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Smartphone application-based pulmonary rehabilitation in COPD: a multicentre randomised controlled trial

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ABSTRACT

Background Pulmonary rehabilitation (PR) is an essential element of chronic obstructive pulmonary disease (COPD) management. However, access to conventional face-to-face PR programmes is limited.

Methods This multicentre, randomised controlled trial recruited patients with COPD from 18 sites in Germany and Switzerland, aiming to evaluate the impact of 12 weeks of a mobile app (intervention group; IVG) on quality of life, measured by COPD Assessment Test (CAT), and exercise capacity, assessed by 1-minute-sit-to-stand-test (1MSTST), compared with a control group (CTG) receiving 'enhanced standard-of-care'.

Results 278 patients were included in the study with a median age of 65 years (IQR 60–70) and forced expiratory volume in 1 s 48% predicted (IQR 37–60). In the intention-to-treat analysis at week 12, CAT improved from baseline by median −4 points versus −3 points in the IVG versus CTG groups, respectively (difference: 0 points (95% CI: −1, 2); p=0.7); 1MSTST improved by 1 vs 2 repetitions, respectively (difference: 1 repetition (95% CI: 0, 2); p=0.12)). In a subset of the IVG, with patients grouped by application adherence (≥3 days/week for≥75% of the weeks), adherent users (40.4%) improved 1MSTST versus non-adherent users by median 2 repetitions (95% CI: 1, 3]; p=0.006. Application use did not raise any safety concerns.

Conclusions Application-based PR improved outcomes in COPD compared with baseline, and adherent users improved exercise capacity more compared with non-adherent users. Although not statistically significant compared with enhanced standard-of-care, this study may support the use of this application for COPD management and addresses the healthcare challenge of access to PR interventions.

Trial registration number DRKS 00024390.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Pulmonary rehabilitation (PR) is widely recognised as a cornerstone in managing chronic obstructive pulmonary disease (COPD). It offers significant benefits in terms of exercise capacity, quality of life and symptom control. However, traditional face-to-face PR programmes have limitations such as limited access, capacity constraints and low uptake rates. Tele-PR has emerged as a potential solution, encompassing various modalities such as videoconferencing, webpages or mobile applications. Although some studies have shown comparable outcomes between tele-PR and centre-based PR, the follow-up effects of tele-PR, particularly application-based applicationroaches, remain underexplored.

WHAT THIS STUDY ADDS

⇒ This multicentre randomised controlled trial aims to investigate the effectiveness of a fully automated, interactive smartphone application in improving symptoms and physical function in COPD. Unlike previous studies, which primarily focused on tele-PR via videoconferencing or web-based platforms, this trial specifically examines the impact of an application-based intervention. The application includes customised exercise training, educational material and breathing/relaxation sessions, making it a comprehensive self-management tool for patients with COPD. This study enhances the existing literature by addressing the gap in knowledge regarding the effectiveness of application-based PR in COPD management, through the use of rigorous methodology and a large sample size across multiple centres.

BACKGROUND

Pulmonary rehabilitation (PR) is an essential part of the management of chronic obstructive pulmonary disease (COPD), comprising exercise training, education and behaviour modification. The evidence for traditional face-to-face PR in COPD is compelling, with beneficial effects on exercise capacity, muscle function, quality of life and symptoms.[1 2] However, such programmes are limited by access, capacity and uptake,[3–5] being used by fewer than 2% of eligible patients with COPD.[6] Tele-PR has been proposed as an alternative strategy in COPD,[7 8] although the term 'tele-PR' encompasses different models, including videoconferences, webpages or mobile apps, with varying telephone support and monitoring.[9–11] A Cochrane review comparing tele-PR with conventional centre-based PR or no rehabilitation found that tele-PR

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HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The study's findings provide valuable insights into the role of mobile applications in COPD management and PR. Although the overall analysis did not show statistically significant differences between the application-using group and the enhanced standard of care group, the study highlights the potential benefits of application-based interventions, particularly for adherent users. Adherent application users showed improved exercise capacity, suggesting that the application could be a promising alternative for patients facing barriers to accessing centre-based rehabilitation (especially compared with the real-life situation where patients with COPD receive less support than in the enhanced standard of care group). Furthermore, the high patient satisfaction and safety profile of the Kaia COPD application highlight its potential as a viable option for addressing the challenges of access and adherence in PR interventions. These findings could guide future research directions, clinical guidelines and healthcare policies to enhance COPD management through innovative digital health solutions.

generated similar outcomes to centre-based PR in terms of exercise capacity and quality of life, and was superior to no rehabilitation.[12] However, the varying approaches, limited number of study participants, and few studies including post-intervention follow-up, mean that identifying the long-term effects of tele-PR is challenging. In particular, of the 15 tele-PR studies included in the Cochrane analysis, only one used an app-based approach. Given the minimal prior data, we conducted a trial to investigate the effectiveness of a fully automated, interactive, mobile app in improving symptoms and physical function in patients with COPD.

METHODS

Study design and participants

This multicentre randomised controlled trial (RCT) was conducted across 18 study centres in Germany and Switzerland, comprising six medical practices, five hospitals, five research institutions and two PR centres (Online supplemental e-table 1).

Participants were aged≥40 years, diagnosed with COPD, with post-bronchodilator forced expiratory volume in 1 s≥30% predicted, COPD Assessment Test (CAT) total score≥20, and receiving stable maintenance COPD treatment (ie, with no treatment changes in the 4 weeks prior to entry). Additionally, they had a good understanding of German and were able to comprehend the study materials, assessments and smartphone apps in general. Patients with physical, cognitive or safety-related problems hindering their ability to participate, receiving long-term oxygen therapy at>3 L/min, or regularly using non-invasive ventilation were ineligible, as were those enrolled in another clinical trial involving an investigational medication/device within 30 days prior to enrolment, with prior experience of a COPD self-management app or web-based programme, or who intended to participate in a conventional PR programme during the study. The trial was registered with the German Clinical Trials Register (registered: 26 May 2021), and was conducted according to Good Clinical Practice and the Declaration of Helsinki.

Study procedure

The study intervention duration was 12 weeks, with additional follow-up after a total of 24 weeks. After enrolment, patients were randomised 1:1 using block randomisation (block size four) to an intervention group (IVG) receiving the app or a control group (CTG). A randomisation list was generated for each site, with treatment assignment concealed from the statistician during the final analysis (although not study staff and participants, due to the nature of the intervention). All participants were provided with a study smartphone, to protect patient privacy by not using personal smartphones, and entered patient-reported outcomes data on a website via this smartphone, with data securely transmitted directly to the electronic case report form (eCRF) as electronic patient-reported outcomes (ePROs).

Intervention group

The study intervention was the multimodal personalised therapy app 'Kaia COPD' (Kaia Health Software, Munich, Germany). This consists of three therapy modules that are components of PR to promote self-management: individualised exercise training; educational content; and breathing/relaxation sessions (figure 1). The app dashboard presented participants with a daily choice of all three modules and encouraged them to complete one, two or all three at a convenient time, preferably daily. The use and completion of each module were automatically tracked by the app, with a weekly usage report provided to study sites. Inactive participants (<3 days of app usage per week) were contacted by study staff and were motivated to use the app.

The core component of the app, the exercise training programme, required minimal equipment (eg, a mat, chair, water bottles as weights or a resistance band). Exercise sessions lasted approximately 15–20 min, were completed in an unsupervised manner and consisted of exercises focusing on muscle strengthening, balance and mobility, with visual and verbal instructions provided by video tutorials and a countdown timer. A standard exercise session consisted of an automatic selection of five exercises out of a pool of 64, with each exercise completed one to three times. After each session, patients rated the perceived difficulty on a five-point scale (very easy to very hard). An algorithm then automatically increased or decreased the difficulty for the next training session according to the patients' ratings, adapting the duration, intensity and exercise type to patients' individual needs.

The educational content was based on the internationally validated 'Living Well with COPD' patient guideline[13] supplemented with videos on correct inhaler use. The breathing/relaxation sessions included audio instructions on relaxation and/or breathing techniques, such as mindfulness or progressive muscle relaxation.

Control group

Patients allocated to the CTG received the 'Living Well with COPD' booklet containing disease management information and exercise instructions, and used a study smartphone to report outcomes, but did not have access to the app. At the request of the lead ethics committee, this group received additional support beyond the standard care to reduce potential psychological bias. This included education and encouragement to exercise, and a paper-based exercise diary. The CTG therefore received an 'enhanced standard of care' rather than the usual care originally planned. Both CTG and IVG participants received telephone calls every 2 weeks from study staff to monitor for adverse events or other safety concerns. These calls did not include additional

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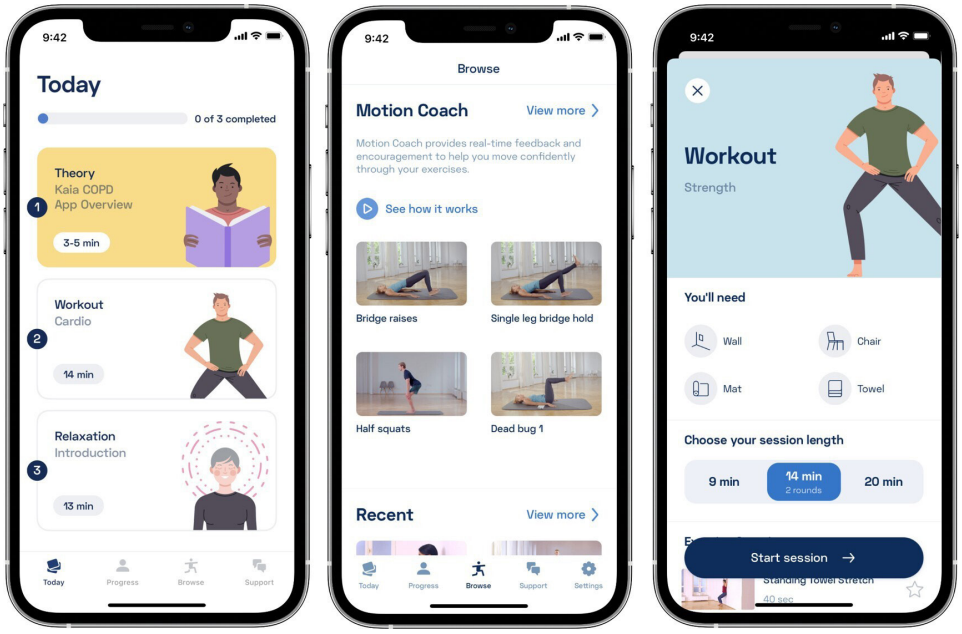

Figure 1 Screenshots of the fully automated mobile Kaia COPD application and its three modules: a digital exercise programme delivered by video instructions, a self-management programme (including relaxation and breathing exercises) delivered by audio instructions and a patient education programme. (Figure provided courtesy of Kaia Health). COPD, chronic obstructive pulmonary disease.

encouragement to exercise for intervention group participants, as their exercise guidance was fully integrated into the app content.

OUTCOMES

The prespecified co-primary outcomes were differences between IVG and CTG at 12 weeks in terms of health status (assessed by CAT) and exercise capacity (measured by 1-minute sit-to-stand test (1MSTST) repetitions). The 1MSTS tests were performed remotely via a video appointment between the participant and the study site staff.[14] Outcome assessors were not blinded to group allocation (as all outcomes except the 1MSTST were collected digitally via an email link).

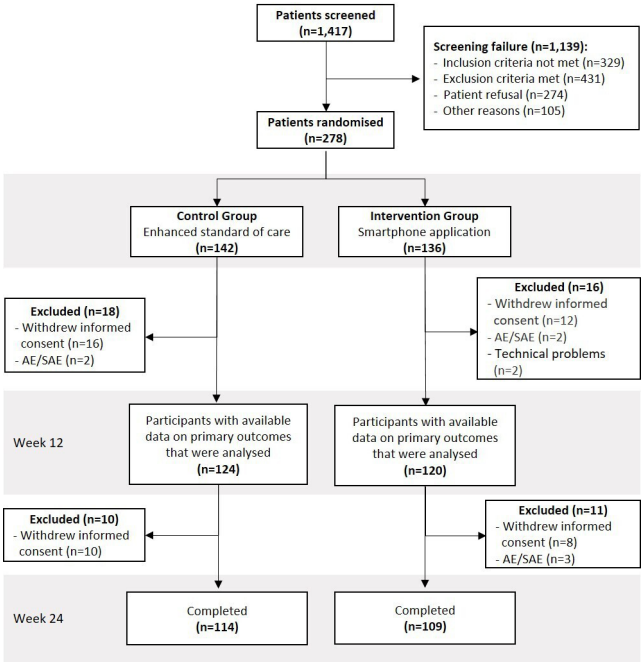

Figure 2 Participant flow through the study. AE, adverse event; SAE, severe AE.

Secondary ePROs at baseline, and after 12 and 24 weeks included levels of anxiety and depression (Hospital Anxiety and Depression Scale (HADS)), health-related quality of life and disease burden (Veterans RAND 12-item health survey (VR-12)), patient engagement in healthcare (Patient Activation Measure 13 (PAM-13)), healthcare resource utilisation, adverse events, CAT and 1MSTST at 24 weeks and app satisfaction and helpfulness (IVG only). Further details on these endpoints are in the Online supplement.

As an exploratory outcome, the effect of the intervention on the incidence of mild, moderate or severe COPD exacerbations (Global Initiative of Chronic Obstructive Lung Disease 2022 definition[15]) was assessed (during telephone calls every two weeks in both groups to ask about the occurrence of any adverse events and any changes in medication).

Sample size and statistical analyses

Based on a two-tailed t-test with 80% power, assuming a mean difference of 2.5±6.0 points in CAT total score,[16] 111 patients per group would be required. For the 1MSTST, assuming a minimally important difference of 3±6 repetitions,[17] 78 patients per arm would be required. Considering both primary endpoints with an initial alpha of 0.025, the CAT score calculation with the higher patient number determined the final sample size of 278 participants, including an expected 25% dropout rate.

Normality was tested using the Shapiro-Wilk test with histograms and qq-plots. Between-group comparisons were conducted using t-tests or Mann-Whitney U test for continuous variables and χ^2 test or Fisher's exact test for non-continuous variables, with median differences calculated using the Hodges-Lehmann estimator. A p value of 0.05 was considered statistically significant, with the co-primary endpoints adjusted for multiple testing using Bonferroni's method. Statistical analyses were performed

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Table 1 Demographic and baseline disease characteristics (intention-to-treat population)

	Control group (n=142)	Intervention group (n=136)	P value
Age, years	64 (59–70)	66 (60–72)	0.166
Sex			0.628
Female	72 (50.7)	65 (47.8)	
Male	70 (49.3)	71 (52.2)	
BMI, kg/m²	26.4 (22.9–31.2)	25.5 (22.6–29.4)	0.083
COPD GOLD			0.999
I	5 (4.2)	4 (3.4)	
II	51 (42.9)	50 (42.7)	
III	63 (52.9)	63 (53.8)	
Smoking status			0.030
Current smoker	53 (37.3)	34 (25.2)	
Former smoker	89 (62.7)	102 (74.8)	
Mean smoking pack years	45 (35–54)	39 (25–49)	0.282
Age at COPD diagnosis	55 (49–61)	55 (50–62)	0.353
Comorbidities			
Cardiovascular	87 (61.3)	89 (66.4)	0.374
Orthopaedic	56 (39.4)	61 (45.2)	0.333
Metabolic	49 (34.5)	46 (34.3)	0.975
Psychological	33 (23.2)	32 (23.9)	0.900
Cerebrovascular	14 (10.0)	14 (10.4)	0.903
Treatment			
LABA	125 (88.0)	126 (92.6)	0.194
LAMA	127 (89.4)	124 (91.2)	0.624
ICS	86 (60.6)	86 (63.2)	0.647
LTOT	27 (19)	27 (20)	0.836
FEV_1, L	1.38 (1.03–1.77)	1.23 (1.04–1.66)	0.327
FEV_1, % predicted	48 (40–61)	48 (36–57)	0.222
FEV_1/FVC	0.52 (0.45–0.58)	0.50 (0.44–0.57)	0.135
COPD Assessment Test total score	23 (21–26)	23 (21–26)	0.617
1-minute sit-to-stand test repetitions	18 (14–22)	17 (13–22)	0.196
Patients with at least one acute COPD exacerbation during the previous 12 months, n (%)	45 (31.6)	50 (36.8)	0.371

All continuous variables are median (IQR) and are compared via Mann-Whitney U test. All categorical variables are the absolute number (percentage), and are compared using χ^2 test.
BMI, body mass index; COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 s; FVC, forced vital capacity; GOLD, Global Initiative for Chronic Obstructive Lung Disease; ICS, inhaled corticosteroid; LABA, long-acting β_2-receptor agonist; LAMA, long-acting muscarinic antagonist; LTOT, long-term oxygen therapy.

using R (V.4.3.1) with R studio (2023.09.1+494, Foundation for Statistical Computing, Vienna, Austria).

The intention-to-treat (ITT) population included all randomised patients, regardless of their eligibility status after randomisation or adherence. The per-protocol (PP) population consisted of all randomised patients who adhered to the study protocol, completed all relevant procedures at baseline and week 12, and had data available at week 12 for at least one co-primary

Table 2 The COPD Assessment Test total score and 1-minute sit-to-stand test at baseline, and change from baseline at 12 (co-primary outcomes) and 24 weeks (follow-up)

	Intention-to-treat population (including all patients)			Per-protocol population (including only adherent application users in the IVG)		
	Control group (n=142)	Intervention group (n=136)	Intervention group vs control group differences	Control group (n=122)	Intervention group (n=46)	Intervention group vs control group differences
COPD Assessment Test total score						
Baseline	23 (21 to 26)	23 (21 to 26)		23 (21 to 25)	22 (20 to 25)	
Week 12, change from baseline	−3 (−8 to 0)	−4 (−8 to −1)	0 (−1 to 2) p=0.697	−3 (−8 to 0)	−4 (−8 to −2)	1 (−1 to 3) p=0.409
Week 24, change from baseline	−3.5 (−8 to 1)	−4 (−9 to −1)	2 (−0 to 3) p=0.074	−3 (−8 to 1)	−4 (−9 to −2)	2 (−0 to 4) p=0.075
1-minute sit-to-stand test, repetitions						
Baseline	18 (14 to 22)	17 (13 to 22)		18 (24 to 23)	18 (13 to 22)	
Week 12, change from baseline	2 (0 to 6)	1 (−1 to 4)	1 (0 to 2) p=0.120	2 (0 to 6)	3 (0 to 4)	0 (−2 to 2) p=0.901
Week 24, change from baseline	4 (0 to 7)	3 (0 to 6)	0 (−1 to 2) p=0.485	4 (0 to 7)	3 (1 to 6.5)	0 (−2 to 1) p=0.709

COPD, chronic obstructive pulmonary disease; IVG, intervention group.

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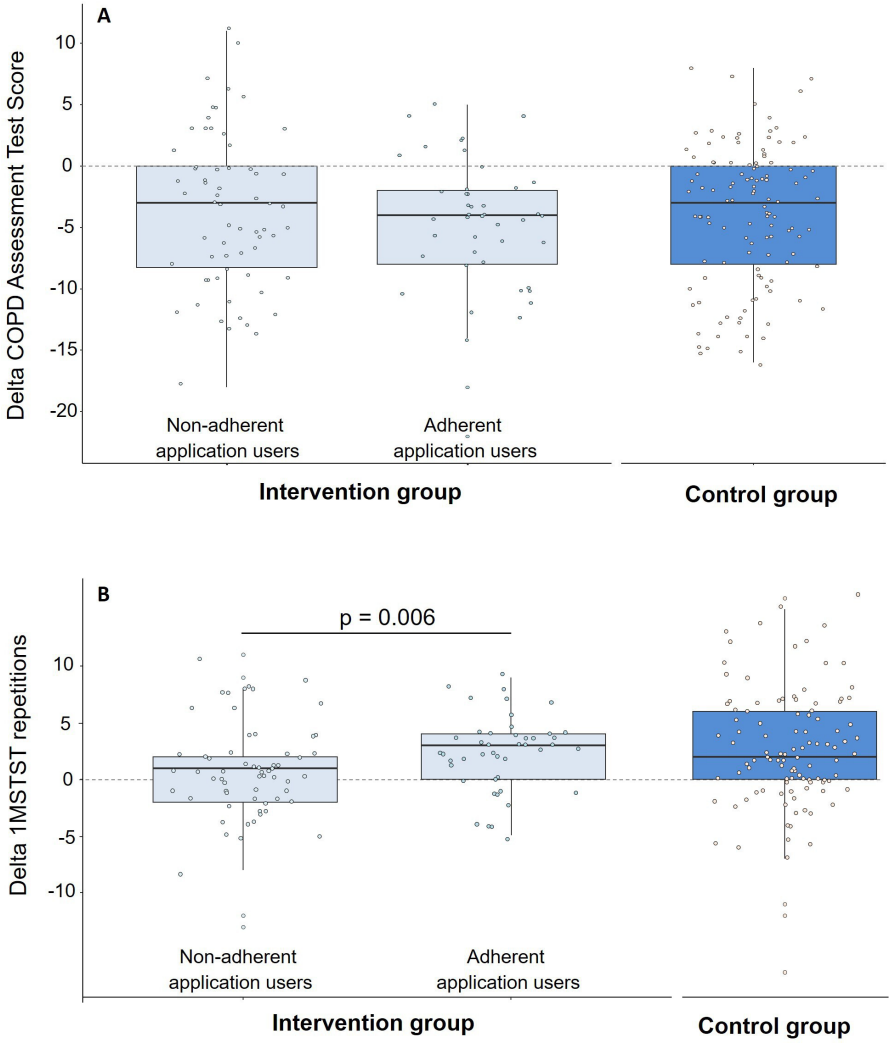

Figure 3 Changes in COPD Assessment Test score (A) and changes in 1-minute sit-to-stand test (1MSTST) repetitions (B) from baseline to week 12 between adherent application users (≥75% adherent training weeks, n=46) and non-adherent application users (<75% adherent training weeks, n=68) in the intervention group and the control group (n=122). COPD, chronic obstructive pulmonary disease.

endpoint.The IVG PP population included only participants who met a predefined app adherence threshold (completion of the exercise programme≥3 days/week for≥75% of the weeks from baseline to week 12, based on app usage data). Subgroup analyses were also prespecified on the co-primary endpoints, with patients grouped by this adherence threshold.

Handling of missing data

Full case analysis is presented for ITT and PP analysis. As a sensitivity analysis, missing data was imputed using a jump-to-reference approach with 2000 bootstrap samples.

RESULTS

Between May 2021 and May 2023, 1417 patients were screened, with 278 randomised (figure 2; baseline demographics are in table 1). A total of 124 and 120 patients in the IVG and CTG, respectively, completed the primary intervention phase (week 12), with 109 and 114, respectively, completing week 24. The PP IVG population consisted of 46 patients (40.4%); 68 patients were excluded on the basis of adherence.

Primary endpoints

In the ITT population, between-group comparisons showed no statistically significant difference in improvement from baseline in the CAT total score at week 12, with a median change of −4 points (IQR −8 to −1; p<0.001) in the IVG and −3 points (IQR −8 to 0; p<0.001) in the CTG (table 2). For the 1MSTST, there were also no significant between-group differences in improvement from baseline at week 12. Within-group changes in the ITT and PP population showed significant improvements from baseline in both CAT total scores and 1MSTST repetitions in both groups.

Furthermore, in a subgroup analysis of the IVG, with participants grouped by adherence, although CAT total score did not differ significantly between adherent and non-adherent patients, there was a greater improvement from baseline for 1MSTST in adherent patients, resulting in 2 (0 to 8) more repetitions in favour of the IVG (p=0.006; figure 3). There was also a significant correlation (p=0.016, online supplemental e-figure 1) between the number of active app training days and improvement in 1MSTST from baseline to week 12 in adherent versus non-adherent app users. There were no significant differences in baseline characteristics between adherent and non-adherent app users (online supplemental e-table 2).

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Table 3 Between-group results in the per-protocol population (ie, including only adherent application users in the intervention group) for changes from baseline in secondary endpoints at weeks 12 and 24

	Control group (n=122)	Intervention group (n=46)	Intervention group vs control group differences
Veterans RAND 12-Item health survey: physical component score			
Baseline	32.3 (27.2 to 37.5)	33.4 (29.3 to 40.7)	
Week 12, change from baseline	0.3 (–2.7 to 6.1)	1.3 (–2.8 to 6.3)	0 (–3 to 2); p=0.764
Week 24, change from baseline	1.9 (–2.7 to 5.8)	1.7 (–2.2 to 4.8)	0 (–3 to 2); p=0.778
Veterans RAND 12-Item health survey: mental component score			
Baseline	47.1 (38.3 to 54.3)	52.2 (38.9 to 59.4)	
Week 12, change from baseline	–2.5 (–7.2 to 3.5)	–0.1 (–4.0 to 2.7)	–2 (–5 to 1); p=0.209
Week 24, change from baseline	–0.9 (–7.2 to 4.8)	0.1 (–6.1 to 3.7)	–1 (–4 to 3); p=0.719
Patient Activation Measure 13			
Baseline	42 (39 to 45)	44 (40 to 47)	
Week 12, change from baseline	0 (–3 to 2)	1 (–1 to 3)	–1 (–2 to 0); p=0.169
Week 24, change from baseline	0 (–2 to 3)	2 (–1 to 4)	–1 (–3 to 0); p=0.152
Hospital Anxiety and Depression Scale: total score			
Baseline	11 (8 to 16)	9 (6 to 16)	
Week 12, change from baseline	1 (–2 to 4)	–1 (–5 to 1)	**2 (0 to 4); p=0.043**
Week 24, change from baseline	0 (–3 to 4)	0 (–3.5 to 3)	1 (–1 to 3); p=0.546
Hospital Anxiety and Depression Scale: anxiety			
Baseline	5 (3 to 8)	5 (3 to 7)	
Week 12, change from baseline	0 (–1 to 2)	0 (–3 to 1)	1 (–0 to 2); p=0.111
Week 24, change from baseline	0 (–2 to 2)	0 (–2 to 2)	0 (–1 to 2); p=0.424
Hospital Anxiety and Depression Scale: depression			
Baseline	6 (4 to 8)	4 (2 to 7)	
Week 12, change from baseline	0 (–2 to 2)	–1 (–2 to 1)	1 (–0 to 2); p=0.056
Week 24, change from baseline	0 (–2 to 2)	0 (–1 to 1.5)	0 (–1 to 1); p=0.634

All continuous variables are shown with median (IQR) and were compared via Mann-Whitney U test.

Secondary endpoints

For the secondary endpoints, there were no differences between IVG and CTG (ITT population) at weeks 12 or 24 (online supplemental e-tables 3 and 4). In the PP population, there were IVG versus CTG differences at week 12 for VR-12 (physical and mental components), PAM-13 and HADS (total score and depression), and at week 24 for PAM-13 and HADS anxiety (online supplemental e-table 3), although the group differences were not statistically significant when expressed as change from baseline (table 3). There were also trends to lower healthcare utilisation in the IVG than the CTG, although again with no statistically significant differences (online supplemental e-table 5). From baseline to 12 weeks, 25.7% of IVG and 30.4% of CTG reported regular participation in outpatient exercise programmes or physiotherapy. On average, 40.4% of patients in the IVG used the app adherently, with consistent use of the physical exercise module for the duration of follow-up (online supplemental e-figure 2 and e-table 6).

Exploratory outcomes

At baseline, the proportion of patients having at least one exacerbation in the previous 12 months in the IVG (36.8%, n=50) was similar to the CTG (31.6%, n=45) (p=0.4). During the 24-week study period, fewer patients in the IVG experienced an exacerbation than the CTG (ITT: 20.5% vs 30.2%, p=0.086; PP: 26.1% vs 32.0%, p=0.582). Furthermore, the total number of exacerbations was lower in the IVG (ITT: 34 vs 52; PP: 16 vs 48) (figure 4).

Application adherence and satisfaction

During the first 12 weeks, 46 patients (40.4%) were adherent app users. Of these, the majority (n=31, 72.1%) remained adherent throughout the follow-up period. Patient satisfaction with the app was very high. In the ITT population, at week 12, 93.6% of patients in the IVG indicated they would recommend the app to another patient (at week 24 follow-up: 94.1%). Furthermore, at week 12, 93.6% of patients were satisfied or very satisfied with the app (at week 24: 94.0%).

Adverse events

During the intervention period, 56 patients (41.2%) reported an adverse event in the IVG, compared with 58 (40.8%) in the CTG, with no difference between groups (p>0.9; online supplemental e-table 7). Over the subsequent follow-up period, a further 38 (27.9%) and 31 (21.8%) patients, respectively, reported an adverse event (p=0.2). None of these adverse events were directly related to the intervention.

DISCUSSION

In this large, multicentre, RCT, there were improvements from baseline in the co-primary endpoints of CAT and 1MSTST in

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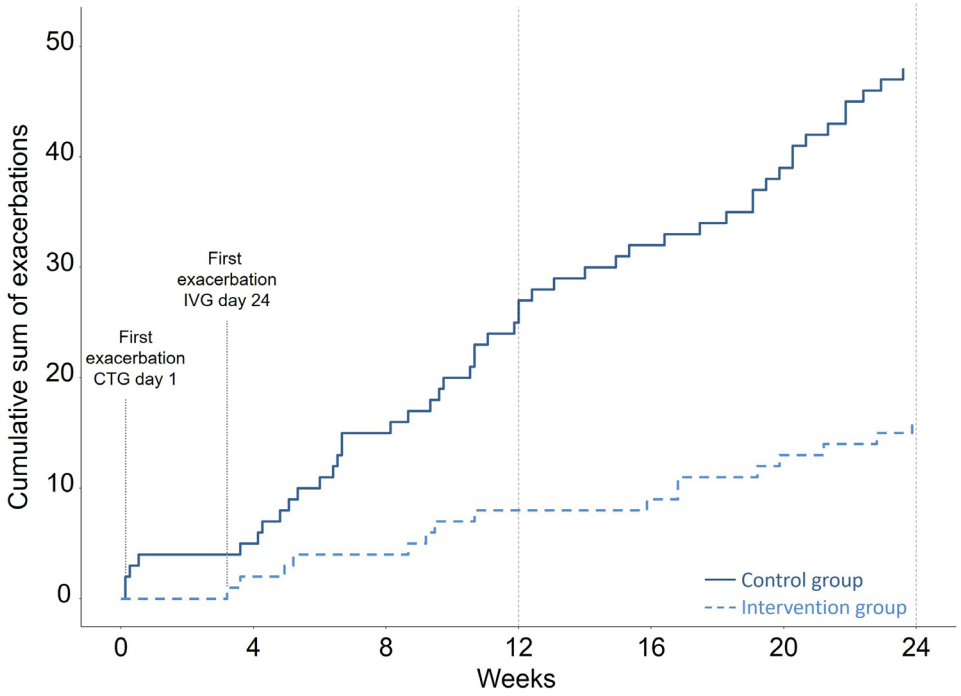

Figure 4 This Kaplan-Meier plot shows the cumulative sum of exacerbations in the per-protocol population over 24 weeks (control group: 48 acute exacerbations and 16 acute exacerbations in the intervention group). The difference was not statistically significant. The first exacerbation occurred on day 1 in the control group (CTG) and on day 24 in the intervention group (IVG); HR (95% CI) IVG 0.83 (0.41, 1.69) (post-hoc analysis).

both the IVG and CTG over both the 12-week main study period and the subsequent follow-up, with between-group differences not statistically significant. Similarly, between-group differences in the secondary endpoints were not statistically significant. However, in the PP population (which excluded patients from the IVG who were not adherent to the app), improvements from baseline during the 12-week intervention period were consistently numerically greater in the IVG than the CTG. Furthermore, in a subgroup analysis of the IVG, there was a significantly greater improvement in 1MSTST in favour of adherent app users compared with non-adherent app users, with an improvement of two repetitions (p=0.006). Adherent app users in the IVG (ie, the PP population) also needed numerically fewer healthcare resources and had fewer exacerbations than the CTG. Importantly, adherence to app usage over 12 weeks in the ITT population was 40%, substantially higher than the 22% adherence in a previous mobile PR app study.[18]

The lack of statistically significant differences between groups for the co-primary endpoints needs to be considered in the context of the CTG receiving 'enhanced standard of care'. The conventional standard of care in a PR study typically results in either no improvement or a deterioration in CAT or 1MSTST.[19 20] In the present study, the CTG received phone calls with encouragement to exercise every 2 weeks. Such phone calls from healthcare professionals can significantly increase daily training duration in patients with COPD.[21] Furthermore, the CTG was provided the 'Living Well with COPD' booklet,[13] which has been shown to enhance the quality of life, reduce exacerbation rates and healthcare usage, and increase the 1MSTST by three repetitions.[22 23] These interventions presumably benefitted the CTG, limiting the potential for further improvement in the IVG. A previous RCT in 166 participants with moderate-to-very severe COPD investigated a monitoring and self-management app called *EDGE*.[24] This study also found no difference in COPD-specific health outcomes over 12 months compared with an 'enhanced standard of care' (who received the same information on leaflets, but without digital monitoring).

In general, only a few mobile exercise or PR applications have been investigated in COPD. In an observational trial, Yonchuk *et al* concluded that their application (*Respercise*) could be easily deployed, and improved the 5-repetition sit-to-stand test by 2.2 s after 13 weeks.[25] However, that application primarily focuses on daily step goals, and includes a limited selection of four strength training exercises. *myCOPD*, applicationroved by the UK National Health Service, is designed to aid individuals with COPD by providing education, self-monitoring and self-management functions. In an RCT involving 60 patients with mild-to-moderate COPD, CAT total score improved by −1.27 points (p=0.44) after 12 weeks in application users compared with usual care.[18] Furthermore, the mobile PR application *efil breath* was evaluated in a Korean RCT that included physical activity monitoring, exercise training and education in patients with COPD.[26] A total of 85 participants were randomly assigned to either application-based PR or usual care. Application-based PR resulted in a non-significant improvement from the baseline of −2.7 points in the CAT total score over 12 weeks. The CAT improvements in both of these studies are considerably smaller than the change from baseline in the IVG in the current study (−4 points).

Application-based coaching interventions can increase physical activity levels in patients with COPD.[27] The application used in the current study has also been evaluated as a PR maintenance intervention in COPD[28]; combined with a physical activity tracker, activity levels were preserved and disease burden was reduced compared with the control group 6 months after a comprehensive 3-week inpatient PR. In the current study, the focus of the intervention has shifted to examining the effects of the application's content—exercise, education and breathing exercises—on improving exercise capacity and quality of life, without including physical activity monitoring or counselling.

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While fully automated apps and video-based interventions offer advantages in terms of accessibility, consistency, staff burden and cost-effectiveness, videoconference-based interventions provide human interaction, individualised guidance and flexibility. Achieving the best possible outcome may require a combination of both, striking a balance between automated services and the human touch. Importantly, digital PR apps that either complement or replace some aspects of usual care offer an opportunity for more convenient, cost-effective care.[29]

The study has some limitations. First, due to the nature of the intervention patients were not blinded. Second, COPD maintenance therapy during the study was not restricted. Third, as discussed above, the CTG received 'enhanced standard of care' differing from typical daily care. Fourth, the app-based exercise programme did not include an aerobic training component, which may have diminished the greater benefits of the app. Finally, the study excluded patients with very severe COPD who may require greater supervision due to their disease severity. As strengths, the current study is noteworthy for its robust design, multisite nature and recruitment of the largest sample size thus far studied for a digital PR app. In addition, several clinical outcomes highly relevant to COPD management were assessed.

Conclusions

This RCT did not show statistically significant differences in the primary outcome between the app-using group and the enhanced standard of care group. However, some benefits were observed in adherent app users, including an improvement in exercise capacity compared with non-adherent users, and no safety issues were identified with app use. These findings suggest that the Kaia COPD app may offer a benefit in the management of COPD. However, we recommend further studies to substantiate these observations and to examine the role of the app compared with conventional usual care.

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