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Effect of community-based palliative care integrated into primary healthcare on death anxiety among patients with advanced cancer: a randomized controlled trial

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Research Article

Keywords: Palliative care, Primary healthcare, Death anxiety, Advanced cancer, Randomized controlled trial

Posted Date: November 26th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11621179/v1

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Additional Declarations: No competing interests reported.

Abstract

Background

Death anxiety is a pervasive and clinically significant phenomenon among patients with advanced cancer, profoundly impacting their quality of life and end-of-life experiences. While community-based palliative care integrated into primary healthcare (PHC) offers a holistic approach to addressing the psychological and existential needs of this population, empirical evidence regarding its efficacy in reducing death anxiety—particularly within the Iranian healthcare context—remains limited. This randomized controlled trial (RCT) aimed to evaluate the effectiveness of an integrated community-based palliative care model on death anxiety among patients with advanced cancer.

Method

This parallel randomized controlled trial was conducted in 2024 in Khorramabad, Iran. A total of 148 patients diagnosed with advanced cancer were recruited and allocated into either an intervention group (n = 74) or a control group (n = 74) using stratified randomized block allocation. The intervention group received a three-month program of community-based palliative care integrated with PHC, whereas the control group received standard usual care. Death anxiety was assessed before and after the intervention using the Templer Death Anxiety Scale. Statistical analyses were performed using SPSS version 27, employing paired and independent t-tests, chi-square, ANCOVA, and the Mann-Whitney U test to ensure rigorous data interpretation.

Results

Following the intervention, the mean death anxiety score in the intervention group decreased significantly by -3.32 ± 2.31 ($p < 0.001$). In contrast, the control group exhibited no significant change in death anxiety scores. Comparative analysis via ANCOVA confirmed that the reduction in death anxiety was significantly greater in the intervention group than in the control group ($p < 0.001$) Subgroup analyses revealed that the intervention's efficacy was consistent across various demographic strata, with no significant interactions observed between the intervention and availability of a substitute caregiver or financial dependency (all $p > 0.05$).

Conclusions

The integration of community-based palliative care into the primary healthcare framework significantly mitigates death anxiety in patients with advanced cancer. These findings underscore the necessity of incorporating structured palliative services into PHC systems to address the complex psychological and existential dimensions of terminal illness.

Trial registration

IRCT20180721040540N6, May 27, 2024.

Background

Cancer represents a formidable global public health challenge (1). In the United States, it stands as the second leading cause of mortality overall and the primary cause of death among individuals under the age of 85. Notably, the COVID-19 pandemic exacerbated this burden; disruptions in healthcare services, loss of employment, and insurance instability, compounded by the fear of viral exposure, led to significant delays in cancer diagnosis and treatment throughout 2020 (2, 3). The long-term consequences of these delays, particularly regarding advanced-stage diagnoses and increased mortality rates, are expected to manifest progressively over the coming years (4). According to 2019 World Health Organization (WHO) estimates, cancer is the second leading cause of mortality in individuals under age 70 in 112 countries and ranks third or fourth in 23 other nations. In Iran, cancer remains the second most significant cause of death (5). Global projections for 2022 estimated 20 million new cancer cases and 9.7 million deaths, with approximately 53.5 million survivors five years post-diagnosis. Furthermore, the incidence is projected to rise by 77%, reaching an estimated 35 million new cases annually by 2050 (6). The socioeconomic impact is equally profound, with cancer accounting for 2.213 million disability-adjusted life years (DALYs) lost in 2016, a figure expected to escalate to 21.6 million annually by 2030 (7). This rising trend poses a severe threat to human development, necessitating robust political commitment and strategic action plans to enhance cancer control (8). In Iran, the incidence of cancer has shown a concerning upward trajectory, nearly doubling between 2000 and 2016 (7). Currently, approximately 130,000 new cases are diagnosed annually in Iran, resulting in 79,000 deaths, with projections suggesting the patient population will grow from 112,000 in 2016 to 160,000 by 2025 (9).

Given its life-threatening nature, cancer profoundly alters an individual's existence and imposes deep existential challenges on both patients and their families. Following diagnosis, patients encounter a complex array of needs, including the necessity for intimate relationships, respect from healthcare professionals, access to accurate information, spiritual fulfillment, hope, and acceptance by their family and social circles. Recognizing these diverse needs—particularly during the critical phase of diagnosis—is essential for healthcare professionals, especially nurses, to provide appropriate counseling and support. Research by Esmaeili et al. emphasizes that the most fundamental requirement for these patients is comprehensive support, encompassing familial assistance, effective communication with medical staff, engagement with relief organizations, and adequate psychological preparation (10).

The chronic and disabling progression of advanced cancer frequently necessitates the transition of care from clinical settings to the home environment. This shift inevitably involves family members in the caregiving process, which can significantly impact their own health and well-being. Caregivers constitute a vital component of the care continuum; however, as they dedicate the majority of their time to patient management, their own needs are often neglected, leading to the emergence of "caregiver burden"(11).

Caregiver burden is a multidimensional construct comprising objective dimensions—such as the quantity of time devoted to care and financial expenditures—and subjective dimensions. Crucially, this burden serves as a potent risk factor for the development of anxiety and depression (12). Research by Reneau et al. indicates that depression and anxiety are among the most prevalent psychological challenges faced by caregivers of cancer patients (11). Studies have consistently demonstrated that family caregivers often experience poorer mental health and lower quality of life compared to the patients themselves. Specifically, Ramirez et al. reported that in the year preceding a cancer patient's death, the prevalence of anxiety and depression among caregivers was approximately 46% and 39%, respectively (12). Furthermore, epidemiological data have reported even higher rates of depression (12%–59%) and anxiety (30%–50%) among this population (13).

Such psychological distress often persists even in the absence of an obvious logical trigger, manifesting as sleep disturbances, cognitive impairment, and somatic complaints such as chronic fatigue, cephalalgia, and muscular pain (14). To mitigate these risks, the mental health of caregivers must be prioritized through routine psychosocial support and evidence-based interventions (13). The psychiatric burden on patients is equally severe, with studies indicating that 50% to 80% of cancer patients suffer from at least one psychiatric disorder. Among these, "death anxiety"—a persistent, abnormal, and pathological fear of death—emerges as a critical psychological diagnosis in oncology (15). Death anxiety is recognized as a pivotal construct across various clinical settings, including cancer screening, psychiatric care, and the management of high-risk diagnoses (11). From the perspective of existential psychology, the contemplation of death is viewed as the most prominent and certain reality of human existence. The inherent conflict between the biological drive for survival and the cognitive awareness of inevitable mortality generates an "existential anxiety," which frequently triggers various adaptive behaviors in patients (16).

The multifaceted challenges faced by cancer patients and their caregivers necessitate effective management strategies, foremost among which is palliative care. The World Health Organization (WHO) defines palliative care as "active, comprehensive care for patients whose disease is no longer responsive to curative treatment," focusing on the control of pain and the mitigation of psychological, social, and spiritual distress to achieve the highest possible quality of life for both patients and their families (17). In 2002, the WHO expanded this definition to emphasize that palliative care "improves quality of life, promotes dignity and comfort, and may positively influence the course of the illness"(18). Palliative care employs a holistic approach, addressing the physical, psychological, social, and spiritual dimensions of the patient (19). This model not only enables patients to maintain an active and dignified life until death but also shields families from the devastating impact of the illness, fostering a more peaceful acceptance of death within the family unit (8).

The evolution of palliative care has transitioned from a philosophy focused solely on end-of-life care to a highly specialized professional discipline over the past five decades. Currently, a comprehensive support system relies on five complementary models: outpatient palliative clinics, inpatient consultation teams, Acute Palliative Care Units (APCUs), community-based palliative care (CBPC), and hospice care. While

these models are complementary, their availability varies globally. For instance, community-based palliative care (CBPC), which provides home visits and telephonic support, is managed by only about 25% of cancer centers (20). Despite these variations, the implementation of CBPC offers undeniable advantages, including improved patient and caregiver access to healthcare, enhanced quality of life, reduced hospital length of stay, and an increase in the frequency of peaceful deaths at home (21).

In the context of Iran, the existing healthcare architecture is built upon a tiered referral system centered on the Primary Healthcare (PHC) model. To achieve Sustainable Development Goals (SDGs) and ensure Universal Health Coverage (UHC), the World Health Confederation has advocated for the integration of home-based palliative care into PHC systems (22). While comprehensive urban and rural health centers provide essential services, community-based palliative care currently lacks a formal, integrated position within this structure; consequently, home-based palliative services are predominantly delivered by private or charitable sectors (21). Although the Iranian PHC model has yielded significant public health successes, such as increased life expectancy (34), it faces substantial structural challenges, including limited flexibility, inequitable resource distribution, and centralized decision-making processes. Strengthening the PHC system could significantly enhance health equity and reduce out-of-pocket expenditures (23).

The high prevalence of anxiety and depressive symptoms among cancer patients necessitates systematic psychological screening within palliative care (PC) frameworks to identify individuals requiring intensive therapeutic intervention. As disease progression intensifies in the home setting, there is an urgent need for enhanced outpatient management, particularly regarding home-based psychosocial support (24). A significant opportunity for addressing these needs lies in the integration of primary palliative care. For instance, the CONNECT intervention—a nurse-led, cluster-randomized approach—demonstrates the potential of utilizing existing oncology nursing staff to provide symptom management and emotional support for patients with advanced cancer and their families. Despite oncological nurses identifying palliative skills as a core component of their professional identity, primary palliative care is often overlooked in routine practice due to a lack of formal training and systemic support (25).

A critical review of existing literature reveals a systemic imbalance: the majority of palliative care research and implementation has been confined to hospital and clinical settings, leaving a significant void in the study of community-based care processes. Furthermore, in the Iranian context, supportive palliative interventions remain largely fragmented and implemented on an isolated, non-systematic basis across various academic institutions, with limited evaluation of their psychological efficacy. There is a critical dearth of systematic research investigating the impact of integrated palliative care on the complex interplay of death anxiety and caregiver burden. Therefore, this randomized controlled trial was designed to evaluate the effectiveness of community-based palliative care, integrated into the existing PHC framework, on mitigating death anxiety among patients with advanced cancer and addressing the psychological needs of their caregivers.

Methods

Trial Design

This study was reported in accordance with the CONSORT guidelines. This study employed a parallel-group, randomized controlled trial (RCT) design to evaluate the impact of an integrated community-based palliative care model. The study was conducted in Khorramabad, Iran, during 2024. Participants were assigned to either the intervention group, receiving community-based palliative care integrated into the Primary Healthcare (PHC) framework, or the control group, receiving standard usual care, using a 1:1 allocation ratio.

Participants and setting

The study was conducted within the setting of comprehensive health service centers and the respective home environments of patients diagnosed with advanced cancer in Khorramabad, Iran. The study population comprised patients with advanced malignancy who were actively registered in the "Sib" electronic health record (EHR) system within the participating comprehensive health centers at the time of the study. All potential participants were screened based on their clinical records to ensure they met the predefined inclusion criteria for the trial.

Inclusion and Exclusion Criteria

To ensure a homogenous study population and minimize potential confounding factors, specific eligibility criteria were established.

Inclusion criteria for participants were:

1. age between 18 and 75 years
2. a confirmed diagnosis of advanced (Stage IV) malignancy by a specialist oncologist
3. presence of an active treatment regimen (e.g., chemotherapy, radiotherapy) or recent oncology consultation for treatment initiation
4. availability of a primary family caregiver
5. maintenance of orientation to time and place
6. absence of significant cognitive, visual, or auditory impairments
7. an active electronic health record within the urban comprehensive health service centers of Khorramabad.

Exclusion criteria

were applied to exclude individuals who

1. exhibited significant cognitive or sensory deficits that precluded informed consent or effective communication
2. were undergoing major life stressors during the intervention period (e.g., bereavement of a family member or legal separation/divorce), which could confound the psychological outcomes
3. demonstrated non-cooperation with the research protocol.

Note

Cases involving patient mortality during the follow-up period were handled according to the intention-to-treat (ITT) principle to maintain the integrity of the randomized allocation.

Sample Size Determination

The sample size was determined based on a power analysis to detect a statistically significant difference between the intervention and control groups. Given the scarcity of previous studies on this specific population, the minimum detectable difference (MDD) between the mean death anxiety scores was set at d = 5.5. With a significance level of α = 0.05 (two-tailed) and a power of 1-β = 0.80, the required sample size was calculated using the following formula:

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \times 2S^2}{d^2}$$

Based on this calculation, a minimum of 62 participants per group was required. To account for a potential attrition rate (estimated at approximately 19%), the sample size was increased to 74 participants per group, resulting in a total sample size of 148 participants. This ensures that the study maintains sufficient statistical power to detect the hypothesized effect even in the event of participant dropout.

[**ADDITIONAL FILE 1 HERE**: Sample size calculation parameters and formula]

Randomization and Allocation

Participants were selected using a stratified multi-stage cluster sampling technique. Initially, six comprehensive health centers were selected as primary strata, representing the northern, central, and southern regions of the city. Subsequently, their affiliated health posts were designated as clusters. Within these clusters, patients were identified through systematic random quota sampling.

To ensure baseline homogeneity between the intervention and control groups, stratification was implemented based on patient age categories (18–25, 26–64, and 65–75 years). Within each age stratum, participants were allocated to the study groups using stratified block randomization with a block size of four. This approach was employed to prevent significant imbalances in group allocation and to maintain a consistent ratio between the intervention and control groups throughout the

recruitment process. The final allocation sequence was generated using a random number generator, ensuring that the assignment was unpredictable and minimized selection bias.

[**ADDITIONAL FILE 2 HERE**: Randomization block sequences and allocation list]

Blinding

Due to the nature of the intervention (home-based palliative care delivered by the researcher), double-blinding of participants and the interventionist was not feasible. Both the researcher providing the intervention and the participants were aware of the group assignments. To minimize potential detection and analysis bias, a single-blind approach was implemented during the data processing stage: the statistical consultant was blinded to the group allocation. The analyst received only aggregated datasets and performed all statistical procedures without access to individual participant identities or group identifiers.

Intervention

The intervention was implemented based on the established community-based palliative care model developed by Heydari et al. (21). The intervention group received a structured, three-month program of community-based palliative care integrated into the Primary Healthcare (PHC) framework. This multidisciplinary intervention was coordinated and delivered by the researcher, acting as a palliative care nurse and case coordinator, in close collaboration with a specialized PHC team comprising a general physician, a psychologist, and a nutritionist.

The intervention protocol encompassed several core components designed to address the holistic needs of patients and their families:

1. Comprehensive Assessment: Initial and ongoing multidimensional assessment of the patient and family, covering physical, psychological, social, economic, and spiritual dimensions.
2. Clinical Status Monitoring: Periodic determination of the Palliative Performance Scale (PPS) to tailor care intensity to the patient's functional status.
3. Direct Clinical Nursing Care: Provision of essential home-based nursing services, including wound management, catheterization, subcutaneous injections, and infection control.
4. Symptom Management and Education: Systematic management of symptoms (e.g., pain, nausea) alongside comprehensive education regarding medication adherence, side-effect mitigation, and home-care protocols.
5. Psychosocial and Existential Support: Implementation of psychological interventions, including individual and group-based life skills training, Cognitive-Behavioral Therapy (CBT), and existential psychotherapy to address death anxiety and emotional distress.
6. Nutritional and Specialized Referrals: Nutritional counseling and facilitated referrals to nutritionists, oncologists, psychologists, or psychiatrists as clinically indicated.

The intervention was delivered through bi-weekly home visits over a three-month period, supplemented by continuous support via telephone and authorized digital communication platforms (e.g., Eitaa). To enhance patient and caregiver empowerment, a specialized educational booklet was provided. The integration of these services followed the standardized referral pathway for supportive and palliative cancer care in Iran (as illustrated in Fig. 1).

Figure 1. Referral pathway for supportive and palliative cancer care. The diagram shows the flow of patients with advanced cancer from diagnosis by an oncologist to referral to the comprehensive health center, initial assessment, home-based palliative care delivery, and referral to higher levels if needed. PPS: Palliative Performance Scale.

[**ADDITIONAL FILE 3 HERE**: Session topics and number of palliative care sessions conducted at patients' homes]

The control group received "usual care" provided by the standard primary healthcare service centers, without any specific intervention or supplemental support from the research team.

Outcomes and Measurement Tools

The primary outcome was the level of death anxiety, assessed using the Templer Death Anxiety Scale (TDAS). The TDAS is a 15-item self-administered instrument, translated into Persian by Rajabi and Bohrani (2001) (26). Based on the factor analysis by Sajino and Klein (1995), the scale comprises three primary dimensions: (i) pure death anxiety (5 items), (ii) a general factor (5 items), and (iii) fear of pain and surgery (5 items) (27). Scoring is dichotomous, where a "yes" response indicates the presence of anxiety, contributing one point to the total score. The total scores range from 0 to 15, with higher scores representing greater death anxiety. A score exceeding 8 is clinically categorized as indicating a high degree of death anxiety (26).

The psychometric properties of the TDAS have been established in various studies. Templer (1970) reported a test-retest reliability of 0.83 (28). Regarding internal consistency, Sajino and Klein (1996) reported Cronbach's alpha coefficients for the three factors as 0.68, 0.49, and 0.60 (27), while Ghasempour et al. (2012) reported an overall Cronbach's alpha of 0.65 (29). Furthermore, the Persian version demonstrated a correlation of 0.34 with the manifest anxiety scale, supporting its validity (26).

Data Collection Procedure

Following approval from the Research and Technology Deputy of Lorestan University of Medical Sciences and formal authorization from the Ethics Committee, this study was registered as a clinical trial [IRCT20180721040540N6]. The study was conducted across various health centers in Khorramabad, which were stratified into three municipal districts (North, Center, and South). A multi-stage sampling approach was employed: first, comprehensive health service centers were selected as strata, followed by the systematic random selection of affiliated health posts as clusters.

Eligible patients were identified through the Sib electronic health system at the selected health posts. After screening for eligibility criteria, 148 patients were recruited and randomly allocated to either the intervention or the control group. Concurrently, one family member was invited to participate as the caregiver for each enrolled patient.

The data collection process spanned a total of approximately four months. Initially, home visits were conducted two weeks after the recruitment period to perform pre-intervention assessments. The Templer Death Anxiety Scale (TDAS) was administered to the patients, with the researcher present to provide clarification and ensure accurate responses. The intervention was delivered through bi-weekly home visits over a three-month period. To evaluate the sustainability of the intervention effects, follow-up assessments were conducted 4–6 weeks after the completion of the three-month intervention period.

[**ADDITIONAL FILE 5 HERE**: Timeline of data collection and intervention delivery]

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics version 27.0. Descriptive statistics were employed to summarize the data; continuous variables were presented as means ± standard deviations (SD), while categorical variables were expressed as frequencies and percentages.

To assess the homogeneity of the two groups at baseline, the Chi-square test was utilized for qualitative variables, whereas the independent t-test and Mann-Whitney U test were used for quantitative variables to compare the intervention and control groups. Intra-group changes (pre-intervention vs. post-intervention) were evaluated using the paired t-test.

To determine the effectiveness of the intervention while controlling for potential confounding factors, Analysis of Covariance (ANCOVA) was performed. This approach allowed for the comparison of mean score changes between the intervention and control groups while adjusting for baseline differences and other covariates. For all statistical tests, a P-value < 0.05 was considered statistically significant.

Results

Participant flow and baseline characteristics

A total of 210 patients with advanced cancer were initially screened for eligibility. Following the exclusion of 62 individuals (42 who did not meet the inclusion criteria and 20 who declined to participate), 148 eligible patients were enrolled and randomly allocated to either the intervention group (n = 74) and the control group (n = 74). There were no losses to follow-up or discontinuations in either group; thus, all 148 participants (100%) were included in the final analysis (Figure 2).

Baseline demographic and clinical characteristics were well-balanced between the two groups. No statistically significant differences were observed regarding gender (P > 0.99), employment status (P = 0.895), marital status (P = 0.209), cancer type (P = 0.121), financial dependency (P = 0.866), or the availability of a substitute caregiver (P = 0.208) (Table 1). Similarly, independent t-tests confirmed that

there were no significant disparities between the groups in terms of mean age (P = 0.885), number of children (P = 0.307), number of caregivers (P = 0.505), or disease duration (P = 0.306) (Table 2). These results indicate that the two groups were homogeneous at baseline.

Table 1. Baseline demographic characteristics of patients with advanced cancer in the two groups (qualitative variables)

Variable	Category	Intervention (n = 74)	Control (n = 74)	Total (n = 148)	Test statistic	P-value
Gender	Male	32 (43.2)	32 (43.2)	64 (43.2)	0.000□	>0.99
	Female	42 (56.8)	42 (56.8)	84 (56.8)		
Employment	Employed	1 (1.4)	0 (0.0)	1 (0.7)	1.093□	0.895
	Self-employed	19 (25.7)	18 (24.3)	37 (25.0)		
	Homemaker	36 (48.6)	37 (50.0)	73 (49.3)		
	Unemployed	9 (12.2)	10 (13.5)	19 (12.8)		
	Retired	9 (12.2)	9 (12.2)	18 (12.2)		
Marital status	Married	73 (98.6)	69 (93.2)	142 (95.9)	2.779□	0.209
	Single	1 (1.4)	5 (6.8)	6 (4.1)		
Cancer type	Breast	37 (50.0)	29 (39.2)	66 (44.6)	7.289□	0.121
	Colorectal	27 (36.5)	24 (32.4)	51 (34.5)		
	Gastric	5 (6.8)	15 (20.3)	20 (13.5)		
	Esophageal	4 (5.4)	3 (4.1)	7 (4.7)		
	Blood	1 (1.4)	3 (4.1)	4 (2.7)		
Financial dependency	No	29 (39.2)	27 (36.5)	56 (37.8)	0.115□	0.866
	Yes	45 (60.8)	47 (63.5)	92 (62.2)		
Availability of substitute caregiver	Yes	68 (91.9)	62 (83.8)	130 (87.8)	2.277□	0.208
	No	6 (8.1)	12 (16.2)	18 (12.2)		

Data are presented as n (%). □ Chi-square test.

Table 2. Comparison of quantitative variables of patients with advanced cancer in the two groups				
Variable	Intervention (n = 74) Mean ± SD	Control (n = 74) Mean ± SD	Test statistic	P-value
Age (years)	60.16 ± 10.72	60.43 ± 11.94	0.145□	0.885
Number of children	3.47 ± 2.23	3.86 ± 2.41	1.024□	0.307
Number of caregivers	1.93 ± 1.06	1.82 ± 0.89	0.688□	0.505
Disease duration (years)	4.72 ± 3.62	4.12 ± 3.57	1.027□	0.306
Data are presented as Mean ± SD. SD: Standard Deviation. □ Independent t-test.				

Primary Outcome: Death Anxiety

The primary analysis revealed a significant reduction in the mean death anxiety score within the intervention group following the intervention (P < 0.001, within-group). In contrast, the control group exhibited no significant change in death anxiety levels (P = 1.000). To evaluate the effectiveness of the intervention while controlling for baseline differences, ANCOVA was performed, which demonstrated a statistically significant difference between the intervention and control groups (P < 0.001, between-group), indicating a significantly greater reduction in death anxiety in the intervention group (Table 3).

Table 3. Comparison of changes in mean death anxiety scores in patients with advanced cancer in the two groups before and after the study							
Variable	Group	Before (Mean ± SD)	After (Mean ± SD)	Mean Change	Effect Size	Within-group P-value	Between-group P-value
Death anxiety	Intervention	7.40 ± 2.99	4.08 ± 1.20	−3.32 ± 2.31	2.31	<0.001□	<0.001□
	Control	7.25 ± 2.32	7.25 ± 2.28	0.00 ± 0.57	0.57	1.000□	
Data are presented as Mean ± SD. SD: Standard Deviation. □ Paired t-test. □ ANCOVA.							

Subgroup Analyses

To evaluate the robustness of the intervention across different demographic strata, subgroup analyses were performed using ANCOVA. The results indicated that the intervention's effectiveness was largely consistent across the studied subgroups.

Specifically, regarding patient gender, a significant interaction was observed between the intervention group and gender (P = 0.028), with the intervention group showing a significantly greater reduction in

death anxiety compared to the control group (P < 0.001). However, no significant differences in baseline death anxiety levels were found between male and female patients (P = 0.885).
Similarly, no significant interactions were observed regarding the availability of a substitute caregiver (P = 0.691) or financial dependency (P = 0.092). In both these subgroups, the intervention group demonstrated a significantly more pronounced reduction in death anxiety scores compared to the control group (both P < 0.001). Furthermore, no significant differences were found between patients with and without a substitute caregiver (P = 1.000) or those with and without financial dependency (P = 0.884) (Table 4).

Table 4. Subgroup analysis of death anxiety by demographic characteristics (gender, availability of substitute caregiver, and financial dependency) in patients with advanced cancer in the two groups

Variable	Category	B	95% CI for B	P-value
Gender	Group (intervention/control)	2.810	(2.113, 3.506)	<0.001
	Gender (male/female)	−0.055	(−0.804, 0.694)	0.885
	Group × Gender	1.190	(0.131, 2.250)	0.028
Availability of substitute caregiver	Group (intervention/control)	3.000	(1.358, 4.642)	<0.001
	Availability of substitute caregiver (yes/no)	−4.441	(−1.036, 1.036)	1.000
	Group × Availability of substitute caregiver	0.353	(−1.387, 2.093)	0.691
Financial dependency	Group (intervention/control)	2.957	(2.282, 3.631)	<0.001
	Financial dependency (yes/no)	−0.058	(−0.839, 0.722)	0.884
	Group × Financial dependency	0.943	(−0.153, 2.039)	0.092

Data are presented as B coefficient and 95% confidence interval (CI). ANCOVA was used to assess the interaction between group and demographic variables. P-values < 0.05 were considered statistically significant.

Discussion

This randomized controlled trial demonstrated that the integration of community-based palliative care into the primary healthcare (PHC) framework significantly mitigates death anxiety among patients with advanced cancer and reduces the psychological burden on their caregivers. Our findings underscore the efficacy of a structured, home-based multidisciplinary approach in addressing the profound existential

and psychological distress experienced by this dual population.

Mitigating Death Anxiety in Patients

The significant reduction in death anxiety observed in the intervention group aligns with a robust body of evidence. A recent meta-analysis of 19 randomized controlled trials confirmed that death education interventions effectively alleviate death anxiety in advanced cancer patients (SMD = −2.11, 95% CI: −5.91 to −0.89, P = 0.008). Similarly, our results are consistent with the findings of Su et al. (2025), who highlighted the effectiveness of tailored interventions in improving psychological well-being (30).

We attribute the success of our intervention to its holistic and integrated nature. A critical driver of this reduction was the inextricable link between physical symptom control and psychological well-being; by alleviating pain, nausea, and other gastrointestinal distress, the intervention lowered the patient's overall existential distress. Furthermore, the delivery of care within the home environment—rather than a clinical setting—provided a sense of security, familiarity, and dignity. This transition from hospital-centric to home-based care likely minimized "hospital-induced anxiety" and fostered a more peaceful environment for facing the end-of-life stage.

Interestingly, our subgroup analyses revealed that the intervention's effectiveness was remarkably robust across various demographic strata. Although a significant interaction was observed between the intervention group and gender (P = 0.028), the intervention group showed a significantly greater reduction in death anxiety regardless of gender, financial dependency, or the availability of a substitute caregiver. This suggests that the integrated PHC-based model provides a universal benefit that transcends socioeconomic disparities, contrasting with studies like Nasreen et al. (2024), which reported higher vulnerability in female patients (31).

Addressing the Caregiver's Burden:

A Dyadic Perspective Beyond the patient, our study highlights the critical impact of the intervention on the caregiver's experience. The findings demonstrated a significant reduction in anxiety, depression, and overall caregiver burden. This suggests that our intervention functioned through a dyadic mechanism, where the reduction of death anxiety in patients and the mitigation of caregiver distress occurred concurrently.

This synergy can be explained through three pathways: direct effects (improved communication and knowledge for caregivers), indirect effects (reduction of the caregiver's stress due to the patient's improved physical state), and dyadic effects (facilitation of a more supportive relationship between the patient and the caregiver). As noted by von Heymann et al. psychological distress in this population is often reciprocal; thus, treating the patient and caregiver as an interdependent unit of care is essential (32). Our results reinforce the notion that providing professional support directly in the home mitigates the "relational and psychological burden" that often leads to caregiver burnout.

Systemic Barriers and Policy Implications

The implementation of this model also revealed critical systemic challenges. Our study highlights that the shortage of trained human resources and limited access to essential palliative medications—such as opioids—remain significant barriers to care. In many low- and middle-income settings, geographical distance to specialized centers often forces families to endure prolonged travel and financial hardship.

Our results underscore that community-based palliative care (CBPC) can mitigate these burdens by reducing travel costs and caregiver fatigue. By empowering community health workers and integrating specialized training into the PHC framework, the healthcare system can transition toward a more equitable and accessible model. Furthermore, the integration of telemedicine and virtual consultations could further optimize this model, bridging the geographical gap for underserved populations and ensuring a seamless continuity of care.

Strengths and Limitations

The primary strength of this study was its dual-target, randomized controlled design, which evaluated the impact of an integrated PHC model on both the patient and the caregiver in a real-world home setting. This approach captured the complex, interdependent relationship between the two groups. However, the study is limited by its reliance on self-reported measures, which may introduce social desirability bias, and its single-center design, which may affect the generalizability of the findings to different socio-cultural contexts.

Conclusions

In conclusion, the integration of community-based palliative care into the primary healthcare system significantly reduces death anxiety in patients and psychological distress in caregivers. By simultaneously addressing physical symptoms, existential needs, and caregiver burden within the comforting environment of the home, this model provides a superior alternative to traditional, fragmented care. We advocate for the systemic incorporation of structured, home-based palliative services into PHC frameworks to enhance the quality of life for terminally ill patients and their families.

Implications and Recommendations

Implications for Nursing and Healthcare Practice

The findings of this study provide a strategic framework for improving palliative care delivery through several key domains:

- Nursing Education and Curriculum Development: There is a critical need to integrate specialized palliative and supportive care modules into both undergraduate and postgraduate nursing and medical curricula. Educational programs should be evidence-based and specifically designed to enhance clinicians' competencies in symptom management, psychosocial support, and existential counseling.

- Clinical Practice and Multidisciplinary Collaboration: Healthcare providers, particularly community health nurses, should implement structured, home-based palliative interventions. This requires fostering robust, multi-sectoral collaborations between primary healthcare providers, specialized oncology centers, social workers, and organizations such as the Red Crescent and welfare services. Furthermore, enhancing the communication channels between specialists and family physicians—potentially through digital health platforms—is essential for ensuring continuity of care.
- Healthcare Policy and Resource Allocation: Policymakers should prioritize the integration of palliative care into the national PHC framework. This includes ensuring the equitable distribution of specialized oncology staff (nurses, physicians, and psychologists) and securing consistent access to essential palliative medications, such as opioids, at the community level. Strengthening formal agreements between health authorities and support organizations is vital to provide the necessary financial and logistical infrastructure for home-based care.
- Community Engagement and Advocacy: Implementing community-based educational workshops and awareness programs is necessary to reduce the social stigma surrounding cancer and death. Such initiatives can empower both patients and caregivers, encouraging early engagement with palliative services.

Recommendations for Future Research

To build upon the current evidence, future studies should focus on the following areas:
- Longitudinal and Comparative Studies: Longitudinal research is required to evaluate the long-term sustainability of community-based palliative interventions. Additionally, comparative studies across different disease types, clinical settings (home vs. center), and diverse socio-cultural populations would enhance the generalizability of these findings.
-**Intervention Optimization:** Future research should investigate the compatibility of various palliative care models with existing PHC structures and explore the efficacy of multidisciplinary, team-based interventions involving diverse specialists.

-**Tool Development and Validation:** There is a significant need for the development and validation of culturally sensitive, linguistically appropriate, and patient-tailored assessment tools for measuring death anxiety and caregiver burden in various Middle Eastern contexts.
- Technological Integration: Exploring the role of digital health and telemedicine in providing real-time, remote symptom monitoring and psychosocial support could offer transformative possibilities for palliative care delivery in underserved or remote areas.

Declarations

Ethics approval and consent to participate

This study was conducted in strict accordance with the ethical principles for medical research involving human subjects. All experimental procedures were performed in accordance with relevant guidelines and regulations, including the Declaration of Helsinki. Formal approval was obtained from the Ethics

Committee of Lorestan University of Medical Sciences (Ethics Code: IR.LUMS.REC.1402.378). Additionally, the study protocol was officially registered in the Iranian Registry of Clinical Trials (IRCT) under the registration number IRCT20180721040540N6.
Prior to participation, all eligible patients were provided with comprehensive information regarding the study's objectives, procedures, and potential risks. Written informed consent was obtained from each participant, explicitly emphasizing their voluntary involvement and the right to withdraw from the study at any stage without any negative consequences to their ongoing care. To ensure participant confidentiality and data privacy, all personal identifiers were removed, and data were anonymized during collection and analysis. All research activities were performed in compliance with the institutional guidelines and recognized ethical standards for clinical research.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to privacy and ethical restrictions but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This study was supported by the research deputy of Lorestan University of Medical Sciences (grant number: 3574).

Authors' contributions

H.F: Conceptualization, Data curation, Writing – original draft.

H.H: Methodology, Investigation, Writing – review & editing.

E.F: Data curation, Investigation, Supervision, Writing – review & editing.

M.B: Data curation, Formal analysis, Writing – review & editing.

M.R:Formal analysis, Writing – review & editing.

Y.B:Writing – review & editing.

All authors read and approved the final manuscript.

Acknowledgements

This article was taken from a part of the thesis of Mr. *Hossain Farhadi*, which was to obtain a master's degree at Lorestan University of Medical Sciences. Authors would like to profusely thank all individuals who supported and helped for conduct this study.

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Figures

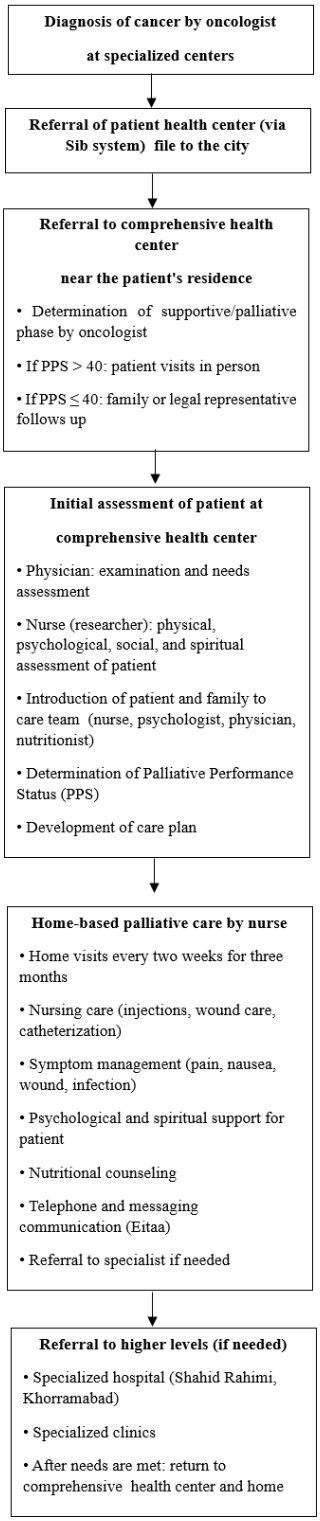

Figure 1

Figure 1. Referral pathway for supportive and palliative cancer care according to the Iranian guideline for management of supportive and palliative cancer care

Referral pathway for supportive and palliative cancer care. The diagram shows the flow of patients with advanced cancer from diagnosis by an oncologist to referral to the comprehensive health center, initial assessment, home-based palliative care delivery, and referral to higher levels if needed. PPS: Palliative Performance Scale.

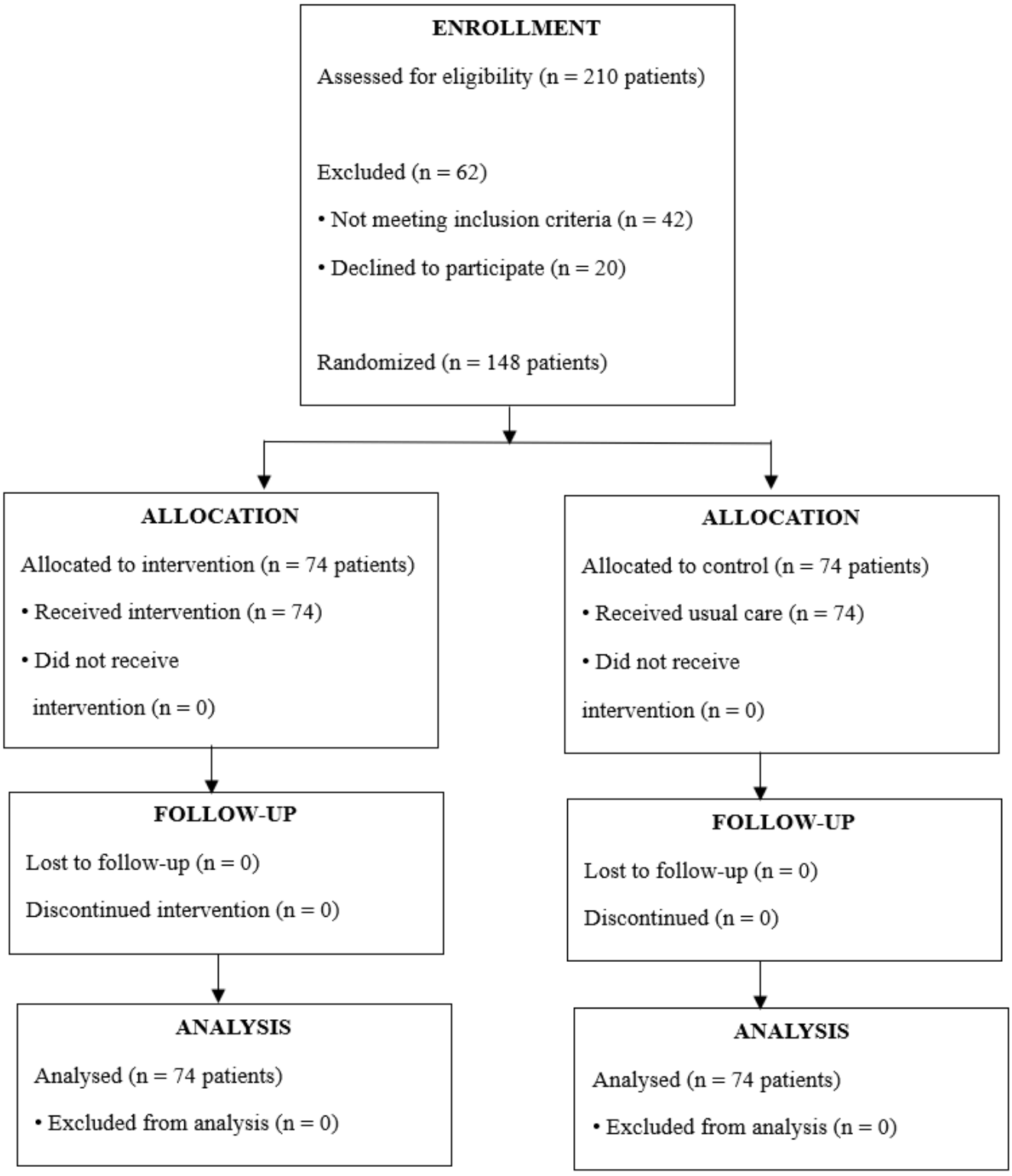

Figure 2

CONSORT flow diagram of patient recruitment, randomization, allocation, follow-up, and analysis. A total of 210 patients with advanced cancer were assessed for eligibility. Of these, 62 were excluded (42 did not meet patient inclusion criteria and 20 declined to participate). The remaining 148 patients were randomized into the intervention group (n = 74) and the control group (n = 74). No patients were lost to follow-up or discontinued the intervention in either group. All 148 patients (100%) were included in the final analysis.

Supplementary Files

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