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The effect of community-based palliative supportive care integrated with primary health care (PHC) on the outcomes of terminally ill cancer patients

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Abstract

Background Cancer is increasing worldwide. Palliative care can help reduce the suffering of patients with cancer. Providing palliative care with a primary health care (PHC) approach can lead to greater patient access to palliative services. Given the lack of studies in this area, the present study aimed to determine the impact of community-based palliative care integrated with PHC on outcomes of terminally ill cancer patients.

Methods This was a randomized controlled trial. Research population included 120 cancer patients in Khorramabad in 2023. A convenience sampling method was conducted, and then subjects were allocated to the intervention and control groups through randomization blocks with size of four. Subjects in the intervention group received PHC-integrated community-based palliative support for two months, while their control peers received their routine health care programs during the same period. The data were gathered using the Palliative Care Outcome Scale before and two months after the intervention and then were analyzed using SPSS 22 software and descriptive and inferential statistics.

Results The mean scores of all dimensions of palliative outcomes, including physical, psychological, emotional, and social, as well as the overall palliative care outcome, improved after the intervention in the experimental group, and these changes were statistically significant ($p < 0.001$). Before the intervention, the mean score of overall palliative care outcome was 22.21 ± 2.89 in the intervention group and 21.88 ± 2.55 in the control group ($P = 0.51$), While after the intervention, the mean scores in the experimental and control groups changed to 17.98 ± 2.88 and 21.83 ± 2.69, respectively, and this difference was statistically significant ($p < 0.001$). The mean changes in the overall palliative outcome score before and after the intervention in the experimental and control groups were 4.23 ± 2.83 and 0.5 ± 0.72, respectively, and this difference was statistically significant ($p < 0.001$).

Conclusion The community-based palliative care integrated into the PHC structure could positively affect all aspects of palliative care. It is recommended that policymakers create conditions where cancer patients can receive

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care through the PHC structure. More studies are required to designate the strengths and weaknesses of this care approach.

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Keywords Advanced cancer patients, Community-based services, palliative care, Primary health care

Background

Cancer is one of the leading causes of death in the world after cardiovascular diseases [1]. According to the World Health Organization (WHO) report, the global incidence of cancer reaches 19,976,499, and the relevant annual mortality rate stands at 9,743,832 [2]. In Iran, the annual incidence of cancer is 137,198 with a 5-year prevalence of 357,906, ending in the death of 87,247 each year [3]. Various cancer treatment methods are in use depending on the type and stage of the disease, including surgery, radiotherapy, chemotherapy, and cell therapy, or a combination of these modalities [4].

Cancer can impose numerous detrimental effects on patients' physical, psychosocial, social, and economic aspects of life. In this regard, it is important to ensure every patient with any life expectancy experiences a desirable quality of life (QoL) [5], and to achieve this goal, palliative and supportive care can be particularly helpful [6].

As announced by the WHO, the ultimate goal of palliative care is to improve the QoL of patients with advanced cancer [7]. Palliative care has a holistic view regarding patients and their all aspects of life, including physical, psychological, social, and spiritual dimensions [8], helping not only patients to preserve an active lifestyle (as possible) for their remaining days, but also their families to cope with the ramifications of the illness and imminent death [7].

Palliative care can be delivered in different places and trough different approaches, one of the most appropriate and cost-effective of which is community-based palliative care [9, 10]. In fact, community-based palliative care is a family-based activity, respecting diversities among families in terms of values, beliefs, and coping strategies to face the illness challenges. In this manner, families contribute to the planning, implementation, and evaluation of care programs [11]. Access to home-based palliative care is one of the important components of sustainable development and universal health coverage (UHC) [12]. According to the WHO, palliative care and primary health care (PHC) share common principles, including continuous care, social accountability, respect for patients' values, and focus on patients in a family context. In this regard, the World Health Confederation (WHC) forwarded a proposal demanding health systems to integrate home-based palliative care into the PHC program to achieve UHC and sustainable development goals [13]. Community-based palliative care can improve QoL, reduce hospitalization rates [14] and referrals to the emergency department, and finally, boost the chance of a peaceful death at home [15].

Measuring improvements in the quality of palliative care is an important issue that has been emphasized worldwide [16]. Measuring palliative care outcomes as a patient-centered care can facilitate access and monitoring of palliative care in patients, which is beneficial for improving palliative care outcomes and reducing concerns of patients and staff [17].

At the present time, palliative care is not provided systematically in Iran, giving the country the rank of 73rd among 80 countries regarding its situation in the provision of palliative care and quality death, according to the annual reports of the WHO and the International Institute for Oversight of End-of-Life Care [18, 19].

In Iran, most patients with incurable diseases experience frequent hospitalizations in their last days of life. This is despite the country's suffering from a shortage in hospital beds, especially in special care departments, where valuable beds are occupied by these patients who continue to receive specific medications until their last moments. Eventually, many of these patients would die on hospital beds and in special care departments. In many cases; however, hospitalization of terminally ill patients in special wards is an useless task with no sensible impact on the patient's outcome [20].

Given the growing trend of aging and the increasing burden of noncommunicable diseases, palliative care should be made available in health centers with a PHC approach [21]. Providing palliative care with a PHC approach can lead to improved quality of life for the patient and family, continuity of care at home, and reduction of unnecessary hospitalizations and hospital infections [21–23]. Despite the efforts of the WHO to develop PHC in low- and middle-income countries, there is still no coherent plan to integrate palliative care into the health care structure in Eastern Mediterranean Region (EMR) countries [24]. A model has been proposed by Gafer and et al. for the integration of palliative care into the PHC program in the EMR countries, with key elements include policy development, community integration, drug availability, education, research, and service delivery [25].

Iran, as one of the countries in the EMR, has made fundamental changes in its health system in recent years from healthcare-centered to community-centered [26]. The basis of Iran's health system relies on multiple healthcare and referral levels, providing healthcare in the context of the PHC model. In this structural framework, comprehensive health centers in rural and urban areas are responsible for providing healthcare services to the population [27], based on which a palliative care delivery model was developed for cancer patients by Hojjat et al. [28]. The effectiveness of some palliative care models in improving outcomes for patients with incurable disease has been evaluated in various studies, and their strengths and weaknesses have been revealed [29, 30]. However, Hojjat et al.'s model is defined in the PHC structure and few studies have been conducted to evaluate it. It is essential to ensure the effectiveness of this model in improving palliative outcomes in cancer patients. Appropriate measures can then be taken to address the weaknesses and improve the strengths of such models. Accordingly, the aim of this study was to determine the impact of community-based palliative care integrated with PHC on the outcomes of patients with advanced cancer.

Materials and methods

This was a randomized controlled trial conducted in Khorramabad, Iran, in 2023. The research population included patients with advanced cancer referring to selected comprehensive health centers in Khorramabad, Iran.

Study subjects

According to previous studies in this field and the standard deviation and average values reported in these reports [31, 32], an 80% test power, as well as a dropout rate of 10%, the sample size was calculated as $n = 60$ per group.

Inclusion criteria were the diagnosis of advanced cancer by an oncologist, being aware of time and place, registry to Integrated Health System (SIB) (a domestic registry for Iranians' health information) and willingness to participate in the study. Exclusion criteria were the lack of access to the patient or his/her family for any reason and withdrawal from participation in the study.

Orientation of patients were assessed by using a short instrument (8Item) of self- reported cancer-related cognitive impairment (CRCI) [33]. In the screening by this instrument if the patient scored 18 or less, he/she was included in the study.

Random sample allocation to the intervention and control groups was through randomization blocks with the size of four following convenient sampling.

Sampling

A clustered, stratified, and sub-stratified sampling method was used in this study. The city of Khorramabad was divided into three clusters: north, center, and south. In each cluster, a comprehensive health center was randomly selected as a category, and sub-group bases were designated as sub-categories. In the selected health bases, systematic random sampling was carried out. Finally, subjects were selected and allocated to the intervention and control groups using the random block method with block size of four (60 subjects per group).

Data gathering

Data collection tools included a questionnaire for gathering the demographic information of patients (age, sex, marriage, educational status, occupation, income, housing situation, stage of cancer, and type of cancer). Palliative outcome was measured using the Palliative Care Outcome Scale (POS) for adults with cancer, developed by Hern et al.. in England in 1999 [34]. In Iran, this tool has been subjected to psychometric analysis for cancer patients by Sirati et al., reporting Cronbach's alpha coefficient and ICC of 0.719 and 0.812, respectively [35]. This tool contains 12 queries pertaining to the patient's physical, psychological, emotional, and social aspects. All questions (except for questions No. 11 and 12) are scored on a 0–4 Likert scale from never to always. Individual subjects could obtain a score between 0 and 40, a lower score indicating a better situation and vice versa. Question No. 11 was a complementary item to question No. 10 and required an open response. Question No. 12 was a 3-score query on how to respond to the questionnaire.

Interventions

The researcher initially visited the selected comprehensive health centers to select participants and extract their information from the SIB. Finally, the subjects were contacted by phone calls.

In the case of a good general condition, the patient along with his/her main caregiver was invited to the healthcare center where he/she was receiving services. Then the patient and the caregiver were introduced to the research team members, including a physician, a psychologist, a nurse, and a nutritionist. This team was responsible for conducting a thorough assessment of the patient at this step. Also, the patient and his/her caregiver were acquainted with the structure of the health system and received the necessary information about the disease and relevant care procedures. Two weeks after the introductory session, a nurse trough comprehensive health centers, visited the patient's home and provided the necessary measures and training to the patient and his/her family tailored to their care needs. Home visits were scheduled once every two weeks (depending on

Table 1 The intervention plan

Session number	Topic of the Session	Content
1	Comprehensive assessment of patients and family caregivers	Explaining about the structure of health system, the role of the comprehensive health service center and their caregivers in the care of cancer patients, how to reach health services in the community and use narcotic drugs, how to refer to clinics and hospitals in the second level of prevention, assessment of the palliative performance of the patient, designing care plans.
2	Visiting the patient's home by the coordinating nurse	Reassessment of the patient's physical and psychological symptoms, including pain, fatigue, loss of appetite, nausea, vomiting, shortness of breath, insomnia.
3	Follow up	Every two weeks, the researcher visited the patient's home after coordination with the comprehensive health center for re-evaluating the patient, delivering the necessary training, and following up with the condition of the patient and his/her family.
4	Follow up	Follow up

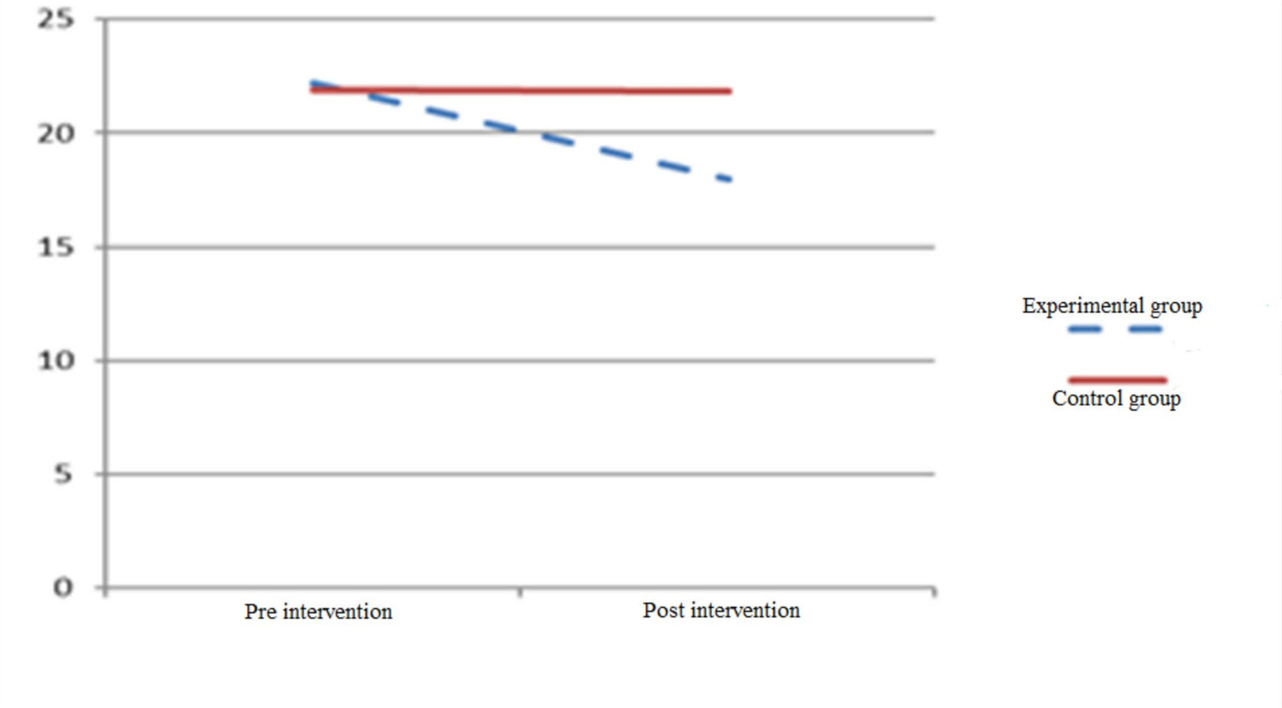

Fig. 1 CONSORT flowchart

the patient's condition) throughout the 2-month period from recruitment (Table 1). From the beginning of the palliative support program, the patient and the family were able to directly contact the nurse via phone or the WhatsApp social messenger to receive answers for their questions. Also, participants in the intervention group received an educational pamphlet containing patient care instructions. After two months of the beginning of the intervention, as well as 4–6 weeks afterwards (to evaluate the durability of effects), the POS questionnaire was completed again by participants in both study groups.

During the study period, subjects in the control group received their routine care, including referral to clinics, hospitals, or private home care centers for receiving health services. Enrollment, intervention allocation, follow-up, and analysis were conducted according to the consolidated standards of reporting trails (CONSORT) guidelines [36].

During the study, out of 120 eligible subjects, four patients in the intervention group and one patient in the control group withdrew due to various reasons (Fig. 1).

Data analysis

The distribution of the variables was evaluated by the Shapiro-Wilk test. Data were analyzed using appropriate descriptive (mean, standard deviation, frequency) and inferential (chi-square test, Fisher's exact test, paired t-test, and independent t-test) statistics. All analyses were conducted in SPSS 22 software. The mean of other data of that variable (with full data) were used for replace of missing data.

Results

Data analysis showed that the two groups did not differ significantly before the study ($P > 0.05$). The mean age of the patients was calculated as 51.48 ± 7.22 years in the intervention group and 50.20 ± 5.73 in the control group (Table 2). Data analysis showed that based on the questions related to the palliative outcome tool, after the intervention, the frequency of palliative outcome scores in the experimental group improved in all questions (Table 3).

The paired t-test revealed a significant difference comparing the mean score of the palliative outcome score improved before and after the intervention in the experimental group, so that the patients' condition improved in all aspects, including physical, psychological, emotional, and social, as well as the overall palliative care outcome, and these mean changes were statistically significant ($p < 0.001$). In the control group, the mean changes were not statistically significant ($p = 0.59$) (Table 4; Fig. 2). Data analysis using independent t-test showed that mean changes in the overall palliative outcome score before and after the intervention in the experimental and control groups were 4.23 ± 2.83 and 0.5 ± 0.72, respectively, and this difference was statistically significant ($p < 0.001$) (Table 4).

Discussion

In this study, the findings showed that community-based PHC-integrated palliative support could improve the palliative care outcomes of cancer patients, promoting their physical, psychological, emotional, and social aspects of life. In line with finding in this study, the results of another study showed that community-based palliative care reduced hospitalization rates, while increased death

Table 2 Frequency distribution of patients' demographic characteristics in the two study groups

Variables	**Categories**	**Intervention group**		**Control group**		**P- Valu**
		Number	**Percentage**	**Number**	**Percentage**	
Age (years)	30–40	2	3.6	2	3.4	* $P=0.29$ df = 113 t = 1.05
	41–50	23	41.1	27	45.8	
	51–60	31	55.4	30	50.8	
	M ± SD	51.48 ± 7.22		50.20 ± 5.73		
Sex	Male	27	48.2	18	30.5	** $X^2=3.78$ df = 1 $p=0.058$
	Female	29	51.8	41	69.5	
Marital status	Single	4	7.1	1	1.7	** $X^2=2.43$ df = 3 $p=0.53$
	Married	45	80.4	48	81.4	
	Widowed	6	10.7	8	13.6	
	Divorced	1	1.8	1.8	3.4	
Educational status	Elementary	7	12.5	2	3.4	** $X^2=3.46$ df = 3 $p=0.34$
	Under diploma	22	39.3	27	45.8	
	Diploma	19	33.9	20	33.9	
	Academic	8	14.3	10	16.9	
Occupation	Retired	22	39.3	15	25.4	** $X^2=5.80$ df = 4 $p=0.21$
	Housekeeper	11	19.6	17	28.8	
	Self-employed	20	35.8	20	33.9	
	Employee	3	5.4	7	11.9	
Income status	Insufficient	24	42.9	15	25.4	** $X^2=4.05$ df = 2 $p=0.11$
	Relatively enough	29	51.8	41	69.5	
	Sufficient	3	5.4	3	5.1	
Housing situation	House owner	34	60.7	43	72.9	** $X^2=1.92$ df = 1 $p=0.23$
	Rental	22	39.3	16	27.1	
Stage of cancer	3	22	39.3	28	47.5	** $X^2=0.78$ df = 1 $p=0.45$
	3 and upper	34	60.7	31	52.5	
Type of cancer	Prostate	16	28.6	9	15.3	** $X^2=6.99$ df = 7 $p=0.43$
	Breast	11	19.6	12	20.3	
	Colon	10	17.9	7	11.9	
	Stomach	4	7.1	3	5.1	
	Esophagus	3	5.4	6	10.2	
	Renal	2	3.6	2	3.4	
	Blader	4	7.1	9	15.3	
	Other	6	10.7	11	18.6	

**: Exact Fish test - *: Indep t-test

Table 3 Frequency of palliative outcomes of two groups in percentage terms

Questions	**Time of study**	**Control group**					**Intervention Group**				
		Always%	**Seldom%**	**Middle%**	**Intense%**	**Very intense%**	**Always%**	**Seldom%**	**Middle%**	**Intense%**	**Very intense%**
1. Have you had pain in the past 3 days?	Before	0	3.3	56	33.9	6.8	0	3.9	55.2	33.8	7.1
	After	0	3.4	54.2	33.9	8.5	0	5.9	61.8	28.6	3.7
2. Have you had symptoms such as nausea, cough or constipation in the past 3 days?	Before	0	3.4	55.9	32.2	8.5	0	1.8	55.4	33.9	8.9
	After	0	3.4	55.9	32.2	8.5	0	7.2	64.3	23.2	5.3
3. Have you felt anxious or worried about your illness or treatment in the past 3 days?	Before	0	0	67.8	22	10.2	0	0	60.7	28.6	10.7
	After	0	0	67.8	22	10.2	0	8.9	83.9	5.4	1.8
4. During the last 3 days, have any of your family members or friends become anxious or worried about you?	Before	0	0	67.8	20.3	11.9	0	0	57.1	30.4	12.5
	After	0	0	66.1	20.3	13.6	0	8.9	71.4	16.1	3.6
5. In the past 3 days, how much information has been provided to you, your family, or friends?	Before	6.8	6.8	55.9	23.7	6.8	7.1	7.1	58.9	19.6	7.1
	After	6.8	6.8	57.6	22	6.8	8.9	48.2	41.1	1.8	0
6. During the last 3 days, have you been able to share your feelings with your family or friends?	Before	15.3	32.3	44.1	8.3	0	12.5	30.4	46.4	8.9	1.8
	After	13.6	32.2	45.8	8.5	0	16.1	46.4	32.1	5.4	0
7. Have you felt depressed in the past 3 days?	Before	0	10.2	59.3	25.4	5.1	0	7.1	58.9	28.6	5.4
	After	3.4	11.9	59.3	20.3	5.1	14.3	46.4	39.3	0	0
8. Have you felt good about yourself as a person in the past 3 days?	Before	0	10.2	61	23.7	5.1	0	14.3	60.7	25	0
	After	0	10.2	61	23.7	5.1	16.1	33.9	46.4	3.6	0
9. During the past 3 days, how much time did you spend on medical procedures, such as waiting for commuting or repeating experiments?	Before	23.7	0	52.6	0	23.7	25	0	48.2	0	26.8
	After	23.7	0	52.5	0	23.7	25	0	51.8	0	23.2
10. During the last 3 days, have the issues including financial or personal problems caused by your illness been dealt with?	Before	25.4	0	49.2	0	25.4	23.2	0	50	0	26.8
	After	25.4	0	49.2	0	25.4	23.2	0	55.4	0	21.4

Table 4 The mean and standard deviation of the score of palliative care outcome among subjects in the two study groups

Palliative care outcome		**Before intervention**	**After intervention**	**Paired t-test**		
		M ± SD	**M ± SD**	**t**	**df**	***P*-Valu**
Physical	Intervention	4.92 ± 1.05	4.67 ± 1.01	2.80	0.55	0.007*
	Control	4.89 ± 0.82	4.93 ± 0.82	1.00	0.58	0.32
Independent t-test		t = 0.17 df = 0.113 *p* = 0.86	t= -1.47 df = 0.113 *p* = 0.043*			
Psychological	Intervention	7.73 ± 1.05	5.39 ±1.05	10.73	0.55	0.001*
	Control	7.11 ± 1.11	7.01 ± 1.21	1.35	0.58	0.18
Independent t-test		t = 1.26 df = 0.113 *p* = 0.20	t= -7.65 df = 0.113 *p* = 0.001*			
Emotional	Intervention	4.17 ± 1.47	3.33 ± 1.48	5.66	0.55	0.001*
	Control	4.23 ± 1.39	4.20 ± 1.38	0.05	0.58	0.98
Independent t-test		t = 0.21 df = 0.113 *p* = 0.82	t= -3.35 df = 0.113 *p* = 0.001*			
Social	Intervention	5.73 ± 1.93	4.57 ± 1.93	6.04	0.55	0.001*
	Control	5.62 ± 1.85	5.64 ± 1.81	0.29	0.58	0.76
Independent t-test		t = 0.29 df = 0.113 *p* = 0.76	t= -3.06 df = 0.113 *p* = 0.003*			
Overall palliative care outcome	Intervention	22.21 ± 2.98	17.98 ± 2.88	11.17	0.55	0.001*
	Control	21.88 ± 2.55	21.83 ± 2.69	0.53	0.58	0.59
Independent t-test		t = 0.65 df = 0.113 *p* = 0.51	t= -7.38 df = 0.113 *p* = 0.001*			
Palliative care outcome change		M ± SD	M ± SD	Indep t-test		
				t	df	P-Valu
		4.23 ± 2.83	0.5 ± 0.72	− 10.95	0.113	0.001*

Statistically significant M ± SD: Mean ± standard deviation

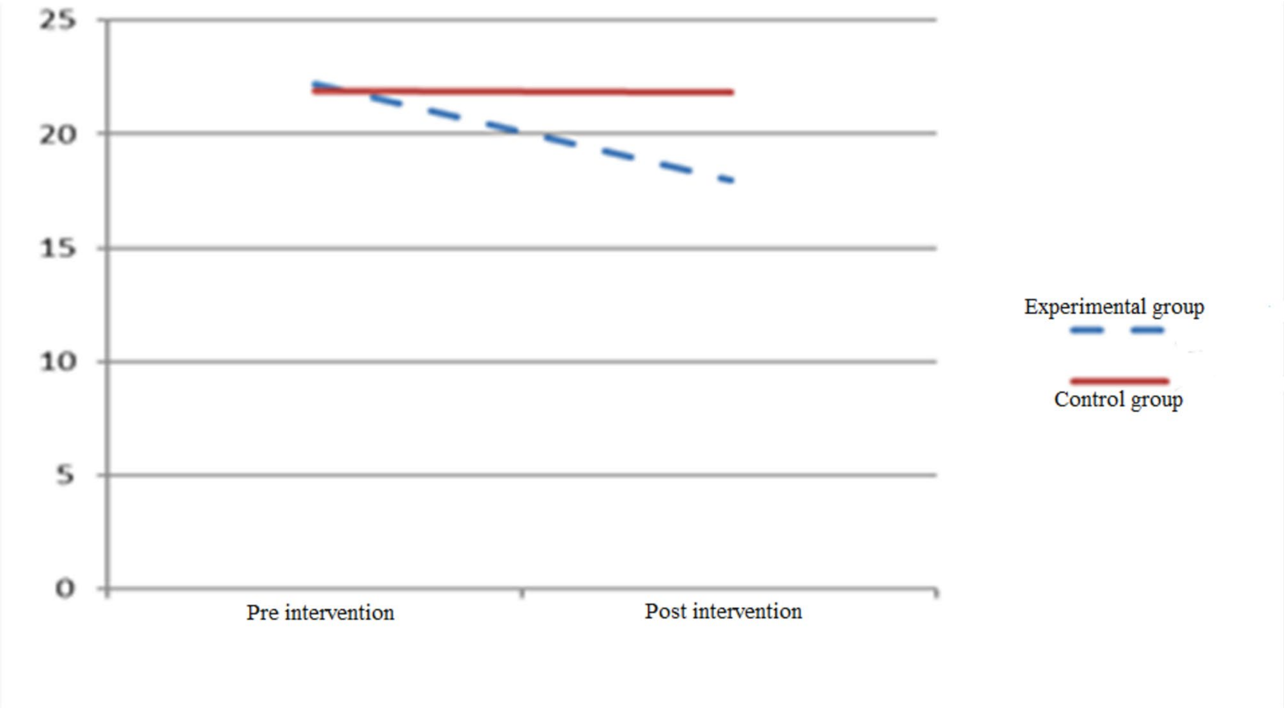

Fig. 2 Trend the change of M ± SD of the score of palliative care outcome among subjects in the two study groups

at home and improved the satisfaction of patients and caregivers with the services provided [37].

According to findings, community-based palliative support could improve the physical status of cancer patients, including pain relief and gastrointestinal problems like nausea and vomiting. In agreement with the findings of the present study, the results of another study revealed that educational interventions were effective in attenuating the severity of symptoms in patients suffering from cancer [38]. Pain is one of the most frequent problems encountered by cancer patients. According to global data, 82% of EMR countries have restrictions on the provision of palliative care, and patients in these countries rarely have available to morphine [39]. Various self-reporting tools, such as the Edmonton Symptom Assessment System (ESAS), can be utilized to assess the intensity of pain and related symptoms endured by cancer patients [40]. In Iran, opioid medications can be available to cancer patients after being prescribed by specialists and the approval of Iran's Food and Drug Administration, which is not easily accessible. It is necessary for cancer patients in community health centers to have access to oral and injectable morphine so that they can take these medications at home [25]. So, if comprehensive healthcare centers are granted with the authority to allocate opioids to patients at the community level, it is possible to provide an easier access route and boost the satisfaction of patients and families.

Cancer patients' gastrointestinal problems may primarily arise from the disease itself or as a consequence of anticancer treatments or associated comorbidities, demanding antiemetic therapies to be directed toward the original cause. Nonetheless, the clinical picture is usually complicated in practice and requires regular reassessments to properly control these symptoms [11, 41]. Nutritional support must be considered for cancer patients experiencing therapy-resistant cachexia and deteriorating physical condition during their last days of life [42] so that patients can enjoy oral feeding and acquire their necessary nutrients [18, 19, 43]. In comprehensive health centers, nutritional instructions are generally offered by nutritionists who have received no special training on the nutritional requirements of end-stage cancer patients. Therefore, it seems that offering specialized training to experts in these centers can help better manage the digestive function of cancer patients.

In this study, the findings revealed that the community-based palliative intervention improved the psychological condition of the patients and reduced their anxiety and stress. In agreement, another study on patients with advanced cancer, initially reporting a prevalence of 44.3% for depression, 25.7% for anxiety, and 52.9% for co-existed depression and anxiety among those receiving hospital-based palliative care [26], asserted that PHC-integrated psychological counseling could alleviate anxiety and depression among these patients.

One of the advantages of health service provision with a PHC approach is the possibility of easier and just access to these services. In this regard, the provision of PHC-integrated community-based palliative care could bring positive social consequences for cancer patients. The results of a review study also disclosed injustice in palliative care provision to cancer patients [44], highlighting the importance of integrating palliative care into the PHC structure to better promote justice in health.

Studies show that the community-based service delivery approach is prioritized in Iran [45, 46]. However, this structure faces problems such as lack of guidelines, lack of human and financial resources, as well as poor insurance coverage in integrating palliative care into the PHC structure [47]. Currently, there are about 1,200 home care centers operating in Iran that can provide palliative care to cancer patients in an integrated manner with primary health care [25, 28]. Therefore, there is a need for further research to demonstrate the challenges of implementing palliative care integration into the PHC structure as well as its benefits for the patient, family, and health system. Care providers in community health centers are not prepared to provide palliative care to cancer patients, so designing a scope of practice and determine the required competencies for their training is essential.

Digital health technologies can also play an important role in improving cancer patients' access to palliative care in community health centers and PHC structure [25]. Therefore, it is suggested that the necessary infrastructure be provided for providing remote palliative care within the PHC structure.

One of the limitations of this study was that patients and their families were not familiar with the community-based care approach and were hesitant to lose the usual treatments. With the explanations and assurances provided by the researchers about the continuance of their routine treatment, they finally agreed to participate in the research. And also, studies in this area were limited, and the authors were unable to compare the findings of this study with other studies.

Conclusion

The findings of this study revealed that community-based palliative care integrated into the PHC structure could positively affect all aspects of palliative care, including physical, psychological, emotional, and social dimensions of patients' lives. It is recommended that health system officials create conditions so that cancer patients can receive care through the PHC structure. More studies are required to designate the strengths and weaknesses of this care approach. It is essential that the micro- and macro-economic benefits of integrating a palliative care approach into PHC are assessed and practical steps are taken to ensure the availability of all components of palliative care within the PHC structure. These steps include political support to strengthen the integration of palliative care into the PHC structure, training of care providers, and ensuring affordable and accessible medicines.

Abbreviations

WHO	World health organization
PC	Palliative care
PHC	Primary health care
POS	Palliative care outcome scale
UHC	Universal health coverage
SIB	Integrated health system
QOL	Quality of life
WHC	World health confederation

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Author contributions

HSH: Investigator; study design, data collection, data analysis, accrual of study, writing the primary draft. MR: study design, data analysis, supervision. HHa: study design, data analysis, accrual of study, supervision. HHe: Investigator; study design, data collection, data analysis, accrual of study, supervision.

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Data availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on request.

Declarations

Ethics approval and consent to participate

All methods were performed in accordance with the relevant guidelines and regulations of the declaration of Helsinki (ethical approval and consent to participate). The study was approved by the ethics committee of Lorestan University of Medical Sciences ethics code of IR.LUMS.REC.1401.258 [47]. The aims and methods of the project were explained to all subjects, and necessary assurance was given to them about the anonymity and confidentiality of their information. Informed consent was taken from all subjects. The subjects had the right to withdraw of study during or at any other time.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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