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The effect of Chronic Care Model-based follow-up on self-efficacy and patient-reported outcomes in COPD patients: a randomized controlled study

Yasemin Sazak^{1*} and Nermin Olgun²

Abstract

Aim This study evaluated the effects of Chronic Care Model-based follow-up on self-efficacy and patient-reported outcomes in COPD patients.

Methods This study was a randomized controlled trial conducted at the Chest Diseases Outpatient Clinic between January 2022 and July 2022. Four components of the Chronic Care Model were used in the study. Patients in the intervention group were given training, and phone calls were made every two weeks. Short informative messages were sent once a week, and the patients were followed up for three months. No intervention was made in the control group.

Results The study was completed with 31 interventions and 30 control patients. The intervention was determined to increase patients' self-efficacy. There were also positive effects on patient-reported outcomes. Patients' satisfaction with care was found to be at a high level. It was found that the walking distance of the patients increased.

Conclusions Our study revealed that using Chronic Care Model-based follow-up in practice may benefit patients. More studies involving the application of the Chronic Care Model in COPD patients are needed to support our research results.

Clinical trial registration Before starting the study, ClinicalTrials.gov was recorded (NCT05029557, Registration Date: August 26, 2021, <https://clinicaltrials.gov/>).

Keywords COPD, Self-efficacy, Nurse, Patient education, Integrated care, Chronic care model

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Introduction

Although Chronic Obstructive Pulmonary Disease (COPD) is a preventable and treatable disease, it remains a major public health problem in developed and developing countries due to its high mortality and morbidity [1]. The application of nonpharmacologic and pharmacologic treatments for treating COPD is very important for controlling symptoms. Patient education, which is one of the nonpharmacologic treatments, has an important place in COPD management. Personalized education and self-management interventions should be applied by considering the patient's needs, preferences, and goals [1]. Self-management education supports individuals to change their health behaviors by increasing self-efficacy and enables them to improve their health status and quality of life and control the disease [2, 3]. A multidisciplinary team approach is necessary to manage and treat COPD successfully. As professional members of this team, nurses have an important role in implementing pharmacologic and nonpharmacologic treatments, disease management, and education [4].

Since COPD is a complex disease with comorbidities and various systemic effects, it requires integrated approaches for optimal management. The American Thoracic Society (ATS) defines integrated care as providing quality, interdisciplinary, patient-centered care by addressing the disease, comorbidities, and systemic symptoms together and maintaining the independence and life of the individual in the community. With this approach, there is a transition from acute care to the Chronic Care Model (CCM) in managing disease. For this reason, ATS stated that integrated care and chronic care models are overlapping and similar concepts. CCM is an important template for providing integrated care [5, 6]. The key to this model is the interaction between the healthcare team and the patient [7, 8]. The model consists of six basic components. These components are decision support, health care organization, self-management support, clinical information systems, community resources policies, and delivery system design [9]. Studies on COPD patients using CCM have shown a reduction in hospitalizations, emergency room visits, and frequency of exacerbations, and an increase in quality of life, self-efficacy, and satisfaction with care [10–14].

Implementing a single component of the CCM is insufficient to achieve the desired goals, and for this reason, it is recommended that practices include at least two components and, if possible, all components [10, 15, 16]. In the CCM, self-management support is the basic component of the model [1]. At the same time, Telemedicine in the CCM is recommended. In patients with COPD, telephone technologies are used for medication compliance, symptom control, disease management, vital signs

monitoring, patient education, and follow-up related to disease management [17, 18].

Although the CCM is effective in the management of chronic illness, it has been criticized over time for not adequately defining the community resources policies component [19]. In this context, Barr et al. developed the Expanded Chronic Care Model (eCCM), which integrates key elements of the CCM with public health principles. eCCM includes broad elements such as community engagement, public health strategies, and policy integration. It addresses the health system and the social, environmental, and cultural factors that influence health. eCCM integrates CCM with public health strategies such as health promotion programs, social support networks, and community engagement. It also emphasizes the importance of prevention and health promotion rather than focusing only on the treatment of chronic diseases. eCCM consists of seven components: self-management/develop personal skills, decision support, delivery system design/re-orient health services, information systems, build healthy public policy, create supportive environments, and strengthen community action [20, 21].

There are differences in the components and application features of the CCM used in researches. This situation leads to the necessity of obtaining stronger evidence by conducting more studies involving the CCM. In the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guideline, it was emphasized that there are uncertainties about care in studies in which integrated care and telemedicine applications are applied together [1]. Therefore, further research on the CCM is needed. In this regard, our research is important in terms of evaluating the effectiveness of our practice, which includes the four components of the CCM in which the nurse takes part as a case manager.

Methods

Aim

This study aimed to evaluate how CCM-based education and telephone follow-up affect self-efficacy and self-reported symptoms among people with COPD.

Research hypotheses

H1₁ Education and follow-up based on the CCM will increase the level of self-efficacy in COPD patients.

H1₂ Education and follow-up based on the CCM will improve patient-reported outcomes in COPD patients.

H1₃ Education and follow-up based on the CCM will increase physical activity levels in COPD patients.

H1₄ Education and follow-up based on the CCM will increase COPD patients' satisfaction with chronic disease care.

Design

This research was conducted as a randomized controlled, single-blind experimental study to investigate the effects of education based on the CCM and telephone follow-up in COPD patients (ClinicalTrials.gov ID: NCT05029557). The study was conducted between January 2022 and July 2022 in the Chest Diseases Outpatient Clinic of a hospital located in the eastern Mediterranean region of Türkiye. Four components of the CCM were applied in the study (Table 1). Moreover, although the CCM components implemented in our study do not include community engagement or public policy integration, they are consistent with eCCM's approach to self-management, individual empowerment, and patient-centered care.

Randomization and blinding

In determining the groups, a simple randomization method was chosen to form the sample in a way to ensure equal numbers and random distribution of the two groups. Randomization was performed using the website (<https://www.randomizer.org/> Access Date: 26.11.2021). Using the website, 33 unique numbers between 1 and 66 were selected. The first selected numbers formed set 1. Before starting the randomization method, it was assumed that the numbers in Set 1 constituted the control group. The remaining numbers constituted set 2, that is, the intervention group. In line with the randomization list, patients who applied to the chest outpatient clinic and met the inclusion criteria were included in the intervention and control groups. Inclusion in the intervention and control groups was made by the researcher following the randomization list. Since the study consisted of

concrete concepts, including counseling and education, blinding of the participants and the researcher was not possible. A statistical expert performed a statistical analysis of the data. Since the groups were specified only in numbers, blinding was performed in statistical analyses. The CONSORT flow chart for the patients included in the study is shown in Fig. 1.

Participants

The study population included COPD patients admitted to the Chest Outpatient Clinic of the hospital. The sample consisted of 66 COPD patients meeting the inclusion criteria. Similar previous studies were used to determine the sample size [22, 23]. The G*Power 3.1.9.4 program was used for sample calculation. It was seen that the sample size was between 13 and 21 patients in each group with 95% power, 5% error, and 95% confidence interval. Considering the data losses and ensuring that parametric tests could be applied, it was decided that the sample size should be 66 people, 33 in the control group and 33 in the intervention group. The study was completed with 61 patients. Information about the patients who were not included in the study is presented in Fig. 1.

The team member chest disease specialist determined the stage and diagnosis of COPD. The GOLD guideline was taken as the basis for determining the stage of COPD. Accordingly, spirometry measurement is based on a Forced Expiratory Volume in 1 s (FEV1)/Forced Vital Capacity (FVC) < 70% after bronchodilator. According to FEV1, patients were classified as Stage I (≥ 80), Stage II (50–79), Stage III (30–49), and Stage IV (< 30) [1].

Inclusion and exclusion criteria

Patients with a confirmed diagnosis of COPD who were admitted to the Chest Outpatient Clinic of the hospital had the ability to communicate and read, could use the

Table 1 Application of CCM components in COPD

Delivery system design	• Determining the roles and responsibilities of the team members involved in the study. • The team members consisted of research nurses, a chest disease specialist, a dietician, and a physiotherapist. Counseling services were received from the team members through the research nurse according to patient needs. • Preparation of the training booklet. • Telephone monitoring of patients and support with short messaging service (SMS) reminders for the training booklet. • The nurse researcher communicates with team members to provide counseling and guidance according to the patient's needs.
Self-management Support	• Preparation of the training booklet. • Assessing the patient's needs, knowledge, attitudes, and habits related to the disease and the factors that affect compliance with treatment by questionnaires. • Providing training to patients in line with the training booklet. • Giving the prepared training guide to the patient. • Monitoring patients by phone and providing motivational support to patients on the issues they need. • Sending motivating and supportive messages via SMS. • Provision of consultancy services.
Decision support	• Conducting patient training and phone calls in line with the training guide and evidence-based guidelines. • Obtaining expert opinions from team members in line with patient needs.
Clinical information systems	• Electronic patient records (Hospital electronic records). • Ensuring the continuity of patients' education and evaluation processes via phone and SMS.

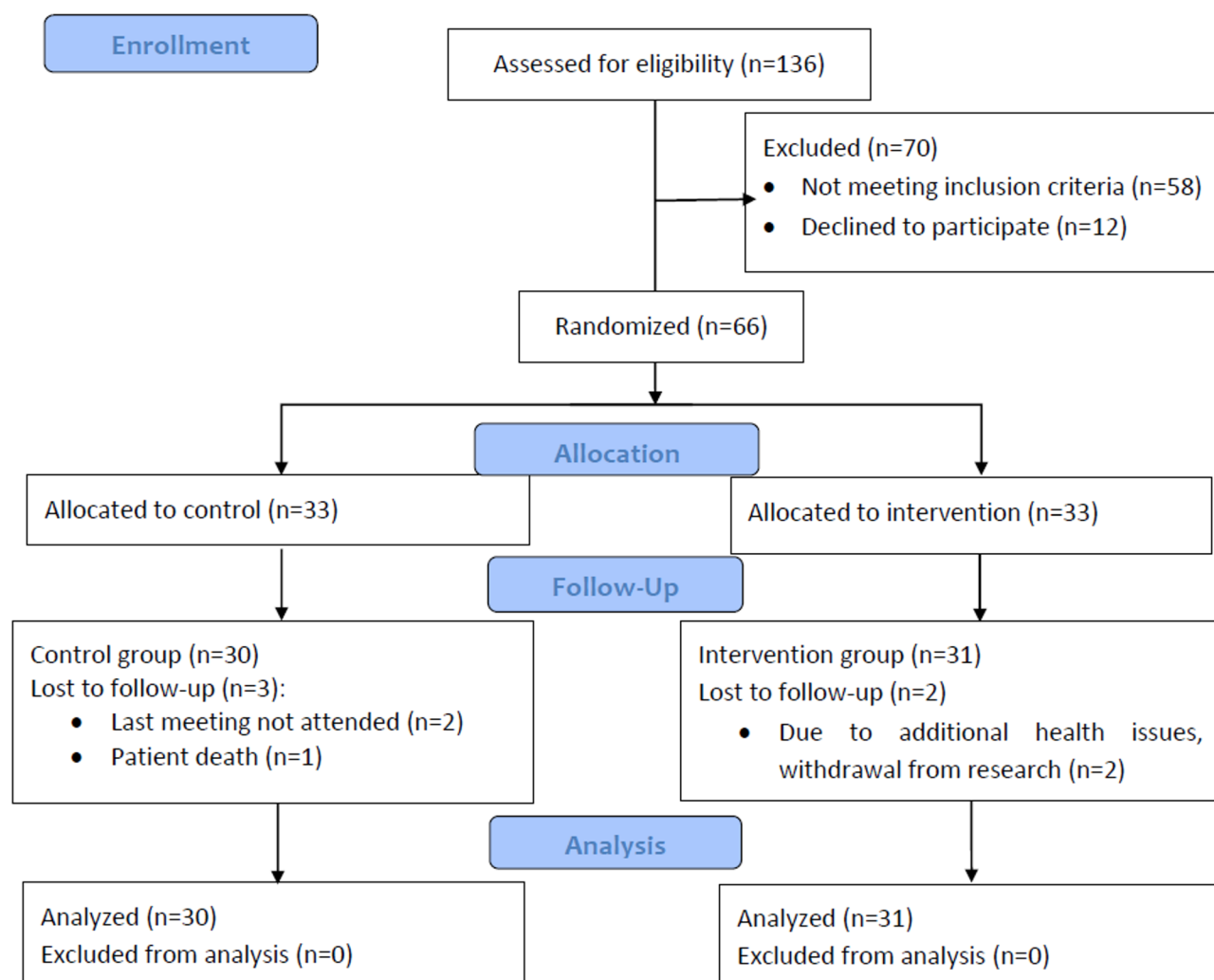


Fig. 1 CONSORT flow diagram of the study

telephone, and volunteered to participate in the study were included in the study. Patients who answered the data collection forms incompletely had a malignant type of disease, were in an exacerbation period, and patients who had contraindications according to the ATS guideline to the application of 6MWT (6-minute walk test) [24]. Patients who voluntarily withdrew from the study, who could not be reached after at least four phone calls, who did not attend the appointment for the post-test, and who failed to meet the inclusion criteria by experiencing general deterioration during the intervention were excluded from the study.

Preparation of training booklet

According to the self-management support components of the CCM, a training booklet to be used in practice was prepared. Research in the literature national and international evidence-based guidelines were utilized in its preparation. To evaluate the content and applicability of

the training booklet, it was presented to the team members and four faculty members. Necessary arrangements were made in line with the suggestions, and the final version was created. The new readability value developed by Bezirci and Yılmaz was used to determine the readability of the training booklet. It was calculated using the program sent by the author. In the evaluation of the new readability value, values between 1 and 8 indicate readability at the primary school level, values between 9 and 12 indicate readability at high school level, values between 13 and 16 indicate readability at undergraduate level, and values above 16 indicate readability at academic level [25]. The new readability value of the COPD Patient Education Booklet was 5.9, and it was determined that its readability was at the primary school level. The content of the training booklet is presented in Table 2.

Table 2 Content of the training booklet

1	Let us get to know our lungs
2	What is COPD?
3	What changes happen in the lung and the airways in COPD?
4	Why and how does COPD develop?
5	What are the symptoms in a patient with COPD?
6	How is COPD diagnosed?
7	What can you and your family do to fight COPD?
7.1	Stop smoking
7.2	Use your COPD medicines correctly and regularly
7.3	Exercise and participate in a pulmonary rehabilitation program
7.4	Eat right, get enough fluid
7.5	Get your flu and pneumonia vaccinations
7.6	Avoid stress
7.7	Monitor respiratory failure symptoms and use oxygen therapy regularly
7.8	Control your attacks
7.9	Regular health checkups
7.10	Regulate your daily activity/mobility
8	Practical methods to live more comfortably with COPD
9	Recommendations for managing your illness
10	My COPD action plan

Data collection

In line with the data collection tools for obtaining the initial data with the patients, pre-test data were collected with the "Patient Identification Form," "COPD Self-Efficacy Scale," "modified Medical Research Council (mMRC) Dyspnea Scale," "COPD Assessment Test (CAT)," "Modified Patient-Reported Outcome Scale for Chronic Obstructive Pulmonary Disease (mCOPD-PRO)," "6MWT application form." The pre-test data collection took approximately 20–30 minutes. Data were collected face-to-face with the patient. For the post-test, the data were collected with the data collection forms used in the pre-test and additionally with the "Patient Assessment of Chronic Illness Care (PACIC) Scale. Data were collected face-to-face with the patient.

To evaluate the applicability and comprehensibility of the training booklet and to identify possible problems related to the implementation process of the study, a pre-application was performed with three COPD patients who met the inclusion criteria. As a result of the pre-application, no changes were made regarding the data collection tools and the intervention process. Patients who underwent the pre-application were not included in the study sample.

Patient identification form

The patient identification form was created by reviewing the literature and consisted of socio-demographic data form, disease information, attitudes and habits about COPD, care satisfaction questions to be asked to the

post-test intervention group, and COPD knowledge status [2, 22, 23].

COPD self-efficacy scale

The scale developed by Wigal et al. in 1991 [26] was adapted to the Turkish language and culture, and validity and reliability studies were conducted by Kara and Mirici in 2002. Cronbach's alpha value of the scale was found to be 0.94. The scale consists of 5 sub-dimensions and a total of 34 items and aims to determine the competence of COPD patients to manage or avoid breathing difficulties in some activities and situations. An increase in the scale mean score indicates that the patient's skill in managing or avoiding respiratory distress has also increased. The lowest score is one, and the highest is 5 [27].

Modified patient-reported outcome scale for chronic obstructive pulmonary disease-mCOPD-PRO

mCOPD-PRO was developed by Li et al. in 2015 as a 17-item scale. In 2020, the same authors developed the scale again and reorganized it as 27 items, and validity and reliability studies were conducted. The 27-item scale consists of 3 sections: the physiological domain with 17 items, the psychological domain with seven items, and the environmental domain with three items [28]. Our study used the new version of the scale consisting of 27 items. The scale has a five-point Likert format, graded between 0 and 4 points. The 13th item in the scale is reverse. Therefore, the score obtained in the 13th item is subtracted from 4. The total score of the scale is obtained by dividing the total points given to each item by the total number of items. The scoring in the sub-dimensions of the scale is obtained by dividing the total score obtained from the sub-dimension by the number of items in the sub-dimensions. The lowest score is 0, and the highest score is 4. A lower score on the scale indicates better health. In the study by Li et al., Cronbach's alpha coefficient for the total items of the scale was 0.954. The Cronbach's alpha values for the sub-dimensions were 0.930 for the physiological domain, 0.929 for the psychological domain, and 0.673 for the environmental domain [28]. In this study, the Cronbach's alpha values of the scale were 0.917 in the pre-test and 0.965 in the post-test.

mMRC dyspnea scale

In 1952, Fletcher developed the dyspnea scale, which was used to compare dyspnea levels during activity in individuals with and without lung disease. Later, the scale was developed by the British Medical Research Council (MRC) to assess the course of diseases. The score is between 0 and 4 points. In the scale, the best situation in terms of dyspnea is defined as 0 points, while the worst situation is defined as 4 points [29, 30].

COPD assessment test (CAT)

The Turkish reliability and validity of the health status assessment scale for COPD was conducted by Yorgancıoğlu et al. The Cronbach's alpha value is 0.911 [31]. Each question is scored from 0 (no symptoms) to 5 (severe symptoms). The scores for the questions in the test range from "0–40". As the score increases, it is determined that the severity of the disease and health status are worsening [32]. In this study, Cronbach's alpha values of the scale were 0.819 in the pretest and 0.915 in the posttest.

Patient assessment of chronic illness care

The scale, developed by Glasgow et al. in 2005 [33] based on the CCM, underwent a Turkish validity and reliability study by Incirkuş and Nahcivan in 2010. The scale consists of 20 easy-to-administer items and five sub-dimensions that allow the patient to evaluate the health care services provided for chronic diseases. A high scale score indicates that individuals with chronic diseases are highly satisfied with the care they receive and that their disease management is adequate. According to the Turkish validity and reliability study of the scale, Cronbach's alpha coefficient was $\alpha=0.91$, and item-total score correlations were $r=0.46$ and 0.69 [34]. In this study, the Cronbach Alpha value of the scale was found to be 0.986.

Intervention

In line with the data collection tools for obtaining the initial data with the patients, pre-test data were collected. Lastly, 6MWTs were performed within the scope of the 6MWT application protocol, and pre- and post-test measurements were recorded. After 6MWT, the patient was allowed to rest for an average of 10 min in line with the patient's state of readiness before starting the educational intervention. In line with the training booklet based on the CCM, the patient was trained for approximately 40–50 min, considering the collected data forms. If the patient had a relative, they were included in the training. In the training, the question-answer method and demonstration method were used together with the training booklet using visual and verbal expression techniques. At the end of the training, the patients were given a training booklet and a respiratory exercise device (Triflo) provided by the researcher with the recommendation of the physiotherapist, who was a team member. The use of the respiratory exercise device was demonstrated to the patient.

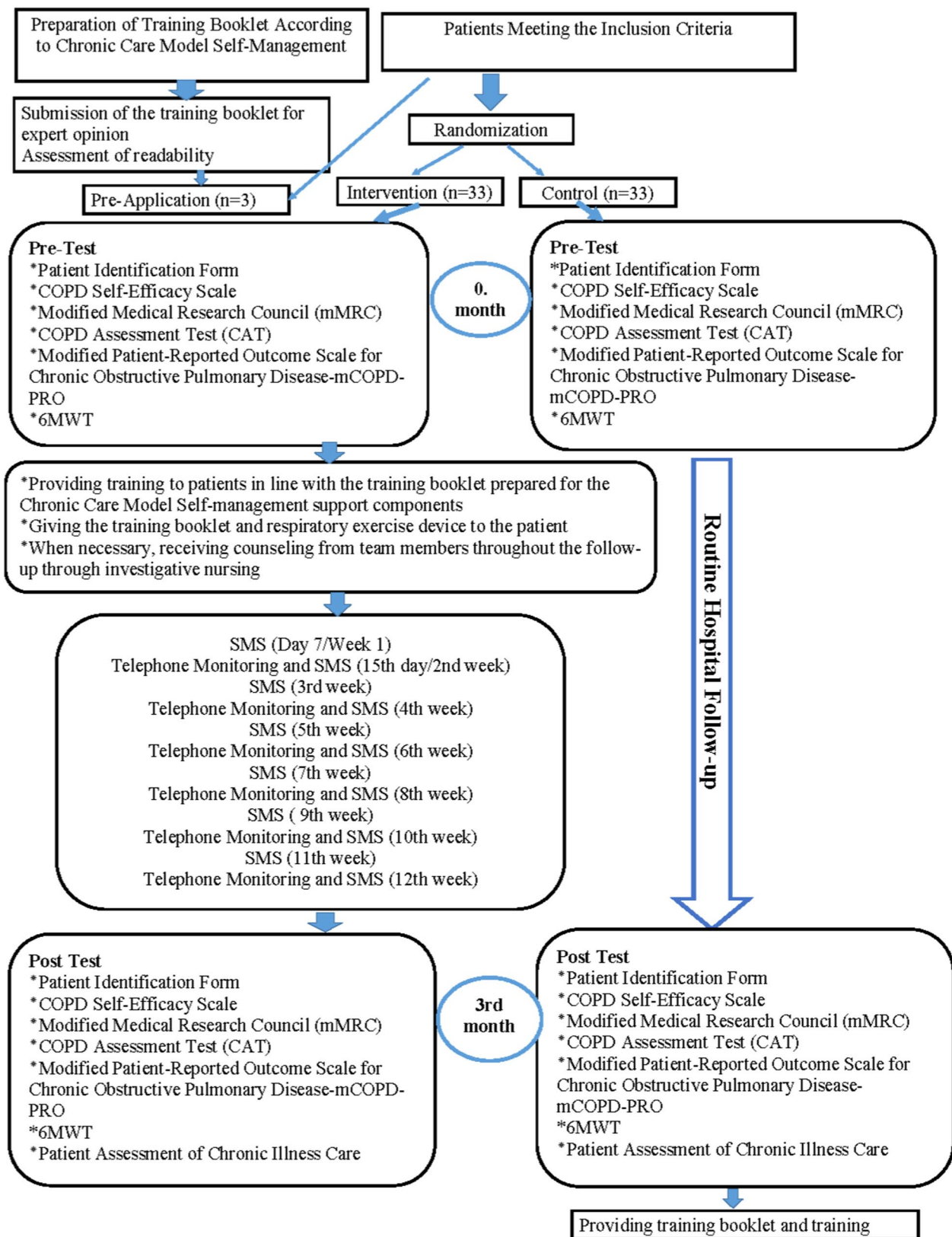
The patient was informed again about phone calls and SMS (short message service) applications. The researcher received online Motivational Interviewing Techniques Training for education and telephone interviews with the patient. Phone calls were made with the patient every two weeks for three months using the patient follow-up

form created by the researcher, and the patient was supported on the issues he/she needed (nutrition, vaccination, medication, exercise, breathing exercises, etc.). Evidence-based guidelines and training booklets were utilized in telephone patient follow-up. Counseling services were obtained from team members when necessary. A total of 6 phone calls were made with the patients every 15 days since the first follow-up. In the last call, the appointment date was reminded, information was given, and the appointment date and time were confirmed. Each phone call lasted approximately 15–25 min. Every week, the messages in the SMS list created in line with the patient education booklet were sent to each patient, specifically in line with their needs, and the patients were supported. A total of 12 SMS messages were sent to the patients during the follow-up period. The researcher nurse shared the information about the patient with the team members and ensured that counseling services were provided to the patients through the researcher nurse when necessary.

Patients in the control group were informed about the study, and their verbal and written informed consent was obtained. Height and weight measurements were made. Pre-test data were collected with data collection tools to obtain the initial data with the patients. In the end, 6 MWTs were performed within the scope of the 6MWT application protocol, and pre- and post-test measurements were recorded. In our study, no intervention was applied to the patients in the control group to evaluate the effect of our follow-up application based on the Chronic Care Model compared to routine follow-up. Patients in the control group continued their routine hospital follow-up and controls. For the post-test, the data were collected from the patient (3rd month) established together with the patient. After the post-test, the patient was trained following the training booklet (Fig. 2).

Data analysis

IBM SPSS 25 package program was used for data analysis. In statistical analysis, mean and standard deviation, median, percentage distribution, and number were used to evaluate the descriptive variables of the patients. The Kolmogorov-Smirnov normality distribution test was performed to evaluate the conformity of the data to normal distribution. The chi-square test was used to analyze categorical data. In comparing pre-test or post-test scores between the groups, the Whitney U test was used for data that did not show normal distribution, and the Independent Groups t-test was used for data that showed normal distribution. In comparing pre-test and post-test scores in each group, the Wilcoxon signed-rank test was used for data that did not show normal distribution, and the Dependent Groups t-test method was used for data that showed normal distribution. Effect size indices were

**Fig. 2** Research application flow chart

calculated for the nonparametric test ($r = Z/\sqrt{N}$). Small, medium, and large effect sizes (r) were defined as values of 0.10, 0.30, and 0.50 respectively [35]. Effect size (d) for parametric tests was calculated with G*Power 3.1.9.4. For effect size (d), small, medium, and large effect sizes are defined as 0.20, 0.50, and 0.80 respectively [35]. Generalized estimating equations (GEE) analysis was used to evaluate the effectiveness of the intervention. The significance level was accepted as $p < 0.05$ in statistical analyses.

Ethical considerations

For non-interventional research, ethics committee approval was obtained by applying to the ethics committee of a university (decision dated 21.06.2021 and numbered 2021/079). Written permission was obtained by applying to the institution where the study data would be collected. In addition, after the patients were informed about the research, their written and verbal consent was obtained voluntarily. Scale use permissions were obtained for the data collection tools used in the study. The principles of the Declaration of Helsinki and publication ethics were followed in our study.

Results

The characteristics of the patients included in the study are presented in Table 2. In the pre-test, it was found that there was no statistically significant difference between the groups according to the socio-demographic and disease characteristics of the patients. It was observed that the patients were homogeneously distributed in the intervention and control groups (Table 3).

At the final interview, it was observed that the patients in the intervention group had higher COPD Self-Efficacy Scale scores in emotional arousal, negative affect, behavioral risk factors, and physical exertion sub-dimensions compared to the control group ($p < 0.05$). This difference was found to have a medium effect size in the dimensions of negative effect and emotional arousal. In the control group, there was no significant change between the pre-test and post-test scores of the COPD Self-Efficacy Scale and its sub-dimensions. In the intervention group, the total score of the COPD Self-Efficacy Scale and the post-test scores in the negative effect, emotional arousal, physical exertion, and behavioral risk status sub-dimensions were found to be higher than the pre-test scores ($p < 0.05$, Table 4). Accordingly, hypothesis H1₁ is confirmed.

The post-test scores of the patients in the intervention group in mMRC, CAT, mCOPD-PRO, and its sub-dimensions were significantly lower than those in the control group ($p < 0.05$). This difference was found to have a large effect size in CAT, mCOPD-PRO, and its sub-dimensions. At the same time, the mean scores of the post-test mMRC dyspnea scale, CAT, and the mCOPD-PRO and its subscales were lower in the intervention group

compared to the pre-test mean scores ($p < 0.05$, Table 4). Accordingly, hypothesis H1₂ is confirmed.

There was a significant difference between the COPD Self-Efficacy Scale and mCOPD-PRO Scale post-test scores between the groups in terms of COPD stage, using nebulizer and oxygen, not using BIBAP, not receiving COPD education before, and having influenza vaccination. In addition, there was a significant difference between the post-test mCOPD-PRO Scale scores of having additional chronic diseases and being vaccinated against pneumococcal disease ($p < 0.05$, Table 5).

In the first interview, there was no difference between the groups in oxygen saturation (SpO₂), dyspnea perception, and walking distance. After the intervention, it was determined that dyspnea perception before and after 6MWT was less in the intervention group compared to the control group, and the effect size of this difference was small. In intragroup comparisons, it was found that SpO₂ and walking distance decreased in the post-test after 6MWT in the control group compared to the pre-test, and dyspnea perception increased after the test. In the intra-group comparison of the intervention group, it was found that there was an increase in SpO₂ and walking distance in the post-test and a decrease in dyspnea perception in the intervention group (Table 6). Accordingly, hypothesis H1₃ is confirmed.

In the intervention group, the total score of the Chronic Disease Care Evaluation Scale and the scores of patient participation, decision-making support, goal setting, problem-solving, and follow-up/coordination subscales were higher than the control group ($p < 0.05$). This difference was found to have a large effect size (Table 7). Accordingly, hypothesis H1₄ is confirmed.

GEE was used to examine the effectiveness of the intervention applied with reference to the pretest scores and the control group. A first-order autoregressive (AR (1)) matrix model was selected to analyze the variables. COPD Self-Efficacy Scale total score ($B = 0.57$, $p < 0.001$), mMRC ($B = -0.71$, $p < 0.001$), CAT ($B = -8.00$, $p = 0.001$), mCOPD-PRO Scale total score ($B = -0.65$, $p = 0.001$) and 6MWT ($B = 24.95$, $p < 0.001$) were significantly better in the intervention group compared to the control group (Table 8).

Adverse effects

In terms of safety in our study, no adverse effects or undesirable effects were encountered in control and intervention groups.

Discussion

This study was designed as a randomized controlled trial to evaluate the efficacy of CCM-based intervention in COPD patients. There are a limited number of studies in literature involving the application of CCM

Table 3 Descriptive characteristics of the control and intervention groups

Variables		Control (n = 30)	Intervention (n = 31)	t	p
		Mean (SD)	Mean (SD)		
Age (min.-max.)		66.13 (8.29) (46–79)	64.84 (8.74) (43–78)	0.593	0.555
Duration of smoking (years)		33.60 (9.41)	36.65 (9.41)	-1.158	0.253
Disease duration (years)		7.27 (5.26)	8.42 (5.23)	-0.857	0.395
Group		n (%)	n (%)	χ^2	p
Gender	Female	6 (20)	5 (16.1)	0.155	0.694
	Male	24 (80)	26 (83.9)		
Marital Status	Married	27 (90)	26 (83.9)	0.503	0.478
	Single/widow/divorced	3 (10)	5 (16.1)		
Education level	Literate	9 (30)	4 (12.9)	3.271	0.195
	Primary education	20 (66.7)	24 (77.4)		
	High school	1 (3.3)	3 (9.7)		
Dampness in living home	Yes	8 (26.7)	7 (22.6)	0.137	0.711
	No	22 (73.3)	24 (77.4)		
Smoking	Smoking cigarettes	5 (16.7)	7 (22.6)	0.343	0.843
	Quitting	20 (66.7)	19 (61.3)		
	Never smoking	5 (16.7)	5 (16.1)		
Alcohol use	Quitting	0 (0)	2 (6.5)	2.001	0.157
	Never alcohol	30 (100)	29 (93.5)		
Family support	Yes	26 (86.7)	27 (87.1)	0.002	0.960
	No	4 (13.3)	4 (12.9)		
Chronic disease other than COPD	Yes	18 (60)	15 (48.4)	0.828	0.363
	No	12 (40)	16 (51.6)		
COPD stages	Stage II	12 (40)	11 (35.5)	0.249	0.883
	Stage III	8 (26.7)	10 (32.3)		
	Stage IV	10 (33.3)	10 (32.3)		
Using nebulizer	Yes	17 (56.7)	19 (61.3)	0.135	0.714
	No	13 (43.3)	12 (38.7)		
Using oxygen concentrator	Yes	8 (26.7)	9 (29)	0.042	0.837
	No	22 (73.3)	22 (71)		
Using BIBAP	Yes	1 (3.3)	1 (3.2)	0.001	0.981
	No	29 (96.7)	30 (96.8)		
Receiving education about COPD	Yes	12 (40)	8 (25.8)	1.394	0.238
	No	18 (60)	23 (74.2)		
Influenza vaccination	Yes	10 (33.3)	9 (29)	0.132	0.717
	No	20 (66.7)	22 (71)		
Pneumococcal vaccination	Yes	8 (26.7)	9 (29)	0.042	0.837
	No	22 (73.3)	22 (71)		

SD: Standard deviation, χ^2 : Chi-square test, t: Independent Sample t-test

in COPD patients. It is seen that our patient education and follow-up application based on CCM increased self-efficacy levels in COPD patients and had a positive effect on patient-reported outcomes. In the literature, it is reported that there are heterogeneous results related to self-efficacy in studies involving CCM practices. In this study, it is predicted that the implementation of the four components of CCM and telephone follow-up of patients were effective in our research results.

Patients with COPD feel insecure about doing some activities due to disease symptoms, especially dyspnea. This insecurity is defined as low self-efficacy in patients

[27]. Our study found that the intervention application increased the scores of emotional states, negative impact, behavioral risk status, and physical effort sub-dimensions of the COPD Self-Efficacy Scale. In studies similar to our study, it was found that patients' self-efficacy levels increased after the interventions [12]. In the literature, studies examining the effects of self-management training given by nurses found that self-management training increased self-efficacy levels in COPD patients [22, 23, 36, 37]. At the same time, as a result of similar studies involving integrated care in COPD patients, it was found that there was no significant difference in the

Table 4 Between-group and within-group comparison of scores on the COPD Self-Efficacy, mMRC, CAT, and mCOPD-PRO scale

Variables		Control (n = 30)		Intervention (n = 31)		Test value; <i>p</i> **	Effect size
		Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)		
COPD Self-Efficacy Scale and subscales							
Total score	Baseline	3.07 ± 0.79	3.32 (1.44)	2.97 ± 0.66	3.03 (1.11)	Z=-0.765, <i>p</i> =0.444	0.10 [†]
	3rd month	3.09 ± 0.87	3.20 (1.44)	3.56 ± 0.44	3.76 (0.58)	Z=-2.230, <i>p</i>=0.026	0.29 [†]
	Z; <i>p</i> *	Z=-1.158; <i>p</i> =0.247		Z=-4.721; <i>p</i><0.001			
Negative affect	Baseline	3.18 ± 0.8	3.38 (1.60)	3.07 ± 0.65	3.00 (0.97)	Z=-0.97, <i>p</i> =0.332	0.12 [†]
	3rd month	3.22 ± 0.89	3.24 (1.55)	3.79 ± 0.38	3.90 (0.45)	Z=-2.565, <i>p</i>=0.010	0.33 [†]
	Z; <i>p</i> *	Z=0.001; <i>p</i> =1.000		Z=-4.787; <i>p</i><0.001			
Emotional arousal	Baseline	3.05 ± 0.86	3.19 (1.63)	2.93 ± 0.77	2.88 (1.50)	Z=-0.731, <i>p</i> =0.465	0.09 [†]
	3rd month	3.14 ± 0.9	3.19 (1.63)	3.73 ± 0.43	3.75 (0.50)	Z=-2.556, <i>p</i>=0.011	0.33 [†]
	Z; <i>p</i> *	Z=-1.085; <i>p</i> =0.278		Z=-4.711; <i>p</i><0.001			
Physical exertion	Baseline	2.82 ± 0.83	3.10 (1.45)	2.66 ± 0.70	2.80 (1.00)	Z=-1.007, <i>p</i> =0.314	0.13 [†]
	3rd month	2.73 ± 0.94	2.90 (1.60)	3.23 ± 0.61	3.60 (1.00)	Z=-2.285, <i>p</i>=0.022	0.29 [†]
	Z; <i>p</i> *	Z=-1.866; <i>p</i> =0.062		Z=-4.145; <i>p</i><0.001			
Weather/ environment effect	Baseline	3.02 ± 0.76	3.17 (1.33)	2.98 ± 0.73	3.17 (1.17)	Z=-0.261, <i>p</i> =0.794	0.03 [†]
	3rd month	3.05 ± 0.85	3.25 (1.25)	3.18 ± 0.74	3.67 (1.17)	Z=-0.772, <i>p</i> =0.44	0.10 [†]
	Z; <i>p</i> *	Z=-0.672; <i>p</i> =0.501		Z=-1.611; <i>p</i> =0.107			
Behavioral risk factors	Baseline	3.24 ± 0.8	3.67 (1.33)	3.25 ± 0.6	3.33 (1.00)	Z=-0.456, <i>p</i> =0.648	0.06 [†]
	3rd month	3.21 ± 0.89	3.66 (1.33)	3.59 ± 0.56	4.00 (1.00)	Z=-2.073, <i>p</i>=0.038	0.27 [†]
	Z; <i>p</i> *	Z=-0.941; <i>p</i> =0.347		Z=-2.753; <i>p</i>=0.006			
mMRC	Baseline	2.67 ± 0.96	3.0 (1.25)	2.81 ± 0.75	3.0 (1.0)	Z=-0.558, <i>p</i> =0.577	0.07 [†]
	3rd month	2.80 ± 1.00	3.0 (2.0)	2.23 ± 0.72	2.0 (1.0)	Z=-2.201, <i>p</i>=0.028	0.28 [†]
	Z; <i>p</i> *	Z=-1.633, <i>p</i> =0.102		Z=-4.025, <i>p</i><0.001			
CAT	Baseline	20.93 ± 5.64	20.5 (8.5)	21.42 ± 3.93	21.0 (5.0)	Z=-0.318, <i>p</i> =0.750	0.04 [†]
	3rd month	22.03 ± 5.85	24.0 (9.25)	14.52 ± 3.02	14.0 (4.0)	Z=-4.821, <i>p</i><0.001	0.62 [†]
	Z; <i>p</i> *	Z=-1.822 <i>p</i> =0.068		Z=-4.872, <i>p</i><0.001			
mCOPD-PRO Scale and subscales							
Total score	Baseline	2.15 ± 0.38	2.19 (0.53)	2.17 ± 0.26	2.19 (0.44)	t=-0.303, <i>p</i> =0.763	0.05 [†]
	3rd month	2.21 ± 0.40	2.20 (0.65)	1.58 ± 0.17	1.59 (0.19)	t=7.906, <i>p</i><0.001	1.57 [†]
	t; <i>p</i> *	t=-2300, <i>p</i>=0.029		t=17.656, <i>p</i><0.001			
mCOPD-PRO physiological domain	Baseline	2.15 ± 0.40	2.12 (0.54)	2.16 (0.26)	2.18 (0.41)	t=-0.122, <i>p</i> =0.904	0.02 [†]
	3rd month	2.22 (0.40)	2.29 (0.66)	1.64 (0.20)	1.65 (0.24)	t=7.049, <i>p</i><0.001	1.45 [†]
	t; <i>p</i> *	t=-2.169, <i>p</i>=0.038		t=15.282, <i>p</i><0.001			
mCOPD-PRO psychological domain	Baseline	2.20 ± 0.40	2.21 (0.50)	2.22 ± 0.33	2.14 (0.43)	Z=-0.117, <i>p</i> =0.907	0.01 [†]
	3rd month	2.25 ± 0.41	2.28 (0.71)	1.54 ± 0.19	1.57 (0.29)	Z=-6.021, <i>p</i><0.001	0.77 [†]
	Z; <i>p</i> *	Z=-1.437, <i>p</i> =0.151		Z=-4.881, <i>p</i><0.001			
mCOPD-PRO environmental domain	Baseline	2.01 ± 0.46	2.0 (0.67)	2.13 ± 0.48	2.0 (1.0)	Z=-0.899, <i>p</i> =0.368	0.12 [†]
	3rd month	2.06 ± 0.50	2.0 (1.0)	1.35 ± 0.17	1.3 (0.0)	Z=-5.576, <i>p</i><0.001	0.71 [†]
	Z; <i>p</i> *	Z=-0.894, <i>p</i> =0.371		Z=-4.669, <i>p</i><0.001			

mCOPD-PRO; modified patient-reported outcome scale for chronic obstructive pulmonary disease, CAT; chronic obstructive pulmonary disease assessment test, mMRC; modified Medical Research Council dyspnea scale, SD; Standard deviation, IQR; Interquartile Range

* Comparison within groups: *Z*; Wilcoxon Signed Ranks test, *t*; Paired samples *t* test

** Comparison between groups: *Z*; Mann-Whitney U test, *t*; Independent Sample *t* test, *p* < 0.05 are in bold

[†] Effect size *r*, [‡]Effect size *d* between groups

self-management skill scores of patients [38, 39]. When similar studies related to our study are examined in literature, it is seen that there are heterogeneous results. It is thought that this difference may be due to the difference in the integrated care or CCM components applied and the difference in motivational support and follow-up systems. In this study, education and telephone follow-up based on the CCM increased the self-efficacy levels in COPD patients.

Patient-reported outcomes are necessary to assess the patient's symptoms, their impact on their lives, and their response to treatment [40, 41]. In clinical trials, the Saint George Respiratory Questionnaire (SGRQ) is most used to assess patient-reported outcomes. In addition, measurement tools such as mMRC, CAT, and Clinical COPD Questionnaire (CCQ) are also used [40, 41]. This research used mMRC Dyspnea, CAT, and mCOPD-PRO. Since there were no studies similar to our study

Table 5 Post-test COPD Self-Efficacy scale and mCOPD-PRO scale scores according to the participants' disease-related descriptive characteristics

Variables	COPD self-efficacy scale		<i>p</i> *	mCOPD-PRO scale		<i>p</i> *
	Control (n = 30)	Intervention (n = 31)		Control (n = 30)	Intervention (n = 31)	
	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	
Chronic disease other than COPD						
Yes	3.01 ± 0.95	3.47 ± 0.44	0.076	2.32 ± 0.37	1.60 ± 0.21	< 0.001
No	3.22 ± 0.74	3.65 ± 0.44	0.364	2.04 ± 0.40	1.56 ± 0.13	< 0.001
COPD stages						
Stage II	3.90 ± 0.36	3.88 ± 0.10	0.578	1.83 ± 0.20	1.54 ± 0.09	0.001
Stage III	3.02 ± 0.45	3.69 ± 0.28	0.002	2.27 ± 0.28	1.50 ± 0.18	< 0.001
Stage IV	2.18 ± 0.58	3.08 ± 0.39	0.003	2.61 ± 0.18	1.72 ± 0.15	< 0.001
Using nebulizer						
Yes	2.52 ± 0.67	3.36 ± 0.46	< 0.001	2.47 ± 0.29	1.61 ± 0.21	< 0.001
No	3.84 ± 0.41	3.88 ± 0.09	0.429	1.86 ± 0.21	1.54 ± 0.09	< 0.001
Using oxygen concentrator						
Yes	2.06 ± 0.55	3.04 ± 0.40	0.003	2.67 ± 0.12	1.74 ± 0.15	< 0.001
No	3.47 ± 0.62	3.77 ± 0.23	0.048	2.04 ± 0.32	1.52 ± 0.14	< 0.001
Using BIBAP						
Yes	1.27 ± 0.0	3.03 ± 0.0	0.317	2.74 ± 0.0	1.67 ± 0.0	0.317
No	3.16 ± 0.81	3.58 ± 0.44	0.032	2.19 ± 0.39	1.58 ± 0.17	< 0.001
Receiving education about COPD						
Yes	3.24 ± 0.99	3.40 ± 0.53	0.757	2.12 ± 0.38	1.57 ± 0.14	0.003
No	3.00 ± 0.80	3.62 ± 0.41	0.009	2.26 ± 0.41	1.59 ± 0.18	< 0.001
Influenza vaccination						
Yes	3.05 ± 0.74	3.64 ± 0.41	0.044	2.28 ± 0.41	1.54 ± 0.11	< 0.001
No	3.12 ± 0.94	3.53 ± 0.46	0.170	2.17 ± 0.40	1.60 ± 0.19	< 0.001
Pneumococcal vaccination						
Yes	2.97 ± 0.79	3.52 ± 0.47	0.122	2.30 ± 0.44	1.58 ± 0.12	0.003
No	3.14 ± 0.91	3.58 ± 0.44	0.103	2.17 ± 0.39	1.59 ± 0.19	< 0.001

*Mann-Whitney U test, mCOPD-PRO; modified patient-reported outcome scale for chronic obstructive pulmonary disease

p < 0.05 are in bold

Table 6 Comparison of 6MWT measurements between and within groups

Variables		Control (n = 30)		Intervention (n = 31)		Test value/ <i>p</i> **	Effect size
		Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)		
Pre-6MWT SpO ₂	Baseline	92.33 ± 4.02	92.00 (7.25)	91.58 ± 3.76	91.00 (5.0)	Z = -0.624, <i>p</i> = 0.533	0.08 [†]
	3rd month	91.2 ± 4.13	92.50 (7.25)	93.06 ± 2.84	93.00 (4.0)	Z = -1.595, <i>p</i> = 0.111	0.20 [†]
	Z/ <i>p</i> *	Z = -3.321, <i>p</i> = 0.001		Z = -3.278, <i>p</i> = 0.001			
Post-6MWT SpO ₂	Baseline	87.73 ± 7.72	90.0 (10.0)	86.06 ± 6.42	87.0 (10.0)	Z = -1.114, <i>p</i> = 0.265	0.14 [†]
	3rd month	84.37 ± 9.8	89.0 (13.0)	88.55 ± 4.86	90.0 (18.0)	Z = -1.345, <i>p</i> = 0.179	0.17 [†]
	Z/ <i>p</i> *	Z = -4.533, <i>p</i> < 0.001		Z = -3.766, <i>p</i> < 0.001			
Pre-6MWT Modified Borg Dyspnea (0–10 points)	Baseline	0.47 ± 0.51	0.5 (1.0)	0.63 ± 0.71	0.5 (1.0)	Z = -0.738, <i>p</i> = 0.461	0.09 [†]
	3rd month	0.40 ± 0.50	0.25 (0.63)	0.15 ± 0.26	0.0 (0.50)	Z = -2.236, <i>p</i> = 0.025	0.29 [†]
	Z/ <i>p</i> *	Z = -1.633, <i>p</i> = 0.102		Z = -3.976, <i>p</i> < 0.001			
Post-6MWT Modified Borg Dyspnea (0–10 points)	Baseline	3.35 ± 1.89	3.0 (3.25)	3.61 ± 1.56	3.61 (2.0)	Z = -0.581, <i>p</i> = 0.561	0.07 [†]
	3rd month	3.80 ± 1.94	4.0 (3.0)	2.77 ± 1.20	3.0 (2.0)	Z = -2.070, <i>p</i> = 0.038	0.27 [†]
	Z/ <i>p</i> *	Z = -2.296, <i>p</i> = 0.022		Z = -3.928, <i>p</i> < 0.001			
6MWT Distance (meters)	Baseline	337.79 ± 111.93	341.95 (208.72)	317.76 ± 96.61	314.60 (154)	t = 0.749, <i>p</i> = 0.457	0.18 [‡]
	3rd month	333.21 ± 111.58	336.82 (198.45)	338.13 ± 90.37	340.60 (159.4)	t = -0.190, <i>p</i> = 0.850	0.06 [‡]
	t/ <i>p</i> *	t = 2.821, <i>p</i> = 0.009		t = -4.030, <i>p</i> < 0.001			

6MWT; Six-Minute Walk Test, SpO₂; Oxygen Saturation, SD; Standard Deviation, IQR; Interquartile Range

* Comparison within groups: Z; Wilcoxon Signed Ranks test, t; Paired samples t test

** Comparison between groups: Z; Mann-Whitney U test, t; Independent Sample t test, *p* < 0.05 are in bold

[†] Effect size *r*, [‡]Effect size *d* between groups

Table 7 Comparison of patients' satisfaction scores with chronic disease care

Variables	Control (n = 30)		Intervention (n = 31)		Test value/ <i>p</i>	Effect size [†]
	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)		
PACIC total	1.88 ± 0.37	1.87 (0.35)	4.68 ± 0.22	4.75 (0.25)	Z = -6.717, <i>p</i> < 0.001	0.86
Patient activation	2.50 ± 0.92	2.33 (1.17)	4.25 ± 0.49	4.33 (0.67)	Z = -6.001, <i>p</i> < 0.001	0.77
Decision support	1.76 ± 0.65	1.67 (0.67)	4.91 ± 0.27	5.00 (0.0)	Z = -7.075, <i>p</i> < 0.001	0.90
Goal setting	2.06 ± 0.42	2.00 (0.40)	4.86 ± 0.20	4.80 (0.20)	Z = -6.815, <i>p</i> < 0.001	0.87
Problem-solving	1.98 ± 0.40	2.00 (0.31)	4.90 ± 0.21	5.00 (0.25)	Z = -6.939, <i>p</i> < 0.001	0.89
Follow-up	1.31 ± 0.39	1.20 (0.60)	4.44 ± 0.44	4.40 (0.60)	Z = -6.748, <i>p</i> < 0.001	0.86

PACIC; Patient Assessment of Chronic Illness Care, Z; Mann-Whitney U test, IQR; Interquartile Range

[†] Effect size *r* between groups*p* < 0.05 are in bold**Table 8** Effectiveness of the intervention implemented using general estimating equations

Variables	B	SE	Waldχ	<i>p</i>
COPD Self-Efficacy Scale total score				
Intercept	3.07	0.14	464.33	0.001
Group	-0.10	0.18	0.30	0.586
Time	0.02	0.06	0.14	0.744
Group x Time	0.57	0.09	38.42	< 0.001
mMRC				
Intercept	2.67	0.17	240.00	0.001
Group	0.14	0.22	0.41	0.520
Time	0.13	0.08	2.92	0.087
Group x Time	-0.71	0.13	31.84	< 0.001
CAT				
Intercept	20.93	1.01	426.88	0.001
Group	0.49	1.23	0.16	0.692
Time	1.10	0.50	4.85	0.028
Group x Time	-8.00	0.69	133.05	0.001
mCOPD-PRO Scale total score				
Intercept	2.15	0.07	1009.62	0.001
Group	0.03	0.08	0.09	0.759
Time	0.06	0.03	5.47	0.019
Group x Time	-0.65	0.04	238.54	0.001
6MWT Distance (meters)				
Intercept	337.79	20.09	282.67	0.001
Group	-20.03	25.36	0.58	0.447
Time	-4.59	1.60	8.23	0.004
Group x Time	24.95	5.22	22.84	< 0.001

Reference group: Group (Control group), Time (Pre-Test), and Group (Control) × Time (Pre-Test)

B: Unstandardized coefficient, SE: Standard error, *p* < 0.05 are in bold

mCOPD-PRO; modified patient-reported outcome scale for chronic obstructive pulmonary disease, CAT; chronic obstructive pulmonary disease assessment test, mMRC; modified Medical Research Council dyspnea scale, 6MWT; Six-Minute Walk Test

using mCOPD-PRO, the patient-reported results of our study were discussed with similar instruments, mMRC dyspnea, CAT, and SGRQ. In our study, we found that our intervention improved the outcomes reported by patients. A study evaluating the effects of the MyCOPD self-management program for COPD patients found

a decrease in CAT scores at the end of the third month in patients who participated in the program [42]. In the study conducted by Öztürk et al., self-management training was given to patients by a multidisciplinary team, and patients were interviewed by phone every two weeks for three months. As a result of the study conducted by Öztürk et al., it was found that the mMRC, CAT, and SGRQ scores of the patients in the intervention group decreased [43]. Our study is like the results of the studies in literature. Within the scope of the structured training program, it is predicted that following up with the patients by phone, sending supportive SMSs, and using motivational interviewing techniques increase self-efficacy in patients with COPD. Increased self-efficacy is thought to help patients cope with symptoms and manage the disease.

COPD Self-Efficacy Scale and mCOPD-PRO post-test scores were compared with the participants' descriptive characteristics related to the disease. In the intervention group, it was observed that the scores were better in patients with advanced COPD stages, who used nebulizer and oxygen, who had not received education about COPD before, and who had flu vaccination. Studies in the literature also indicate that educational interventions in COPD patients increase self-efficacy and are effective in reducing symptom outcomes [23, 43]. This shows that the education-based intervention we applied in our study can increase the coping skills of individuals even if the COPD stage increases and that the intervention can be effective in individuals with higher symptom burden.

6MWT is used to determine exercise capacity and assess response to treatment in individuals with chronic lung disease [24]. Our study found an increase in SpO₂ and walking distance in the post-test compared to the pre-test and a decrease in dyspnea perception in the intervention group. In a systematic review, exercise capacities were evaluated in COPD patients with 6MWT, and it was found that the integrated care model resulted in an increase in 6MWT distance [44]. In the COPD-net study by Koolen et al. using the CCM as a guide, it was reported that patients who received integrated care

had an increase in 6MWT distance [45]. In the proactive, integrated care model study conducted by Koff et al., in which integrated care and remote monitoring were combined, it was found that the patients had increased SpO₂ at a distance of 6MWT and after 6MWT [46]. The findings obtained in this study are like the studies in literature. At the same time, it is thought that self-management support is given to patients, follow-up of breathing exercises and compliance with exercise plans with telephone calls and performing breathing exercises with triflo decreased dyspnea and increased SpO₂ values in patients. It is predicted that patients can walk more due to decreased dyspnea and increased saturation values.

Measurement tools are needed to assess and improve the quality of care provided and to evaluate the impact of interventions. Patient perceptions regarding the evaluation and quality of the care provided by patients are the basic elements in evaluating the quality of care [47]. Our study found that the patients in the intervention group had high scores on the Patient Assessment of Chronic Illness Care Scale. The applied intervention increased satisfaction with care in patients. In the literature, when the studies in which the CCM was applied in COPD were examined, it was observed that patients' satisfaction with chronic disease care was higher [13, 44]. The findings obtained in this study are like the studies in literature. Since the evaluation of the quality of chronic care and patient satisfaction will positively affect the management of diseases, it is considered necessary to make these evaluations in the provision of health services. According to this assessment, planning patient care and organizing patient follow-ups will increase the quality of care and patient satisfaction with care.

Limitations of the study

The application of study in a single center reduces the generalizability of our results. The fact that the study was completed with 61 patients caused the sample size to remain relatively small. This may negatively affect the statistical significance and generalizability of the results obtained, especially by limiting the power of multivariate statistical analyses. In our study, except for the 6DYT, self-efficacy and patient-reported results include subjective results. Participants could not be blinded due to the nature of the study. This may lead to information bias. Patients' awareness of the intervention they receive may affect the responses given by patients. This is especially important in terms of self-efficacy assessments and subjective outcomes reported by patients. In addition, the study was planned to be conducted in a chest disease service. However, due to the merging of wards in the hospital due to COVID-19, there was a decrease in patient hospitalizations. Therefore, it was decided to conduct the study in the Chest Diseases Outpatient Clinic. In

addition, the 3-month duration of our study limits the evaluation of the long-term effects of our intervention.

Conclusion

In our study, in which nurses were the case managers, it was observed that patients' self-efficacy increased, the results reported by the patient were positive, and physical activity levels increased. It was observed that patients had a high level of satisfaction with the chronic care they received. Chronic Care Model-based education and telephone monitoring can be used in practices. Since there are heterogeneous results on self-efficacy in integrated care in COPD, more studies are needed. It is recommended to conduct randomized controlled trials with a follow-up period longer than three months to evaluate the long-term effects of our intervention, which includes follow-up based on the CCM.

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Author contributions

Y.S. wrote the main manuscript text and prepared figure 1; Tables 1, 2, 3, 4 and 5. Y.S. and N.O. conducted the literature review and designed the study. All authors reviewed the manuscript.

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Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

Before starting the study, ethical approval was obtained from Hasan Kalyoncu University, Faculty of Health Sciences, Non-Interventional Research Ethics Committee (Ethics approval code: 2021/079). Participation in the study was voluntary. Accordingly, the patients were informed about the study and verbal, and written informed consent was obtained from the patients who agreed to participate in the study. Institutional permission was obtained from the institution where the study was conducted. Before starting the study, ClinicalTrials.gov was recorded (NCT05029557, Registration Date: August 26, 2021, <https://clinicaltrials.gov/>). The principles of the Declaration of Helsinki and publication ethics were followed in our study.

Consent for publication

Not applicable.

Other information

This study was derived from a doctoral dissertation and presented as an oral abstract at the 25th National Congress of Internal Medicine (October 8–12, 2023, Antalya, Türkiye).

Competing interests

The authors declare no competing interests.

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