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ORIGINAL RESEARCH

Feasibility, Usability, and Pilot Efficacy Study of a Software-Enabled, Virtual Pulmonary Rehabilitation with Remote Therapeutic Monitoring

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Objective: Fewer than 3% of adults with Chronic Obstructive Pulmonary Disease (COPD) attend in-person, center-based pulmonary rehabilitation (PR) despite demonstrated health benefits and reduction in mortality. This study evaluated the feasibility and usability of a novel home-based, virtual PR (V-PR) intervention compared to center-based PR (C-PR). The virtual PR intervention was supported by remote therapeutic monitoring (V-PR+RTM; Blue Marble Platform, Blue Marble Health, Altadena, CA). Additionally, we collected data on the 6-Minute Walk Test to explore the efficacy of the V-PR compared to C-PR.

Patients and Methods: Adults with stable COPD referred for PR were recruited. The participants self-selected C-PR or V-PR and were provided a 6-8-week personalized exercise and COPD self-management educational program. In addition, weekly phone contacts with the V-PR group were made. Feasibility was measured using qualitative analysis of adherence, reasons for withdrawal, and self-reported barriers to using the software at home. Usability was measured with the System Usability Scale (SUS). Efficacy was evaluated with the 6 minute Walk Test (6MWT) and various functional performance and patient-centered health-related quality of life (HRQoL) questionnaires.

Results: Forty-eight participants were enrolled, and 40 (83.3%) completed the intervention, n=17 in the C-PR group and n=23 in the V-PR group. Four participants from each group withdrew due to reasons related to health issues (appendicitis, thrush, COVID, back pain) or the health status of their spouse, no-shows, and time constraints. Adherence to the exercise dose (3x/week) and educational offerings were >80% in both groups. Participants in the V-PR group scored the software as having high usability. In both groups, 6MWT distance improved significantly, as did scores on the CAT and SGRQ. No adverse events were reported in either group.

Conclusion: A software-enabled virtual PR program with remote therapeutic monitoring is feasible, usable, and effective. It could offer an alternative model that increases PR uptake for those unable or unwilling to attend in-person, center-based PR.

Plain Language Summary: Pulmonary rehabilitation (PR) is a treatment program that improves breathlessness and quality of life for adults with lung diseases such as chronic obstructive pulmonary disease (COPD). Typically, PR is conducted in a clinic, which is often inaccessible for many adults with COPD; only 3% of Medicare-eligible patients with COPD participate in PR. Recently, new telehealth models of PR that do not require transport to a clinic have been shown to be as beneficial as clinic-based PR. This study measured the feasibility, usability, and effectiveness of a virtual home-based program supported by a remote therapeutic monitoring software platform and a weekly phone call from the clinician to the patient compared to traditional clinic-based PR. We found that both PR models were effective and that the virtual, home-based model supported by a remote monitoring software platform was feasible and usable.

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Introduction

Pulmonary rehabilitation (PR) is a multi-disciplinary, evidence-based, guideline-recommended intervention involving supervised exercise training and self-management education targeting long-term behavior change designed to safely increase physical activity for adults with chronic respiratory disease (CRD), including chronic obstructive pulmonary disease (COPD). Participation in PR improves dyspnea, health-related quality of life (HRQoL), and exercise capacity.[1] In patients hospitalized for COPD, PR is associated with a reduction in hospitalization rate[2] and mortality.[3–5] Despite consistent evidence supporting the benefits of PR in COPD, only 3% of Medicare-eligible patients with COPD participate in PR.[6,7]

Traditionally, in the United States, PR has been delivered in person at center-based outpatient clinics and consists of 2–3 weekly visits for 2 to 3 months. Barriers to participation include transportation,[8] distance to the nearest facility, availability of PR programs,[9] and cost/co-pay.[10] Considering these barriers, professional societies, including the American Thoracic Society (ATS) and the European Respiratory Society (ERS), have recommended developing novel telehealth PR programs to improve access to PR services,[11,12] Telehealth PR utilizes telecommunication technology to deliver PR services directly to patients' homes. A 2021 Cochrane review compared telehealth PR to hospital-based PR and standard of care.[13] This review indicated that telehealth PR showed comparable gains in exercise capacity and health-related quality of life (HRQoL) to those achieved in center-based PR, and compared to usual care, telehealth PR significantly improved exercise capacity and HRQoL. Furthermore, the review identified no safety issues with telehealth PR. Informed by the evidence, the 2023 ATS Clinical Practice Guidelines for PR recommend that adults with stable CRD be offered the choice of center-based PR or telehealth PR.[14] Despite evidence supporting telehealth PR, program design and delivery methods that address individual patient needs are not well understood.

We aimed to evaluate the feasibility, usability, and pilot efficacy of a new PR program design and delivery method that incorporates an asynchronous, home-based virtual PR (V-PR) program supported by a digital assessment, exercise, self-management, and remote therapeutic monitoring platform (V-PR+RTM Platform), (Blue Marble Health, Altadena CA, USA). We hypothesized that the V-PR+RTM model would be feasible, usable, and effective.

Methods

Study Design

A non-randomized, preference-based feasibility, usability, and pilot efficacy study was conducted at five locations: two federally qualified health centers in West Virginia, US, and three center-based clinics in North Carolina, US. The study complied with the Declaration of Helsinki, was approved by Alpha IRB, San Clemente, CA, and registered with ClinincTrials.gov (NCT03801330).

Screening

All patients referred to PR at the study sites were screened for potential enrollment. Eligible patients met the following criteria: 1) a clinical diagnosis of COPD with a post-bronchodilator FEV_1/FVC ratio of less than 70% and an $FEV_{1\%}$ predicted of 20%-80% recorded within the last 12 months, 2) a previous pre-PR 6 minute Walk Test (6MWT) demonstrating a minimal distance of 100 meters with adequate oxygenation on less than or equal to 4 liters per minute (LPM) with ambulation, 3) Wi-Fi access at home, 4) ability to speak, read, and understand English at or above the 6^{th}-grade level (as indicated by having a driver's license or completion of some high school), 5) ability to learn how to use the V-PR tablet, and 6) physician approval. Participants were excluded if they met any of the following: 1) attended PR within the last six months, 2) a history of a cardiac event within the last six months, 3) chronic oxygen use exceeding 4 LPM, 4) co-morbidities including but not limited to coronary artery disease with unstable angina, higher fall risk per physician determination, neurological conditions which precluded the following of a typical COPD exercise

program, active cancer with an anticipated survival of less than six months or requiring treatment that precludes participation in PR.

Interventions

After obtaining informed consent, both PR intervention options were described to the participant, who then self-selected either in-person center-based PR (C-PR) or virtual home-based PR (V-PR). Some participants enrolled during the COVID-19 pandemic indicated they selected the V-PR option out of fear of being in a group setting. Others with more risk factors selected the C-PR group because they felt more comfortable being monitored in person during exercise.

The C-PR program consisted of personalized aerobic, strengthening, and balance exercises under the direct supervision of the study clinician (respiratory therapist or physical therapist) (See Supplementary Material – Table S1). Clinicians progressed the exercise program based on the individual participant's abilities. The exercise was designed to occur at least 3x/week for 6–8 weeks; however, due to the global COVID-19 pandemic and subsequent partial clinic closures, some C-PR study participants completed two days of PR in the clinic and were encouraged to exercise one day per week at home and to record their exercise using the study exercise log. The educational portion of the program consisted of 30–60-minute classes reviewing topics related to COPD self-management and, depending upon the subject discussed, was led by clinical staff (respiratory therapist, physical therapist, nutritionist, Licensed Clinical Mental Health Counselor (LCMHC), or psychologist).

The V-PR program used a novel proprietary software Platform that required a unique login and password (Figure S1a-S1b) and contained several standardized assessments (Figure S2). The clinician created a personalized PR program to be completed at home using the Clinician Home Program Wizard™ (Figure S3). The home program consisted of avatar-guided exercises (Figure S4a-S4b), digital translations of clinical-guideline-informed educational material (Figure S5a-S5c), a health diary, a daily COPD Action Plan (Figure S6a-S6b), and a goal-setting feature (See Supplementary Material for additional description). With this system, the exercises included upper extremity strengthening exercises, lower extremity strengthening, balance and coordination exercises, and walking as a form of aerobic exercise. TheraBand™ (yellow, green, and red) was used to provide resistance for both upper and lower extremity exercises. The personalized exercise programs (See Supplemental Table S1 for a list of exercises and the percentage of patients each exercise was assigned to) ranged from 8 to 35 minutes, with the average exercise time being about 21 minutes. The self-guided interactive educational material was designed as a conversation between the PR clinician and patient and includes multiple-choice knowledge check-ins and quizzes. After remotely monitoring the patient's progress using the web-based dashboard and discussing their progress during their weekly telephone research visits, the clinician modified the participant's PR program and sent the updates to the participant's app for use the following week. As with the C-PR program, exercise was designed to occur at least 3x/week for 6–8 weeks.

Patient Assessments

Patient-reported HRQoL surveys and functional performance tests were performed in person at research study visit #1 (ie, baseline visit) and repeated at the end of the program at study visit #2 (ie, follow–up visit). Trained study clinicians were not blinded to group preference and guided the participants in completing the assessments.

Feasibility and Usability

Feasibility for patients in both groups was defined as completing 80% or more of the total assigned exercise sessions. For participants in the V-PR group, feasibility criteria also included completing 80% or more of the educational modules and COPD action plans. Additional details obtained from the V-PR group included the number of hours engaged with the app and the number of days logged into the app. Qualitative feasibility data was further assessed by capturing barriers to home-based PR during the weekly telephone visits and in-person follow-up study visit #2. The app's usability in the V-PR group was evaluated using the industry standard System Usability Scale[15] (SUS). The SUS is a reliable, easy-to-use, usability measurement for hardware, software (mobile devices/apps), and websites. The scale consists of 10 statements in which participants respond by selecting 1-Strongly Agree to 5-Strongly Disagree. Scores are categorized as OK/average (scores = 50.9–71.3), good (scores = 71.4–85.4), excellent (scores =85.5–90.8), and best imaginable (scores >90.8) usability.[16]

Program Efficacy

We aimed to explore efficacy of the virtual PR program and hypothesized that there would be no differences between groups in the primary outcome, the 6 minute Walk Test (6MWT). The 6MWT[17,18] distance was completed with or without supplemental oxygen, per individual clinic protocols. Patients were instructed to perform two walks pre-intervention and two walks post-intervention. The longest distances walked from the pre-and post-interventions were selected for analysis. Supplemental oxygen was maintained at the level used during baseline testing unless oxygen levels dropped below 88% or, if the patient had a cardiac history, then supplemental oxygen was maintained above 90%. Oxygen levels were not maintained from baseline to post-test in n=5 participants, and thus, only tests using consistent oxygen supplementation were used in the final analysis per ATS recommendations.[19]

Secondary efficacy-related outcomes included the modified Medical Research Council[20] (mMRC), COPD Assessment Test[21] (CAT), Fall Risk Questionnaire[22] (FRQ), Timed Up and Go Test[23] (TUG), Depression Screen[24] (DS), Single Item Literacy Screener (SILS),[25] NIH-PROMIS,[26] Veteran-Rand-12 health Survey[27] (VR12), 4 Stage Balance Test[28] (4SBT), St. George Respiratory Questionnaire[29] (SGRQ), and Lung Information Needs Questionnaire[30] (LINQ). Briefly, the mMRC is a common valid clinical assessment of dyspnea in COPD.[31] The CAT measures COPD's impact on a person's life.[21,32] The FRQ[22] measures predictors of falls such as history of falls, muscle weakness, incontinence, sensation and medications. This test was used to detect fall risk since adults with COPD experience more falls than healthy older adults.[33] The TUG is a common clinical assessment of mobility[23] and measures the time taken to stand from a chair, walk 3m, turn around, walk back, and sit down. The DS is a short screen of depression.[24] The SILS[25] is a single-item survey that can be used to identify patients needing help with printed health material. NIH-PROMIS[26] is a survey that measures self-reported physical, mental, and social health. Similarly, the VR-12[27] measures self-reported physical and mental health and evaluates health-related quality of life. The 4SBT[28] is a measure of static balance. This test measures the ability to stand with feet together, semi-tandem, tandem, and on one leg for 10 seconds in each position. The SGRQ[29] measures health impairment in adults with COPD. The LINQ[30] is a self-reported questionnaire consisting of 6 knowledge domains (knowledge about disease, medication, self-management, exercise, diet and smoking). The LINQ can be used to evaluate PR programs.

Statistical Analysis

Baseline characteristics by treatment groups were described using standard reporting statistics. Data were analyzed using JASP V.0.18.3 (JASP Team, University of Amsterdam). The primary outcomes were feasibility, defined as completing 80% of the assigned exercise sessions, and usability, assessed using the SUS. The primary efficacy outcome was the change in 6MWT distance, comparing the longest 6MWT distance post-intervention vs pre-intervention. A sample size of 30 participants has 95% power to detect an effect size of 0.6 on functional performance (measured by the 6MWT). Statistical power was estimated using an MCID=30m for the 6MWT.[1]

We completed both between-group and within-group analyses. To examine the change between groups, we used analysis of covariance (ANCOVA), with baseline scores as the covariate, to determine the effect of the intervention on between-group post-test scores. Participants with missing data were removed from the analyses for each outcome. To measure the effect of the intervention within each group, we used either paired sample (two-sided) t-tests for normally distributed outcomes, or Wilcoxon signed ranks for non-normally distributed outcomes. P-values < 0.05 were considered statistically significant in all analyses.

Results

Recruitment

Patients were recruited from February 2020 to March 2023. Data collection was suspended for approximately six months due to the COVID-19 pandemic. Forty-eight participants were recruited from five academic and community medical centers (Supplementary Material Table S2).

Enrolled Participants

Among the 48 patients enrolled, 21 selected C-PR and 27 selected V-PR. Eight participants withdrew (4 from each group), leaving 40 evaluable participants (Figure 1).

Comparing participants in the C-PR and V-PR groups, respectively, the mean age in years (range) was 72 (61–83) vs 69 (54–89); predominantly male 62% vs 52%; FEV1% predicted mean (SD) of 49% (3%) vs 54% (3%); and a mean (SD) severity of dyspnea measured by Modified Medical Research Council (mMRC) Dyspnea Scale of 2.3 (0.23) vs 1.4 (0.18), respectively (Table 1).

Outcomes

Feasibility of the V-PR+RTM Platform

In the V-PR group, 87% (20 of 23 patients) completed greater than 80% of the assigned exercise sessions compared to 94% (16 of 17 patients) in the C-PR group ($\chi^2_{(1)}$=.450, p<0.05; χ^2<critical value 4.55, null hypothesis accepted). In the V-PR group, 100% completed more than 80% of the educational modules. In the C-PR group, one center did not track education adherence, but of the remaining 13 patients, 11 (85%) met the education adherence target (/$\chi^2_{(1)}$=.308, p<0.05; χ^2<critical value 4.55, null hypothesis accepted).

During the study period, the V-PR group logged into the app an average of 36 (SD 14) days (65% of total days in the study; 150% of expected days (expected days = 3x/wk).) and engaged with the app for a mean of 25 (SD 12) hours while in the program. Feasibility was further evaluated in the V-PR group by assessing patient-reported qualitative data related to reasons for withdrawal from the study and barriers towards using the software, captured during the weekly phone call study visits (typical call length was 10–20 minutes) and Visit 2. These findings include the inability to use the app without Wi-Fi, poor internet speed at home causing the app to move slowly, difficulty using an Amazon Fire tablet, difficulty switching to the home-based Wi-Fi after connecting to the clinic Wi-Fi during Visit 1, and the study tablet lacking cellular capacity, which impaired usefulness outdoors.

Usability of the V-PR+RTM Platform

Using the System Usability Scale (SUS), V-PR patients scored the app usability as 76.5 ±16.0 (mean±SD) at baseline and 84.1 ±15.2 at the follow-up visit. Over 87% of participants scored the software as "good or better", 56.5% scored the software as "excellent or best available", and 34.8% scored the software as "best available." The overall SUS scores

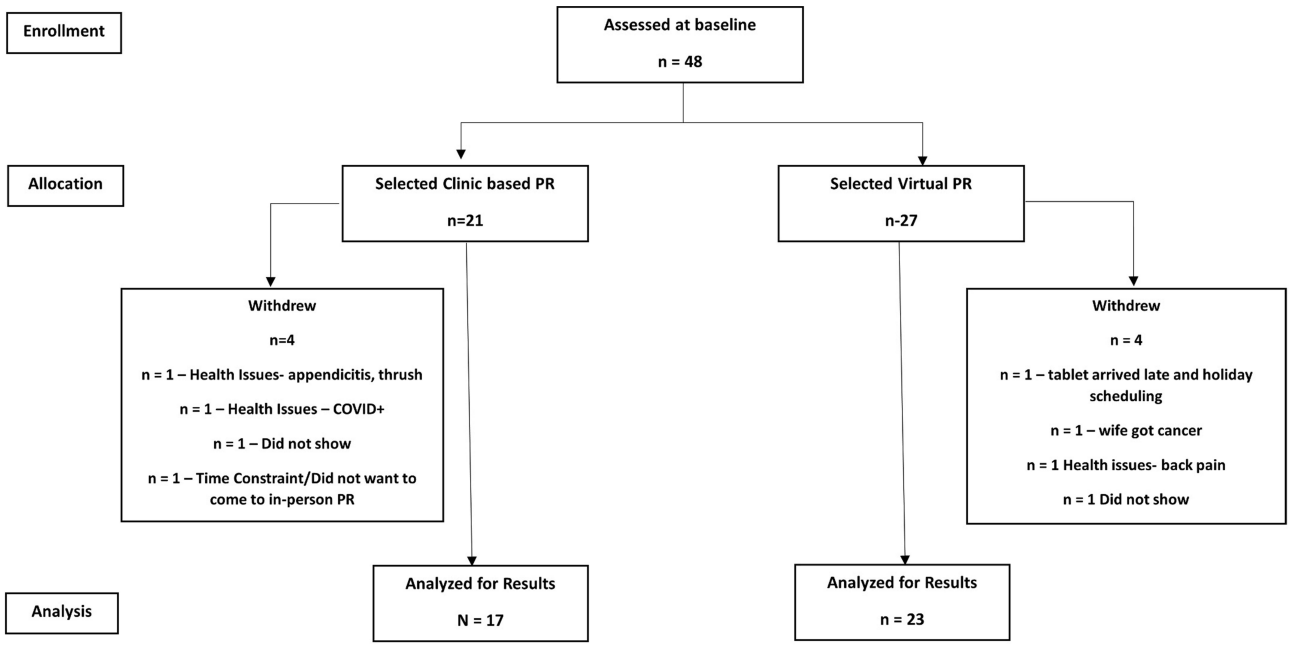

Figure 1 Consort diagram showing participant flow through the study.

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Table 1 Baseline Characteristics of the Study Cohort. Only the mMRC Was Statistically Different Between Groups

	In-Clinic (C-PR)	Virtual (V-PR)
Participants enrolled, n	21	27
Age (yr.), mean (SD, range)	71.9 (7.3, 61–83)	69.0 (9.2, 54–89)
Female, n (%)	8 (38.1%)	13 (48.1%)
Ethnicity – non-Hispanic, n (%)	21 (100%)	27 (100%)
Race – African American/Black, n (%)	3 (14.3%)	0 (0%)
Race – White n (%)	18 (85.7%)	27 (100%)
Charlson Index mean (SD, range)	5.1 (1.8, 2–9)	4.3 (4.3, 2–10)
Myocardial Infarction	4 (19.0%)	2 (7.4%)
Congestive Heart Failure	5 (23.8%)	1 (3.7%)
Peripheral Vascular Disease	1 (4.8%)	2 (7.4%)
Cerebrovascular accident or transient ischemia attack	1 (4.8%)	1 (3.7%)
COPD	21 (100%)	27 (100%)
Peptic Ulcer Disease	0 (0%)	2 (7.4%)
Liver Disease	1 (4.8%)	0 (0%)
Diabetes Mellitus	3 (14.3%)	4 (14.8%)
Chronic Kidney Disease	2 (9.5%)	2 (7.4%)
Solid Tumor	4 (19.0%)	3 (11.1%)
Dementia, CTD, Hemiplegia, Leukemia, Lymphoma, AIDS	0 (0%)	0 (0%)
FEV1% predicted, mean (SD)	48.65 (3.2)	53.56 (3.12)
Oxygen Use		
Percent requiring oxygen during exertion	66.6%	19.2%
Range of oxygen supplementation	0–3	0–4
Average flow rate;	1.7	0.6
Average saturation at rest	97.4	96.9
mMRC* scale, mean (SD)	2.3* (0.23)	1.4* (0.18)
Smoking History	21 (100%)	27 (100%)
Continues to smoke	3 (14.3%)	2 (7.4%)

Note: *Indicates significant differences between groups at baseline.

measured at baseline and follow-up visits improved by a mean of 8 points (p=0.029). The change in SUS sub-scores comparing baseline visit vs follow-up visit were +7.2 points for usability and +10.9 points for learnability, which were significantly improved (p=0.041 and p=0.023, respectively).

Six Minute Walk Test

Changes in follow-up vs baseline visit in the 6MWT distance could not be calculated appropriately in 5 of the 40 participants because of a lack of consistent oxygen use from baseline to post-test. Three participants, one in the V-PR

group and two in the C-PR group, had an increase in oxygen use, and two participants in C-PR had a decrease in oxygen. Also, due to COVID-19 indoor precautions, one VPR participant's data was not included because the baseline 6MWT was performed outdoors in a parking lot using a walking track that was 76 feet long compared to the post-test indoor walking track that was 56 feet long. An ANCOVA was conducted using the remaining 34 participants (13 C-PR and 21 V-PR participants) to compare the effectiveness of two different pulmonary rehab models on 6MWT scores while controlling for both baseline 6MWT and mMRC scores as covariates. We found no significant differences (p=0.437) between groups on post-test 6MWT scores (effect size η^2_p =0.020, CI: −23.8–53.8) well below Cohen's guideline of small effect, ie, 0.2. While our study was not statistically designed to show non-inferiority, we were not surprised there was no statistical difference. The mean (SD) change in 6MWT distance between pre-PR and post-PR was 47.7 meters (SD 48.7, p=0.004, Cohen's d −0.979), an average improvement of 15.5% in walking distance, in the C-PR group. Eight of the 13 participants (61.5%) achieved a change score exceeding the 30m MCID.[34] The mean (SD) change in 6MWT distance in the V-PR group was 34.0 meters (SD 50.4, p=0.006, Cohen's d −0.674), an average improvement of 17.2% in walking distance. Nine 9 of 21 achieved a change score exceeding the 30m MCID, and an additional n=3 participants also achieved change scores of 28m or 29m. (Figure 2 and Supplementary Material Table S3).

Secondary Outcomes

Significant within-group improvements were seen in the C-PR and V-PR groups in the SGRQ (p = 0.014, p = 0.005), CAT (p = 0.004, p = 0.031), LINQ (p<0.001, p<0.001), and NIH PROMIS (physical) (p = 0.04, p = 0.003), respectively (Supplementary Material Table S3). The SGRQ MCID is 4 units[35] and the CAT MCID is 2 points.[36] The mean improvements in SGRQ and CAT exceeded the MCID in both groups. Across these outcome measurements, we observed no significant between-group (C-PR vs V-PR) differences.

The C-PR group showed significant improvement in the 30STST, while the V-PR group did not. The V-PR group showed significant improvement in the VR12 PCS (physical) and 4SBT, while the C-PR group did not. Neither group showed significant changes in TUG, DS, FRQ, SILS, or VR12 MCS (mental).

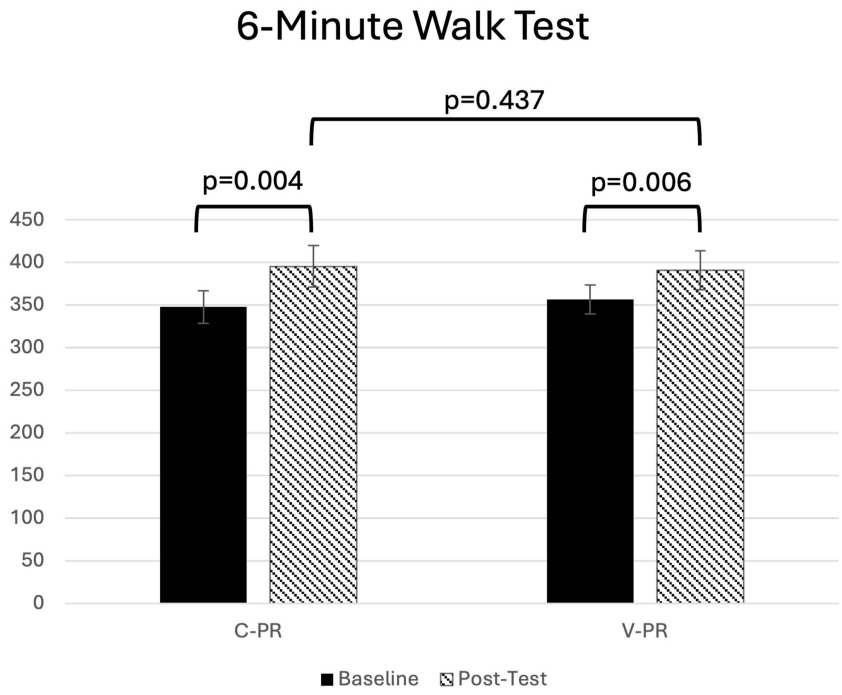

Figure 2 Bar graphs depicting mean (SE) 6MWT distance pre- and post-intervention for each group. Significance is depicted for change in 6MWT in each group and no significance is depicted between groups post-6MWT scores.

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No adverse events related to the V-PR+RTM were reported. Individual participants developed non-study-related health issues, such as thrush, appendicitis, COVID-19, or a back injury, after opening a window; all these health-related conditions were unrelated to the interventions.

Discussion

In this study, we used a multi-site network of community and academic medical centers to evaluate the feasibility and usability of a digital, remote therapeutic monitoring platform for virtual pulmonary rehabilitation. In addition, we assessed changes in the 6MWT distance, functional performance tests, and health-related quality of life (HRQOL) measurements comparing V-PR vs C-PR. We observed that the group that chose virtual pulmonary rehabilitation was slightly younger and in somewhat better health (ie, lower Charlson Index, higher FEV_1, better mMRC), which may reflect a more naturalistic selection of virtual PR by patients with less disease impact.

We found the VPR+RTM Platform is feasible and usable in supporting virtual, remote, asynchronous PR involving a weekly review of the participant's progress using the remote monitoring dashboard and a phone call from the clinician to the participant. In addition, we found that the average change in 6MWT distance, comparing baseline vs follow-up, exceeded the MCID in both groups, and there was no significant difference between the two groups. Moreover, we observed significant within-group improvements in both groups in the SGRQ, CAT, LINQ, and NIH PROMIS (physical), and no significant between-group differences were observed across these outcomes. No adverse events related to the V-PR program supported by the V-PR+RTM Platform were reported. These findings collectively support using a V-PR +RTM Platform as a potentially beneficial model for delivering virtual PR effectively.

The V-PR+RTM Platform was usable as 87% of patients completed at least 80% of the exercise sessions and 100% completed at least 80% of the education modules. The V-PR+RTM completion rates are similar to or exceed those of prior studies. Bondarenko and et.al found that 75% completed the program,[37] whereas Candy and et.al found only 53% completed it.[38] The differences in clinician monitoring and engagement may explain this difference in completion rates. Candy's model offered no clinical engagement aside from SMS text. At the same time, in our study and that of Bondarenko, the clinician contacted each participant weekly via phone, suggesting that routine clinician contact may impact the completion rate. Based on the SUS scores, we also found that participants scored the V-PR+RTM Platform as having "good" usability at baseline (SUS score = 76.5). At follow-up, 56.5% of participants scored the software as "excellent or best available." A recent meta-analysis including 114 studies evaluating the usability of digital health apps with SUS found the average score of all apps was 76.64 (SD 15.12); however, the distribution was skewed due to the higher scoring "physical activity" apps, which averaged 83.28 (SD 12.39). When excluding the "physical activity" apps, the average SUS score dropped to 68 (SD 14.05). The V-PR+RTM Platform used a combination of "physical activity", education or "health information", and assessments and scored higher than average at post-test (SUS score = 84.4) when compared to "all apps" combined, as well as "physical activity" apps.

The between-group difference in the mean change in 6MW distance between C-PR and V-PR was not significantly different. This finding supports previous studies showing no significant difference in 6MWD pre- and post-rehab programs comparing C-PR and V-PR. A prior meta-analysis of randomized clinical trials comparing outpatient PR to telerehabilitation reported a change in 6MWD ranging from 11–29m in the outpatient group, and improvement was similar between groups (mean difference 0.06 m, 95% CI −10.82 to 10.94 m).[13] In contrast, the C-PR and V-PR groups' mean change in 6MWD in our study exceeded the MCID of 30 meters. The V-PR group's mean change in 6MWD was 32.3 meters (SD 50.8), which exceeded the improvement seen in prior studies[37,39,40] and the meta-analysis.[13] The V-PR group in our study compared to earlier studies could be due to our progressive increase in exercise intensity in the V-PR group's home program, weekly phone calls with a clinician, preference-based choice in intervention, and the novel application platform, which instructed and tracked patient progression and allowed clinicians to monitor their progress remotely.

The C-PR and V-PR groups demonstrated a mean improvement in SGRQ and CAT scores that exceeded the MCID. The between-group differences in the mean change in SGRQ and CAT scores were not significantly different between groups. The mean improvement in the SGRQ for C-PR (−7.0 pts) and V-PR (−9.1 pts) exceeded the SGRQ MCID of −4 points. The improvement in the V-PR group exceeded a prior meta-analysis, which reported a mean change in SGRQ

score of 1.3 points lower in telerehabilitation than the C-PR group (95% CI −3.97–1.45). Among the V-PR group, the mean improvement in the CAT score was 2.8 points, exceeding the CAT MCID of 2 points. This improvement was similar to, if not slightly better than, the reported change among the telerehabilitation group in the meta-analysis (95% CI −3.1–0.36).[13]

Additional secondary outcomes showed that the intervention model resulted in a mix of outcomes in each group. For example, the C-PR group significantly improved in the 30STST, while the V-PR group did not, which may reflect better performance when performing the exercise in the clinician's presence. The V-PR group showed significant improvement in the VR12 PCS (physical) and 4SBT, while the C-PR group did not. A ceiling effect may explain the lack of change in the C-PR group's 4SBT score. The improved VR12 (physical) scores may reflect the perception that the virtual PR program improved the V-PR group's physical functioning more than the C-PR group's perception of physical function improvement.

Our study has several limitations. First, to model what may occur in a typical clinic, group assignment was not randomized, which resulted in differences in baseline characteristics between the two groups. These differences, while taken into consideration in the ANCOVA, could have impacted our results, particularly concerning intervention adherence. Despite this limitation, among participants who selected V-PR compared to those who selected C-PR, we found that both groups improved in several outcomes. Considering the nature of the intervention, our findings provide meaningful results related to software-supported asynchronous virtual PR models. These results demonstrate that among participants who are able and interested in participating in V-PR, our program was found to be feasible, usable, and improved 6MWT, SGRQ, CAT, LINQ, and NIH PROMIS (physical). Second, the COVID-19 pandemic impacted the availability of performing exercises at the center during a portion of the study, which meant up to one-third of exercise sessions in some centers were conducted at home in a center/home hybrid model. However, C-PR patients still exceeded the MCID in both 6MWT distance and multiple HRQOL measurements, suggesting a valid treatment response in the comparator group. The off-protocol practice of adjusting supplemental oxygen support during the 6MWT in 5 participants and a change in 1 participant's testing environment limited the number of valid walk tests for analysis. However, we reported the change in 6MWT distance in 34 participants, which provided a statistically meaningful enough sample size to expect valid results.[41]

Given that less than 3% of adults living with COPD attend PR in the United States, new effective models must be developed and validated to determine if they are beneficial to those with COPD (and potentially other chronic lung diseases) who lack access to center-based PR. Taken together, the results of this study support V-PR with remote monitoring as a meaningful alternative to center-based PR in those who are safe to exercise at home but are unable to attend the clinic frequently, live in remote areas with barriers to accessing center-based PR, or are experiencing health disparities that preclude their participation in center-based PR.

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