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ORIGINAL ARTICLE

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A Randomized Controlled Trial

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Abstract

Rationale: Despite the benefits of pulmonary rehabilitation in chronic obstructive pulmonary disease (COPD), many patients do not access or complete pulmonary rehabilitation, and long-term maintenance of exercise is difficult.

Objectives: To compare long-term telerehabilitation or unsupervised treadmill training at home with standard care.

Methods: In an international randomized controlled trial, patients with COPD were assigned to three groups (telerehabilitation, unsupervised training, or control) and followed up for 2 years. Telerehabilitation consisted of individualized treadmill training at home supervised by a physiotherapist and self-management. The unsupervised training group performed unsupervised treadmill exercise at home. The control group received standard care. The primary outcome was the combined number of hospitalizations and emergency department presentations. Secondary outcomes included time free from the first event; exercise capacity; dyspnea; health status; quality of life; anxiety; depression; self-efficacy; and subjective impression of change.

Measurements and Main Results: A total of 120 participants were randomized. The incidence rate of hospitalizations and emergency department presentations was lower in telerehabilitation (1.18 events per person-year; 95% confidence interval [CI], 0.94–1.46) and unsupervised training group (1.14; 95% CI, 0.92–1.41) than in the control group (1.88; 95% CI, 1.58–2.21; $P < 0.001$ compared with intervention groups). Telerehabilitation and unsupervised training groups experienced better health status for 1 year. Intervention participants reached and maintained clinically significant improvements in exercise capacity.

Conclusions: Long-term telerehabilitation and unsupervised training at home in COPD are both successful in reducing hospital readmissions and can broaden the availability of pulmonary rehabilitation and maintenance strategies.

Keywords: COPD; exercise; telemedicine; clinical trial

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At a Glance Commentary

Scientific Knowledge on the Subject: Despite the evidence of the benefits of pulmonary rehabilitation, many patients with chronic obstructive pulmonary disease (COPD) do not access or complete pulmonary rehabilitation, and long-term maintenance of exercise is difficult. Efforts to reduce hospital readmissions in COPD must be made to decrease the societal burden and improve patient outcomes. Long-term telerehabilitation and unsupervised training at home represent promising alternatives to traditional pulmonary rehabilitation and maintenance strategies.

What This Study Adds to the Field: Long-term unsupervised exercise training at home is an effective treatment strategy that can reduce hospital readmissions for patients with COPD, similar to the effect of a supervised telerehabilitation strategy. These interventions have the potential to improve uptake and access to pulmonary rehabilitation and support long-term exercise maintenance strategies. Unsupervised training at home could be offered to patients with COPD who do not access pulmonary rehabilitation or maintenance programs. Telerehabilitation may be useful for patients who are unsuitable for unsupervised training and need a closer follow-up.

Chronic obstructive pulmonary disease (COPD) imposes a substantial burden on patients, healthcare providers, and society (1, 2). Patients with COPD experience frequent exacerbations, which, in the most severe cases, may result in hospital admissions (3, 4). COPD exacerbations are commonly characterized by acute worsening of symptoms, including dyspnea, cough, sputum production, and sputum purulence (5). Patients with COPD also experience impaired exercise capacity, difficulty with activities of daily living, poor quality of life (6), anxiety, and depression (7). Chronic respiratory diseases contribute 7% to the global burden of disease, with COPD accounting for 56% of the costs of chronic respiratory diseases (8). Hospitalizations alone account for up to 70% of all COPD-related costs (9). Moreover, discharge from the hospital after a severe exacerbation is associated with an increased risk of readmission (10). Efforts to reduce recurrent exacerbations and hospitalizations must be made to improve patient outcomes and reduce societal burden (11).

Pulmonary rehabilitation (PR) is widely recognized as a core component of the management of COPD (12, 13). PR aims to improve the physiological and psychological condition of participants through exercise training accompanied by education and behavior change (14). PR leads to clinically important gains in exercise and functional capacity, dyspnea, health status, and health-related quality of life (12–14). PR has also been proven to be effective in reducing healthcare usage (15).

Despite the evidence of the benefits of PR for patients with COPD, there are several barriers to PR participation, including patient travel (16) and a severe shortage of programs because of a lack of knowledge, underfunding, and poor institutional support (17). The majority of PR programs are located in urban areas, thus limiting access for rural patients (18). Referral rates to PR after an exacerbation are low (17). Only 1.5% of patients are reported to initiate PR within 90 days of discharge (15), and fewer than 10% of patients complete PR programs (19). Sustaining long-term adherence to exercise training is difficult because of disease progression with intervening exacerbations, variation in day-to-day conditions, and transportation problems (13). In the absence of any maintenance program, the gains from PR typically wane over 6–12 months (14, 20). Maintenance rehabilitation consists of ongoing supervised exercise at a lower frequency than PR programs (21). However, the optimum maintenance intervention and supervision frequency are still unclear, and interventions have had varying impacts (20, 22).

Telerehabilitation, defined as the use of information and communication technologies to provide rehabilitation services remotely to people in their homes (23), has the potential to improve uptake and access to PR (24) and support long-term maintenance strategies (13, 25). A recent systematic review suggests that telerehabilitation achieves outcomes similar to those of traditional center-based PR (26). Patients with COPD have a lower likelihood of acute exacerbations and hospitalizations when undertaking maintenance telerehabilitation compared with no rehabilitation (27, 28). The duration of intervention for studies of maintenance telerehabilitation ranged from 4 months (28) to 12 months (27, 29). Few studies followed people up after the intervention was finished, and no intervention lasted longer than 1 year, making it difficult to draw conclusions about the long-term effectiveness. Unsupervised home-based structured exercise represents another promising strategy to deliver maintenance rehabilitation with minimal resources (24). Although unsupervised exercise interventions have been proven to be effective at improving health-related quality of life and exercise capacity in the medium term (24, 30), there is insufficient evidence for its provision to reduce hospital admissions and improve other outcomes, as well as long-term maintenance of benefits.

The aim of the present study was to compare the long-term telerehabilitation of patients with COPD or unsupervised exercise training at home with standard care with respect to the combined number of hospitalizations and emergency department (ED) presentations occurring during 2 years as well as other secondary outcomes (31).

Methods

Study Design

The iTrain study was an international multicenter randomized controlled trial (RCT) conducted in three countries (Norway, Australia, and Denmark), in which 120 participants with COPD were randomly assigned to three groups (telerehabilitation, unsupervised training, or control) in a 1:1:1 ratio. Each participant was followed up for 2 years since the day of inclusion in the study, and the interventions were delivered for the entire period of follow-up. Web-based computerized block randomization was performed, with randomization stratified by center and disease severity (FEV_1 under 50% vs. FEV_1 of at least 50%). The RCT received approval from the Regional Committee for Medical and Health Research Ethics in Norway (2014/676/REK nord), the Alfred Hospital Human Research Ethics Committee (289/14), and the North

Denmark Region Committee on Health Research Ethics (N-20140038). The complete study protocol, including full details of the interventions, has been previously published (31) and was prospectively registered (ClinicalTrials.gov: NCT02258646).

Eligibility Criteria

Eligible patients had: *1*) a diagnosis of COPD on the basis of an FEV_1/FVC ratio under 0.70; *2*) moderate, severe, or very severe airflow limitation, with FEV_1% predicted under 80%; *3*) at least one COPD-related hospitalization or COPD-related ED presentation in the 12 months before enrolment; *4*) age between 40 and 80 years; and *5*) capacity to provide signed written informed consent.

Participants were excluded if they had at least one of the following criteria: *1*) attendance at a rehabilitation program in the 6 months before enrolment; *2*) participation in another clinical study that might have had an impact on the primary outcome; *3*) physically incapable of performing the study procedures; *4*) presence of comorbidities which might prevent participants from safely exercising at home; and *5*) home environment not suitable for installation and use of rehabilitation and monitoring equipment (e.g., limited space for the treadmill and internet connection not good enough).

Participants were recruited by hospital facilities with a pulmonary medicine department treating patients with COPD. Supervision in the telerehabilitation intervention was provided by physiotherapists specialized in PR.

Interventions

Participants in both intervention groups underwent a supervised in-person training session on the treadmill with an experienced physiotherapist to ensure safety.

Participants in the telerehabilitation group were offered an integrated intervention consisting of exercise training at home, telemonitoring, and self-management. Each participant received an individualized training program of regular exercise on a treadmill and strength training exercises according to guidelines (14). Depending on the participant's exercise tolerance and the clinician's preference, a program of continuous training (moderate intensity, Borg scale [32] ratings up to four) or interval training (1–4 minute intervals, high intensity, Borg scale ratings up to six) was assigned, with sessions lasting for at least 30 minutes (*see* the online supplement). The frequency prescribed was 3–5 times/wk for continuous training and 3 times/wk for interval training (31). Progression was made according to a standardized protocol (*see* the online supplement). The equipment included a treadmill, a pulse oximeter, a tablet computer, and a holder for the tablet computer (Figure E1 in the online supplement). The equipment was provided and delivered by the research team. A customized website was used by participants for self-management. They could access the individual training program (Figure E2), fill in a daily diary (Figure E3) and a training diary (Figure E4), review historical data, exchange electronic messages, schedule videoconferencing sessions, and facilitate individual goal setting and goal attainment. The information sent through the website was monitored and interpreted weekly by a physiotherapist. Participants had scheduled exercise sessions supervised by a physiotherapist via videoconferencing, which followed a standardized protocol (*see* the online supplement). After each supervised session, the physiotherapist could adjust the program if necessary and was also informed if a patient had been hospitalized. Telerehabilitation was delivered with two levels of supervision: *1*) an intensive 8-week program (one videoconferencing session per week in the first 8 weeks, plus once-weekly for 1 month after any readmission, supplemented by unsupervised sessions); and *2*) a lower-intensity maintenance program (one videoconferencing session per month commencing after the initial 8-week intensive program, supplemented by unsupervised sessions). Additional contacts with the physiotherapist could be arranged if necessary.

Participants in the unsupervised training group were provided with a treadmill only to perform unsupervised exercise at home. They also received an exercise booklet, a paper exercise diary to record their training sessions, and an individualized training program (*see* the online supplement) as prescribed to the participants in the telerehabilitation group, but without regular review or progression of the program. Participants were advised not to exercise if they felt unwell (more coughing, wheezing, breathless, or having more sputum than usual), had less energy, or had a loss of appetite. Participants in the control group were offered standard care.

Study Procedures

Assessments were performed by appropriately trained study personnel blinded to group allocation. At baseline, participants were asked to perform spirometry, the 6-minute-walk test (33), and complete the study questionnaires. Measures were repeated at 6-month, 1-year, and 2-year follow-ups. Data on hospitalizations and ED presentations were collected from health records or registries after the end of the trial. Data on deaths, transplantations, dropouts, and adverse events were collected systematically during the trial and at each follow-up. Participants also received information on self-management of exacerbations (*see* the online supplement).

Outcome Measures

The primary outcome was the combined number of hospitalizations and ED presentations occurring in the three groups during the entire 2-year duration of the trial. These data were collected from health records (Australia) and registries (Denmark and Norway) at the end of the trial. Secondary outcomes included: hospitalizations and ED presentations (analyzed separately), time free from the first event, functional exercise capacity measured with the 6-minute-walk distance (6MWD) (33), dyspnea measured with the mMRC (modified Medical Research Council) dyspnea scale, health status measured with the COPD assessment test (CAT) (34), health-related quality of life measured with the EQ-5D (EuroQol 5 dimensions) questionnaire (35), anxiety and depression measured with HADS (Hospital Anxiety and Depression Scale) (36), self-efficacy measured with GSES (Generalized Self-Efficacy Scale) (37), and subjective impression of overall change measured with PGIC (Patient Global Impression of Change) scale (38). Results on the remaining secondary outcomes, including degrees of physical activity, cost-effectiveness, and experiences in telerehabilitation, will be reported separately.

Statistical Analysis

The sample size requirements were intended to provide adequate power for the analysis of the primary outcome. From studies with participants with similar characteristics, we estimated an incidence density used as a null hypothesis of two events per person-year and a 40% relative reduction in the primary outcome (31). Allowing for a 20% dropout, we calculated that a sample size of 40 participants per group would allow a power

of 95% to detect an incidence rate ratio of 0.60, with a type-I error (α) of 0.05.

Descriptive statistics at baseline are reported as mean and standard deviation for continuous variables and count and percentage for categorical variables. An intention-to-treat analysis was performed on all randomized subjects. The primary outcome and related secondary outcomes were measured with the incidence density, defined as the number of events in a group divided by the total person-time accumulated during the study in that group. Differences between study groups were tested by the comparison of incidence rates. A two-sided test and a significance level of $\alpha = 0.05$ were used. All events from the day after randomization to participant exit or death were included. Linear mixed models were used to measure changes from baseline to all assessment time points in 6MWD, mMRC scale, CAT score, EQ-5D scores, and GSES. The minimal important difference (MID) used for the 6MWD was 30 meters (33). Baseline variables with differences among groups were also added as covariates to the comparison of incidence rates and mixed models. Kaplan-Meier curves and the log-rank test were used to determine if there were differences in the survival distribution of the time free from the first event for the telerehabilitation, unsupervised training, and control groups. The Wald test computed using binary logistic regression was used for the HADS (score less than eight = no case; a score of at least eight = case). The chi-square test was used for the PGIC. Differences in mortality rates between study groups were tested by the comparison of incidence rates. A *P* value less than 0.05 was considered significant for all tests. Statistical analyses were performed using IBM SPSS Statistics (Version 25; IBM Corp).

Results

Study Conduct and Population

Between October 2014 and December 2016, 502 individuals were assessed for eligibility, and 120 (24%) were recruited and randomized (Figure 1). At the end of the study, data were available for the primary outcome and related secondary outcomes for 115 (96%) participants, comprising 37 (93%) in the telerehabilitation group, 40 (100%) in the unsupervised training group, and 38 (95%) in the control group. Details of the number of participants with complete data for each outcome at all assessment time points are reported in Table E1.

Demographic and clinical characteristics of the study participants were similar between study groups at baseline (Table 1). There were slightly more participants on long-term oxygen therapy (LTOT) in the telerehabilitation group (30%) than in the unsupervised training group (22.5%) and control group (15%), and more current smokers in the control group (37.5%) than in the telerehabilitation group (20%) and unsupervised training group (27.5%).

No treadmill-related injuries were reported during the study period (Table E2). Adverse events included problems with the study equipment, most frequently the incline function on the treadmill, and medical problems that prevented participants from exercising (e.g., cancer, surgery, and arthritis).

Hospitalizations and ED Presentations

For the assessment of the incidence rate of hospitalizations and ED presentations, there were 71.05 person-years in the telerehabilitation group, 76.93 person-years in the unsupervised training group, and 74.59 person-years in the control group (Table 2). By the end of the study, a total of 312 events (combined number of hospitalizations and ED presentations) occurred in the study population. Specifically, 84 events were reported in the telerehabilitation group, 88 in the unsupervised training group, and 140 in the control group. The incidence rate for the primary outcome was lower in both the telerehabilitation group (1.18 events per person-year; 95% confidence interval [CI], 0.94–1.46; $P = 0.0007$) and the unsupervised training group (1.14 events per person-year; 95% CI, 0.92–1.41; $P = 0.0002$) compared with the control group (1.88 events per person-year; 95% CI, 1.58–2.21). Similarly, the difference in the incidence rate for hospitalizations and ED presentations analyzed separately was significantly lower in both telerehabilitation and unsupervised training groups compared with the control group (Table 2). Adding smoking status and LTOT as covariates to the model did not change the results. There was a larger proportion of participants without hospital presentations (consisting of hospitalizations and ED presentations) occurring during the study period in the telerehabilitation (40.6%) and unsupervised training group (45.0%) compared with the control group (28.9%) (Table 3 and Table E3). In addition, the control group has a higher proportion of participants with recurrent (at least two) hospital presentations (55.3%) compared with telerehabilitation (35.1%) and unsupervised training group (35.0%).

The survival distributions of the time-to-first hospitalization or ED presentation in the three groups were not significantly different [$\chi^2(2) = 2.345$; $P = 0.310$] (Figure 2A). Similar results were obtained for the time-to-first hospitalization ($\chi^2(2) = 2.946$; $P = 0.229$) (Figure 2B) and time-to-first ED presentation [$\chi^2(2) = 2.545$; $P = 0.280$] (Figure 2C).

Secondary Outcomes

The telerehabilitation group experienced statistically significant changes at 6 months in CAT score ($P = 0.037$) and mMRC scale ($P = 0.037$) compared with the control group (Table 4). The gains in health status and dyspnea were not maintained after 2 years. On average, participants had improvements in 6MWD that exceeded the MID at all time points. In contrast, participants in the control group experienced a decline in the 6MWD. A considerably higher proportion of participants in the telerehabilitation group (53.1%) experienced a significant, favorable change in the PGIC at 6 months compared with the unsupervised training group (24.2%) and the control group (13.3%, $P = 0.001$). No differences between groups were detected for self-efficacy, anxiety, and depression. Adding smoking status and LTOT as covariates to the model did not change the results.

The unsupervised training group also experienced improved CAT score ($P = 0.002$) and mMRC scale ($P = 0.027$) at 6 months compared with the control group (Table 4). Degrees of dyspnea were maintained for 2 years, whereas the gains in health status were maintained for 1 year. Participants had improvements in 6MWD that exceeded the MID for the entire 2-year period. However, there was only a statistically significant difference between the unsupervised training group and the control group at 2 years. Participants in the control group experienced an earlier decrease in their health-related quality of life at 6 months (EQ-5D utility index) compared with the unsupervised training group ($P = 0.036$), with similar findings for EQ-VAS at 2 years ($P = 0.040$). No differences between groups were detected for self-efficacy, anxiety, and depression.

The mortality rate at the end of the trial was 7.5% (3/40 participants), 10% (4/40 participants), and 5% (2/40 participants) in the telerehabilitation, unsupervised training, and control groups, respectively, with no difference between groups.

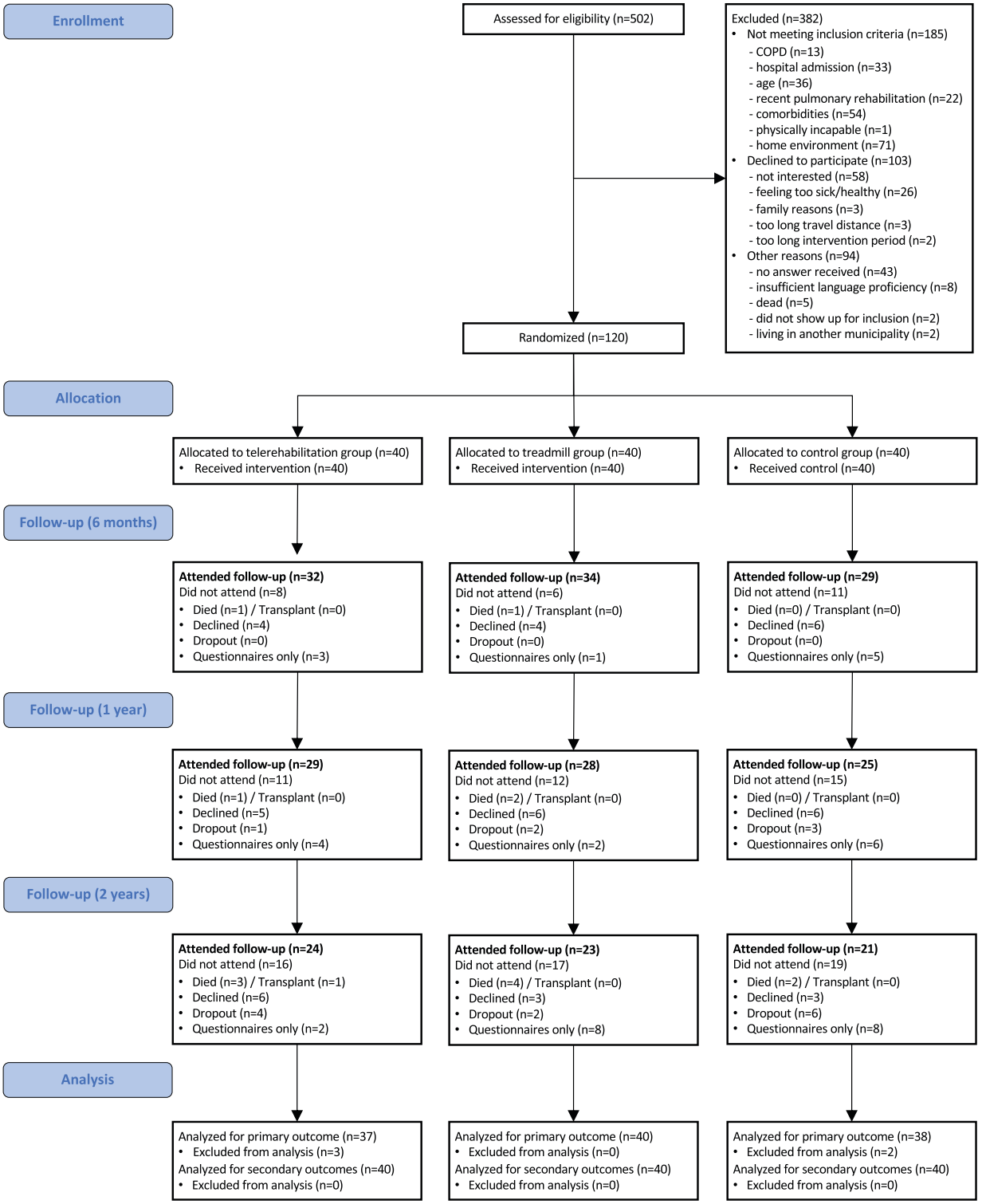

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram for study flow. COPD = chronic obstructive pulmonary disease.

Discussion

To our knowledge, this was the first trial delivering a 2-year telerehabilitation intervention to patients with COPD. The iTrain study demonstrated that both long-term telerehabilitation and unsupervised training at home were successful in reducing the number of hospital readmissions for patients with COPD. Telerehabilitation and unsupervised training groups experienced better health status for 1 year. Intervention

Table 1. Baseline Participant Characteristics

	Telerehabilitation	Unsupervised Training	Control
Participants, *n*	40	40	40
Age (yr), mean ± SD	64.9 ± 7.1	64.0 ± 7.7	63.5 ± 8.0
Male, *n* (%)	23 (57.5)	20 (50)	23 (57.5)
Stratification			
FEV_1 (% predicted) < 50%, *n* (%)	28 (70)	28 (70)	28 (70)
FEV_1 (% predicted) ⩾ 50%, *n* (%)	12 (30)	12 (30)	12 (30)
COPD diagnosis (yr), mean ± SD	8 ± 7	10 ± 8	7 ± 7
LTOT, *n* (%)	12 (30)	9 (22.5)	6 (15)
mMRC scale, *n* (%)			
0	0 (0)	2 (5)	4 (10)
1	14 (35)	12 (30)	12 (30)
2	13 (32.5)	13 (32.5)	10 (25)
3	10 (25)	12 (30)	12 (30)
4	3 (7.5)	1 (2.5)	2 (5)
BODE index (points), *n* (%)			
0–2	11 (27.5)	11 (27.5)	11 (27.5)
3–4	13 (32.5)	17 (42.5)	16 (40)
5–6	12 (30)	9 (22.5)	7 (17.5)
7–10	4 (10)	3 (7.5)	6 (15)
Smoking history			
Current smoker, *n* (%)	8 (20)	11 (27.5)	15 (37.5)
Ex-smoker, *n* (%)	31 (77.5)	28 (70)	24 (60)
Never smoked, *n* (%)	1 (2.5)	1 (2.5)	1 (2.5)
Pack-year, mean ± SD	31 ± 17	38 ± 21	35 ± 16
FEV_1 (L), mean ± SD	1.18 ± 0.61	1.21 ± 0.52	1.14 ± 0.52
FEV_1 (% predicted), mean ± SD	40.4 ± 16.5	44.6 ± 17.1	40.3 ± 16.1
FVC (L), mean ± SD	2.48 ± 0.89	2.60 ± 0.75	2.63 ± 0.91
FVC (% predicted), mean ± SD	68.9 ± 19.1	75.4 ± 18.2	74.4 ± 23.7
FEV_1/FVC (%), mean ± SD	50.1 ± 14.8	49.5 ± 12.8	46.7 ± 14.9
Comorbidities, *n*	2.9 ± 1.6	2.7 ± 1.7	2.6 ± 2.1
BMI (kg/m^2), mean ± SD	27 ± 6	28 ± 7	26 ± 6
Living arrangements, *n* (%)			
Alone	19 (47.5)	20 (50)	17 (42.5)
With spouse	15 (37.5)	16 (40)	15 (37.5)
With family	5 (12.5)	4 (10)	7 (17.5)
With friends	1 (2.5)	0 (0)	1 (2.5)
Supported accommodation	0 (0)	0 (0)	0 (0)
Social status			
Working, *n* (%)	5 (12.5)	8 (20)	11 (27.5)
Retired, *n* (%)	35 (87.5)	32 (80)	29 (72.5)
Distance to outpatient clinic (km), mean ± SD	37 ± 67	37 ± 59	21 ± 35
Digital competence, *n* (%)			
Daily user or nearly every day	25 (62.5)	26 (65)	28 (70)
At least once a week, but not every day	8 (20)	9 (22.5)	5 (12.5)
No experience	7 (17.5)	5 (12.5)	7 (17.5)

Definition of abbreviations: BMI = body mass index; BODE = body mass index, airflow obstruction, dyspnea, and exercise; COPD = chronic obstructive pulmonary disease; LTOT = long-term oxygen therapy; mMRC = modified Medical Research Council.

participants reached and maintained clinically significant improvements in exercise capacity.

A systematic review suggested a lower likelihood of acute exacerbations and hospitalizations for maintenance telerehabilitation compared with no rehabilitation (26). The evidence, however, was limited to two studies (27, 28), neither of which had an intervention lasting longer than 12 months. The iTrain study was designed assuming an incidence rate of two events per person-year and expecting a 40% relative reduction in the primary outcome. Results showed a 37.3% reduction (−0.70 events per person-year) in the telerehabilitation group and a 39.4% reduction (−0.74 events per person-year) in the unsupervised training group compared with the control group (1.88 events per person-year). There was a larger proportion of participants without hospital presentations in the intervention groups. In addition, the control group had a higher proportion of participants with recurrent (at least two) hospital presentations. Despite no significant difference in the time-to-first event, both interventions appear to be better than the control. Moreover, although incidence rates were very similar among intervention groups, participants in the telerehabilitation group presented to the ED sooner than those in the unsupervised training group (Figure 2C). One possible reason is that they were supervised regularly by a health professional, suggesting that telerehabilitation might allow earlier detection of problems.

It was expected that participants in the telerehabilitation group would gain additional benefits because of the remote supervision by a physiotherapist (39). The findings from this trial indicate that both interventions seem to work well and produce beneficial results compared with standard care. These results might be explained by the characteristics and preferences of the participants. Positive attitudes toward supervised and unsupervised maintenance programs have been reported (40). However, although some patients need ongoing support for exercise participation, others can maintain the gains of PR regardless of intervention (41). As such, unsupervised training at home is a simple intervention using minimal resources that could be offered to patients with COPD who do not access PR or maintenance programs. Telerehabilitation is likely to be more expensive, but it may be useful for patients who are unsuitable for unsupervised training because of factors such as disease severity, anxiety, depression, poor social support, or low motivation (13). Remote supervision by a physiotherapist can provide those individuals additional benefits, as confirmed by the higher proportion of participants in the telerehabilitation group who experienced a favorable change in the PGIC. These benefits can, in turn, result in better adherence to exercise. Identifying these patient groups is an important challenge for both clinicians and researchers (41). Future research should focus on adapting PR and maintenance programs to the individual needs of the participants to maximize the benefits while making good use of healthcare resources (42).

A variety of strategies have been used to sustain the clinical gains achieved in traditional center-based PR (14, 20), but outcomes have been inconsistent (41). Maintenance models in COPD are heterogeneous in terms of supervision

Table 2. Hospitalizations and Emergency Department Presentations

Outcome Measure	Telerehabilitation	Unsupervised Training	Control
Hospitalizations and ED presentations* (combined), *n*	84	88	140
Person-years, *n*	71.05	76.93	74.59
Incidence rate (per person-year) (95% CI)	1.18 (0.94–1.46)	1.14 (0.92–1.41)	1.88 (1.58–2.21)
Incidence rate ratio (95% CI)	0.63 (0.48–0.83)	0.61 (0.46–0.79)	1 [reference]
P value†	0.0008	0.0002	—
Hospitalizations, *n*	68	74	126
Person-years, *n*	71.05	76.93	74.59
Incidence rate (per person-year) (95% CI)	0.96 (0.74–1.21)	0.96 (0.76–1.21)	1.69 (1.41–2.01)
Incidence rate ratio (95% CI)	0.57 (0.42–0.76)	0.57 (0.43–0.76)	1 [reference]
P value†	0.0002	0.0001	—
ED presentations,‡ *n*	71	75	118
Person-years, *n*	71.05	76.93	74.59
Incidence rate (per person-year) (95% CI)	1.00 (0.78–1.26)	0.97 (0.77–1.22)	1.58 (1.31–1.89)
Incidence rate ratio (95% CI)	0.63 (0.47–0.85)	0.61 (0.46–0.82)	1 [reference]
P value†	0.0022	0.0009	—

Definition of abbreviations: CI = confidence interval; ED = emergency department.
*Data include only ED presentations not followed by hospitalization.
†*P* value for test of equality versus control group.
‡Data include all ED presentations, including those followed by hospitalization.

(supervised or unsupervised), frequency (once weekly to monthly or less frequent supervision) (21), modality (in-person or remote supervision), (22) and self-management education (42). Supervised maintenance exercise can be effective in improving CAT scores at 6–12 months after PR (22). The evidence for maintaining exercise capacity and quality of life is weak (22, 42). Supervised maintenance programs of monthly or less frequent supervision seem to be insufficient to maintain the gains of PR (21). In a multicenter RCT, a weekly maintenance program was proven modestly effective in improving 6MWD and health status for 2 years after completing PR (43). Unsupervised home-based structured exercise can also help maintain 6MWD and quality of life (24). Giving brief advice to continue exercising may have similar benefits to light-touch strategies or more intensive supervised programs, at least in some patients (41). Maintenance telerehabilitation may achieve improvements in CAT score, mMRC scale, as well as exercise capacity compared with no rehabilitation (26). In an earlier study, the 6MWD was better maintained in subjects attending a 12-month maintenance program, but it returned to prerehabilitation levels by 24 months (44). The iTrain study demonstrated that long-term telerehabilitation and unsupervised training at home lead to gains in CAT score and mMRC scale at 6 months, but these were not maintained after 2 years. Moreover, participants in both intervention groups achieved and maintained clinically significant improvements in 6MWD over 2 years. In contrast, participants in the control group experienced a decline, normally attributable to low adherence to exercise, disease progression, and exacerbations (45). There were no changes in the other outcomes. CAT score and 6MWD are more responsive to PR than other patient-centered outcomes (13), and this can explain the results in the two intervention groups. The study, however, was not powered for the secondary outcomes. The lack of changes in HADS might also be explained by the low number of participants with anxiety or depression at baseline. The PRAISE (Pulmonary Rehabilitation Adapted Index of Self-Efficacy) might have been more suitable to measure changes in self-efficacy because of five additional pulmonary rehabilitation-specific questions (46). However, validated translations in Norwegian and Danish were not available.

Table 3. Distribution of Patients by Number of Hospitalizations and Emergency Department Presentations Occurred in the Study Period

Hospitalizations and ED Presentations	Telerehabilitation (%)	Unsupervised Training (%)	Control (%)
0	40.6	45.0	28.9
1	24.3	20.0	15.8
⩾2 (recurrent hospital presentations)	35.1	35.0	55.3
2–5	21.6	22.5	36.9
6–10	10.8	10	7.9
⩾10	2.7	2.5	10.5

Definition of abbreviation: ED = emergency department.

The results from traditional maintenance programs in COPD are applicable only to individuals who attend and complete PR (41). However, because of very low rates of referral, attendance, and completion, the majority of patients with COPD do not access PR or maintenance programs (15, 17, 19). The iTrain study addressed the unmet needs of those patients by offering easily accessible home-based models. Earlier RCTs showed that home-based primary PR models (8 wk) delivered with minimal resources and little supervision (weekly telephone calls) could produce short-term clinical improvements similar to those of center-based PR (24, 47). The interventions tested in the iTrain study, which combined components of primary and maintenance rehabilitation, not only can reduce the number of hospital readmissions and lead to improvements in health status

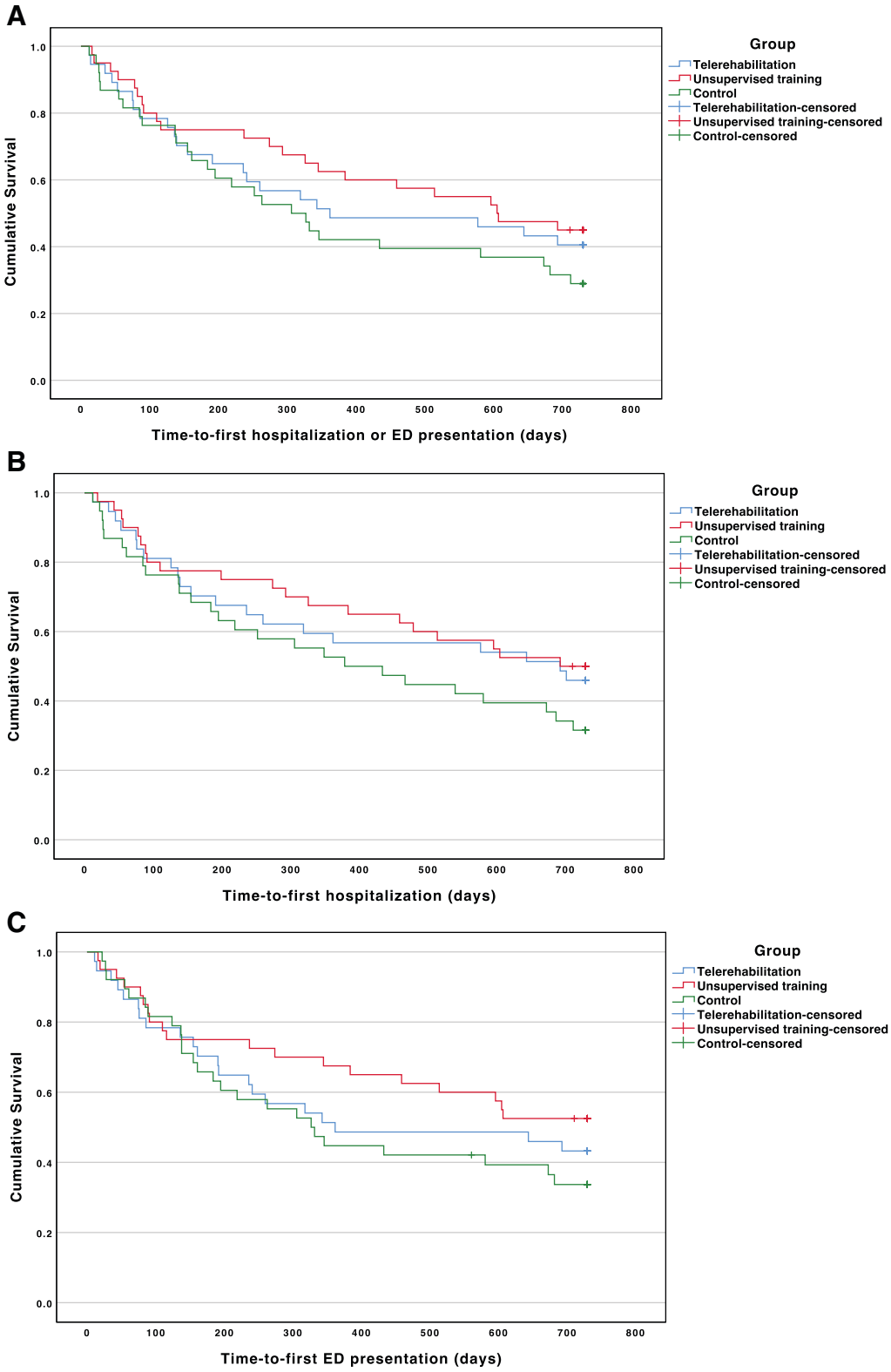

Figure 2. Time-to-first event: (*A*) hospitalization or emergency department presentation, (*B*) hospitalization, and (*C*) emergency department presentation. ED = emergency department.

Table 4. Secondary Outcomes

Outcome Measure	Telerehabilitation		Unsupervised Training		Control
	Mean ± SD or *n* (%)	*P* Value	Mean ± SD or *n* (%)	*P* Value	Mean ± SD or *n* (%)
6MWD (m)	—	0.380*	—	0.065*	—
Baseline	367 ± 125	—	367 ± 111	—	384 ± 111
6 mo	420 ± 126	0.126	406 ± 114	0.332	389 ± 101
1 yr	415 ± 146	0.209	431 ± 117	0.057	374 ± 116
2 yr	400 ± 142	0.235	460 ± 126	**0.009**	357 ± 102
CAT (total score)	—	0.189*	—	**0.023***	—
Baseline	19.6 ± 6.2	—	20.1 ± 6.3	—	19.7 ± 8.1
6 mo	18.2 ± 6.9	**0.037**	15.2 ± 7.6	**0.002**	20.8 ± 7.2
1 yr	18.7 ± 6.9	0.086	17.5 ± 7.6	**0.047**	20.8 ± 7.0
2 yr	19.0 ± 7.1	0.373	18.4 ± 8.6	0.272	19.8 ± 6.8
mMRC (score)	—	0.131*	—	**0.033***	—
Baseline	2.1 ± 1.0	—	1.9 ± 1.0	—	1.9 ± 1.1
6 mo	1.7 ± 1.2	**0.037**	1.5 ± 1.0	**0.027**	2.2 ± 0.8
1 yr	1.8 ± 1.2	0.089	1.5 ± 1.0	**0.012**	2.2 ± 1.1
2 yr	1.9 ± 1.2	0.105	1.5 ± 1.1	**0.008**	2.3 ± 1.1
EQ-5D (utility index)	—	0.280*	—	0.119*	—
Baseline	0.739 ± 0.110	—	0.744 ± 0.155	—	0.759 ± 0.180
6 mo	0.728 ± 0.154	0.089	0.768 ± 0.184	**0.036**	0.685 ± 0.190
1 yr	0.671 ± 0.215	0.903	0.747 ± 0.171	0.373	0.674 ± 0.236
2 yr	0.725 ± 0.153	0.259	0.686 ± 0.280	0.740	0.673 ± 0.228
EQ-5D (EQ-VAS)	—	0.654*	—	0.208*	—
Baseline	51.9 ± 21.0	—	52.0 ± 17.7	—	52.4 ± 19.6
6 mo	58.7 ± 16.4	0.299	55.4 ± 21.6	0.735	55.1 ± 16.8
1 yr	56.3 ± 18.9	0.653	58.0 ± 19.1	0.381	53.7 ± 19.5
2 yr	54.9 ± 21.4	0.295	58.4 ± 21.2	**0.040**	50.0 ± 20.8
GSES (total score)	—	0.70*	—	0.160*	—
Baseline	30.7 ± 5.4	—	31.4 ± 5.3	—	32.0 ± 5.8
6 mo	30.9 ± 5.4	0.165	31.1 ± 4.6	0.263	30.3 ± 4.7
1 yr	30.5 ± 5.5	0.462	31.5 ± 4.7	0.215	30.3 ± 7.8
2 yr	30.4 ± 5.6	0.311	30.6 ± 5.4	0.576	32.7 ± 5.6
HADS, participants free from anxiety					
Baseline	30/40 (75.0)	—	31/40 (77.5)	—	28/40 (70.0)
6 mo	26/35 (74.3)	0.599	29/35 (82.9)	0.970	25/32 (78.1)
1 yr	22/32 (68.8)	0.829	24/30 (80.0)	0.351	18/30 (60.0)
2 yr	20/27 (74.1)	0.318	23/31 (74.2)	0.290	25/30 (83.3)
HADS, participants free from depression					
Baseline	35/40 (87.5)	—	33/40 (82.5)	—	33/40 (82.5)
6 mo	31/35 (88.6)	0.110	27/35 (77.1)	0.362	22/32 (68.8)
1 yr	23/32 (71.9)	0.208	24/30 (80.0)	0.945	25/30 (83.3)
2 yr	22/27 (81.5)	0.521	22/31 (71.0)	0.201	26/30 (86.7)
PGIC, participants with a score at 6 mo					
PGIC < 5	15 (46.9)	—	25 (75.8)	—	26 (86.7)
PGIC ⩾ 5	17 (53.1)	**0.001**	8 (24.2)	0.271	4 (13.3)

Definition of abbreviations: 6MWD = 6-minute-walk distance; CAT = chronic obstructive pulmonary disease assessment test; EQ-5D = EuroQol 5 dimensions; EQ-VAS = EuroQol visual analog scale; GSES = general self-efficacy scale; HADS = hospital anxiety and depression scale; mMRC = modified Medical Research Council; PGIC = patient global impression of change.

Differences between groups for change over time were analyzed with linear mixed models for 6MWD, mMRC, CAT, EQ-5D utility score, EQ-VAS, and GSES.

The Wald test computed by means of binary logistic regression was used for the HADS. The chi-square test was used for the PGIC. Participants free from anxiety/depression: participants classified as normal (score < 8).

Bold values are statistically significant.

**P* value for the overall group by time interaction. *P* values at follow-ups represent a comparison of the intervention and control group at each time point. The baseline time point and control group were used as references.

and exercise capacity but also result in better maintenance of the benefits over the long term.

Study Strengths and Limitations

We successfully conducted a complex RCT with participants recruited from three countries. The interventions were innovative models combining elements of primary and maintenance rehabilitation, and the findings are novel. Although previous studies lasted up to 1 year, making it difficult to draw conclusions about the long-term effectiveness, our study had a unique long-term follow-up of 2 years. The RCT used robust methods, including intention-to-treat analysis, blinding of assessors, sample size requirements, and adherence to CONSORT (Consolidated Standards of Reporting Trials) guidelines. The primary outcome was relevant to both patients and healthcare systems.

Recruitment lasted for 2 years. The technical setup of the interventions was challenging. However, we successfully offered a common website in three languages and the same or very similar equipment. The applicability of our rehabilitation approaches in different health systems and funding models or groups with lower digital literacy remains to be established. Although the presence of at least one hospitalization or ED admission in the previous 12 months was an inclusion criterion, we did not record the time point at which these occurred. Rehabilitation interventions may have larger effects in recently hospitalized patients, so this could have affected the study outcomes. The study was not powered for secondary outcomes. It was not possible to compare the benefits of the interventions with traditional center-based PR or maintenance programs on the basis of the study design, and it was not possible to compare intervention fidelity across groups, as few participants in the unsupervised training group returned their paper-based training diaries. Despite randomization, the number of current smokers in the control group was higher than in the intervention groups, and the number of LTOT in the control group was lower. Controlling for these factors in the analysis of secondary outcomes did not change the pattern of findings, but we cannot exclude an effect of this imbalance in demographic characteristics. Although traditional PR programs have been conducted in groups of 8 to 12 participants (48), our telerehabilitation intervention consisted of individual sessions. Peer support in the form of group-based online exercise sessions (49, 50), both supervised and unsupervised, has the potential to increase motivation, self-efficacy (39), and the ability to exercise in the long term (42).

Conclusions

Long-term telerehabilitation and unsupervised exercise training at home were both successful in reducing the number of hospitalizations and ED presentations for patients with COPD. Telerehabilitation and unsupervised training groups experienced better health status for 1 year. Intervention participants reached and maintained clinically significant improvements in exercise capacity. The delivery of long-term telerehabilitation or unsupervised exercise training at home has the potential to broaden the availability of PR programs and maintenance strategies, especially for those living in remote areas and with no access to center-based exercise programs. ■

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