Golestan University of Medical Sciences

Journal of Research Development in Nursing and Midwifery
(J Res Dev Nurs Midw)
Online ISSN: 2588-3038

Telehealth palliative care for chronic obstructive pulmonary disease in Iran: The Study Protocol of a Randomized Controlled Feasibility Trial

Zahra Arabi [1], Arvin Mirshahi [2,3], Hosein Kazemi Zadeh [4], Shima Haghani [5], Anand Iyer [6], Rachel Wells [7], Marie Bakitas [3,8], Mehraban Shahmari [9], Arpi Manookian [1*]

1. Department of Medical-Surgical Nursing, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran
2. Students' Scientific Research Center, Department of Medical-Surgical Nursing, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran
3. Center for Palliative and Supportive Care, University of Alabama at Birmingham, Birmingham, Alabama, United States of America
4. Department of Pulmonology, School of Medicine, Imam Khomeini Hospital, Tehran University of Medical Sciences, Tehran, Iran
5. Biostatistics Nursing Care Research Center, Iran University of Medical Sciences, Tehran, Iran
6. Department of Medicine, Division of Pulmonary, Allergy, and Critical Care Medicine, University of Alabama at Birmingham, Birmingham, Alabama, United States of America
7. School of Nursing, University of Alabama at Birmingham, Birmingham, Alabama, United States of America
8. Department of Medicine, School of Nursing, Division of Gerontology, Geriatrics, and Palliative Care, University of Alabama at Birmingham, Birmingham, Alabama, United States of America
9. Department of Medical - Surgical, School of Nursing and Midwifery, Ardabil University of Medical Sciences, Ardabil, Iran

* Correspondence: Arpi Manookian. Department of Medical-Surgical Nursing, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran. Tel: +982166914368; Email: Manookianarpi@gmail.com

Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a progressive, irreversible respiratory condition that imposes a significant physical and psychological burden, often leading to a poor quality of life. Although palliative care can help address these challenges, in Iran it is typically limited to cancer patients and is not commonly provided to those with COPD. Globally, the early integration of palliative care for chronic illnesses is expanding. The present study aims to investigate the feasibility and acceptability of an early tele-palliative care intervention for patients with COPD in Iran and to explore its potential effects on quality of life, anxiety, depression, and emergency department readmissions.

Methods: This randomized controlled feasibility trial protocol involves a 3-month early tele-palliative care program delivered by two nurse coaches, targeting patients with COPD. Participants were randomly assigned to either the intervention group (n = 26) or the control group (n = 26) using permuted block randomization. Both groups received traditional COPD care; however, the intervention group also received six weekly telephone sessions and six weeks of follow-up support via phone call and WhatsApp Messenger. The primary objective was to assess the feasibility and acceptability of early tele-palliative care, measured through recruitment and attrition rates, questionnaire completion rates, patient satisfaction, attitudes toward the intervention, and adherence to the intervention. The secondary outcome included changes in quality of life, anxiety, depression, and hospital readmissions. These were measured using validated instruments at two time points: Baseline (Pre-intervention) and three months post-intervention. Statistical analyses were performed using SPSS version 22, including the independent samples t-test, paired samples t-test, chi-square test, and Fisher's exact test. Analysis of covariance (ANCOVA) was used to compare the mean outcomes between the two groups while statistically controlling for the effect of baseline values. Statistical significance was set at $p < 0.05$.

Conclusion: This study protocol aimed to determine the feasibility and acceptability of an early tele-palliative care intervention for patients with COPD in Iran. The findings provided essential data to inform the design of a future large-scale clinical trial and support the potential integration of early telehealth palliative care into standard COPD management in the country.

Article Type: Protocol

Article History

Received: 25 July 2025
Received in revised form: 28 September 2025
Accepted: 12 October 2025
Available online: 9 December 2025
DOI: 10.29252/jgbfnm.22.4.14

Keywords

Pulmonary disease, Chronic obstructive
Telehealth
Palliative care
Quality of life
Feasibility studies

Introduction

Chronic obstructive pulmonary disease (COPD) is a progressive and irreversible respiratory condition characterized by persistent airflow limitation and chronic airway inflammation (1). COPD is associated with excessive mucus secretion (Chronic bronchitis), destruction of lung tissue (Emphysema), and fibrosis of the small airways (Bronchiolitis), all of which contribute to increased airflow resistance and systemic inflammation (2). The disease results from long-term exposure to harmful particles or gases, primarily tobacco smoke; however, environmental pollutants, occupational exposures, genetic factors, such as alpha-1 antitrypsin deficiency, and smoke from cooking fires also contribute to a lesser extent (3,4).

COPD is a significant global health challenge and ranks as the third leading cause of death and morbidity worldwide (5). In 2019, approximately 392 million people were living with COPD, leading to an estimated 3.23 million deaths related to the disease (6). The prevalence of COPD in Iran is estimated at 4.9% (7). It is predicted that the number of COPD cases will rise to 600 million by 2050 (6,8). This increase is primarily driven by an aging global population (9), as well as factors such as smoking, exposure to high levels of industrial air pollution, and urbanization (10).

Chronic diseases, such as COPD, impact both the physical and mental health of individuals (11). Patients with COPD often experience respiratory symptoms, such as shortness of breath, chronic cough, and sputum production, which progressively worsen over time (12). As the

disease advances, acute exacerbations become more frequent and often require hospitalization (13). Beyond physical limitations, patients often face psychological challenges, with approximately 90% experiencing symptoms of anxiety and depression (14,15), which can lead to a significant reduction in their quality of life (1). Patients often feel disappointed and frustrated because they are unable to engage in their desired activities (16). Given these challenges, effective disease management requires a comprehensive, patient-centered approach that addresses the physical, psychological, and spiritual dimensions of care while actively involving patients and their families (17).

Palliative care is a promising approach to eliminating these challenges, playing a vital role in alleviating the complex symptoms of COPD and enhancing patients' overall well-being by addressing both their physical and psychological needs (18). The World Health Organization (WHO) defines palliative care as an approach that improves the quality of life for patients and their families facing problems associated with life-threatening illnesses. It prevents and relieves suffering through the early identification, accurate assessment, and treatment of pain and other issues, whether physical, psychosocial, or spiritual (19). The main goal of palliative care is to maintain the highest possible quality of life until death. It emphasizes the value of life and regards death as a natural process, without seeking to hasten or delay it (20). While palliative care was associated primarily with cancer, it is now recommended for a wide range of chronic, life-limiting illnesses, such as dementia, Alzheimer's disease, heart failure, and end-stage renal disease. COPD is also among these conditions that can significantly benefit from palliative interventions (21). By providing these services, the burden of disease on individuals, families, and the community is reduced, unnecessary hospitalizations are prevented, and healthcare costs are saved (22).

Initiating palliative care early, from the time of diagnosis, plays a crucial role in improving quality of life and mitigating anxiety and depression (23). Providing palliative care integrated with routine treatment soon after diagnosis helps patients receive comprehensive support, including effective symptom management (Such as relief from breathlessness and fatigue), psychological counseling to address anxiety and depression, and advance care planning to prepare for future healthcare decisions (24,25). These services should be available at all stages of the disease, regardless of the diagnosis, prognosis, or likelihood of death (26). Despite these benefits, palliative care is often provided only when patients are near the end of life (27).

One evidence-based model of early palliative care is the educate, nurture, advise, before life ends (ENABLE) program, which is based on Wagner's Chronic Care Model (CCM)-a patient-centered approach that promotes proactive care planning, self-management support, and effective interaction between an informed, active patient and a prepared, responsive healthcare team (28). ENABLE is designed to educate and support patients with cancer and their caregivers from diagnosis to end of life, focusing on symptom management, advance care planning, decision-making, communication, and coping and problem-solving skills (23).

The ENABLE intervention is a telephone-based early palliative care program designed to overcome key barriers to effective palliative care delivery (23). It ensures access to care for patients in remote or underserved areas, reduces the risk of infectious disease transmission, enhances family involvement in the patient's care process, lowers healthcare costs by improving service efficiency, enables timely care for urgent cases, and minimizes patients' travel and waiting times (29). These advantages make tele-palliative care an effective and equitable approach for delivering palliative care to individuals with life-limiting illnesses (30).

Based on the core content, format, and delivery of ENABLE, the early palliative care in COPD (EPIC) program has been specifically developed to address the unique needs of individuals living with COPD and their family caregivers (27). It integrates palliative care principles to support functional independence, emotional well-being, and care planning through a nurse-led, telephone-based approach tailored to the daily realities of older adults with COPD (31).

Despite increasing global recognition of palliative care, many countries still lack dedicated palliative care programs within their healthcare systems (32). In Iran, palliative care is a relatively new concept and remains in its early stages of development (8). It is currently available in only a limited number of centers and, even then, is primarily provided to cancer patients. As a result, patients with COPD in Iran do not receive any form of palliative care.

To address this gap, the present study represents the first clinical trial to implement and evaluate an early tele-palliative care intervention for patients with COPD in Iran. The primary objective was to assess the feasibility and acceptability of delivering early tele-palliative care. Secondary outcomes included the effects of early tele-palliative care on quality of life, anxiety, depression, and hospital readmission rates.

Methods

Study design and setting

The protocol detailed in this paper outlines a randomized controlled feasibility trial, designed as a two-group, single-site, open-label study aimed at evaluating the feasibility and acceptability of early tele-palliative care interventions for patients with COPD in Iran. This study was conducted at the respiratory clinic of Imam Khomeini Complex Hospital (IKHC), one of the most prominent centers providing professional respiratory care. All patients were asked to sign informed consent forms, ensuring their full awareness of the study's details and agreement to participate. This protocol was developed in accordance with the 2022 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (33).

Eligibility criteria

Before starting the intervention, the physician, together with the nurse interventionist, evaluated all patients during the initial examination. This evaluation assessed each patient's educational needs and specific symptoms. Consequently, patients' eligibility to participate in the study was determined based on the following criteria.

The inclusion criteria for this study included a confirmed diagnosis of COPD by a physician in accordance with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, age over 40 years, ability to read and write in Persian, access to and ability to use a smartphone, proficiency with the WhatsApp application, no cognitive disorders, no uncorrectable visual or hearing impairments, and no comorbid conditions requiring specialized palliative care (e.g., cancer).

Importantly, the term "early" in this study referred to the initiation of tele-palliative care immediately after the diagnosis of COPD, regardless of disease stage, prognosis, or likelihood of death. Therefore, any patient with a confirmed diagnosis of COPD was considered eligible for inclusion.

Patients were excluded from the study if they showed reluctance to participate, failed to cooperate in continuing the research by missing two consecutive sessions, progressed to the acute phase of the illness, or died during the study.

Intervention group

At the beginning, patients were evaluated in person by a pulmonologist and a nurse interventionist to determine their eligibility for participation. Each patient underwent a comprehensive, individualized assessment to identify their specific educational needs. This care program was designed as a patient-centered intervention, tailored to the specific needs, limitations, and preferences of individuals living with COPD.

The intervention in this study consisted of early tele-palliative care for patients with COPD. It included six structured telephone sessions based on the EPIC program (27), delivered by two trained nurse coaches. Additionally, patients in the intervention group received a guidebook titled *"Palliative Care in Patients with COPD"* during their initial in-person visit. This guidebook, reviewed and approved by five nursing professors, covered topics such as positive problem-solving strategies, self-care practices, symptom management, communication about important issues, and decision-making skills.

Each telephone session lasted approximately 30 to 45 minutes and was scheduled at a mutually agreed-upon time between the researcher and the patient. To enhance adherence and engagement, participants received reminder messages before each session. The design of the intervention is illustrated in Figure 1, in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for trial reporting (34).

The content of the weekly sessions is outlined in Table 1. The first session introduced the concepts of palliative care and COPD. The second session focused on the Creativity, Optimism, Planning, and

Expert information (COPE) model, emphasizing problem-solving strategies through a positive attitude. The third session emphasized self-care practices, including healthy eating, physical activity, smoking cessation, and relaxation techniques. The fourth session addressed strategies for managing physical and emotional symptoms. In the fifth session, patients' priorities were assessed, and individualized support was provided to facilitate appropriate decision-making. Finally, the sixth session involved a reflective review of the patients' lives and accomplishments (35).

All educational content from the sessions was shared weekly via a WhatsApp group created for the intervention group participants, where they could also ask questions and share their experiences.

Following the 6-week intervention period, patients were monitored for an additional 6 weeks. During this follow-up phase, weekly phone calls were conducted to ensure continuity of care, reinforce the educational content provided during the intervention, and maintain patient engagement. Researchers also addressed participants' questions through both phone calls and a WhatsApp group.

At week 12, patients visited the pulmonary clinic at IKHC for final examinations and to complete questionnaires. During this session, patients also reported any hospitalizations that occurred during the 3-month study period. The SPIRIT diagram (36) (Table 2) outlines different times for enrollment, assignment of activities, delivery of interventions, and data collection.

Control group (Usual care)

The control group received the same treatment process as the intervention group, except for early tele-palliative care. Patients in the control group received traditional COPD care provided by physicians and nurses in the respiratory clinic, which included guidance on managing respiratory symptoms, such as dyspnea, cough, and sputum production. Patients were instructed on the correct use of medications, including inhalers and other prescribed treatments, as well as receiving with nutritional advice and general health education. Additionally, they were trained on respiratory exercises and breathing techniques to enhance their overall respiratory health.

Study measures and data collection

This study evaluated the effectiveness of a 12-week early tele-palliative care intervention by assessing the primary and secondary outcomes outlined below.

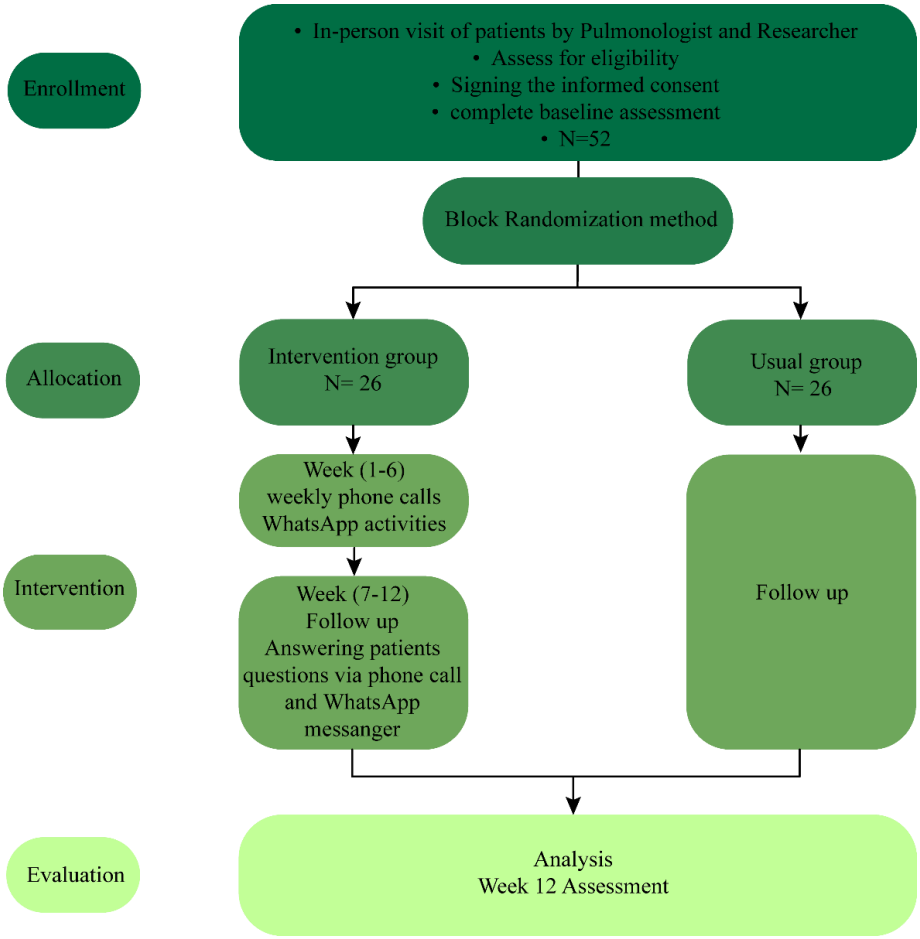

Figure 1. Study diagram

Table 1. Content of weekly sessions

Nurse coach weekly telephone sessions	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Session content	**Your health, your care** What is COPD? What is palliative care?	**Positive attitude against challenges** Coping, problem solving	**Taking care of yourself** Self-care, nutrition, exercise, support	**Controlling symptoms** Symptom management (Physical, emotional, spiritually)	**Priorities and choices** What matters most and making choices	**Life story** Life review and accomplishments

COPD: Chronic Obstructive Pulmonary Disease

Table 2. The schedule for enrolment, interventions, and assessments in this study

Study phases and assessments	Study period				
	Enrolment	Allocation	Post-allocation		Close-out
Time point**	**Baseline**	**0**	**Week 1-6**	**Week 7-12**	**Week 12**
Enrollment	-	-	-	-	-
Eligibility screen	X	-	-	-	-
Informed consent	X	-	-	-	-
Randomization	-	X	-	-	-
Interventions	-	-	-	-	-
Early tele-palliative care	-	-	X	X	-
Usual care	-	-	X	X	-
Assessments	-	-	-	-	-
Demographic	X	-	-	-	-
Physical examination	X	-	-	-	-
Comorbidities	X	-	-	-	-
Smoking status	X	-	-	-	-
Health insurance	X	-	-	-	-
Oxygen saturation	X	-	-	-	-
Occupation	X	-	-	-	-
Place of residency	X	-	-	-	-
Education level	X	-	-	-	-
GOLD classification of COPD	X	-	-	-	-
Primary outcome	-	-	-	-	-
Feasibility and acceptability	-	-	-	-	X
Secondary outcome	-	-	-	-	-
Quality of life	X	-	-	-	X
Anxiety and depression	X	-	-	-	X
Hospital readmission	X	-	-	-	X

GOLD: Global Initiative for Chronic Obstructive Lung Disease; COPD: Chronic Obstructive Pulmonary Disease

Primary outcomes

- To assess the feasibility of the intervention: Participant engagement and questionnaire completion rates were evaluated. The intervention was considered feasible if the following criteria were met: 70% of eligible patients successfully enrolled in the study, the completion rate of the initial evaluation exceeded 80%, the completion rate of the final evaluation was greater than 70%, and the attrition rate was less than 20%.
- To evaluate the acceptability of the intervention: Participants were interviewed via phone call after completing the study. They were asked to rate their satisfaction with the palliative care provided through phone calls using a 5-point Likert scale (Completely unsatisfied, unsatisfied, neutral, satisfied, completely satisfied). Additionally, participants rated their adherence to the intervention on a 5-point Likert scale and their satisfaction with the information shared via the WhatsApp group on a 5-point Likert scale. They were also asked to discuss any challenges they faced during the study, how they addressed these challenges, and to provide suggestions for improving palliative care services. Furthermore, participants were asked whether they would be willing to participate again in this study or recommend it to others (Yes/No). The intervention was considered acceptable if the following criteria were met: More than 80% participation in scheduled phone calls, a commitment score of 4 and above on the Likert scale, and a satisfaction score of 4 and above on the Likert scale, with over 75% of participants expressing a willingness to either continue participation or recommend the program to others.

Control group (Usual care)

The control group received the same treatment process as the intervention group, except for early tele-palliative care. Patients in the control group received traditional COPD care provided by physicians and nurses in the respiratory clinic, which included guidance on managing respiratory symptoms, such as dyspnea, cough, and sputum production. Patients were instructed on the correct use of medications, including inhalers and other prescribed treatments, as well as receiving with nutritional advice and general health education. Additionally, they were trained on respiratory exercises and breathing techniques to enhance their overall respiratory health.

Study measures and data collection

This study evaluated the effectiveness of a 12-week early tele-palliative care intervention by assessing the primary and secondary outcomes outlined below.

Primary outcomes

- To assess the feasibility of the intervention: Participant engagement and questionnaire completion rates were evaluated. The intervention was considered feasible if the following criteria were met: 70% of eligible patients successfully enrolled in the study, the completion rate of the initial evaluation exceeded 80%, the completion rate of the final evaluation was greater than 70%, and the attrition rate was less than 20%.
- To evaluate the acceptability of the intervention: Participants were interviewed via phone call after completing the study. They were asked to rate their satisfaction with the palliative care provided through phone calls using a 5-point Likert scale (Completely unsatisfied, unsatisfied, neutral, satisfied, completely satisfied). Additionally, participants rated their adherence to the intervention on a 5-point Likert scale and their satisfaction with the information shared via the WhatsApp group on a 5-point Likert scale. They were also asked to discuss any challenges

they faced during the study, how they addressed these challenges, and to provide suggestions for improving palliative care services. Furthermore, participants were asked whether they would be willing to participate again in this study or recommend it to others (Yes/No). The intervention was considered acceptable if the following criteria were met: More than 80% participation in scheduled phone calls, a commitment score of 4 and above on the Likert scale, and a satisfaction score of 4 and above on the Likert scale, with over 75% of participants expressing a willingness to either continue participation or recommend the program to others.

Secondary outcomes

Quality of life

Clinical COPD Questionnaire (CCQ) is a tool used to assess health-related quality of life in patients with COPD. The original version of this questionnaire was published in 2003 (37). The CCQ, comprising 10 items, is a concise, user-friendly, and easy-to-use tool that is not time-consuming, making it appropriate for clinical practice. It quantifies the impact of COPD on a patient's quality of life (38,39). The CCQ consists of three domains: A. Functional status domain (4 questions: 7, 8, 9, and 10), B. Symptoms domain (4 questions: 1, 2, 5, and 6), and C. Mental situation domain (2 questions: 3 and 4).

Each question is scored on a 7-point scale, where 0 indicates no symptoms and 6 indicates severe symptoms with full limitation. The total score is calculated by summing all 10 question scores and dividing by 10 (The number of questions). Domain-specific scores can also be calculated separately. An overall score of 0 reflects excellent quality of life, while a score of 6 indicates very poor quality of life.

The Functional Assessment of Chronic Illness Therapy-Palliative Care (FACIT-PAL-14) is a 14-item questionnaire designed to assess the quality of life in patients receiving palliative care for severe illnesses (40). The original FACIT-PAL was published by Webster et al. in 2003 (41), and a brief version was subsequently developed by Zeng et al. (42). This brief version consists of 14 questions; each rated on a 5-point Likert scale (Ranging from 0 to 4). The total score ranges from 0 to 56, with higher scores indicating better quality of life. A score above 33.7 suggests good performance status and a prognosis exceeding 6 months (43). The questionnaire has been translated into Persian and validated by Mirshahi et al. (44).

Anxiety and depression

The Hospital Anxiety and Depression Scale (HADS), developed by Zigmond et al. in 1983 (45), is a widely used tool for assessing symptoms of anxiety and depression (46). The scale comprises 14 items, each rated on a 4-point Likert scale. Seven items assess anxiety (Questions 1, 4, 5, 8, 9, 12, and 13), and the remaining seven assess depression (Questions 2, 3, 6, 7, 10, 11, and 14). The total score for either anxiety or depression ranges from 0 and 21. Scores between 11 and 21 indicate clinically significant symptoms, 8 to 10 reflect borderline cases, and 0 to 7 are considered within the normal range. The validity and reliability of the tool have been confirmed in previous studies. Construct and content validity were established by Montazeri et al. in 2003, and the instrument demonstrated internal consistency, with Cronbach's alpha reported as 0.78 for the anxiety subscale and 0.86 for the depression subscale (47).

Number of emergency department visits

At the end of the 3-month study period, patients reported the number of hospitalizations, reasons for readmission, and the timing of these events. These data were collected by an outcome assessor blinded to group assignments to minimize bias and ensure an accurate assessment of the intervention's effects.

Data collection

Before randomization, demographic and baseline characteristics were collected from the patients' medical records and self-reported information. All participants completed the CCQ, FACIT-PAL-14, and HADS questionnaires at two time points: At the beginning of the study (Week 1) and at the end (Week 12). These assessments took place at the respiratory clinic of IKHC, Tehran, under the supervision of a trained assessor. The primary objective of this study was to evaluate feasibility and acceptability, which was performed through a structured interview during week 12.

Sample size

The sample size for this feasibility trial was estimated to ensure adequate precision for assessing feasibility outcomes and to detect a potential signal of efficacy for the secondary outcomes. The calculation was based on the secondary outcome of health-related quality of life, informed by a previous randomized controlled trial conducted by Quynh Thi Huong Bui et al. (48), which evaluated a pharmacist-led educational intervention for patients with COPD. In that study, the primary outcome was the change in the total CCQ score. The mean change (± standard deviation) was -0.90 (± 0.65) in the intervention group and -0.26 (± 0.74) in the control group. From these data, the effect size (Cohen's d) was calculated to be approximately 0.92, which is considered a large effect.

For our study, to ensure a conservative estimate, the sample size was calculated using a 95% confidence interval (CI) and 80% power to detect a slightly smaller, yet still large, effect size of 0.7. The minimum required sample size was determined to be 22 participants per group. To account for a potential 20% attrition rate, the final sample size was increased to 26 participants per group, resulting in a total of 52 individuals.

Recruitment

The study population consisted of patients with COPD attending the respiratory clinic at IKHC. Patients were selected based on predefined inclusion and exclusion criteria, and the process continued until the desired sample size was reached. After explaining the study's aims and methods, patients were asked to complete and sign informed consent forms. To promote ongoing patient engagement, reduce attrition, and improve adherence to the intervention, regular reminders were provided via phone calls and a WhatsApp group.

Randomization and blinding

Participants were randomly assigned to either the intervention group or the control (Usual care) group using a permuted block randomization method with a 1:1 allocation ratio. The randomization sequence was generated using blocks of size four, ensuring that within each block, two participants were allocated to the intervention group and two to the control group. All six possible permutations of assignments within the blocks (i.e., AABB, ABAB, ABBA, BBAA, BAAB, BABA, where A is intervention and B is usual care) were utilized to maintain unpredictability.

To ensure allocation concealment, the assignment sequence was placed inside sequentially numbered, sealed, opaque envelopes by a third party not involved in patient recruitment. An envelope was opened only after a participant had been enrolled in the study and all baseline data had been collected.

Due to the nature of the study, both participants and researchers were aware of group assignments. To minimize bias, the outcome assessor and statistician remained blinded to group allocation. The outcome assessor was a different individual from the nurse interventionist was not involved in delivering the intervention. The assessor followed a standardized script during data collection sessions to prevent accidental unblinding. Participants were instructed not to disclose any details about their treatment or study-related activities to the outcome assessor.

Data management

Participants completed the study questionnaires in-person using paper-and-pencil forms at baseline and at the end of week 12. The collected data were entered into SPSS software (Version 22) by the researcher. To maintain participant confidentiality, all data were stored using anonymized identification (ID) codes. Data analysis was conducted by an epidemiologist or statistician.

Statistical methods

Quantitative variables were described using the mean and standard deviation for normally distributed data, or the median and interquartile range for non-normally distributed data. Qualitative variables were summarized using frequency tables and corresponding percentages. To evaluate the feasibility and acceptability of the intervention, the participation rate, response rate, and percentage of participants lost to follow-up were calculated, along with a 95% CI. The Shapiro–Wilk test was used to assess the normality of the data. To compare baseline characteristics between the two groups, the independent t-test (Or its non-parametric equivalent, i.e., Mann-Whitney U test) was used for quantitative variables, and the chi-square test or Fisher's exact test, as appropriate, was used for qualitative variables. All baseline comparisons were unadjusted.

The primary analysis of the secondary outcomes was a complete-case analysis, including only participants with complete data for the

outcomes at both baseline and the 12-week follow-up. The number and reasons for dropouts in each group were reported. To investigate potential attrition bias, we compared the baseline demographic and clinical characteristics of participants who completed the study with those who dropped out using independent t-test or chi-square test, as appropriate.

The paired t-test was employed to evaluate the effectiveness of the intervention within each group (Control and intervention). To compare changes in the secondary outcomes (Quality of life, anxiety, and depression) between the two groups, analysis of covariance (ANCOVA) was the primary analytical method. The ANCOVA model used the post-intervention score as the dependent variable, the study group (Intervention versus control) as the independent variable, and the baseline score of the outcome variable as a covariate to increase statistical power and adjust for any random baseline differences. Furthermore, if key pre-specified baseline characteristics, namely age and GOLD classification, showed significant imbalances between the groups, they were also included as covariates in the ANCOVA model to ensure a more robust comparison. All statistical tests were two-sided, with statistical significance set at a p-value of less than 0.05. Analyses were performed using SPSS software (Version 22).

Conclusion

This study represents the first trial in Iran to evaluate the feasibility and acceptability of early tele-palliative care for patients with COPD. By assessing patient recruitment, engagement, adherence, and satisfaction, the trial provided critical insights into the practical implementation of early telehealth palliative care. The findings generated essential data to inform the design of a future, larger-scale definitive trial. Ultimately, this research aimed to support the integration of patient-centered, accessible palliative care strategies into routine COPD management, with the potential to improve quality of life, reduce psychological distress, and optimize healthcare resources for this vulnerable population.

Acknowledgement

This study protocol pertains to Z.A.'s MSc thesis in Medical-Surgical Nursing at Tehran University of Medical Sciences. The author would like to express sincere gratitude to the Vice-Chancellor for Education, Research, and Technology at Tehran University of Medical Sciences. We sincerely thank Dr. Marie Bakitas, Dr. Anand Iyer, and Dr. Rachel Wells from the University of Alabama, Birmingham, as the principal researchers of the EPIC project, for their invaluable guidance during the design of the intervention and their thoughtful review of the manuscript, which significantly contributed to improving the quality of this work.

Funding sources

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethical statement

The present trial was approved by the Ethics Committee of Tehran University of Medical Sciences (TUMS) on October 13, 2024 (IR.TUMS.FNM.REC.1403.107). The protocol has also been registered with the Iranian Clinical Trials Registry (IRCT) [IRCT20241008063299N1]. To ensure adherence to ethical principles in research, an electronic version of the educational booklet was provided to the control group participants at the end of the study during their final clinic visit. Informed consent was completed by all participants prior to randomization. The informed consent process was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki (49). All patient information remained confidential. Participants were fully informed of their rights to voluntary participation and their ability to withdraw at any stage of the study. The researcher's contact information was provided to the patients in case they had any questions or need required.

Conflicts of interest

No conflict of interest.

Author contributions

Principal investigator of the trial: Z.A.; Study design initiation: A.M., M.B., R.W., A.I., and Dr. A.M.; Physician in charge of the pulmonary clinic at Imam Khomeini Hospital Complex: H.K.Z.; Executive manager of the project: Dr. A.M.; Data collection and Implementation: Z.A., H.K.Z., and A.M.; Preparing informed consent and Data collection forms: Z.A. and A.M.; Preparing educational guidebooks: Z.A. and A.M.; Providing statistical expertise in clinical trial design and Performing the statistical analysis: S.H.

All authors contributed to the refinement of the study protocol and are accountable for all aspects of the work.

Data availability statement

This study has no data to share.

References

1. Baraniak A, Sheffield D. The efficacy of psychologically based interventions to improve anxiety, depression and quality of life in COPD: a systematic review and meta-analysis. Patient Educ Couns. 2011;83(1):29-36. [View at Publisher] [DOI] [PMID] [Google Scholar]
2. Pyszora A, Lewko A. Non-pharmacological Management in Palliative Care for Patients With Advanced COPD. Front Cardiovasc Med. 2022;9:907664. [View at Publisher] [DOI] [PMID] [Google Scholar]
3. Decramer M, Janssens W, Miravitlles M. Chronic obstructive pulmonary disease. Lancet. 2012;379(9823):1341-51. [View at Publisher] [DOI] [PMID] [Google Scholar]
4. Agarwal AK, Raja A, Brown BD. Chronic Obstructive Pulmonary Disease. In:Agarwal AK, Raja A, Brown BD, editors. StatPearls. Treasure Island (FL): StatPearls Publishing; 2024. [PMID]
5. D'Andria Ursoleo J, Bottussi A, Sullivan DR, D'Andria C, Smirnova N, Rosa WE, et al. Chronic obstructive pulmonary disease: A narrative synthesis of its hallmarks for palliative care clinicians. Eur J Intern Med. 2025;133:25-34. [View at Publisher] [DOI] [PMID] [Google Scholar]
6. Lu W, Aarsand R, Schotte K, Han J, Lebedeva E, Tsoy E, et al. Tobacco and COPD: presenting the World Health Organization (WHO) Tobacco Knowledge Summary. Respir Res. 2024;25(1):338. [View at Publisher] [DOI] [PMID] [Google Scholar]
7. Haghparast A, Okhovvat M, Khoddam H, Khandashpour M, Kolagari S. A mobile-based self-care application for patients with chronic obstructive pulmonary disease: A protocol for design, implementation, and evaluation. Health Sci Rep. 2024;7(7):e2259. [View at Publisher] [DOI] [PMID] [Google Scholar]
8. Barasteh S, Rassouli M, Parandeh A, Vahedian-Azimi A, Zaboli R, Khaghanizadeh M. Palliative Care in the Health System of Iran: A Review of the Present Status and the Future Challenges. Asian Pac J Cancer Prev. 2020;21(3):845-51. [View at Publisher] [DOI] [PMID] [Google Scholar]
9. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Pocket Guide to COPD Diagnosis Management and Prevention: 2023 Report. Version 1.2, 17 Feb 2023. Available from: https://goldcopd.org/wp-content/uploads/2023/03/POCKET-GUIDE-GOLD-2023-ver-1.2-17Feb2023_WMV.pdf ار [View at Publisher] [Google Scholar]
10. Safiri S, Carson-Chahhoud K, Noori M, Nejadghaderi SA, Sullman MJM, Ahmadian Heris J, et al. Burden of chronic obstructive pulmonary disease and its attributable risk factors in 204 countries and territories, 1990-2019: results from the Global Burden of Disease Study 2019. BMJ. 2022;378:e069679. [View at Publisher] [DOI] [PMID] [Google Scholar]
11. Vu GV, Ha GH, Nguyen CT, Vu GT, Pham HQ, Latkin CA, et al. Interventions to Improve the Quality of Life of Patients with Chronic Obstructive Pulmonary Disease: A Global Mapping During 1990-2018. Int J Environ Res Public Health. 2020;17(9):3089. [View at Publisher] [DOI] [PMID] [Google Scholar]

12. Landt E, Çolak Y, Lange P, Laursen LC, Nordestgaard BG, Dahl M. Chronic Cough in Individuals With COPD: A Population-Based Cohort Study. Chest. 2020;157(6):1446-54. [View at Publisher] [DOI] [PMID] [Google Scholar]
13. Broese J, van der Kleij RM, Verschuur EM, Kerstjens HA, Bronkhorst EM, Engels Y, et al. The effect of an integrated palliative care intervention on quality of life and acute healthcare use in patients with COPD: Results of the COMPASSION cluster randomized controlled trial. Palliat Med. 2023;37(6):844-55. [View at Publisher] [DOI] [PMID] [Google Scholar]
14. Sundh J, Ställberg B, Lisspers K, Montgomery SM, Janson C. Co-morbidity, body mass index and quality of life in COPD using the Clinical COPD Questionnaire. Copd. 2011;8(3):173-81. [View at Publisher] [DOI] [PMID] [Google Scholar]
15. Strutt R. When to refer patients with advanced COPD to palliative care services. Breathe (Sheff). 2020;16(3):200061. [View at Publisher] [DOI] [PMID] [Google Scholar]
16. Zamzam MA, Azab NY, El Wahsh RA, Ragab AZ, Allam EM. Quality of life in COPD patients. Egyptian journal of chest diseases and tuberculosis. 2012;61(4):281-9. [View at Publisher] [DOI] [Google Scholar]
17. Leemans G, Vissers D, Ides K, Van Royen P. Perspectives and Attitudes of General Practitioners Towards Pharmacological and Non-Pharmacological COPD Management in a Belgian Primary Care Setting: A Qualitative Study. Int J Chron Obstruct Pulmon Dis. 2023;18:2105-15. [View at Publisher] [DOI] [PMID] [Google Scholar]
18. Iyer AS, Sullivan DR, Lindell KO, Reinke LF. The Role of Palliative Care in COPD. Chest. 2022;161(5):1250-62. [View at Publisher] [DOI] [PMID] [Google Scholar]
19. Organization WH. Palliative care [Internet]. 2020 [cited 2025 Oct 15]. Available from: https://www.who.int/news-room/fact-sheets/detail/palliative-care [View at Publisher]
20. Dzierżanowski T. Definitions of palliative care-narrative review and new proposal. Medycyna Paliatywna/Palliative Medicine. 2021;13(4):187-200. [View at Publisher] [DOI] [Google Scholar]
21. Mir WAY, Siddiqui AH, Paul V, Habib S, Reddy S, Gaire S, et al. Palliative care and chronic obstructive pulmonary disease (COPD) readmissions: a narrative review. Cureus. 2021;13(8):e16987. [View at Publisher] [DOI] [PMID] [Google Scholar]
22. Ahmadi M, Rassouli M, Gheibizadeh M, Ebadi A, Asadizaker M. Experiences of Iranian Patients with Thalassemia Major Regarding Their Palliative and Supportive Care Needs: A Qualitative Content Analysis. Int J Community Based Nurs Midwifery. 2025;13(2):113-25. [View at Publisher] [PMID] [Google Scholar]
23. Bakitas M, Lyons KD, Hegel MT, Balan S, Brokaw FC, Seville J, et al. Effects of a Palliative Care Intervention on Clinical Outcomes in Patients With Advanced Cancer: The Project ENABLE II Randomized Controlled Trial. JAMA. 2009;302(7):741-9. [View at Publisher] [DOI] [PMID] [Google Scholar]
24. Temel JS, Greer JA, Muzikansky A, Gallagher ER, Admane S, Jackson VA, et al. Early palliative care for patients with metastatic non-small-cell lung cancer. N Engl J Med. 2010;363(8):733-42. [View at Publisher] [DOI] [PMID] [Google Scholar]
25. Yen Y-F, Lee YL, Hu H-Y, Lai Y-J, Sun W-J, Ko M-C, et al. An Interventional Study for the Early Identification of Patients With Palliative Care Needs and the Promotion of Advance Care Planning and Advance Directives. J Pain Symptom Manage. 2020;59(5):974-82.e3. [View at Publisher] [DOI] [PMID] [Google Scholar]
26. Kowalczys A, Bohdan M, Wilkowska A, Pawłowska I, Pawłowski L, Janowiak P, et al. Comprehensive care for people living with heart failure and chronic obstructive pulmonary disease-Integration of palliative care with disease-specific care: From guidelines to practice. Front Cardiovasc Med. 2022;9:895495. [View at Publisher] [DOI] [PMID] [Google Scholar]
27. Iyer AS, Wells RD, Dionne-Odom JN, Bechthold AC, Armstrong M, Byun JY, et al. Project EPIC (Early Palliative Care In COPD): A Formative and Summative Evaluation of the EPIC Telehealth Intervention. J Pain Symptom Manage. 2023;65(4):335-47.e3. [View at Publisher] [DOI] [PMID] [Google Scholar]
28. Wagner EH, Austin BT, Von Korff M. Organizing Care for Patients with Chronic Illness. Milbank Q. 1996;74(4):511-44. [View at Publisher] [DOI] [PMID] [Google Scholar]
29. Mohammed HM, El-Sol A. Tele-nursing: Opportunities for nurses to shape their profession's future. International journal of novel research in healthcare and nursing. 2020;7(3):660-76. [View at Publisher] [Google Scholar]
30. Imam SN, Braun UK, Garcia MA, Jackson LK. Evolution of Telehealth-Its Impact on Palliative Care and Medication Management. Pharmacy (Basel). 2024;12(2). [View at Publisher] [DOI] [PMID] [Google Scholar]
31. Byun JY, Wells R, Bechthold AC, Coffee-Dunning J, Armstrong M, Taylor R, et al. Project EPIC (Empowering People to Independence in COPD): Study protocol for a hybrid effectiveness-implementation pilot randomized controlled trial of telephonic, geriatrics-palliative care nurse-coaching in older adults with COPD and their family caregivers. Contemp Clin Trials. 2024;140:107487. [View at Publisher] [DOI] [PMID] [Google Scholar]
32. Gholami Motlagh F, Nobahar M, Bahrami M. Barriers and Facilitators of Palliative Care in Older Adults With Heart Failure: A Qualitative Content Analysis. J Palliat Care. 2024;39(4):271-81. [View at Publisher] [DOI] [PMID] [Google Scholar]
33. Butcher NJ, Monsour A, Mew EJ, Chan A-W, Moher D, Mayo-Wilson E, et al. Guidelines for reporting outcomes in trial reports: the CONSORT-outcomes 2022 extension. JAMA. 2022;328(22):2252-64. [View at Publisher] [DOI] [PMID] [Google Scholar]
34. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials. Ann Intern Med. 2010;152(11):726-32. [View at Publisher] [DOI] [PMID] [Google Scholar]
35. Steinhauser KE, Alexander SC, Byock IR, George LK, Olsen MK, Tulsky JA. Do preparation and life completion discussions improve functioning and quality of life in seriously ill patients? Pilot randomized control trial. J Palliat Med. 2008;11(9):1234-40. [View at Publisher] [DOI] [PMID] [Google Scholar]
36. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-7. [View at Publisher] [DOI] [PMID] [Google Scholar]
37. van der Molen T, Willemse BW, Schokker S, ten Hacken NH, Postma DS, Juniper EF. Development, validity and responsiveness of the Clinical COPD Questionnaire. Health Qual Life Outcomes. 2003;1:13. [View at Publisher] [DOI] [PMID] [Google Scholar]
38. Hill K, Geist R, Goldstein RS, Lacasse Y. Anxiety and depression in end-stage COPD. Eur Respir J. 2008;31(3):667-77. [View at Publisher] [DOI] [PMID] [Google Scholar]
39. Kania A, Celejewska-Wójcik N, Żurowska K, Barczyk A. Effectiveness of chronic obstructive pulmonary disease (COPD) treatment with a combination of tiotropium / olodaterol in Polish standard clinical practice as measured by the improvement of the Clinical COPD Questionnaire score: an observational study. Pol Arch Intern Med. 2022;132(7-8):16268. [View at Publisher] [DOI] [PMID] [Google Scholar]
40. Shinall MC, Ely EW, Karlekar M, Robbins SG, Chandrasekhar R, Martin SF. Psychometric Properties of the FACIT-Pal 14 Administered in an Outpatient Palliative Care Clinic. Am J Hosp Palliat Care. 2018;35(10):1292-4. [View at Publisher] [DOI] [PMID] [Google Scholar]
41. Webster K, Cella D, Yost K. The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System: properties, applications, and interpretation. Health Qual Life Outcomes. 2003;1:79. [View at Publisher] [DOI] [PMID] [Google Scholar]
42. Zeng L, Bedard G, Cella D, Thavarajah N, Chen E, Zhang L, et al. Preliminary results of the generation of a shortened quality-of-life assessment for patients with advanced cancer: the FACIT-Pal-14. J Palliat Med. 2013;16(5):509-15. [View at Publisher] [DOI] [PMID] [Google Scholar]

43. Bakitas MA, Dionne-Odom JN, Ejem DB, Wells R, Azuero A, Stockdill ML, et al. Effect of an early palliative care telehealth intervention vs usual care on patients with heart failure: the ENABLE CHF-PC randomized clinical trial. JAMA Intern Med. 2020;180(9):1203-13. [View at Publisher] [DOI] [PMID] [Google Scholar]
44. Mirshahi A, Bakitas M, Khoshavi M, Khanipour-Kencha A, Riahi SM, Wells R, et al. The impact of an integrated early palliative care telehealth intervention on the quality of life of heart failure patients: a randomized controlled feasibility study. BMC Palliat Care. 2024;23(1):22. [View at Publisher] [DOI] [PMID] [Google Scholar]
45. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand. 1983;67(6):361-70. [View at Publisher] [DOI] [PMID] [Google Scholar]
46. Puhan MA, Frey M, Büchi S, Schünemann HJ. The minimal important difference of the hospital anxiety and depression scale in patients with chronic obstructive pulmonary disease. Health Qual Life Outcomes. 2008;6:46. [View at Publisher] [DOI] [PMID] [Google Scholar]
47. Montazeri A, Vahdaninia M, Ebrahimi M, Jarvandi S. The Hospital Anxiety and Depression Scale (HADS): translation and validation study of the Iranian version. Health Qual Life Outcomes. 2003;1:14. [View at Publisher] [DOI] [PMID] [Google Scholar]
48. Bui Q, Nguyen A. Effectiveness of education intervention carried out by clinical pharmacist on quality of life of patients with COPD: A randomized controlled trial. Pharmaceutical Sciences Asia. 2020;47(3):238-45. [View at Publisher] [DOI] [Google Scholar]
49. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191-4. [View at Publisher] [DOI] [PMID] [Google Scholar]

Cite this article as:
Arabi Z, Mirshahi A, Kazemi Zadeh H, Haghani Sh, Iyer A, Wells R, et al. Telehealth palliative care for chronic obstructive pulmonary disease in Iran: The Study Protocol of a Randomized Controlled Feasibility Trial. *J Res Dev Nurs Midw.* 2025;22(4):14-21. http://dx.doi.org/10.29252/jgbfnm.22.4.14