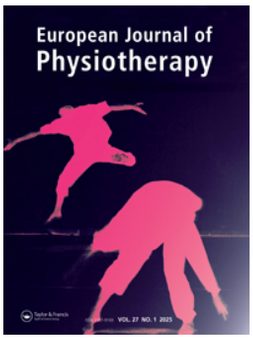

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Effect of a 4-week pulmonary telerehabilitation program for people with respiratory post-acute sequelae of COVID-19 – A randomised controlled trial

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ABSTRACT

Purpose: To evaluate a 4-week pulmonary telerehabilitation (PTR) program compared to usual care for people with persistent respiratory post-acute sequelae of COVID-19 (PASC).

Methods: A multi-centre randomised controlled trial with remote assessment and assessor blinding. Participants were randomised 1:1 to 4-weeks, twice-weekly PTR or usual care (Control Group (CG)). PTR exercise intensity was titrated based on fatigue and dyspnoea. After the control period, participants in CG could cross-over into PTR to form a combined group (PTR-X). Primary outcome: 1-minute sit-to-stand test (1-minSTST). Secondary outcomes: 5-repetition sit-to-stand test; Montreal Cognitive Assessment blind-version; COVID-19 Yorkshire Rehabilitation Scale; COPD Assessment Test; 36-Item Short-Form Health Survey; Hospital Anxiety and Depression Scale; Fatigue Severity Scale; Kessler Psychological Distress Scale, all assessed at baseline and following intervention or control periods. Data were analysed using a linear mixed effects model.

Results: Of 50 participants recruited, 39 completed the study (PTR group $n=14$, CG $n=25$). There were no statistically significant between-group differences in any outcomes. For the PTR-X group ($n=27$) there was a statistically significant within-group improvement in 1-minSTST (2.4 repetitions, 95%CI 0.6–4.2).

Conclusions: A 4-week (8 session) PTR intervention for respiratory PASC showed no significant between-groups differences suggesting that longer PTR programs or alternative interventions should be evaluated.

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Post-acute sequelae of COVID (PASC), pulmonary rehabilitation; randomised controlled trial; respiratory symptoms; telehealth; telerehabilitation

Introduction

As reported by the World Health Organisation (WHO), the COVID-19 pandemic has led to over 775 million severe acute respiratory syndrome coronavirus (SARS-CoV-2) or 'COVID-19' infections globally [1]. More than 50 symptoms are commonly reported in the post-acute infective period [2], including respiratory symptoms such as dyspnoea and cough in 21% and 18% of people respectively [3]. It is well established that for people with chronic respiratory disease, pulmonary rehabilitation (PR) [4] and pulmonary telerehabilitation (PTR) [5] improves health-related quality of life (HRQoL), dyspnoea, functional capacity, anxiety, and depression. Given respiratory symptoms are common in those reporting post-acute sequelae of COVID (PASC), PR and PTR are considered potentially applicable for people with these sequelae following COVID-19 [6]. A recent systematic review of seven randomised controlled trials (RCTs) evaluated rehabilitation for people with PASC and provided some evidence of improved functional capacity and fatigue [7]. However, the included studies were heterogenous in terms of whether exercise sessions were centre-based or *via* remote access, and some trials did not deliver exercise-based interventions similar to those provided in a traditional PR program [8].

Two RCTs in which exercise training was similar to traditional PR but provided as either centre-based or *via* remote supervision have shown differing findings [9,10]. In one study, non-hospitalised individuals were randomised to an 8-week program of supervised moderate-intensity exercise twice a week, with an additional day of light-intensity exercise, compared to a control of an educational pamphlet, and showed improvements in aerobic capacity, strength, HRQoL, fatigue, depression, and functional status [9]. In contrast, a 12-week rehabilitation program involving remotely-supervised exercise in post-hospitalised individuals with PASC, compared to a control of an educational pamphlet and weekly check-in

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calls, did not find statistically significant between-groups differences in the 30 s sit-to-stand test, timed up-and-go test, modified Medical Research Council (mMRC) dyspnoea scale, clinical frailty scale, or other physical, cognitive, or HRQoL outcomes [10]. There have been no studies to date that have evaluated PTR specifically in those reporting respiratory sequelae post-COVID infection.

As the prevalence of PASC is higher in individuals of working age [11], centre-based PR programs of eight weeks or longer may not be feasible for this cohort due to work commitments. Additionally, many individuals who had mild COVID-19 and were not hospitalised, report ongoing respiratory symptoms that qualify as PASC [12]. The aim of this study was to evaluate the effect of a short 4-week, twice-weekly, supervised PTR program compared to usual medical care on functional capacity (primary outcome), and symptoms, cognition, anxiety, depression, HRQoL and fatigue (secondary outcomes), in people with persistent respiratory PASC.

Methods

Study design

This was a prospective, multi-centre, assessor-blinded RCT which adhered to the Guidelines for Reporting Outcomes in Trial Reports (CONSORT). The study protocol has previously been published [13]. A concealed computer-generated sequence using a secure data management software, Research Electronic Data Capture (REDCap), was used to randomise participants 1:1 to either the intervention of PTR (PTR group) or a control group (CG) of usual medical care. Randomisation was stratified for age (≤ 50 or >50 years) and sex (male/female). Participants in the CG were invited to cross-over into the PTR group after the completion of the control period, to form a combined PTR-X group. The reason to include an option to cross-over was twofold: (1) advice from our Long-COVID lived experience group was that all participants needed the opportunity to participate in any rehabilitation being offered; (2) to enable augmentation of data on rehabilitation outcomes, which was important given the limited number of studies published in telerehabilitation for people with persistent respiratory PASC at the time of study conception.

The trial was approved by the Sydney Local Health District (SLHD) Human Research and Ethics Committee (Royal Prince Alfred Zone) and was registered (ACTRN 12622000355774). The trial was funded by an SLHD Allied Health Research Grant.

Participants

Participants were those at least four weeks post a confirmed diagnosis of SARS-CoV-2 *via* either a polymerase chain reaction (PCR) test or a rapid antigen test (RAT) and who attended a novel Post-COVID Respiratory Clinic for people with persistent respiratory sequelae including dyspnoea, cough, or wheeze. We chose four weeks post infection to exclude the 'acute phase' of COVID which the National Institute for Health and Care Excellence (NICE) defines as within the first 4 weeks from infection [14]. The Clinics were at one of two major tertiary metropolitan hospitals in Sydney, Australia. Prior to recruitment, all participants were screened face-to-face at a Post-COVID Respiratory Clinic which consisted of a medical assessment by a respiratory physician to ensure physical and cognitive suitability for PTR, and a 1-minute sit-to-stand test (1-minSTS) with pulse oximetry monitoring under the supervision of a respiratory physiotherapist. Those who met the inclusion criteria and none of the exclusion criteria (Figure 1) and provided informed consent were invited to participate regardless of whether they were hospitalised or managed in the community during the period of their acute infection. Details of safety considerations for participation in the intervention can be found in our published protocol [13].

Intervention group

Pulmonary telerehabilitation (PTR)

Participants randomised to the PTR group received rehabilitation *via* videoconferencing (Zoom Video Communications Inc.). At the initial videoconferencing session, a physiotherapist performed a safety check of the area where the participant intended to undertake the PTR sessions by visually scanning for trip hazards and aiding with the selection of an appropriate chair for seated exercises. PTR sessions were supervised twice-weekly for four weeks by a physiotherapist experienced in remote exercise monitoring and rehabilitation. Participants were continuously visible on the physiotherapist's screen and were able to see and converse with each other and the physiotherapist throughout the class in real-time through the videoconferencing technology. The total duration of each session was 40 min and consisted of both aerobic and resistance exercises. Full details of the PTR intervention are provided in the published protocol [13]. Briefly, aerobic exercises involved multi-directional stepping with or without added arm movements for 25 min. Resistance exercises involved either using

Inclusion Criteria	Exclusion Criteria
• People with respiratory sequelae who attended a Post-COVID Respiratory Clinic at two metropolitan tertiary hospitals • Identified by their treating physician as suitable for rehabilitation • ≥18 years of age • Able to provide informed consent	• People with a severe COVID-19 infection admitted to an intensive care unit (ICU) and who develop post-ICU syndrome • Acute symptoms of any illness where exercise is not recommended • Medically unstable as diagnosed by their treating physician • Pregnant or post-partum women • No access to appropriate technology (i.e., internet and computer) • Difficulty understanding English and unable to access an interpreter • Severe cognitive impairment or other comorbidities which would make remote exercise unsafe as assessed by the treating physician

Figure 1. Inclusion and exclusion criteria for a post-COVID pulmonary telerehabilitation randomised controlled trial.

body weight such as squats and sit-to-stands, and/or hand weights for bicep curls, shoulder flexion/abduction, upright row either in standing or sitting, typically for 1-minute intervals for a total duration of approximately 15 min. The intensity of the exercises was titrated to each participant's level of fatigue or breathlessness, whichever was greatest, aiming for 2 ('slight') to 3 ('moderate') on a 0–10 category-ratio scale [15]. Groups were limited to five participants to ensure individualised programs of exercise intensity for each participant according to their reported symptoms. Prior to the start of each session, participants were asked to report their level of fatigue for the 12–24 h after the previous session, using a modified 0–10 category-ratio scale. If fatigue increased by ≥2 points from the start of the previous session to 12–24 h following the session, the participant undertook a modified program of reduced intensity to manage any post-exertional malaise (PEM).

Control group

The CG received usual medical care which consisted of medical treatment and follow-up with their treating respiratory physician (accessed through a Post-COVID Respiratory Clinic) as well as the WHO education pamphlet. Participants who completed the control period were invited to cross-over into the PTR group.

Participant education

All participants received the WHO Pamphlet *Support for rehabilitation: self-management after COVID-19-related illness* [16] (Supplementary Document S1) during screening at a Post-COVID Respiratory Clinic. Participants in the PTR Group additionally received education based on the WHO Pamphlet and were also referred to the Lung Foundation Australia (LFA) *Understanding long COVID* booklet [17] (Supplementary Document S2). Education topics discussed included: strategies to manage fatigue; pacing with daily activities; staying physically active; managing anxiety and depression; and returning to work. Additionally, participants in the PTR group received advice on safely performing exercise following the intervention period.

Outcome measures

Demographic and anthropometric data were collected at the initial assessment. Physical, cognitive, and patient reported outcomes were collected at the initial assessment and end of PTR or control periods. For those participants who crossed over to PTR, the end control period assessment was used as the baseline for the PTR intervention. All outcome measures were collected remotely.

Physical outcomes

The primary outcome was the number of repetitions achieved during a 1-minSTST [18] as a measure of functional capacity. The 1-minSTST has been validated and widely used across the age-span [19] and has a moderate correlation with the six-minute walk test distance [20]. The 1-minSTST does not have a learning effect when performed in a cohort of post-COVID-19 patients [21] and has demonstrated good inter-rater reliability in a remotely assessed post-COVID cohort who were previously hospitalised [22]. The five-repetition sit-to-stand test (5STST, measuring the time taken to achieve five repetitions) was used to measure lower limb functional performance. Sit-to-stand tests performed *via* telehealth are considered safe, valid, and reliable according to recent evidence [23–25]. All sit-to-stand tests were supervised by a physiotherapist *via* videoconferencing to ensure standardised assessments at all timepoints. The same standard chair of 46 cm-height without armrests [18], (or a chair closest in height if the standard chair was not available) was used for testing at all assessment timepoints.

Cognitive outcomes

The Montreal Cognitive Assessment suitable for remote assessment (MoCA-BLIND) [26] was administered by a physiotherapist to evaluate cognitive function. To reduce a possible practice effect, alternative versions were used for each re-assessment (Version 7.1, 8.2, and 8.3).

Patient reported outcomes

The following patient reported outcomes questionnaires were emailed to participants through REDCap at all assessment timepoints. Additionally, participants in both groups were asked to complete a weekly symptom diary during the four-week intervention or control period, also distributed through REDCap.

Participant HRQoL was measured using the 36-Item Short-Form Health Survey (SF-36) [27] comprising 36 questions across eight domains of health. Anxiety and depression were measured using the Hospital Anxiety and Depression Scale (HADS) [28] and psychological distress using the Kessler Psychological Distress Scale (K6+) [29]. Fatigue was measured using the Fatigue Severity Scale (FSS) [30]. Respiratory symptoms were measured using the COPD Assessment Test (CAT) [31], suggested as useful for assessing respiratory symptoms post-COVID [32]. The COVID-19 Yorkshire Rehabilitation Scale (YRS-19) [33], was used as a comprehensive COVID-specific questionnaire

Assessors were blind to group allocation and participants were asked not to divulge their group allocation at any assessment. Statistical analyses were performed with blinding to the group.

Sample size

The sample size was calculated using the minimal clinically important difference of 3.5 repetitions (standard deviation 4 repetitions) for the 1-minSTST [18]. Forty-two participants were necessary for an 80% chance of detecting, as significant at the 5% level, a between-group difference of 3.5 repetitions. To account for a 15% dropout, we aimed to recruit 48 participants. Ultimately, 50 participants were recruited, due to

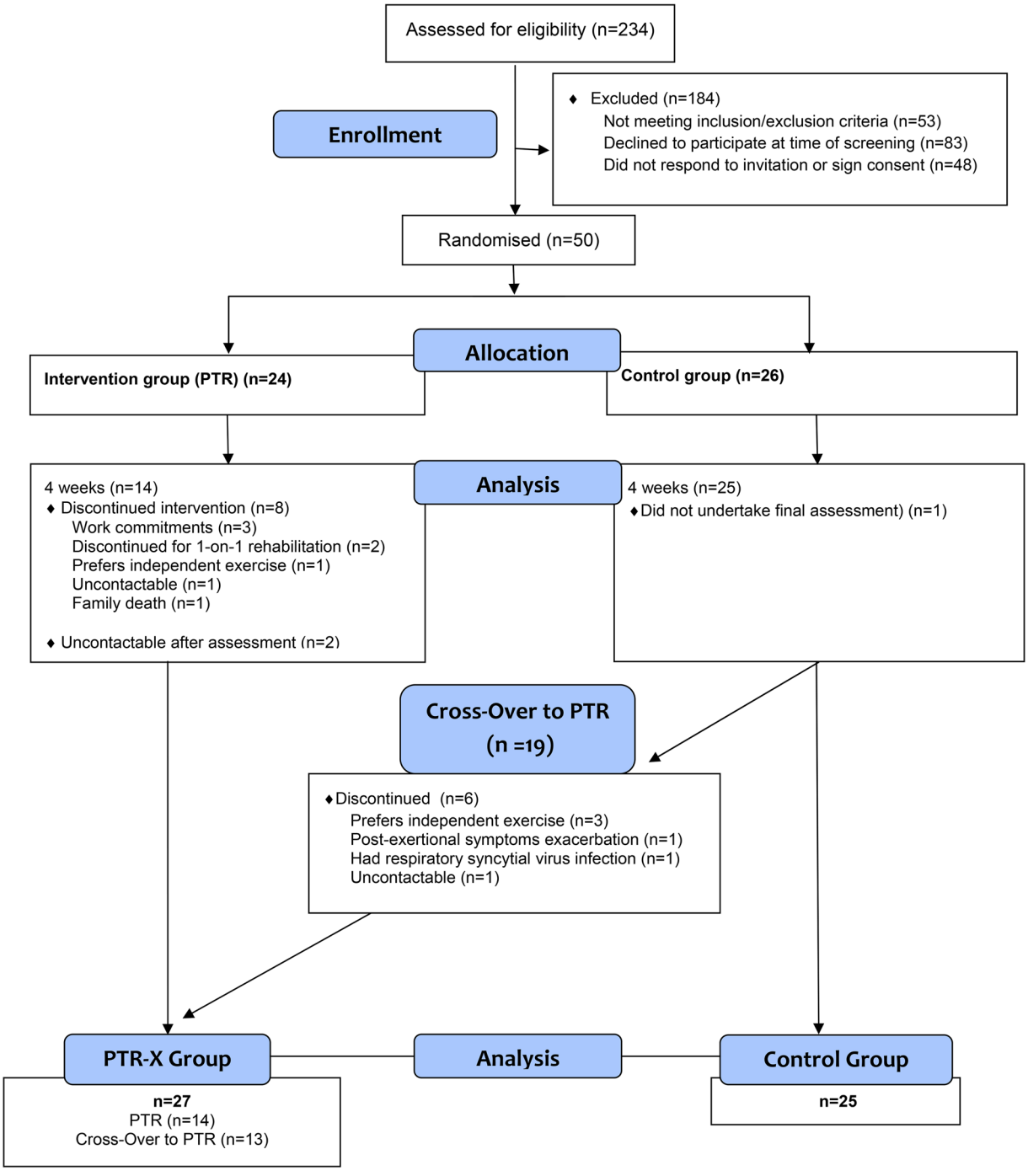

Figure 2. CONSORT flow diagram. PTR: Pulmonary telerehabilitation, PTR-X Group: Participants of both the intervention group and those who crossed over into the intervention from the control group.

the timing of participants agreeing to participate after the initial invitation.

Statistical analysis

Statistical analysis was performed using IBM SPSS version 28 (IBM Corporation, Armonk, NY, USA). Baseline characteristics were compared between groups. Data were assessed as parametric or non-parametric and baseline data were analysed with independent sample t-tests or Mann–Whitney *U* tests respectively for continuous variables. Chi squared tests were used for categorical variables. Normality was assessed using a Shapiro-Wilk Test. Analysis of between-group differences at the end of the initial intervention/control period used linear mixed effects model ANOVA for the primary and secondary outcome measures, with adjustments for any statistically significant differences in baseline covariates between the groups. The same analysis was used to compare the CG with the combined PTR-X group, (the PTR group plus the CG participants who chose to cross-over into the PTR group following the control period). Maximum likelihood estimation through the linear mixed effects model ANOVA was used for missing data. The level of significance for all outcomes was set at an alpha of <0.05.

Table 1. Baseline characteristics of participants in a post-COVID pulmonary telerehabilitation randomised controlled trial.

Variables	Overall ($n=50$)	Randomised participants		
		PTR Group ($n=24$)	Control Group ($n=26$)	p value
Age, years	54.2 ± 14.2	53.9 ± 11.2	54.5 ± 16.7	.156
Female	30 (60%)	14 (58%)	16 (62%)	1.000
BMI, kg/m^2	30.1 ± 7.8	30.53 ± 9.26	29.84 ± 6.51	.299
Hospitalised	10 (20%)	3 (13%)	7 (30%)	.358
Smoking history	24 (48%)	12 (50%)	12 (46%)	1.000
History of respiratory disease	17 (34%)	7 (29%)	10 (38%)	.693
Lives alone	16 (32%)	8 (33%)	8 (31%)	1.000
Has caring responsibilities for others	11 (22%)	8 (33%)	3 (12%)	.129
Outcomes				
1-MinSTST	21.2 ± 6.7	21.8 ± 6.1	20.7 ± 7.2	.589
5STST	13.3 ± 4.2	13.1 ± 3.7	13.4 ± 4.6	.263
CAT	20.4 ± 7.2	19.5 ± 6.9	21.1 ± 7.4	.776
HADS				
anxiety	9.0 ± 4.4	8.8 ± 4.3	9.1 ± 4.5	.242
depression	8.5 ± 5.0	8.2 ± 4.9	8.8 ± 5.2	.456
FSS	47.5 ± 12.9	50.9 ± 10.7	44.8 ± 14.0	.114
K6+	9.5 ± 5.5	9.7 ± 5.7	9.4 ± 5.5	.167
MoCA-Blind	18.6 ± 3.0	19.0 ± 2.7	18.3 ± 3.2	.817
C19-YRS				
breathless – rest	2.3 ± 2.2	2.1 ± 2.2	2.5 ± 2.3	.511
breathless – dressing	2.9 ± 2.4	3.3 ± 2.3	2.7 ± 2.4	.411
breathless – stairs	5.5 ± 2.7	5.6 ± 2.0	5.5 ± 3.1	.870
mobility	3.8 ± 2.6	3.5 ± 2.6	4.0 ± 2.7	.501
fatigue	6.7 ± 2.8	6.6 ± 2.7	6.9 ± 2.9	.702
pain/discomfort	4.2 ± 2.5	4.6 ± 2.5	3.8 ± 2.4	.307
anxiety	4.5 ± 3.0	4.3 ± 2.9	4.7 ± 3.1	.640
depression	4.0 ± 3.3	3.4 ± 2.9	4.6 ± 3.5	.242
symptoms severity subscale	25.3 ± 13.5	23.0 ± 13.9	27.2 ± 13.1	.297
functional disability subscale	15.4 ± 9.3	13.9 ± 8.5	16.6 ± 9.9	.321
Global perceived health	4.8 ± 2.2	4.9 ± 1.7	4.7 ± 2.6	.751
SF-36				
physical Functioning	37.4 ± 22.7	37.3 ± 20.3	37.4 ± 24.8	.991
role, physical health	17.8 ± 31.8	13.8 ± 26.3	21.0 ± 35.9	.454
role, emotional problems	32.5 ± 43.9	33.3 ± 47.1	31.9 ± 42.0	.917
energy/fatigue	24.9 ± 19.0	26.0 ± 17.6	24.0 ± 20.4	.730
emotional well-being	52.4 ± 21.2	52.7 ± 19.0	52.1 ± 23.2	.924
social functioning	45.7 ± 26.7	45.0 ± 21.6	46.4 ± 30.7	.869
pain	54.4 ± 26.5	51.0 ± 28.7	57.2 ± 24.8	.447
general health	37.9 ± 20.1	39.3 ± 15.9	36.8 ± 23.2	.678

Data are presented as mean ± SD or frequency (%). 1-MinSTST: 1-minute sit-to-stand test; 5STST: 5 repetition sit-to-stand test; BMI: body mass index; CAT: COPD Assessment Test; C19-YRS: COVID-19 Yorkshire Rehabilitation Scale; FSS: Fatigue Severity Scale; HADS: Hospital Anxiety and Depression Scale; K6+: Kessler Psychological Distress Scale; MoCA-Blind: Telephone version of the Montreal Cognitive Assessment; PTR: pulmonary telerehabilitation; SF-36: 36-Item Short-Form Health Survey. Statistical significance $p < .05$.

Results

Participant flow through the study is shown in Figure 2. Fifty participants were randomised to either the PTR group ($n=24$) or the CG ($n=26$). Eleven participants dropped-out of the study, with 10 of these being from the PTR group. There were no significant differences in baseline characteristics between those who completed the intervention arm of the study and those who withdrew from the intervention arm (Supplementary Table S3). Of the 26 participants randomised to the CG, 19 participants crossed over into the combined PTR-X group after the completion of the control period and 13 completed the intervention. Participants were recruited between March 2022 and June 2023 and had an average time since COVID infection to initial assessment in the PTR group of mean (±SD) 6 ± 3 months and CG of 8 ± 7 months, with no difference between groups ($p=.362$).

Baseline characteristics for the participants are reported in Table 1. There were no significant between-group differences in any measured variables at baseline. The participants were typically: female (60%); middle-aged (54 ± 14 years); overweight (30 ± 8 kg/m^2); non-hospitalised (80%); and with no concurrent respiratory disease (66%). The baseline functional capacity of the study population, as measured by the 1-minSTS, was below the reported normal range based on a predictive equation developed in a Portuguese population (normal range 31 ± 7 repetitions [34]; our study cohort 21 ± 7 repetitions). Both the PTR Group and CG had reduced baseline lower limb functional performance, as measured by the 5STST (normal range 8 ± 3 s [35]; our study cohort 13 ± 4 s). Furthermore, baseline HADS scores were above the threshold of normal, suggesting a tendency towards anxiety and depression in the study population (normal range for both anxiety and depression <7 [28]; our study cohort anxiety score 9 ± 4, and depression score 9 ± 5). Moderate psychological distress was indicated on the K6+ (moderate distress range 7-13 [36]; our study cohort 10 ± 6). Fatigue was a prominent feature on the FSS (normal range ≤36 [30]; our study cohort 53 ± 9). Cognition was in the normal range using the MoCA-Blind instrument (normal range ≥18 [26]; study cohort 19 ± 3). A high burden of respiratory symptoms was indicated on the CAT (normal range <5; study cohort 20 ± 7).

Table 2. Outcomes from a linear mixed effects model of a pulmonary telerehabilitation randomised controlled trial for the PTR group ($n = 14$) and control group ($n = 25$).

	Baseline		Reassessment		Within-group			
Outcomes	PTR Group	Control Group	PTR Group	Control Group	PTR Group	Control Group	Between-group	*p* value
1-MinSTST	22.7 ± 6.3	20.4 ± 7.4	24.8 ± 8.1	21.8 ± 7.2	2.1 (−0.7 to 5.1)	1.3 (−1.0 to 3.7)	0.8 (−3.0 to 4.6)	.563
5STST	13.5 ± 3.3	14.1 ± 4.5	14.0 ± 5.0	12.8 ± 4.7	0.5 (−3.0 to 4.0)	−1.3 (−3.2 to 0.6)	1.8 (−5.3 to 1.6)	.528
CAT	16.4 ± 5.6	21.0 ± 7.1	16.1 ± 8.4	19.7 ± 7.1	−0.3 (−6.5 to 6.0)	−1.4 (−4.6 to 1.9)	1.1 (−4.9 to 7.1)	.830
HADS								
anxiety	7.2 ± 4.1	9.1 ± 4.8	6.7 ± 3.1	8.5 ± 4.8	−0.5 (−2.5 to 1.5)	−0.3 (−1.5 to 0.8)	0.2 (−1.7 to 2.0)	.826
depression	6.8 ± 4.7	8.8 ± 5.2	6.9 ± 3.8	8.5 ± 4.8	0.1 (−1.9 to 2.1)	−0.5 (−1.4 to 0.5)	0.5 (−1.4 to 2.3)	.781
FSS	49.6 ± 12.3	48.0 ± 11.4	50.3 ± 11.3	48.2 ± 13.1	−0.6 (−8.1 to 9.4)	0.2 (−3.3 to 3.7)	0.4 (−7.0 to 7.9)	.829
K6+	7.7 ± 4.9	9.3 ± 5.1	7.0 ± 4.3	10.3 ± 6.3	−0.7 (−2.8 to 1.4)	1.1 (−0.6 to 2.7)	−1.8 (−4.4 to 0.9)	.120
MoCA-Blind	19.5 ± 2.7	17.9 ± 3.3	20.1 ± 1.2	18.0 ± 2.4	0.6 (−1.1 to 2.3)	0.6 (−0.8 to 0.9)	0.5 (−1.1 to 2.2)	.209
C19-YRS								
breathless – rest	2.6 ± 2.7	2.3 ± 2.3	1.0 ± 1.0	2.7 ± 2.7	−1.5 (−4.0 to 0.8)	0.4 (−0.5 to 1.4)	0.1 (−1.9 to 2.2)	.951
breathless – dressing	4.9 ± 2.0	2.8 ± 2.5	3.4 ± 3.1	2.8 ± 2.7	−1.4 (−4.2 to 1.3)	−0.1 (−1.1 to 0.9)	0.7 (−0.9 to 2.2)	.265
breathless – stairs	5.2 ± 2.1	5.6 ± 3.1	5.0 ± 2.1	4.6 ± 3.2	−0.2 (−2.5 to 2.1)	−1.0 (−2.0 to 0.0)	0.8 (−1.3 to 2.9)	.486
mobility	3.0 ± 2.3	3.8 ± 2.5	3.4 ± 2.5	2.9 ± 2.8	0.4 (−0.9 to 1.8)	−1.0 (−1.9 to 0.0)	1.4 (−0.2 to 3.0)	.095
fatigue	6.1 ± 2.6	7.1 ± 2.8	6.1 ± 2.7	6.3 ± 3.6	0.0 (−1.6 to 1.6)	−0.8 (−1.9 to 0.4)	0.8 (−1.1 to 2.6)	.473
pain/discomfort	3.8 ± 2.4	3.9 ± 2.3	3.4 ± 2.4	3.5 ± 2.7	−0.5 (−1.2 to 0.2)	−0.5 (−1.4 to 0.5)	−0.0 (−1.4 to 1.4)	.765
anxiety	3.6 ± 2.4	4.8 ± 3.1	3.6 ± 2.4	4.3 ± 2.9	0.0 (−1.4 to 1.4)	−0.5 (−1.3 to 0.3)	0.5 (−0.9 to 1.9)	.613
depression	2.5 ± 2.4	4.8 ± 3.4	2.1 ± 2.0	4.5 ± 3.7	−0.5 (−1.2 to 0.3)	−0.4 (−1.3 to 0.6)	−0.1 (−1.4 to 1.2)	.117
symptoms severity subscale	21.0 ± 9.2	27.9 ± 12.7	21.9 ± 10.7	24.5 ± 14.4	0.9 (−4.5 to 6.3)	−3.4 (−7.2 to 0.5)	4.3 (−2.0 to 10.5)	.198
functional disability subscale	14.3 ± 8.0	16.1 ± 8.7	12.7 ± 8.3	12.8 ± 8.1	−1.5 (−4.6 to 1.5)	−3.4 (−6.6 to 0.1)	−1.8 (−2.9 to 6.5)	.376
Global perceived health	5.2 ± 2.0	4.6 ± 2.3	5.5 ± 2.1	4.8 ± 2.6	0.3 (−0.3 to 0.9)	0.2 (−0.9 to 1.3)	0.1 (−1.4 to 1.6)	.789
SF-36								
physical Functioning	37.6 ± 16.2	36.8 ± 22.2	40.3 ± 19.2	38.5 ± 22.7	2.7 (−2.9 to 8.3)	1.7 (−5.2 to 8.7)	0.9 (−7.6 to 9.5)	.851
role, physical health	20.5 ± 33.2	23.8 ± 38.5	13.6 ± 30.3	31.3 ± 41.3	−6.8 (−20.0 to 6.4)	7.5 (−11.1 to 26.1)	−14.3 (−40.6 to 12.0)	.274
role, emotional problems	50.0 ± 52.7	36.7 ± 43.1	30.0 ± 42.9	38.3 ± 48.7	−20.0(−52.2 to 12.2)	1.7 (−6.3 to 9.6)	−21.6 (−54.4 to 11.0)	.065
energy/fatigue	27.3 ± 21.8	23.1 ± 20.7	25.0 ± 14.5	31.0 ± 21.9	−2.3 (−9.2 to 4.7)	7.9 (1.2 to 14.6)	−10.2 (−20.2 to −0.1)	.047
emotional well-being	54.5 ± 21.3	49.9 ± 13.9	57.8 ± 14.7	53.8 ± 19.0	3.3 (−3.9 to 10.5)	0.1 (−5.9 to 6.1)	3.2 (−6.2 to 12.5)	.494
social functioning	46.3 ± 22.9	48.0 ± 30.4	43.8 ± 19.8	54.6 ± 24.0	−2.5 (−15.0 to 10.0)	6.6 (−2.7 to 15.9)	−9.1 (−24.1 to 5.9)	.224
pain	50.9 ± 29.3	56.3 ± 24.1	56.1 ± 27.3	58.0 ± 24.5	5.3 (−5.7 to 16.1)	1.8 (−10.3 to 13.8)	3.5 (−14.1 to 21.1)	.689
general health	45.0 ± 16.0	36.8 ± 22.0	39.1 ± 13.0	38.0 ± 18.3	−5.9 (−13.2 to 1.4)	1.3 (−5.5 to 8.0)	7.2 (−17.3 to 3.0)	.160

Data are presented as mean ± SD or mean difference (95% CI). 1-MinSTST: 1-minute sit-to-stand test; 5STST: 5 repetition sit-to-stand test; BMI: body mass index; CAT: COPD Assessment Test; C19-YRS: COVID-19 Yorkshire Rehabilitation Scale; FSS: Fatigue Severity Scale; HADS: Hospital Anxiety and Depression Scale; K6+: Kessler Psychological Distress Scale; MoCA-Blind: Telephone version of the Montreal Cognitive Assessment; PTR: pulmonary telerehabilitation; SF-36: 36-Item Short-Form Health Survey. Statistical significance $p < .05$.

The within- and between-groups differences for the PTR group vs CG are presented in Table 2. While a larger within-group change for the 1-minSTST (primary outcome) was seen in the PTR group (2.1 repetitions, 95% CI: −0.7 to 5.1) than the CG (1.3 repetitions, 95% CI: −1.0 to 3.7), there was no between-group difference (0.8 repetitions, 95% CI: −3.0 to 4.6, $p = .563$). The frequencies of participants in the PTR group and CG meeting the MCID for outcomes, the 1-minSTST [18,37], 5STST [38], FSS [39], and CAT [40], are shown in Supplementary Table S4. The only significant within- or between-group difference was a small improvement in the SF-36 'energy/fatigue' domain in favour of the CG. Data from the weekly symptoms diary of participants was not analysed due to a poor response rate.

The PTR-X group was compared to the initial CG using a linear mixed effects model (Table 3). There were no statistically significant between-group differences in any of the outcomes. In the PTR-X group there was a statistically significant within-group change for the 1-minSTST (2.4 repetitions 95% CI: 0.6–4.2), but not for any other outcomes. Twelve of the 25 PTR-X participants (48%) achieved the minimal clinically important difference (MCID) of three repetitions for the 1-min STST [18,37]. Seven out of the twelve (58%) had a history of chronic respiratory disease prior to COVID-19 infection. The frequencies of participants meeting the MCID for outcomes of the PTR-X Group are also shown in Supplementary Table S4.

Discussion

In this randomised trial of PTR versus usual care in people with persisting respiratory symptoms after COVID-19, there were no significant differences in the primary outcome of functional capacity or secondary outcomes of HRQoL and symptoms scores.

To our knowledge, this is the first RCT to evaluate telerehabilitation specifically for people with persisting respiratory sequalae after COVID-19, irrespective of prior hospitalisation for COVID-19. Similar to our study, two previous randomised

Table 3. Outcomes from a linear mixed effects model for the PTR-X group ($n = 27$) and control group ($n = 25$).

	Baseline		Reassessment		Within-group			
Outcomes	PTR-X Group (n = 27)	Control Group (n = 25)	PTR-X Group	Control Group	PTR-X Group	Control Group	Between-group	p value
1-MinSTST	21.0 ± 6.0	20.4 ± 7.4	23.4 ± 6.7	21.8 ± 7.2	**2.4 (0.6 to 4.2)**	1.3 (−3.7 to 1.0)	1.1 (−1.7 to 3.9)	.391
5STST	13.5 ± 4.2	14.1 ± 4.5	12.8 ± 4.0	12.8 ± 4.7	−0.7 (−2.5 to 1.1)	−1.3 (−3.2 to 0.6)	0.6 (−1.9 to 3.1)	.920
CAT	17.8 ± 6.7	21.0 ± 7.1	16.9 ± 8.0	19.7 ± 7.1	−0.9 (−3.8 to 2.0)	−1.4 (−4.6 to 1.9)	0.5 (−3.8 to 4.7)	.971
HADS								
anxiety	8.0 ± 4.1	9.1 ± 4.8	7.9 ± 3.8	8.5 ± 4.5	0.0 (−1.2 to 1.2)	−0.7 (−1.6 to 0.3)	0.6 (−0.9 to 2.1)	.551
depression	7.8 ± 4.6	8.8 ± 5.2	8.1 ± 5.0	8.4 ± 4.6	0.3 (−0.8 to 1.4)	−0.5 (−1.4 to 0.5)	0.7 (−0.7 to 2.2)	.383
FSS	49.5 ± 12.8	48.0 ± 11.4	48.8 ± 12.2	48.2 ± 13.1	−0.7 (−5.3 to 3.8)	0.2 (−3.3 to 3.7)	−0.9 (−6.6 to 4.7)	.570
K6+	9.5 ± 5.3	9.3 ± 5.1	9.1 ± 5.0	10.3 ± 6.3	−0.4 (−1.8 to 1.0)	1.1 (−0.6 to 2.7)	−1.5 (−3.5 to 0.6)	.115
MoCA-Blind	19.1 ± 2.6	17.9 ± 3.3	18.9 ± 2.9	18.0 ± 2.6	−0.2 (−1.2 to 0.8)	0.1 (−0.8 to 0.9)	−0.2 (−1.6 to 1.1)	.777
C19-YRS								
breathless – rest	2.3 ± 2.7	2.3 ± 2.3	2.4 ± 2.9	2.6 ± 2.7	0.01 (−1.1 to 1.2)	0.3 (−0.6 to 1.2)	−0.3 (−1.7 to 1.2)	.647
breathless – dressing	2.7 ± 2.8	2.8 ± 2.5	2.9 ± 2.7	2.7 ± 2.6	0.2 (−0.4 to 0.7)	−0.1 (−1.0 to 0.8)	0.3 (−0.8 to 1.3)	.727
breathless – stairs	5.3 ± 2.9	5.5 ± 3.0	5.1 ± 2.4	4.6 ± 3.1	−0.2 (−1.3 to 0.8)	−0.9 (−2.0 to 0.2)	0.7 (−0.8 to 2.1)	.520
mobility	3.0 ± 2.3	3.6 ± 2.6	3.2 ± 2.3	2.7 ± 2.8	0.2 (−0.7 to 1.0)	−0.9 (−1.8 to 0.0)	1.1 (−0.1 to 2.3)	.109
fatigue	6.7 ± 2.9	7.2 ± 2.8	6.5 ± 2.7	6.4 ± 3.5	−0.1 (−1.0 to 0.8)	−0.8 (−1.8 to 0.3)	0.6 (−0.7 to 2.0)	.333
pain/discomfort	3.8 ± 2.8	3.9 ± 2.2	3.5 ± 2.7	3.4 ± 2.6	−0.3 (−1.1 to 0.6)	−0.5 (−1.4 to 0.5)	0.2 (−1.0 to 1.4)	.885
anxiety	4.1 ± 2.6	4.6 ± 3.1	4.3 ± 2.6	4.1 ± 2.9	0.2 (−0.6 to 1.0)	−0.5 (−1.3 to 0.2)	0.7 (−0.4 to 1.8)	.153
depression	3.7 ± 3.3	4.9 ± 3.4	3.3 ± 3.1	4.6 ± 3.7	−0.3 (−1.0 ± 0.3)	−0.3 (−1.2 to 0.6)	0.1 (−1.1 to 1.0)	.860
symptoms severity subscale	23.2 ± 12.5	27.9 ± 12.4	23.2 ± 13.3	24.4 ± 14.0	0.1 (−4.3 to 4.5)	−3.5 (−7.2 to 0.1)	3.6 (−1.9 to 9.2)	.217
functional disability subscale	4.8 ± 2.6	15.8 ± 8.6	5.2 ± 2.3	12.6 ± 8.0	−0.8 (−2.5 to 0.9)	**−3.2 (−6.3 to −0.1)**	2.4 (−1.0 to 5.8)	.152
Global perceived health	2.3 ± 2.3	4.5 ± 2.2	2.6 ± 2.7	4.8 ± 2.5	0.4 (−0.3 to 1.0)	0.3 (−0.8 to 1.3)	0.1 (−1.1 to 1.2)	.986
SF-36								
physical Functioning	36.9 ± 18.6	36.8 ± 22.2	36.9 ± 18.6	38.5 ± 22.7	3.5 (−0.4 to 7.3)	1.8 (−5.2 to 8.7)	1.7 (−5.7 to 9.2)	.502
role, physical health	22.8 ± 35.3	22.8 ± 35.3	18.5 ± 33.9	18.5 ± 33.9	−4.3 (−12.8 to 4.1)	7.5 (−11.1 to 26.1)	−11.8 (−31.9 to 8.2)	.205
role, emotional problems	39.1 ± 47.8	36.7 ± 41.2	27.5 ± 39.8	38.3 ± 48.7	−11.6 (−25.8 to 2.6)	1.7 (−6.2 to 9.6)	13.3 (−3.2 to 29.1)	.108
energy/fatigue	44.8 ± 7.0	45.0 ± 7.6	47.4 ± 7.1	44.0 ± 7.2	2.6 (−0.8 to 6.1)	−1.1 (−3.9 to 1.7)	−3.7 (−8.1 to 0.7)	.183
emotional well-being	51.1 ± 12.5	49.9 ± 13.9	50.6 ± 11.4	51.8 ± 12.1	−0.5 (−4.1 to 3.1)	1.9 (−2.1 to 5.8)	2.2 (−2.7 to 7.6)	.303
social functioning	48.4 ± 20.7	50.6 ± 31.8	47.3 ± 21.6	55.6 ± 23.8	−1.1 (−8.5 to 6.4)	5.0 (−4.4 to 14.4)	6.1 (−5.4 to 17.6)	.306
pain	51.9 ± 27.7	56.3 ± 24.1	61.3 ± 24.9	58.0 ± 24.5	9.5 (−1.0 to 1.0)	1.8 (−10.3 to 13.8)	−7.7 (−23.1 to 7.7)	.151
general health	41.3 ± 17.2	36.8 ± 22.0	37.4 ± 15.7	38.0 ± 18.3	−3.9 (−7.7 to 0.1)	1.3 (−5.5 to 8.0)	5.2 (−2.0 to 12.4)	.233

Data are presented as mean ± SD or mean difference (95% CI). 1-MinSTST: 1-minute sit-to-stand test; 5STST: 5 repetition sit-to-stand test; BMI: body mass index; CAT: COPD Assessment Test; C19-YRS: COVID-19 Yorkshire Rehabilitation Scale; FSS: Fatigue Severity Scale; HADS: Hospital Anxiety and Depression Scale; K6+: Kessler Psychological Distress Scale; MoCA-Blind: Telephone version of the Montreal Cognitive Assessment; PTR-X: pulmonary telerehabilitation group plus the control group participants who chose to cross-over into the PTR group following the control period; SF-36: 36-Item Short-Form Health Survey. Statistical significance $p < .05$.

controlled trials of PTR of six- and twelve-weeks duration in people who were hospitalised with COVID-19 also showed minimal differences in outcomes [41,42]. The study with the six-week PTR intervention showed no between-group differences in physical outcomes including the timed up-and-go test (TUG) and the short physical performance battery [42]. In the 12-week PTR trial, there were also no between-group differences in any physical outcomes, including the 5STST, TUG, and 6-minute walk test [41].

While RCTs of PTR have shown minimal improvements in physical outcomes for people with PASC, previous cohort studies of centre-based or in-patient PR have demonstrated improvements in functional capacity and HRQoL [43–46]. A potential reason for the improvement in some studies is that participants were hospitalised with severe COVID-19 [43,44,46–48] and therefore were likely deconditioned. Our study specifically excluded people who had severe COVID-19 that required prolonged intensive care unit (ICU) admission because randomisation to a control group of no rehabilitation would have been unethical as such patients often have ICU-acquired weakness and deconditioning, requiring rehabilitation.

Rehabilitation dosage may also impact the likelihood of improving physical outcomes. In the 12-week RCT of PTR [41], the authors postulated that the lack of statistically significant change may have been the inability to achieve sufficient aerobic intensity or resistance training volume to increase functional capacity. This was a plausible contributing factor to the findings in the present study. Post-exertional fatigue has been widely reported as an adverse effect of exercise for some people with ongoing symptoms after COVID-19 infection [49]. While PR interventions typically titrate intensity based on exertional dyspnoea, exercise intensity in the current trial was titrated based on both exertional dyspnoea and the participant's report of fatigue (before, during, and 12–24 h post exercise) in order to prioritise safety during rehabilitation. In some participants who consistently

reported post-exertional fatigue, exercise intensity during PTR was steadily reduced, which may have impacted the mean improvement in functional capacity for the PTR group as a whole. Additionally, the optimal length of a PTR program for people with persistent respiratory PASC is unknown. We chose to evaluate a 4-week telerehabilitation program as PASC affects people across the age-span and predominantly those of middle-age [11], therefore participants were likely to still be working in which case a shorter duration program may have been more acceptable. However, a 4-week intervention may have been inadequate to improve physical function.

As previously mentioned, an 8-week PTR study demonstrated a within-group improvement in the physical test of 5STS [9]. Our study also showed a significant within-group difference in the physical test of 1-minSTST in the PTR-X group. Post-hoc evaluation of the characteristics of the 12 participants in the PTR-X group who met the MCID of three repetitions for 1-minSTS suggested the greatest benefit for the 4-week PTR intervention was in those with pre-existing respiratory disease. This is perhaps not surprising given the established evidence-base for PTR in patients with chronic respiratory disease [5]. It is likely that viral exacerbation of established respiratory disease contributed to the persisting respiratory symptoms in this subgroup.

A strength of the study was that natural recovery from the effects of COVID-19 was accounted for with the randomised study design. Most people reporting PASC have symptom resolution over time, with one recent study suggesting that the majority of people reporting PASC at eight months post-infection had resolution of symptoms and biomarkers for immune dysregulation, as well as improved HRQoL, by 24 months post-infection [50]. The only indication of natural recovery in this study cohort was a small significant improvement in the SF-36 'energy/fatigue' domain in the CG. Natural recovery was not evident in any other outcomes during the 4-week control period, which may have been due to the relatively short duration.

There were several limitations in this study. Firstly, the majority of the 22% who dropped out of the study were from the PTR group, which may have reduced the power to detect a difference between groups. Of the 11 participants who dropped out of the study, three (27%) were due to work commitments. A previous study also reported a high drop-out rate in the telerehabilitation group (36%) due to participants' work commitments and a lack of time [41]. Secondly, the pre-determined inclusion/exclusion criteria did not discriminate on an individual's severity of acute SARS-CoV-2 infection. While this study cohort was homogenous in that all participants reported persistent respiratory PASC and were recruited from a Post-COVID Respiratory Clinic, they were heterogenous in their hospitalisation status with only 20% being hospitalised at the time of their COVID-19 infection. Notably, the two RCTs evaluating telerehabilitation for participants with PASC excluded non-hospitalised participants [41,42]. Given this, our study findings may be less generalisable to people with respiratory PASC who were hospitalised during their COVID-19 infection. Finally, our second linear mixed effects model ANOVA of the combined PTR-X group compared to the CG-treated participant data as independent samples. Therefore, the analysis may not have accounted for the effect of individuals who were both in the PTR-X group and the CG. Despite this, there were no statistically significant between-group differences in any outcomes.

Based on the outcomes of our study, while people with persistent respiratory symptoms following COVID-19 infection often concurrently report fatigue (including PEM) and physical limitations, clinicians should consider whether an individual exhibits physical deconditioning prior to prescribing physical rehabilitation. Additionally, future trials should consider whether the 1-min STST, or other physical outcomes measures adequately capture the physical limitations that patients in this population report. Future trials should further investigate the characteristics of responders vs non-responders to rehabilitation programs in order to identify those who are likely to benefit from rehabilitation, the optimal length of programs, and compare centre-based vs telerehabilitation programs in this cohort.

In conclusion, a 4-week (8 session) pulmonary telerehabilitation program for people with persistent respiratory sequelae following COVID-19 infection, the majority of whom had not been hospitalised, did not improve functional capacity, symptoms, cognition, anxiety, depression, HRQoL, or fatigue compared to usual medical care. These findings suggest that longer telerehabilitation programs or alternative interventions should be evaluated to aid symptom management for this population.

Ethical approval

This human study was approved by the Sydney Local Health District (SLHD) Human Research and Ethics Committee (Royal Prince Alfred Zone). All adult participants provided written informed consent to participate in this study. The study's clinical trial registration number is ACTRN12622000355774 registered with https://www.anzctr.org.au/

Disclosure statement

There are no conflicts of interest to declare that relate to this manuscript. Three authors (TJ, LT, JR) report speaker fees, grants or contracts, honoraria, support for attending meetings, and/or participation on a data safety and monitoring board from some or all of the following companies: Boehringer Ingleheim, Bristol Myers Squibb, Roche, Pharmaxis, 4D, Pliant, Bridge Biotherapeutics, Avalyn Therapeutics, DevoPro, BioMedicine, Cincera, and Erbe Elektromedizin GmbH.

Trial registration

The study's clinical trial registration number is ACTRN12622000355774 registered with https://www.anzctr.org.au/

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Data availability statement

The data files may be available from the authors upon reasonable request, subject to permission being granted by the Sydney Local Health District (SLHD) Human Research and Ethics Committee.

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