

Impact of a Follow-Up Care Model on the Lifestyle and Self-Care of Patients with Chronic Obstructive Pulmonary Disease: A Randomized Clinical Trial

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Abstract

Background: Despite advancements in the treatment of chronic obstructive pulmonary disease (COPD), it is an irreversible disease with poor prognosis. Individuals with COPD not only experience progressive shortness of breath and physical limitations, but also face psychological and social challenges.

Aim: This study was conducted with aim to determine the impact of the continuous care model on the lifestyle and self-care of patients with COPD.

Method: This randomized controlled clinical trial was conducted on 70 patients with chronic obstructive pulmonary disease at Sina Respiratory Hospital at Zabol, southeastern Iran in 2023-2024. The participants who met the inclusion criteria were randomly allocated into intervention and control groups. The Miller Lifestyle Questionnaire and the Miller Self-Care Questionnaire were completed for data collection. For the intervention group, the continuous care model was implemented over 3 months in 4 stages: familiarization, sensitization, control, and evaluation. The statistical analysis was conducted by SPSS software (version 26). $p < 0.05$ was considered statistically significant.

Results: The mean lifestyle score after the intervention decreased in both groups (control: 76.40 ± 4.55 to 75.71 ± 6.62 ; intervention: 71.23 ± 4.65 to 48.05 ± 4.97); however, only the decrease in the intervention group was statistically significant compared with the pre-intervention value ($p < 0.05$), and the mean self-care after the intervention significantly increased compared to the mean before the intervention in the intervention group ($p < 0.05$).

Implications for Practice: The continuous care model can improve self-care behaviors and lifestyles of patients. Therefore, the use of this model is recommended in clinical settings and after discharge for respiratory patients, especially those with COPD, which is a chronic disease.

Keywords: Chronic Obstructive Pulmonary Disease, Follow-Up Care Model, Lifestyle, Self-Care

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Introduction

Chronic Obstructive Pulmonary Disease (COPD) describes progressive lung diseases including emphysema, chronic bronchitis, and treatment-resistant asthma (irreversible) (1). According to the World Health Organization, over 210 million people worldwide are affected by chronic obstructive pulmonary disease, and more than three million people die each year due to this disease (2). In Iran, a study conducted in 2019 revealed that the overall prevalence of this disease is 4.9 percent (3). Therefore, these patients require a treatment regimen as well as daily self-care behaviors and lifestyle changes to prevent, control, and manage the physical, emotional, and social consequences of the disease (4). Self-care includes activities carried out by individuals to promote and maintain health, prevent diseases, and cope with sickness or disability, with or without the support of healthcare providers (5). Self-care is particularly important in managing chronic diseases as it enables individuals to cope with symptoms and treatment regimens, make lifestyle changes related to the disease, and adapt to physical, psychological, and social consequences (6). Therefore, individuals with COPD must continuously adapt their self-care behaviors to new behaviors and circumstances they encounter. The most common self-care behaviors aimed at limiting the physical impacts of COPD include physical exercise, breathing techniques, respiratory muscle training, and skill development for managing shortness of breath (7, 8).

Today, over 70% of diseases are somehow related to an individual's lifestyle, such that many diseases are directly or indirectly related to an individual's way of life, or at least affect the exacerbation or duration of symptoms (9). Improving lifestyle empowers individuals to recognize the factors influencing personal and social health and make correct decisions regarding health behaviors, leading to adherence to a healthy lifestyle (10). Lee et al. demonstrated that engaging in health-promoting behaviors leads to individuals maintaining and controlling their health (11). Modifying lifestyle in acute and chronic diseases is considered an important and determining factor in disease prognosis and complications (12, 13).

Theory is a tool that makes action more efficient and effective, minimizing the energy and time spent by nurses comprehensively evaluating additional topics by having a theoretical perspective (14). Therefore, it appears that a manageable program run by nurses, alongside telephone follow-up, could be a successful and practical model. Additionally, using nursing models can be one of the important and fundamental steps toward achieving this goal. In Iran, the follow-up care model was designed and evaluated by Ahmadinejad (2001) concerning patients with chronic coronary disease. Their aim was to create and maintain dynamic, flexible, and continuous care connections between nurses and patients to improve lifestyle (15). Given that the follow-up care model has yielded positive results in improving the status of chronic patients in various aspects, it has not yet been studied in COPD patients. Considering the role of nurses in promoting lifestyle and changing self-care behaviors among patients using educational methods, this study was conducted with aim to examine the impact of the follow-up care model on self-care and the lifestyle of COPD patients.

Methods

This single-blind clinical trial was conducted on 70 eligible patients at Sina Respiratory Hospital in Zabol, southeastern Iran in 2023-2024. Participants were recruited using convenience sampling. They were then randomly assigned to the intervention and control groups using a computer-generated randomization sequence created in Microsoft Excel. Allocation concealment was ensured through sequentially numbered, opaque, sealed envelopes prepared by an independent researcher. The patients were blinded to group allocation.

Patients with a confirmed diagnosis of COPD who met the inclusion criteria—age ≥ 40 years, availability for a 3-month follow-up, provision of written informed consent, disease duration > 1 year, and literacy—were considered eligible. Exclusion criteria were cognitive or psychiatric disorders, employment of the patient or a first-degree family member in educational or healthcare settings, prior formal education or training in COPD-related self-care, participation in similar research, or the presence of malignant or other debilitating conditions. All potential participants were screened against these criteria before enrollment, and only eligible patients were recruited and randomized.

The sample size was calculated based on the primary outcome (lifestyle score) using data reported by Salari et al. (16). Assuming an expected between-group mean difference of 6 points and a pooled standard deviation of 7.5 (standardized effect size, Cohen's $d = 0.80$), with a two-sided significance

level of 0.05 and 90% power, the required sample size was estimated to be 31 participants per group. To compensate for an anticipated dropout of approximately 10–12%, the sample size was increased to 35 participants in each group. The data collection instruments included a demographic questionnaire, the Miller Self-Care Behaviors Questionnaire, and the Miller and Smith Lifestyle Questionnaire.

Lifestyle was assessed using the 20-item Miller–Smith Lifestyle Questionnaire (1988) (17). This instrument was selected because it has been used in clinical and epidemiological studies and has been culturally adapted and psychometrically validated in Persian-speaking populations. The questionnaire was translated into Persian using forward–backward translation and comprises 20 items scored on a 5-point Likert scale (Always = 1 to Never = 5), yielding a total score range of 20–100, with higher scores indicating unhealthier lifestyle. In Iranian studies, the internal consistency of the Persian version has been reported as acceptable (Cronbach's $\alpha = 0.85$) (18) and ($\alpha = 0.84$) (19). This questionnaire yields a total score ranging from 20 to 100. Each item is scored on a 5-point Likert scale (Always = 1 to Never = 5). Importantly, higher total scores indicate less healthy lifestyle, whereas lower scores reflect a healthier lifestyle. Therefore, a decrease in the total score after the intervention indicates an improvement in lifestyle behaviors.

Although newer lifestyle instruments are available, many lack validated Persian versions or COPD-specific applicability; therefore, to ensure cultural relevance and comparability with prior national studies, the Miller–Smith questionnaire was used in the present study (17). This questionnaire was translated to Persian and consists of 20 questions, each with five options (Always=1, Often=2, Sometimes=3, Rarely=4, and Never=5). Higher scores indicate an unpleasant and unhealthy lifestyle. A total score of 100 indicates an unhealthy lifestyle, while a total score of 20 indicates a healthy lifestyle. In the study by Fadaei and colleagues (2011) (19), the reliability of the lifestyle questionnaire was obtained using the Cronbach's alpha method at 0.85. Furthermore, the reliability of the questionnaire in the study by Ahmadi (2016) was calculated using the Cronbach's alpha method at 0.84, indicating that the tool is reliable (18,19).

The Self-Care Behavior Questionnaire developed by Miller in 1982 was used for assessing self-care. This tool was utilized in some studies (20). It consists of 20 items measured on a five-point Likert scale covering areas such as adherence to prescribed diets, non-smoking, physical activities, adherence to prescribed medications, and adjustments for the effects of stressors. The minimum score is 20, and the maximum is 100. According to the Likert scale, scores from one to four indicate low likelihood, while a score of five indicates high likelihood of compliance with self-care behaviors. Therefore, scores from 20 to 79 indicate undesirable self-care behaviors, while scores from 80 to 100 indicate desirable self-care behaviors. The validity and reliability of this questionnaire were examined by Niakan and colleagues (2013) (21). In their research, the Cronbach's alpha coefficient for dietary prevention, non-smoking, physical activity, adherence to prescribed medications, and the adjustment for stressors after hospital discharge were determined to be 0.95, 0.98, 0.81, 0.92, and 0.80, respectively, signifying internal consistency in the tool's domains. This questionnaire was completed in two phases: prior to the intervention, and after the intervention, and simultaneously in the control group (21-23).

Samples were selected based on the inclusion criteria and then randomly allocated into two groups of intervention and control using random allocation software and a list created with Excel software. For the intervention group, the model of continued care was implemented for duration of 3 months in 4 phases. The phases included: Familiarization, Sensitization, Control, and Evaluation (Figure 1).

1. Familiarization Phase: This phase lasted for 30-45 minutes during a session in the presence of the patient and the primary caregiver. It included familiarizing the parties with each other, clarifying mutual expectations, recommending the necessity of continuous cooperation, and avoiding the cessation of the therapeutic care relationship between the parties until the end of the specified time. Additionally, there was an agreement on in-person and phone meetings and how communication could be maintained.

2. Sensitization Phase: Topics covered included self-care practices, causes and factors leading to COPD, recognition of symptoms and complications of the disease, dietary needs, physical activity, the necessity of performing these actions, the importance of proper use of prescribed medications, and tips related to medications and reducing complications of the disease. This was conducted over 4 sessions (30-45 minutes each), with one session every week by the researcher as consultations, discussions, and presentations. These sessions took place during hospitalization and continued after

discharge at home. At the end of this phase, the content was provided to patients in a booklet format. The total duration of the first two phases was one month.

3. Control Phase: To ensure the continuation of care and health behaviors, a phone call was made to the patient or the caregiver once a week for four weeks. The consultations regarding the patient's needs, problems, and encouragement to continue the educational program were provided. Additionally, advice was given regarding the patient's need to visit a doctor. For this purpose, a phone number was provided to the patients for answering their questions.

4. Evaluation Phase: The final phase of this model involved completing the questionnaires one month after the completion of the third phase (Control). The phases of continued care, the quality of care, and the level of change in patients were assessed, along with any new issues arising or unresolved problems. At the end, care protocols were also provided to the control group, and an educational booklet was delivered to the patients.

After collecting the data, normality was assessed using the Shapiro-Wilk test with SPSS software (version 26). Descriptive statistics (statistical tables, mean \pm standard deviation) and inferential statistics (independent t-tests, paired t-tests, and chi-square tests) were employed to analyze demographic information, lifestyle, and self-efficacy between the two groups and to compare and evaluate the effect of the intervention before and after. $p < 0.05$ was considered statistically significant.

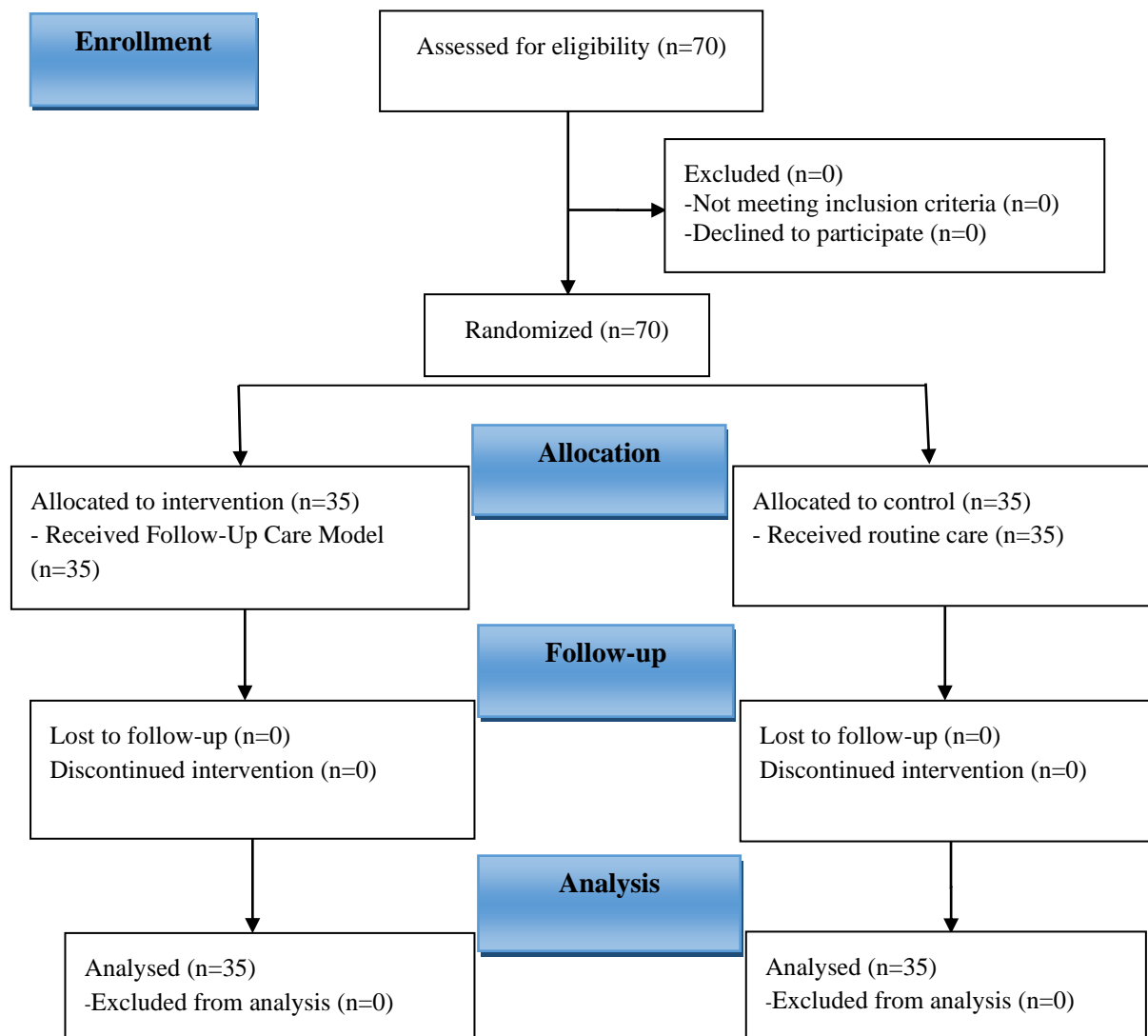


Figure 1. Flowchart of the impact of the continuous care model on the lifestyle and self-care of patients with COPD

Ethical Consideration

The study was approved by the Research Ethics Committee of Zabol University of Medical Sciences (ethical code: IR.ZBMU.REC.1402.047). The research was also registered in the Iranian Registry Clinical Trial (code: IRCT202371105740N1). Patients who participated in this study were willing to provide informed consent via a written form.

Results

A total of 70 participants were studied in this study. Table 1 shows the demographic characteristics of the participants. In the intervention group, 57.1% (n=20) of the participants were female, while in the control group, 54.3% (n=19) were female. The Chi-square test showed no significant difference between the two groups regarding gender ($p=0.810$). The mean age of the participants was 54.57 ± 6.22 years overall, 53.8 ± 6.1 years in the intervention group, and 55.34 ± 6.29 years in the control group. There was no statistically significant difference between the two groups regarding age (Independent t-test: $t = 1.038$, $df = 68$, $p=0.303$). The results of the preliminary analysis did not show a statistically significant difference between the intervention and control groups concerning demographic characteristics (Table 1).

Table 1. Distribution of demographic characteristics of samples in the intervention and control groups

Variable	Intervention n (%)	Control n (%)	Total n (%)	Chi-square	p-value
Gender					
Male	15 (42.9)	16 (45.7)	31(44.3)	$\chi^2 = 0.055$	0.810
Female	20 (57.1)	19 (54.3)	39(55.7)		
Marital Status					
Married	29 (82.9)	24 (68.6)	53 (75.7)	$\chi^2 = 3.65$	0.163
Single	6 (17.1)	11 (31.4)	17 (24.3)		
Occupation					
Housewife	12 (34.3)	16 (45.7)	28 (40.0)	$\chi^2 = 3.36$	0.674
Office worker	9 (25.7)	6 (17.1)	15 (21.4)		
Self-employed	8 (22.9)	6 (17.1)	14 (20.0)		
Unemployed	6 (17.1)	7 (20.0)	13 (18.6)		
Smoking					
Yes	13 (37.1)	16 (45.7)	29 (41.4)	$\chi^2 = 0.53$	0.467
No	22 (62.9)	19 (54.3)	41 (58.6)		
Education					
Below diploma	15 (42.9)	17 (48.6)	32 (45.7)	$\chi^2 = 1.27$	0.908
Diploma	11 (31.4)	9 (25.7)	20 (28.6)		
Associate degree or higher	4 (11.4)	5 (14.3)	9 (12.9)		

The mean of lifestyle before the intervention in the intervention group was 6.62 ± 75.71 , and in the control group, it was 4.55 ± 76.40 . The independent t-test showed no significant difference between the two groups in lifestyle before the intervention ($p=0.615$). The mean of lifestyle after the intervention in the intervention group was significantly lower, at 4.97 ± 48.05 , compared to the control group at 4.65 ± 71.23 . The independent t-test showed a significant difference between the two groups in lifestyle after the intervention ($p=0.001$). The mean of self-care before the intervention was 10.08 ± 40.97 in the intervention group and 9.78 ± 42.91 in the control group. The independent t-test showed no significant difference between the two groups in self-care before the intervention ($p=0.416$). The mean of self-care after the intervention was 9.13 ± 77.82 in the intervention group and 8.34 ± 42.82 in the control group. The independent t-test showed a significant difference between the two groups in self-care after the intervention ($p=0.001$). A score between 20 to 79 indicates undesirable self-care behavior, whereas a score between 80 to 100 indicates desirable self-care behavior. All participants exhibited undesirable self-care behavior before the intervention (both intervention and control groups) (Table 2).

Table 2. Mean of lifestyle and self-care before and after the intervention

Variable	Time	Control (Mean ± SD)	Intervention (Mean ± SD)	Independent t- test (df)	p-value
Lifestyle score	Before intervention	76.40 ± 4.55	75.71 ± 6.62	-0.505(68)	0.615
	After intervention	71.23 ± 4.65	48.05 ± 4.97	19.961(68)	0.001
Self-care behavior score	Before intervention	42.91 ± 9.78	40.97 ± 10.08	-0.818(68)	0.416
	After intervention	42.82 ± 8.34	77.82 ± 9.13	16.734(68)	0.001
Adherence to diet regimen	Before intervention	2.19 ± 7.37	2.19 ± 6.62	-1.414(68)	0.162
	After intervention	1.12 ± 6.97	16.54 ± 1.78	26.811(68)	0.001
Not smoking	Before intervention	6.41 ± 13.82	6.56 ± 13.25	-0.368(68)	0.714
	After intervention	6.41 ± 14.08	15.17 ± 5.43	0.764(68)	0.448
Adherence to drug regimen	Before intervention	1.93 ± 7.08	2.10 ± 7.22	0.296(68)	0.768
	After intervention	1.56 ± 7.20	1.42 ± 1.73	23.332(68)	0.001
Adjusting to stressors' effect	Before intervention	2.18 ± 8.14	2.25 ± 7.80	-0.645(68)	0.521
	After intervention	1.61 ± 7.74	13.28 ± 2.43	11.231(68)	0.001
Adherence to physical activities	Before intervention	1.42 ± 6.48	1.83 ± 6.05	-1.094(68)	0.278
	After intervention	1.24 ± 6.82	16.40 ± 1.24	32.165(68)	0.001

The paired t-test results indicated that the mean lifestyle score decreased significantly after the intervention compared to before the intervention in both groups, with the decrease in the intervention group being statistically significant (pre-intervention: 71.23 ± 4.65 vs. post-intervention: 48.05 ± 4.97, $p=0.001$, Cohen's $d \approx 4.82$), reflecting a substantial improvement in lifestyle. Additionally, the paired t-test showed that the mean self-care score in the intervention group significantly increased after the intervention compared to before the intervention (Table 3). A score between 20 to 79 indicates undesirable self-care behavior, while a score between 80 to 100 indicates desirable self-care behavior.

Table 3. The mean of lifestyle and self-care before and after the intervention

Variable		Mean ± SD	Mean difference	p-value	
Lifestyle	Intervention	Before intervention	6.62±75.71	-27.66	0.001
		After intervention	4.97±48.05		
	Control	Before intervention	4.55±76.40	-5.17	0.029
		After intervention	4.65±71.23		
Self-care behavior	Intervention	Before intervention	10.08±40.97	+36.85	0.001
		After intervention	9.13±77.82		
	Control	Before intervention	9.78±42.91	-0.09	0.855
		After intervention	8.34±42.82		

Moreover, 24.3% of participants in the intervention group achieved desirable self-care after the intervention, while all participants in the control group remained in the undesirable category, with a statistically significant difference between the two groups ($p=0.001$). Although only about one-fourth of the intervention group reached the desirable level, this represents a clinically meaningful improvement from baseline, as none of the participants were at this level before the intervention. This suggests that the intervention had a notable positive impact on self-care behaviors, even if further strategies may be needed to help more patients achieve optimal self-care.

Table 4. Distribution of frequency based on self-care after the intervention

Variable		Total N (%)	Intervention N (%)	Control N (%)	p-value
Self-care behavior	Favorable	53(75.7)	18(51.4)	35(100)	0.001

Discussion

The purpose of the present study was to examine the impact of a follow-up care model on the lifestyle and self-care behaviors of patients with Chronic Obstructive Pulmonary Disease (COPD). It is crucial for individuals managing COPD, a progressive and irreversible chronic disease, to enhance their self-care behaviors, as this can improve patients' quality of life and reduce the frequency of hospital admissions and the incidence of dyspnea. The results of the study indicated that the average scores of self-care and its domains, as well as the lifestyle score, were poor in both intervention and control groups before the intervention. In this regard, the results of the study by Bugajski et al. also indicated low self-care skills and symptom management in COPD patients (24). Cardiovascular diseases, stroke, obesity, diabetes, hypertension, and respiratory diseases, especially COPD, are defined as lifestyle-related diseases that fall under non-communicable diseases. They arise from a lack of physical activity, unhealthy nutrition, alcohol consumption, drug use, and smoking, all of which impacting lifestyle (25). The results of the study by Gomaa et al. (2020) showed that more than three-fifths of the studied patients were smokers, and the majority had a low level of awareness. Their dietary habits, physical activity, motivation, mental status, adherence to medication regimens, and smoking habits were inadequate, indicating a poor lifestyle (1) that aligns with the findings of the present study.

The results of the current study showed that utilizing the Miller follow-up care model effectively led to improvements in lifestyle and self-care behaviors. This model emphasizes structured education, regular follow-up, goal-setting, and continuous support, which likely facilitated behavioral changes by increasing patients' awareness, motivation, and adherence to healthy practices. The combination of individualized guidance and consistent monitoring appears to be the key feature contributing to the observed improvements. In support of the application of this follow-up care model in improving lifestyle, Shahrani et al. (2016) (26) and Malazem et al. (2013) (27) conducted studies on patients with hypertension and myocardial infarction, where the results indicated improvements in patients' lifestyles. Education of patients and reinforcement through repetition, monitoring, and management by nurses can be significant factors in promoting behavioral change and lifestyle modification in these patients. Additionally, the study by Elohyari et al., which examined the impact of the follow-up care model on the self-care behaviors of diabetic patients, indicated that the use of this model led to improvements in self-care behaviors, confirming the findings of the current study (28).

Park et al. assessed the impact of education through mobile applications on the self-care behaviors of COPD patients, and the results indicating that the use of this program was effective, particularly for patients with limited access to healthcare providers who often experience symptom exacerbations (29). Wang et al. also investigated self-care behaviors, physical activity, smoking cessation, and quality of life in COPD patients using mobile applications, showing improvements in these areas (30). Differences between the mentioned studies and the current study may be related to the type of intervention model applied, the duration of the intervention, and the tools used. However, the results of this study indicate that the implementation of a follow-up care model—part of which involves telephone follow-ups—similar to using mobile applications, can be effective in enhancing self-care behaviors. Given that the locally adapted follow-up care model was designed to fit the cultural conditions and context of Iran, aiming to create insight among clients for continuous care, the similarity in the results regarding the improvement of self-care and lifestyle in the studies mentioned can be justified. This model has been applied in chronic diseases and situations where clients need education and ongoing care and has been utilized in various fields, such as sleep quality, dialysis adequacy, and quality of life in hemodialysis patients, self-care in heart failure patients, emotional health dimensions and social communications, quality of life in infertile women, and anxiety in mothers and children from pediatric surgery, among many other studies (31).

In the present study, the average scores of the domains of self-care behaviors in the intervention and control groups after the intervention had statistically significant differences, with scores in the dietary adherence, treatment regimen, stress modulation, and physical regimen domains increasing in the intervention group. However, the score for the domain of non-smoking did not show a statistically significant difference after the intervention, only reflecting that the average score of the intervention group was higher than that of the control group. Given the lengthy process of smoking cessation and the necessary supportive actions for quitting smoking, the results obtained were not unexpected, consistent with the findings of Kerman Saravi and Ismailpour (32, 33).

The increase in the scores of the self-care domains suggests that patients were able to achieve positive changes in these areas following the implementation of the follow-up care program. Xiaolian et al. conducted a study in China, and the results showed that patients exhibited sufficient self-care behaviors regarding medication adherence and smoking cessation (34). This aligns with the current study regarding medication adherence, but there was a difference concerning smoking cessation. In areas of participation, recreational activities, and engagement in non-medical management activities and practicing breathing techniques, patients demonstrated inadequate self-care behaviors (34). In contrast, the results of the present study indicated that patients showed desirable self-care behaviors when follow-up care was pursued. The difference between the results of the mentioned study and the current one may be attributed to cultural, social, and lifestyle differences among the studied groups. Some studies show that individuals with COPD regularly focus on medication adherence and exercise (29), while the results of the present study conducted before the intervention indicated that patients had poor scores in areas of physical activity and treatment adherence, which improved after the intervention. In this regard, the study by Yiğit et al. showed that patients with COPD exhibit low levels of physical activity (35). Self-care behaviors may be carried out on the advice of nurses or considered beneficial actions that individuals should undertake consistently. Nurses play an important role in assessing patients' self-care levels, motivating for self-care, and educating them. By supporting patients in this way, nurses contribute to better health outcomes (29). Nursing models provide guidelines for delivering nursing care. Utilizing nursing models, especially those compatible with the culture of the community, can be effective in providing nursing care and ensuring continuity of care, while also controlling potential conflicts in care delivery.

One of the limitations in the implementation of this plan was the difficulty in accessing patients, as most patients were located in rural and remote areas. The researcher had to travel long distances to reach the patients and provide education and care. In term of statistical analysis, although paired t-tests were used to assess changes within groups, a repeated-measures ANOVA would have allowed a more comprehensive evaluation of the interaction between time and group. Due to the completed dataset, this analysis was not performed; future studies with larger samples are recommended to use repeated-measures designs.

Implications for practice

Implementing a follow-up program for patients during and after hospital discharge by nurses who are aware of the disease status and individual conditions can lead to increased awareness and improved self-care behaviors. Additionally, emphasizing healthy behaviors will contribute to lifestyle changes in patients, leading to better control of disease symptoms, prevention of complications, and recurrence of symptoms, as well as reducing hospital readmissions. The study results indicated that the continuous care model, which is a local model, can improve self-care behaviors and lifestyles of patients. Thus, the use of this model in clinical settings and after discharge for respiratory patients, especially those with COPD, which is also a chronic disease, is recommended.

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Conflicts of interest

The authors declared no conflict of interest.

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Authors' Contributions

T.SSH, M.PM, H.SH, and H.P contributed to the conception, design, data collection, data analysis and drafting the manuscript. T.SSH, M.PM, and H.SH performed conception, design, supervision of project, and revising the manuscript. T.SSH and H.P conducted data collection and revising the manuscript. All authors contributed to the writing of the manuscript.

AI Statement

The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript, nor for the creation of images, graphics, tables, or their corresponding captions.

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