all the essential components (supervised exercise training and self-management education), be delivered directly into the home using readily available equipment and achieve equivalent clinical outcomes. The aims of this study, in people with chronic respiratory disease, were to: (1) determine whether telerehabilitation was equivalent to centre-based pulmonary rehabilitation for clinical outcomes; (2) compare completion rates of telerehabilitation to centre-based pulmonary rehabilitation; and (3) compare the costs of telerehabilitation and centre-based pulmonary rehabilitation. We hypothesised that telerehabilitation would achieve equivalent clinical outcomes to those of centre-based pulmonary rehabilitation. The present paper reports on clinical outcomes; a full economic analysis will be published separately.

METHODS

Study design and population

A randomised, controlled, assessor-blinded equivalence trial was conducted at three tertiary centres in metropolitan, and one rural centre, in Victoria, Australia. The trial was registered prospectively and the trial protocol published.[14] Participants were recruited from pulmonary rehabilitation referral lists. Full details relating to eligibility, inclusion and exclusion criteria have been published previously[14] and are detailed in the online supplement. Initially, only individuals with a diagnosis of COPD were eligible for inclusion, however due to slower than anticipated recruitment over the first 6 months of the trial and changing diagnostic referral patterns across all sites, recruitment was opened to all individuals with a primary diagnosis of a chronic respiratory disease following approval of a protocol amendment in March 2017. All participants provided written informed consent. Reasons for declining to participate in the trial were recorded, including a preference for centre-based pulmonary rehabilitation or declining pulmonary rehabilitation altogether.

Randomisation and masking

At the conclusion of a centre-based baseline assessment, participants were randomised 1:1 to centre-based pulmonary rehabilitation or telerehabilitation, using a computer generated block randomisation scheme. Randomisation was stratified for site of recruitment, status (stable vs post hospitalisation) and diagnosis (ILD vs other). Randomisation was stratified ILD versus all other diagnoses to ameliorate the potentially different disease trajectory that may be experienced by people with ILD—namely rapidly, progressive disease—and to ensure the proportion of participants with ILD was balanced across groups. The randomisation sequence was generated by an individual independent of the study. An assessor blind to group allocation completed all follow-up assessments. The extent to which assessor blinding was maintained at the end of 12 months follow-up was evaluated by asking assessors if they were aware of patient group allocation and to indicate which group they thought the participant had been allocated to. Due to the nature of the intervention it was not possible to blind participants nor those delivering the interventions.

Study procedures

Participants in both groups undertook an 8-week, 16-session pulmonary rehabilitation programme in keeping with clinical guideline recommendations in the Australian rehabilitation context.[15] In accordance with Australian and international guidelines all participants received education and self-management training,[1 15] in addition printed and online self-management education resources from Lung Foundation Australia were provided which are designed to support pulmonary rehabilitation participants to undertake relevant education at their convenience.[16] Education opportunities were also available in a group format—in-person for centre-based rehabilitation participants, and in a virtual group for telerehabilitation participants. For all participants, self-management education included discussion of long-term exercise planning. Recognising and managing an acute exacerbation was included in self-management training for participants with COPD or asthma. Additional education and self-management training topics were individualised for participants who identified a relevant health goal (see online supplemental file for further details).

Exercise training comprising aerobic and resistance training, supervised and progressed by a suitably qualified healthcare professional, was undertaken two times per week. Full intervention details, including the protocol for prescription and progression of exercise training, are described elsewhere[14] and in the online supplement (online supplemental table S1). Briefly, individuals randomised to centre-based pulmonary rehabilitation attended their centre of recruitment. Individuals randomised to telerehabilitation were provided with all necessary equipment for the 8-week rehabilitation period. The telerehabilitation equipment 'kit' comprised: a step-through exercise bike to maximise safety (Bodyworkx A915); a 4G enabled tablet computer (Apple iPad, Apple, Cupertino, California, USA) with mobile data, fixed to a stand for video conferencing; and a pulse oximeter (Nonin Palmsat 2500A; Nonin Medical, Plymouth, Minnesota, USA) to monitor peripheral oxygen saturation and pulse rate during training and at rest (online supplemental figure S1). Their initial exercise training session was undertaken during a home-visit with the physiotherapist. After the initial home-visit, the remaining 15 telerehabilitation sessions were conducted in a virtual group of up to six participants, two times per week over 8 weeks. At the conclusion of the 8-week rehabilitation period the telerehabilitaiton equipment 'kit' was removed from the patients home by the research team. Fidelity of the exercise training intervention was assessed 6 monthly from exercise training records by an independent clinician (online supplemental table S3).

Pulmonary rehabilitation programme completion, irrespective of location of delivery, was determined a priori as undertaking at least 70% (≥11) of planned sessions.[6]

Outcomes

All participants undertook centre-based assessment of clinical outcome measures at baseline, end-rehabilitation and after 12 months follow-up. The primary outcome was change in the dyspnoea domain of the Chronic Respiratory Disease Questionnaire Dyspnoea (CRQ-D) from baseline to end-rehabilitation. Secondary outcomes (see online supplement) included measures of health-related quality of life (HRQoL), exercise capacity, symptoms, psychological well-being and self-efficacy. A medical record review was undertaken after 12 months of follow-up to determine hospitalisations during the study period.

Analysis

In accordance with the Consolidated Standards of Reporting Trials (CONSORT) Extension for reporting of non-inferiority and equivalence trials[17] equivalence limits were prespecified. The upper and lower bound of the equivalence limits represented ± the minimal important difference (MID), being the smallest clinically meaningful change.[18] Sample size calculations indicated 128 participants (64 in each group) were required to be 80% sure that the 95% CI would exclude a difference in change in CRQ-D of at least 2.5 points, corresponding to the MID.[19] This difference assumes a SD of the change in CRQ-D of 4.8 points.[20] This sample size also provided sufficient power to exclude a difference in 6-minute walk distance (6MWD) greater than the MID of 30 m,[21] endurance cycle time greater than the MID of 150s[22] and programme completion using a completion estimate of 85%. An additional 14 participants were randomised to allow for 10% dropout.

Statistical analyses were conducted using IBM SPSS Statistics (V.26.0; IBM Corp). All data were analysed by intention-to-treat (ITT). Continuous variables were analysed by fitting linear mixed models, controlling for recruitment centre and baseline values. The proportion of participants classified as programme completers (attended ≥70% of sessions) were compared between groups using a χ^2 test and the relative risk of non-completion was determined. Kaplan-Meier curves and Cox proportional hazards modelling were used to evaluate time to hospital admission. Kappa statistics were used to assess the success of assessor blinding at the end of the 12-month follow-up period. A per-protocol analysis (programme completers) was also conducted to reduce the risk of Type 1 error, as recommended in the CONSORT Extension for reporting of non-inferiority and equivalence trials.[17] Alpha was set at 0.05.

RESULTS

Between 18 August 2016 and 5 February 2019, 651 individuals were screened, 152 participants (23%) recruited and 142 randomised (figure 1). At the end of the trial data were available for the primary outcome for 135 participants (95%) (telerehabilitation: n=68 (97%); centre-based pulmonary rehabilitation n=67 (96%)). As the volume of missing data were small, imputation of missing values was not performed.

Characteristics of participants included in the ITT analysis, at baseline, are presented in table 1 (see online supplemental table S2 for characteristics of all randomised participants). Participant diagnoses were COPD (n=100), ILD (n=11), bronchiectasis (n=19) and asthma (n=12). There was no difference between groups in terms of self-rated computer experience or confidence (experience: both median (IQR) 2 (1–3); confidence: telerehabilitation 4 (3–5), centre-based 4 (3–4)). Groups were similar in terms of the proportion of rural and metropolitan participants; participants randomised within 4 weeks of hospital discharge; and never smokers. There were slightly more participants on long-term oxygen in the telerehabilitation group (n=8 (12%) versus centre-based rehabilitation n=3 (5%)) (table 1).

The ITT analysis showed both groups achieved clinically important gains in CRQ-D at end-rehabilitation with no significant between-group difference (table 2). However, the lower limit of the CI for the between group difference was below the lower bound of the equivalence margin, indicating inferiority of telerehabilitation could not be excluded (figure 2A). The findings for CRQ-D were similar at 12 months (figure 2A).

No between-group differences were identified for any secondary outcomes at either time point. At end-rehabilitation, equivalence of telerehabilitation was demonstrated for 6MWD (mean difference (MD) −6 m, 95%CI −26 to 15) as the 95%CI for the MD between groups fell wholly within the equivalence margin of ±30 m. Superiority of telerehabilitation for 6MWD unable to be excluded at 12 months as the upper limit of the 95% CI exceeded the prespecified upper bound of the equivalence margin (MD 14 m, 95% CI −10 to 38)(figure 2B). For endurance capacity, the upper limit of the confidence interval exceeded the upper bound of the equivalence margin at end-rehabilitation (MD 109s (95% CI −77 to 284) and at 12 months (MD −11s, 95% CI −208 to 187) indicating superiority for telerehabilitation cannot be excluded at either time point (figure 2C).

The emotional function and fatigue domains of the CRQ both demonstrated equivalence at end-rehabilitation (table 2), while inferiority of telerehabilitation for the CRQ mastery domain could not be excluded as the lower limit of the CI fell below the lower margin of the equivalence limit (MD 0.9 points, 95% CI −2.5 to 0.7). At 12-month follow-up telerehabilitation demonstrated equivalence for CRQ fatigue and mastery domains, with superiority for the emotional function domain unable to be excluded as the upper limit of the 95%CI exceeded the upper bound of the equivalence margin (MD 0.7 points (95% CI −2.4 to 3.9)) (table 2).

There were no statistically significant differences between groups for self-efficacy on Pulmonary Rehabilitation Adapted Index of Self-Efficacy, breathlessness on modified Medical Research Council, Hospital Anxiety and Depression Scale scores for anxiety or depression or for physical activity (table 2, online supplemental figure S2).

The mean (±SD) number of exercise training sessions attended by participants did not differ between groups (telerehabilitation: 13 (±3) sessions; centre-based pulmonary rehabilitation 13 (±4) sessions (range 1–16 sessions for both groups)). Summary data for fidelity of the exercise training intervention by group allocation is presented in online supplemental table S3. More participants in the telerehabilitation group engaged with education and self-management training (n=68 (97%) telerehabilitation versus n=59 (84%) centre-based pulmonary rehabilitation; $\chi(1)=6.9$, p=0.009) (see also online supplemental table S4). No adverse events related to the intervention occurred in either group during the rehabilitation period (online supplemental table S5). The proportion of participants who completed ≥70% of prescribed sessions was high (84% telerehabilitation vs 79% centre-based rehabilitation, p=0.4). The relative risk of non-completion in the centre-based group compared with telerehabilitation was 1.4 (95% CI 0.7 to 2.7). The per-protocol analysis (including only programme completers) demonstrated similar findings to the ITT analysis (see online supplemental table S6).

During the 8-week intervention period six participants (4%) experienced a hospitalisation for a respiratory cause (n=4 telerehabilitation; n=2 centre-based rehabilitation) (online supplemental table S5). During the 12-month follow-up period there

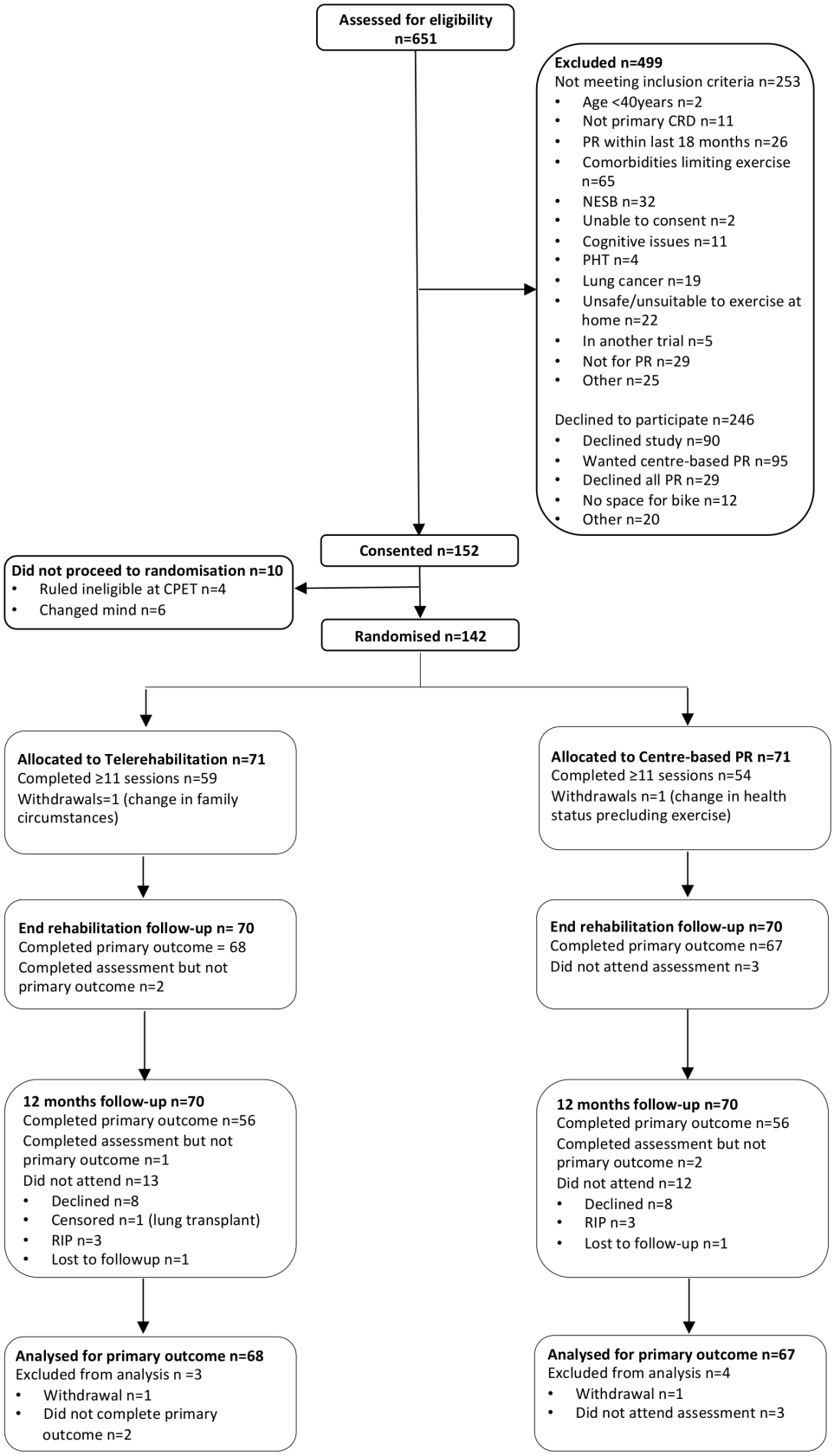

Figure 1 Consolidated Standards of Reporting Trials diagram for study flow. CPET, cardiopulmonary exercise test; PR, pulmonary rehabilitation.

was no difference between groups in the number of participants who had at least one all-cause hospitalisation (table 3, both n=24, p=1.0) or respiratory-related hospitalisation (telerehabilitation n=12 vs centre-based rehabilitation n=11, $\chi(1)=0.05$, p=0.8). There was no difference between groups for time to first all-cause hospitalisation (Mantel-Cox log rank $\chi(1)=0.02$, p=0.9)

Table 1 Participant characteristics

	Telerehabilitation n=68	Centre-based pulmonary rehabilitation n=67
Age, years	68 (9)	67 (9)
Male/female, n	30/41	36/35
Diagnosis, n (%)		
COPD	47 (69)	50 (70)
ILD	5 (7)	6 (8.5)
Bronchiectasis	10 (15)	9 (13)
Asthma	6 (9)	6 (8.5)
Smoking status, n (%)		
Current smoker	11 (15.5)	8 (11)
Ex-smoker	49 (69)	53 (75)
Never smoker	11 (15.5)	10 (14)
Pack years, median (IQR)	40 (15 to 60)	35 (14 to 53)
FEV1, L	1.5 (0.7)	1.6 (0.7)
FEV1, %predicted	59 (25)	63 (26)
FVC, L	2.9 (0.9)	2.9 (1.1)
FVC, %predicted	84 (21)	86 (26)
FEV1/FVC, %	54 (20)	56 (19)
BMI, kg/m^2	28 (6)	28 (7)
6-minute walk distance, m	416 (115)	435 (85)
CPET*	n=46	n=47
%predicted VO_2 max	60 (20)	59 (21)
Peak watts	71 (27)	74 (23)
Endurance cycle time*	n=46	n=43
Seconds median (IQR)	234 (143 to 332)	251 (168 to 330)
LTOT, n (%)	8 (12)	3 (5)
CRQ		
Dyspnoea	15 (6)	15 (6)
Fatigue	14 (6)	15 (6)
Emotion	33(10)	32 (10)
Mastery	20 (6)	20 (5)
Total	82 (23)	82 (21)
mMRC, median (IQR)	2 (1 to 3)	1 (1 to 2)
mMRC, n (%)		
0	2 (3)	1 (2)
1	23 (33)	34 (51)
2	25 (37)	20 (30)
3	14 (21)	11 (16)
4	4 (6)	1 (2)
HADS anxiety†, n (%)		
No case	53 (78)	52 (78)
Case	15 (22)	15 (22)
HADS depression†, n (%)		
No case	60 (88)	62 (93)
Case	8 (12)	5 (8)
SF-36v2		
PCS	37 (9)	40 (7)
MCS	49 (13)	49 (12)
pulmonary rehabilitationAISE	48 (7)	48 (7)
Physical activity, min/day		
Sedentary (<1.5 METs)	532 (165)	494 (149)
Light (≥1.5–2.99 METs)	271 (106)	285 (90)
Moderate-vigorous (≥3 METs) median (IQR)	63 (29 to 111)	63 (38 to 99)
Number of comorbidities, median (IQR)	3 (2 to 5)	4 (2 to 5)
Participants recruited within 4 weeks of a hospital admission for a respiratory exacerbation, n (%)	3 (4)	2 (3)
Participants with a hospital admissions in the year prior to pulmonary rehabilitation, n (%)	11 (16)	15 (22)
Metropolitan/rural, n (%)	48/20 (71/29)	48/19 (72/28)
Naïve to pulmonary rehabilitation, n (%)	49 (72)	57 (85)

Data are mean (SD) unless indicated.
*Only participants recruited in metropolitan Melbourne had the capacity to undertake baseline CPET assessment and endurance cycle testing due to a lack of available testing facilities in the rural location.
†HADS case definition scoring: 0<11=no case; ≥11=case.
BMI, body mass index; COPD, chronic obstructive pulmonary disease; CPET, cardiopulmonary exercise test; CRQ, Chronic Respiratory Disease Questionnaire; FEV_1, forced expiratory volume in 1 s; FVC, forced vital capacity; HADS, Hospital Anxiety and Depression Scale; ILD, interstitial lung disease; L, litres; LTOT, long-term oxygen therapy; MCS, mental component summary; METs, metabolic equivalent; mMRC, modified Medical Research Council; n, number; PCS, physical component summary; %predicted, percentage of predicted normal; PRAISE, Pulmonary Rehabilitation Adapted Index of Self-Efficacy; pulmonary rehabilitation, pulmonary rehabilitation; SF36-v2, Medical Outcomes Survey Short-form 36-v2; VO_2max, maximum oxygen uptake.

or time to first respiratory hospitalisation (Mantel-Cox log rank $\chi(1)=0.1$, $p=0.7$) (see online supplemental figures S3 and S4). There was no difference between groups in the relative risk of hospitalisation (all-cause: HR=0.96, 95% CI 0.5 to 1.7; respiratory hospitalisation: HR=0.93, 95% CI 0.5 to 1.6).

In a subgroup analysis comprising participants with COPD, there was a statistically significant difference between groups in CRQ-D score at 12-month follow-up favouring centre-based rehabilitation (see online supplemental table S7). In individuals with COPD, inferiority of telerehabilitation for 6MWD could not be excluded at end-rehabilitation. Similar to the results in the main analysis, superiority of telerehabilitation for improvement in 6MWD at 12-month follow-up and for endurance cycle time at both time points could not be excluded. In a post-hoc analysis of participants who were naïve to pulmonary rehabilitation, in keeping with the main analysis, inferiority of telerehabilitation for CRQ-D could not be excluded at either time point (online supplemental table S8). For participants' naïve to pulmonary rehabilitation, inferiority of telerehabilitation for 6MWD could not be excluded at end-rehabilitation. Similar to the results of the main analysis, in participants naïve to pulmonary rehabilitation superiority of telerehabilitation for improvement in 6MWD at 12 months and for endurance cycle time at both time points could not be excluded.

Table 2 Clinical outcomes—intention-to-treat analysis

		Within group differences from baseline (95% CI)				Between group differences	
		Telerehabilitation n=68		Centre-based rehabilitation n=67		Telerehabilitation—centre (95% CI)	
		End-rehabilitation	1 year	End-rehabilitation	1 year	End-rehabilitation	1 year
Primary outcome	CRQ—dyspnoea	3.9 (2.4 to 5.4)	0.7 (–1.3 to 2.6)	4.6 (2.7 to 6.5)	1.7 (–0.7 to 4.1)	–1.0 (–3.3 to 1.2)*	–1.3 (–3.6 to 1.1)*
Secondary outcomes	CRQ—						
	Emotion	2.0 (–0.5 to 4.5)	2.6 (–0.3 to 5.6)	3.0 (0.6 to 5.5)	1.9 (–0.6 to 4.3)	–0.2 (–3.2 to 2.7)	0.7 (–2.4 to 3.9)†
	Fatigue	2.1 (0.6 to 3.6)	1.9 (0.3 to 3.5)	1.6 (0.1 to 3.2)	1.6 (0.1 to 3.0)	0.2 (–1.5 to 1.8)	–0.2 (–2.0 to 1.6)
	Mastery	0.3 (–1.2 to 1.9)	0.9 (–0.9 to 2.8)	1.8 (0.6 to 3.1)	1.3 (–0.0 to 2.6)	–0.9 (–2.5 to 0.7)	0.1 (–1.6 to 1.8)
	Total	9.1 (3.5 to 14.8)	7.5 (1.5 to 13.5)	11.2 (5.4 to 17.0)	7.2 (1.1 to 13.3)	–2.6 (–9.0 to 3.7)	0.8 (–5.9 to 7.6)
	6MWD, m	23 (10 to 36)	22 (2 to 42)	25 (11 to 40)	0.1 (–23 to 23)	–6 (–26 to 15)	14 (–10 to 38)†
	Endurance cycle time, s	296 (153 to 439)	121 (–9 to 250)	186 (50 to 322)	71 (–65 to 208)	109 (–77 to 284)†	–11 (–208 to 187)*†
	pulmonary rehabilitationAISE	1.2 (–0.4 to 2.8)	0.5 (–1.4 to 2.5)	0.2 (–1.3 to 1.8)	0.6 (–1.3 to 1.9)	1.0 (–1.1 to 3.0)	–0.1 (–2.3 to 2.2)
	mMRC	–0.4 (–0.7 to –0.2)	–0.2 (–0.4 to 0.1)	–0.3 (–0.5 to –0.1)	0.1 (–0.2 to 0.3)	0.0 (–0.3 to 0.3)	–0.2 (–0.5 to 0.1)
	HADS-A	–0.9 (–2.1 to 0.3)	–1.5 (–2.9 to 0.01)	–0.5 (–1.7 to 0.6)	–1.2 (–2.5 to 0.05)	–0.2 (–1.5 to 1.2)	–0.6 (–2.0 to 0.9)
	HADS-D	–0.2 (–1.0 to 0.6)	–0.4 (–1.4 to 0.7)	–0.5 (–1.5 to 0.6)	–1.3 (–2.4 to –0.2)	0.5 (–0.7 to 1.6)	0.8 (–0.4 to 2.0)
	SF36-v2						
	PCS	2.2 (0.5 to 3.9)	0.9 (–1.2 to 3.0)	–0.1 (–1.7 to 1.5)	–1.6 (–3.7 to 0.5)	0.7 (–1.7 to 3.1)	2.0 (–0.6 to 4.5)
	MCS	1.3 (–1.0 to 3.5)	2.4 (–0.7 to 5.4)	2.5 (0.02 to 4.9)	–0.5 (–3.2 to 2.2)	–1.2 (–4.4 to 2.0)	3.0 (–0.4 to 6.4)
	Physical activity, min						
	Sedentary	–27.5 (–68.6 to 13.6)	–24.5 (–72.3 to 23.4)	–23.4 (–67.3 to 20.4)	–0.6 (–53.6 to 52.3)	–23.6 (–26.8 to 74.1)	0.4 (–58.9 to 59.8)
	LIPA	–4.1 (–35.6 to 27.4)	8.9 (–26.3 to 44.1)	9.5 (–21.2 to 40.2)	–9.7 (–44.0 to 24.7)	–21.6 (–60.6 to 17.4)	20.9 (–24.8 to 66.6)
	MVPA	6.7 (–4.6 to 17.9)	3.7 (–6.5 to 13.9)	5.0 (–8.9 to 18.9)	–3.1 (–13.8 to 7.6)	–2.3 (–18.1 to 13.5)	7.7 (–10.8 to 26.1)

Data are mean difference and 95% CIs adjusted for baseline values.
No statistically significant difference between groups for any outcome.
*CI exceeds the lower equivalence limit and cannot exclude inferiority of telerehabilitation.
†CI exceeds the upper equivalence limit of the minimal important difference and cannot exclude superiority of telerehabilitation.
CRQ, Chronic Respiratory Disease Questionnaire; HADS-A, Hospital Anxiety and Depression Scale—anxiety score; HADS-D, Hospital Anxiety and Depression Scale—depression score; LIPA, light intensity physical activity; MCS, mental component summary; MCS, mental composite score; mMRC, modified Medical Research Council scale; MVPA, moderate-vigorous intensity physical activity; 6MWD, 6-minute walk distance; PCS, physical composite score; PCS, physical component summary; PRAISE, Pulmonary Rehabilitation Adapted Index of Self-Efficacy; SF36-v2, Medical Outcomes Survey Short-form 36-v2.

At the conclusion of the trial, blinded assessors correctly identified group allocation for n=41 (59%) participants in the telerehabilitation group and n=42 (60%) participants in the centre-based pulmonary rehabilitation group (κ=0.1, p=0.5).

DISCUSSION

This trial was unable to demonstrate equivalence of telerehabilitation to centre-based pulmonary rehabilitation for all outcomes. However, both groups demonstrated clinically meaningful improvements in symptoms (CRQ-D) at end-rehabilitation which exceeded the MID of 2.5 points (table 2). For the primary outcome of CRQ-D, inferiority of telerehabilitation could not be ruled out at end-rehabilitation or after 12 months follow-up. This home-based, virtual group, model of telerehabilitation, achieved improvements in exercise capacity that were at least equivalent to those achieved with centre-based pulmonary rehabilitation; superiority of telerehabilitation was unable to be excluded at 12 months follow-up. Both programmes were safe,

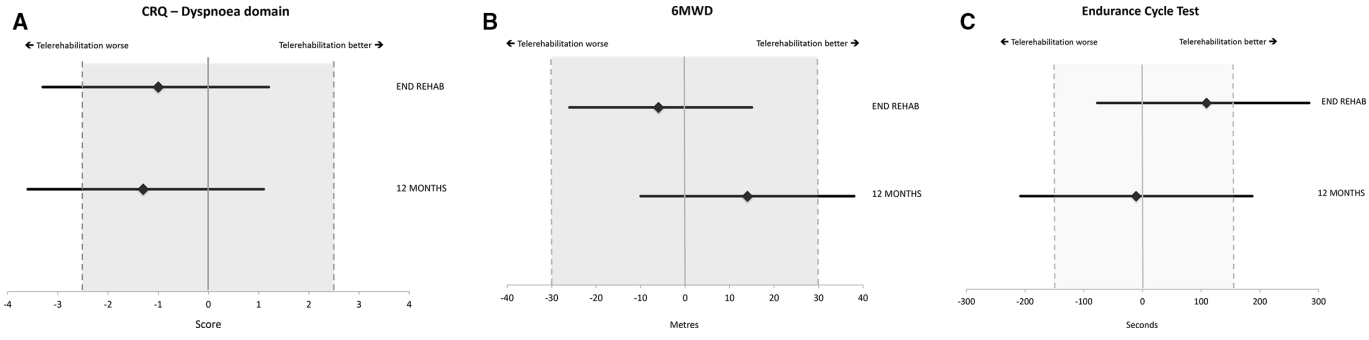

Figure 2 Difference between groups for (A) CRQ-D, (B) 6MWD and (C) endurance cycle time and equivalence limits at end-rehabilitation and 12 months follow-up. Data are mean and 95% CI for difference between groups. Shaded area represents equivalence limits, which are ±minimal important difference. CRQ-D, Chronic Respiratory Disease Questionnaire—Dyspnoea domain; END REHAB, end-rehabilitation; 6MWD, 6-minute walk distance.

Table 3 Hospitalisation in the 12 months following pulmonary rehabilitation

	Telerehabilitation (n=70)	Centre-based rehabilitation (n=70)	P value
Number admitted (% of group)	24 (34)	24 (34)	1.0
Number admitted for respiratory cause (% of group)	12 (17)	11 (16)	0.8
Number of admissions (all cause)	62	50	0.9*
Hospital days (all cause), median (IQR)	6 (3 to 13)	5 (1 to 22)	0.4*
Frequency of all cause admissions (n)			
0	46	46	
1	12	11	
≥2	12	13	
Number of respiratory admissions	20	21	0.8*
Hospital days for respiratory admissions, median (IQR)	6 (3 to 9)	5 (2 to 11)	1.0*
Frequency of respiratory admissions (n)			
0	58	59	
1	12	11	
≥2	0	0	

*Mann-Whitney U-test.

with no intervention-related adverse events recorded. Adherence to supervised exercise training was high in both programmes.

Equivalence of telerehabilitation was demonstrated for CRQ emotional function and fatigue domains at end-rehabilitation, and for CRQ fatigue and mastery domains at 12-month follow-up. However, only participants in the telerehabilitation group achieved a clinically meaningful improvement in CRQ fatigue domain at end-rehabilitation. While benefit of pulmonary rehabilitation for HRQoL has been demonstrated over no-rehabilitation comparisons,[2] our findings are in keeping with other recent studies of telerehabilitation, which also demonstrated modest impact on HRQoL. In two studies of home-based telerehabilitation using video conferencing and supervised exercise training, no difference in HRQoL was seen at end-rehabilitation when compared with a wait-list control group[23] or to centre-based pulmonary rehabilitation.[9] Additionally, in the study by Hansen *et al* no improvement in HRQoL greater than the MID was seen in either group.[9] In contrast, when telerehabilitation was delivered using a hub and spoke model delivered from a specialist centre to smaller regional hubs, clinically meaningful change was seen in St George's Respiratory Questionnaire (SGRQ) in both groups, with no between-group difference.[10] In this model where participants exercised in a group at both locations, under the supervision of in-person and remotely located healthcare professionals, clinically meaningful change was seen in SGRQ in both groups.[10] Whether this difference in outcomes reflects the presence of in-person healthcare professional supervision and peer social support versus remote or virtual supervision and support is unclear. A better understanding of the patient experience of telerehabilitation is necessary to identify elements of remote pulmonary rehabilitation that may be impacting participant perception of well-being and mastery.

In the present study, equivalence of telerehabilitation for exercise capacity (6MWD) was demonstrated at end-rehabilitation, and superiority was unable to be excluded at 12 months follow-up (6MWD and endurance cycle time). Both groups achieved improvements in endurance cycle time that exceeded the clinically meaningful difference. Improvements in endurance cycle time have also been reported at the conclusion of the intervention period for telerehabiliation delivered using a website,[11] over the telephone[24] or via video conferencing.[23] This would suggest that an adequate exercise-training stimulus can be delivered remotely using a variety of telecommunications technologies. Of note, the current telerehabilitation participants maintained their exercise capacity at 12-month follow-up. Maintaining gains in exercise capacity after traditional centre-based pulmonary rehabilitation is notoriously difficult,[25] and a return to baseline 6MWD was evident in the centre-based rehabilitation group under investigation. Very few trials of telerehabilitation have included follow-up beyond the end of the intervention period. In one study of telerehabilitation using video conferencing and comprising largely supervised strength training, telerehabilitation participants demonstrated a slight improvement in 6MWD at approximately 3 months post intervention compared with centre-based rehabilitation participants whose 6MWD declined.[9] In two studies where telerehabilitation was delivered by telephone with follow-up at or around 12 months, improvements in 6MWD at end-rehabilitation had returned to baseline for participants in both the home-based telerehabilitation group and centre-based rehabilitation comparison.[6 24] Whether one specific component of the telerehabilitation programme under investigation, or a combination of factors, contributed to maintenance of exercise gains in this study is not clear. It is possible that real-time supervised rehabilitation interventions delivered into the home help provide confidence in being able to exercise independently, although we did not find differences in physical activity between the groups at 12 months; this requires further exploration.

Despite the documented clinical benefits,[2] pulmonary rehabilitation is underused globally. Telerehabilitation is one option for increasing access to pulmonary rehabilitation services,[8] while simultaneously addressing common barriers to centre-based pulmonary rehabilitation attendance.[7] The telerehabilitation model investigated here mitigated common barriers to rehabilitation attendance associated with travel and transport by providing equipment and specialist supervision directly into the patient's home. It was able to provide experienced staffing support to an under-resourced rural location, with centralised delivery of the telerehabilitation programme; and achieved programme completion rates (84%) exceeding that typically documented with centre-based pulmonary rehabilitation.[3] Such advantages, in addition to the ability to remotely supervise an

adequate exercise-training stimulus as evidenced in this study, have the potential for even greater impact amidst the current COVID-19 pandemic. Global circumstances have mandated an almost immediate shift from face-to-face rehabilitation service delivery models to programmes which can maintain physical distancing, or isolation, while achieving effective clinical outcomes. Implementation of effective telerehabilitation into clinical practice requires financial, infrastructure, resource and training support. Identified barriers to the implementation of telerehabilitation into clinical practice include workload changes, time constraints and uncertain or limited access to support for equipment and technology.[26] Whether the features of the current telerehabilitation model that enabled the remote delivery of a comprehensive remote pulmonary rehabilitation programme can be easily implemented into practice and are acceptable to clinicians, patients and health funders in the real-world clinical environment remains to be determined.

Strengths of this study include powering for equivalence—including for secondary outcomes of exercise capacity and programme completion. This is the first trial of real-time supervised telerehabilitation powered for equivalence, thereby enabling small differences in outcomes between telerehabilitation and centre-based pulmonary rehabilitation to be detected. Specifically, equivalence of telerehabilitation to centre-based pulmonary rehabilitation for exercise capacity at the end of the rehabilitation intervention, and superiority of telerehabilitation for exercise capacity at 12 months follow-up are novel findings. By recruiting individuals with a variety of chronic respiratory diseases the participants in this trial were reflective of those referred to real-world pulmonary rehabilitation programmes. This strategy is supported by the similar findings across all outcomes for the participants with COPD. Unlike previous trials that have required participants to be familiar with the internet, own their own smartphone or device or have used bespoke equipment, the present trial was open to all individuals regardless of familiarity with the internet or technological devices and used equipment purchased from general consumer outlets. This supports the scalability of this telerehabilitation model into clinical practice. Recruitment of participants and delivery of remote pulmonary rehabilitation to individuals in rural locations over 400 km from the site of the pulmonary rehabilitation clinicians demonstrates the utility of telerehabilitation to increase access to pulmonary rehabilitation irrespective of geographical location and local staffing resources.

Limitations

Six months into recruitment we sought approval to amend the trial protocol and open recruitment to all individuals with a primary chronic respiratory disease. While this strategy reflects that people with diverse lung diseases benefit from and are referred to pulmonary rehabilitation, it also makes it difficult for our results to be generalised to any particular disease group. It was not possible to identify differential effects of the intervention in people with non-COPD diagnoses, as the numbers in each diagnostic group (ILD, asthma, bronchiectasis) were too small. Whether individuals with a specific lung disease respond better, or worse, to a programme of telerehabilitation is not clear. Although clinically meaningful improvement in CRQ-D score was demonstrated, mean improvements in 6MWD did not exceed the MID. Despite the modest improvement in 6MWD, the 95% CI for change in 6MWD for both groups does include the accepted MID of 30 m.[27] The number of rehabilitation sessions offered to participants in this study was in keeping with clinical guideline recommendations in the Australian rehabilitation context.[15] Whether a longer rehabilitation duration would have resulted in improvements in exercise capacity that exceed the MID for 6MWD is not clear. Gains in 6MWD reported here are also similar or greater than those reported for both centre-based pulmonary rehabilitation and telerehabilitation in a recent Cochrane review of telerehabilitation in chronic respiratory disease,[28] suggesting the improvement in 6MWD is comparable to that seen in contemporaneous clinical trials. It is possible that differences between groups due to the proportion of individuals who were naïve to pulmonary rehabilitation may have occurred by chance (72% telerehabilitation vs 85% centre-based rehabilitation). A post-hoc analysis of the participant's naïve to pulmonary rehabilitation demonstrated similar findings to the main analysis (online supplemental table S8). This suggests it is unlikely that the small difference in those who were naïve to pulmonary rehabilitation in each group had a significant impact on outcomes. Providing and then removing equipment at the completion of rehabilitation had the potential to deny participants the necessary tools for ongoing exercise participation. However, maintenance of exercise capacity gains at 12-month follow-up by participants in the telerehabilitation group would suggest that removal of familiar equipment did not limit their ability to continue exercise participation. Recruitment and all assessments were conducted at the pulmonary rehabilitation centres, which may contribute to recruitment bias in that anyone not able to attend a centre was unable to be considered for the trial. Similarly, recruited participants were individuals prepared to undertake either telerehabilitation or centre-based pulmonary rehabilitation, based on random assignment. Nearly 20% of eligible individuals declined to participate because they had a preference for centre-based rehabilitation, which may have contributed to recruitment bias. This highlights the potential benefits of accommodating patient preference in the choice of rehabilitation location/model of delivery to enhance programme uptake, support adherence and optimise patient outcomes.[29] Assessing exercise capacity is key to ensuring prescription of adequate training intensity during pulmonary rehabilitation. Presently there are no suitable exercise tests that can be undertaken remotely, which detect desaturation and from which exercise training can be prescribed.[30] The programme completion rates for both groups were relatively high (≥79%) but, while higher than those typically reported for conventional outpatient pulmonary rehabilitation programmes,[3] are in keeping with completion rates reported for home-based models of pulmonary rehabilitation.[6] Reasons underlying high programme completion rates in this study are not clear, but possibly relate to frequency of interaction with the research team. More modest completion outcomes may be anticipated with real-world implementation of telerehabilitation.

CONCLUSIONS

Home-based telerehabilitation, with readily available equipment and direct supervision of exercise training, may not be equivalent to centre-based pulmonary rehabilitation for all outcomes, but was safe and achieved clinically meaningful improvements. For the primary outcome of CRQ-D, inferiority of telerehabilitation could not be excluded. For exercise capacity, superiority of telerehabilitation could not be excluded, particularly at 12-month follow-up. To achieve equivalent outcomes to centre-based pulmonary rehabilitation, and to support implementation into clinical practice, modifications to the telerehabilitation programme may be required. When centre-based pulmonary rehabilitation is not available, telerehabilitation may provide an alternative programme model.

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