Contemporary Clinical Trials Communications 33 (2023) 101114

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

The feasibility and acceptability of an early tele-palliative care intervention to improve quality of life in heart failure patients in Iran: A protocol for a randomized controlled trial

Arvin Mirshahi [a,b], Shahrzad Ghiasvandian [a], Meysam Khoshavi [c], Seyed Mohammad Riahi [d], Ali Khanipour-Kencha [a,b], Marie Bakitas [e], J. Nicholas Dionne-Odom [f], Rachel Wells [g], Masoumeh Zakerimoghadam [a,*]

[a] Department of Medical-Surgical Nursing, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran
[b] USERN Care (TUMS) Office, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran
[c] Department of Cardiology, School of Medicine, Imam Khomeini Hospital, Tehran University of Medical Sciences, Tehran, Iran
[d] School of Medicine, Cardiovascular Diseases Research Center, Birjand University of Medical Sciences, Tehran, Iran
[e] School of Nursing, and Department of Medicine, Division of Gerontology, Geriatrics, and Palliative Care, University of Alabama at Birmingham, Birmingham, AL, USA
[f] School of Nursing, University of Alabama at Birmingham (UAB) and UAB Center for Palliative and Supportive Care, USA
[g] School of Nursing, University of Alabama at Birmingham, Birmingham, AL, USA

ARTICLE INFO

Keywrods:
Palliative care
Heart failure
Telemedicine
Clinical trial protocol
Feasibility studies
Iran

ABSTRACT

Background: Heart failure (HF) has become a global health problem that has affected the quality of life of millions of people. One approach to improving patients' quality of life (QoL) with chronic diseases such as HF is palliative care. In Iran, the bulk of palliative care research is directed to patients with cancer, with the primary focus on the physical aspect rather than the psychosocial and spiritual aspects of palliative care. To address this gap, this study aims to determine the feasibility and acceptability of this early tele-palliative care intervention to improve quality of life in heart failure patients in Iran.

Methods: The early tele-palliative care versus usual care study is designed as a single-centre, randomised, feasibility trial of 50 patients with heart failure aged 18 to 65 and clinician-determined New York Heart Association class II/III or American College of Cardiology stage B/C HF, recruited in Imam Khomeini Hospital Complex, Tehran, Iran. This intervention contains 6 weekly educational webinars and concurrent WhatsApp® group activities. Program feasibility and acceptability will be assessed by measuring the recruitment, attrition, and questionnaire completion rates; satisfaction and attitudes about the intervention will be measured via a telephone-based interviews. Secondary outcomes of Qol, mood status and number of emergency department visits will be measured with validated instruments. Participants in both groups will be followed up for 6 weeks, and the measures will be re-administered. Appropriate statistical tests will be used to analyse the data.

Conclusion: This is the first early tele-palliative care intervention designed for heart failure patients in Iran. The intervention has been developed by a multidisciplinary team of academic and clinical professionals with patient stakeholder input to create a rigorous and culturally responsive approach for palliative care delivery for heart failure patients in Iran.

Trial registration: IRCT registration number - IRCT20100725004443N29.

* Corresponding author. Departments of Medical-Surgical Nursing, School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Sq., Post Code: 14197-33171, Tehran, Iran.

E-mail addresses: Mirshahiarvin13750@gmail.com (A. Mirshahi), Shghiyas@yahoo.com (S. Ghiasvandian), meysamkhoshavi@yahoo.com (M. Khoshavi), riahim61@gmail.com (S.M. Riahi), ali.khanipour76@gmail.com (A. Khanipour-Kencha), mbakitas@uab.edu (M. Bakitas), dionneod@uab.edu (J.N. Dionne-Odom), raduncan@uab.edu (R. Wells), Zakerimo@tums.ac.ir (M. Zakerimoghadam).

https://doi.org/10.1016/j.conctc.2023.101114
Received 5 December 2022; Received in revised form 27 February 2023; Accepted 10 March 2023
Available online 20 March 2023

1. Introduction

Heart failure (HF) is a complex clinical syndrome caused by structural or functional heart disorders that impair the ventricles' ability to fill or send blood out of the heart [1]. HF prevalence is rising in light of the aging population, improvement in treatment, and increased survival in patients with cardiac diagnoses, such as myocardial infarction, which is the leading cause of HF [2]. HF has become a global health problem that has affected millions of people. In 2017, 64.3 million people worldwide [3] and six million Americans older than 20 suffered from HF. Moreover, it is projected that the HF prevalence will increase by 46% from 2012 to 2030, affecting more than 8 million people above the age of 18 [4]. Despite a lack of reliable studies to estimate the incidence/prevalence of patients with HF in Iran, the 1-year mortality rate of in-hospital patients with HF reported to be 31.7% [5]. Nearly two percent of all developed countries' budgets is spent on HF-related healthcare [6]. In the United States, the annual median total medical costs for HF care were estimated at $24,383 per patient per year [7], leading a cost of $43 billion annually; these costs represent a significant financial and health care burden [8].

The consequences of HF exert much pressure on patients and the treatment system, such as frequent hospitalizations, health care costs, and reduced quality of life (QOL) [9,10].

Guideline-directed HF medical therapy focuses on improving patient's clinical condition, functional capacity, QOL, decreasing re-hospitalization and mortality [11]. Patients in the advanced stages of the disease experience not only the physical impacts of the disease but also psychological and social effects, such as depression, mental distress and reduced QOL [12].

One approach to improving patients' QOL with chronic diseases such as HF is palliative care [13]. The World Health Organization (WHO) defines palliative care as: "An approach that improves the QOL of patients (adults and children) and their families who are facing problems associated with a life-threatening illness. It prevents and relieves suffering through early identification, correct assessment, and treatment of pain and other physical, psychosocial, or spiritual problems" [14]. Previously, there has been a debate about the role of palliative care in HF due to several issues such as difficulties in prognostication, sudden cardiac death, and an erratic illness trajectory [15]. Nonetheless, there is currently sufficient evidence to support the conclusion that a palliative approach in HF is significantly can improve patient outcomes, including physical, mental and spiritual symptoms, with a considerable reduction in mortality, costs, and medical utilization [16–21]. Notably, however, most studies have assessed hospital-based palliative care [21–23], and few clinical trials have evaluated the integration of HF palliative care in outpatient and community settings, indicating the need for further research in this area [24,25].

Moreover, according to the WHO and the American College of Cardiology Foundation/American Heart Association's (ACC/AHA) Guideline for the Management of Heart Failure, palliative care should be integrated early into the routine care for patients with HF alongside disease-modifying treatment [26]. In Feder et al. study of 113,555 HF patients, only about 1 in 20 patients with reduced ejection fraction (HFrEF) and 1 in 25 patients with mid-range ejection fraction (HFmEF) and dpreserved ejection fraction (HFpEF) received palliative care annually [27]. Therefore, integrating palliative care earlier for patients with HF, when they are relatively healthy and functional, may help patients and their families have a better QOL [28,29].

In Iran, most palliative care research is directed at patients with cancer, with the primary focus on the physical aspect rather than the psychosocial and spiritual aspects of palliative care [30]. Therefore, given the lack of randomized clinical trials to investigate palliative care for patients with HF in Iran [30], the aims of this study is are 1) to determine the feasibility and acceptability of this intervention and 2) to examine preliminary efficacy of patient outcomes including QOL, mood status (anxiety and depression) and emergency department visits of those receiving nurse-led, twelve-week early tele-palliative care compared to patients receiving usual care.

2. Methods/design

2.1. Study design and setting

This study is a single-site, Open-label, pilot randomised controlled trial. Patients will be recruited from the Imam Khomeini Hospital Complex (IKHC) HF clinic which is affiliated with Tehran University of Medical Sciences (TUMS) in Tehran, Iran. The Institutional Review Board at TUMS approved the study protocol (IR.TUMS.FNM.REC.1400.071) and patients will be requested to provide written informed consent. The protocol is based on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2022 guideline [31].

2.2. Eligibility criteria

A nurse interventionist will screen the medical records of adult patients in the HF clinic for the following eligibility criteria:

1) age 18–65 years, 2) clinician-determined NYHA class II/III or ACC/AHA stage B/C HF, 3) ability to read and write Persian language, 4) access and ability to use personally-owned smartphones 4) ability to use WhatsApp® messenger properly. Exclusion criteria include: 1) having cognitive disorders documented in the medical record, 2) having uncorrectable vision and hearing disorders, 3) existence of a comorbid disease that requires specialized palliative care such as cancer, and 4) NYHA Class IV or AHA/ACC Stage D of HF.

2.3. Intervention

This nurse-led, twelve -week early tele-palliative care intervention consists of three components: (1) a joint face-to-face visit by the HF specialist and the nurse interventionist, (2) six-week educational webinars alongside a WhatsApp ® group activities (see Fig. 1) following a 6-week WhatsApp® follow-up. A schematic representation of the study design is shown in Fig. 2.

Patients and their eligibility will be assessed in the in-person visits. Before the intervention initiates, patients in the intervention group will

Intervention

Webinar sessions (30-45 minutes)	
Week 1	• Heart Failure: Know your illness • What is palliative care?
Week 2	• COPE: A Positive Problem-Solving Attitude • Seven Steps Of Problem-Solving
Week 3	Control of symptoms (Dietary habits / Medications)
Week 4	Control of symptoms (Physical / psychological)
Week 5	Control of symptoms (Exit Smoking, exercise, relaxation)
Week 6	Spirituality / Talk about What matters most / Decision making

Social Media Groups Activities (2-3 hours a week)
Pre-prepared messages for daily sending (Similar to webinar topics)
Studying Scenarios and sharing patients experience

Fig. 1. Schematic representation of the intervention.

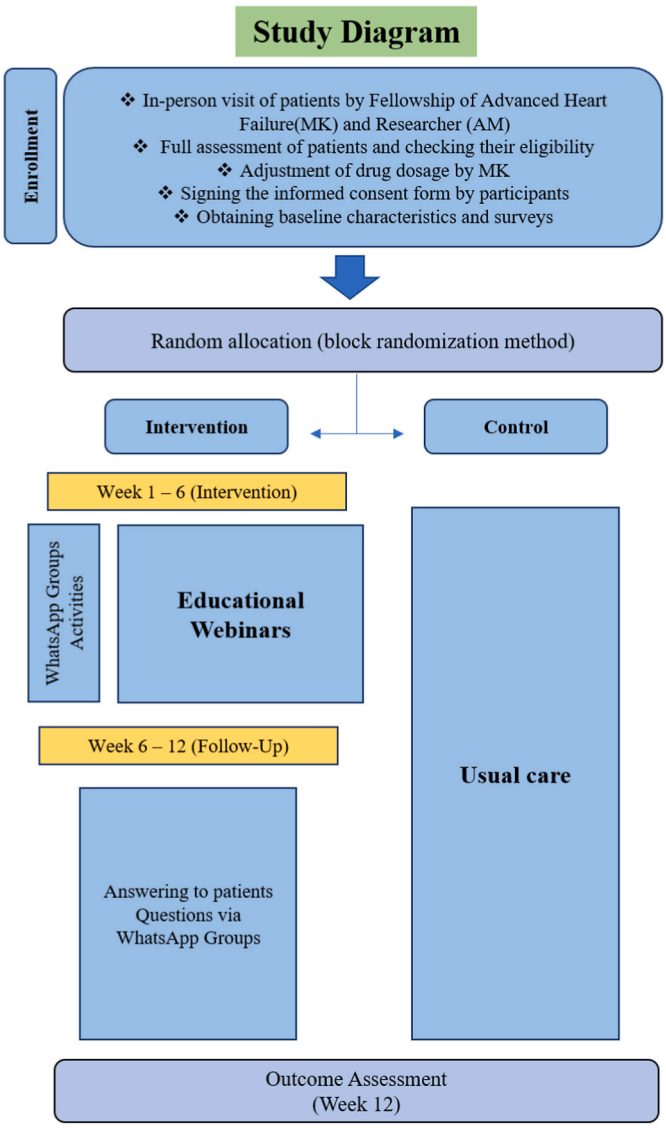

Fig. 2. Schematic representation of the study design.

be divided into groups of 10–15, and these patients will remain in these groups until the end of the intervention. The nurse interventionist will deliver six weekly-held webinars on topics consistent with Bakitas et al.'s ENABLE CHF-PC program(25) and international HF guidelines and recommendations published by the American Heart Association (AHA) as well as reliable scientific sources. Adapted topical content is included in a six-chapter booklet entitled "Palliative care in patients with heart failure", which will be given to intervention group patients during the in-person visit prior to starting virtual group sessions. In brief, Chapter 1 introduces heart failure and palliative care. Chapter 2 discusses COPE(creativity, optimism, problem-solving, and expert information): a positive problem-solving attitude and seven problem-solving steps. Chapters 3, 4 and 5 address self-care and symptom management and includes dietary habits, medication adherence, physical and psychological symptom management, smoking cessation, exercise and relaxation. Chapter 6 comprises spirituality, discussion of what matters most, and decision-making. Notebly, the booklet was approved by five nursing faculty members and a heart failure specialist.

Regarding the webinar sessions, on an Iranian webinar platform called Skyroom®, each webinar will be held and last 30 and 45 min after which, patients can share their questions and opinions regarding the discussed topic and listen to the opinions of other patients. Patients will join predetermined WhatsApp® groups where standardized content will be shared with patients corresponding to the same week's webinar topic. Also, according to each weeks' webinar topic, the nurse interventionist will send a case scenario to the groups. Subsequently, the nurse interventionist will pose questions about the case, and patients will be encouraged to comment synchronously based on the information provided to them on the webinars. Afterward, patients will be encouraged to express their successful and unsuccessful experiences relative to the discussed case scenario. This part of the intervention aims to engage patients with case scenarios and empower them to make appropriate decisions when they experience a similar situation. Also, this part of the intervention focusses on peer education to learn better the contents expressed in the scenarios and use the experiences of other patients.

Finally, patients will be followed up for six weeks after the intervention, during which the nurse interventionist will answer patients probable questions in the WhatsApp® messenger.

The SPIRIT 2013 template [32] describes the study schedule enrolment, interventions, and assessments (Table 1).

2.4. Usual care group

The usual care group will receive routine care. In the IKHC cardiology clinic, routine HF care consists of in-person visits performed by HF specialists and brief instructions about dietary habits, physical activity, taking medications as prescribed, and weight monitoring. For ethical considerations, the digital content about HF self-care will be sent to control group patients via WhatsApp® at the end of the study.

2.5. Study measures and data collection

We will examine whether 12-week early tele-palliative care program affects the following outcomes:

2.5.1. Primary outcomes (feasibility and acceptability)

- The feasibility of the study will be measured by determining the recruitment and questionnaire completion rates. Adequate feasibility metrics for this study include: 80% of interested individuals agreeing to screening; 60% of those eligible enrolling into the trial; and baseline assessment completion (>80%).
- The acceptability of the study will be measured by a telephone-based interview where participants will rate their perceived adherence to the intervention (10-point Likert scale), satisfaction with the webinar sessions (5-point Likert scale), satisfaction with the WhatsApp group activities (5-point Likert scale) and if they would do the study again or recommend it to others (yes/no). The study procedures and intervention will be considered "acceptable" as evidenced by attrition rate (<20%), session attendance rate (≥80%), perceived adherence to the intervention (≥7), satisfaction with the interventions (≥4), and if they would do the study again or recommend it to others (≥75%).

2.5.2. Secondary Outcomes

2.5.2.1. QOL. The Persian version of the Kansas City Cardiomyopathy Questionnaire (PKCCQ) and 14-item Functional Assessment of Chronic Illness Therapy–Palliative-14 (FACIT PAL-14) will be self-reported by HF patients at baseline and 12 weeks after the enrollment to evaluate for a signal of intervention effect. PKCCQ was translated into Persian and culturally adapted and validated for Persian-speaking patients by Tamartash et al., in 2017 [33]. KCCQ's 15 items are on a five- or six-point Likert scale covering seven domains, including symptom frequency, symptom burden, symptom stability, physical limitations, social limitations, QOL, and self-efficacy [33]. All KCCQ scores are scaled from 0 to 100 and typically summarized in 25-point ranges representing

Table 1
Schedule for enrolment, interventions and assessments in this study.

TIMEPOINT	Baseline	0	Week 1-6	Week 6-12	Week 12
ENROLMENT:					
Eligibility Screen	*				
Informed Consent	*				
Randomization		*			
INTERVENTION GROUP:					
Early-tele palliative care			* ←	*	* →
Usual Care			* ←	*	* →
ASSESSMENTS:					
Demographics	*				
Level of education	*				
Medical history	*				
Occupation	*				
Insurance	*				
Body mass index (kg/m2)	*				*
Blood pressure	*				*
Smoking	*				
Place of residency	*				
NYHA functional class (II– III)	*				*
Ejection Fraction	*				*
PRIMARY OUTCOME:					
Quality of Life	*				*
SECONDARY OUTCOMES:					
Mood Status	*				*
Hospital Readmission	*				*

health status: 0 to 24: very poor to poor; 25 to 49: poor to fair; 50 to 74: fair to good; and 75 to 100: good to excellent. A change of 5 points is considered a small but clinically important change, whereas changes of 10 and 20 points are considered moderate-to-large and large-to-very large clinical changes, respectively [34].

FACIT PAL-14, a shorter version of the FACIT-Pal questionnaire, is one of the most popular instruments for measuring the QOL in palliative care [35]. The FACIT PAL-14 consists of 14 items measured on a five-point Likert scale ranging from "not at all" to "very much". The score range is between 0 and 56; higher scores indicate better QOL [36]. This questionnaire was translated and linguistically validated into Persian by our research team, in conjunction with the FACIT group following an established FACIT Multilingual Translation Methodology [37,38], which was developed and validated to ensure that resulting translations of quantitative measures reflect conceptual equivalence with the source document rendered in language that is culturally acceptable and relevant to the target population, and is consistent with consensus opinion [39].

2.5.2.2. Mood status. The Persian version of 14-item Hospital Anxiety and Depression Scale (HADS) which was translated and validated by Montazeri et al., in 2003 [40] will measure the mood status. Seven items measure anxiety symptoms, and seven items measure depressive symptoms (subscale ranges, 0–2; scores >8 indicate clinically high symptoms [41]; and a change of 1.7 is considered a clinically significant difference) [42].

2.5.2.3. Number of emergency department visit. The number of emergency department visits during the study will be obtained from participants in both groups by an outcome assessor blinded to study group assignment immediately after the study. In the case of admission to other healthcare settings except for IKHC, data will be collected according to the participants' self-reports. If the participant is admitted to IKCH, data will be confirmed by the hospital information system(HIS) following the participant's self-report.

2.5.3. Data collection

The nurse interventionist will collect demographic and clinical characteristics using patients' self-reports and a medical chart. A trained assessor, will collect participants' baseline surveys, including PKCCQ, FACIT Pal-14, and HADS, during the in-person IKCH HF clinic visit at the start and end of the study using paper-and-pencil questionnaire. The main outcome of the study (feasibility and acceptability) will be measured by a trained interviewer.

2.6. Sample size

Assuming a medium effect size, sample size calculations are as: the power of 80% ($\beta = 0.2$), type 1 error of 5% ($\alpha = 0.05$), an effect size of 75% and allocation ratio N2/N1 = 1. Given a possible 10% attrition rate, the estimated number of participants is n = 25 patients per group and a total sample size of 50.

2.7. Participant recruitment

Patients will be screened for eligibility while attending the HF clinic of IKHC, and this process will continue until the target population is achieved. Additionally, the HF specialist will confirm the potential eligibility of the patient. During the clinic visit, in addition to the usual care provided, the HF specialist will confirm the patient's potential eligibility, discuss additional study details, and encourage participation. To keep patients engaged in the intervention, to reduce attrition and to improve intervention adherence, we will use reminders in our webinar sessions and whatsApp group activites.

2.8. Randomization and blinding

Block randomization will be used in a clinical trial to achieve balance

in the allocation of individuals to treatment arms. In this study, random assignment, stratified by gender and NYHA classification of heart failure, will block-balanced with variable block sizes of four patients. Finally patients will be randomized by 1-to-1 assignment to either intervention or usual care group. The nurse interventionist notifies participants about their allocation status. Due to the nature of the study, participants and nurse interventionist are aware of allocation to the intervention group. Participants will be asked not to discuss their study activities with the outcome assessor. The outcome assessor and statistician will be blinded to study group.

2.9. Data management

After preparing a database using SPSS software(Version 22), the nurse interventionist will enter data from the paper questionnaires. After finishing the data entry, all data will be double-checked by a research team member who is unaware of the data management process. An epidemiologist or statistician will perform data cleaning and data analysis.

2.10. Statistical methods

Mean and standard deviation (or median and interquartile range) will be used to describe numerical variables. As for categorical variables, frequency tables will be utilized as a percentage.

The groups' participation rate, response rate, and attrition rate will be reported as a percentage and a confidence limit of 95%(95%CI) for measuring the intervention's feasibility and acceptability. The average length of follow-up in the two groups will be compared using a T-test or Mann-Whitney test. For analyzing the Secondary Outcomes, The Shapiro–Wilk test will be used to check the normality of the data distribution. The T-test or Mann-Whitney test will compare numerical variables in the two groups. The chi-square or Fisher's exact test will examine categorical variables in the groups. Linear regression analysis or analysis of covariance (ANCOVA) will be applied to adjusted confounding variables. The significance level in this study will be considered as $P < 0.05$.

2.11. Ethics approval and consent to participate

All the protocol study, data collection forms, educational booklet, and the informed consent form template were reviewed and approved by the Research Ethics Committee (REC) at TUMS on July 17, 2021 (No. IR.TUMS.FNM.REC.1400.071). The HF specialist and nurse interventionist will explain the intervention to eligible patients to obtain informed consent. All participants will be requested to sign the written informed consent form. The form has been prepared according to the Declaration of Helsinki [43]. All the personal information will be collected and maintained by the nurse interventionist in locked filing cabinets and behind password protected computer files that are only accessible to the study principal investigator.

3. Discussion

Palliative care is not well understood by the general public and even some healthcare workers, who are unaware that it is appropriate prior to patients' end-of-life [28]. However, for patients with life-threatening health conditions such as heart failure, early implementation of palliative care is currently regarded as a helpful approach that benefits both patients and their caregivers [44]. This randomized controlled trial will contribute to palliative care science by determining feasibility and acceptability in an Iranian HF sample and by examining factors impacting patient intervention trial participation (e.g., health literacy, coping, decision-making, social support, peer education, and empowerment). After implementing this study, information such as participants perceived adherence to the intervention, satisfaction with the webinar sessions and WhatsApp group activities and their intention to participate in the study again or recommend it to others will inform our future trial.

A key strength of this study is that this intervention, will introduce a holistic early tele palliative care program concentrating on different aspects such as health literacy, symptom-controlling methods, novel problem-solving, and decision-support techniques. On the other hand, a potential limitation of this study is because it is a telehealth, internet-based intervention, some patients may not have a proper internet access at some points which will affect their ability to be fully involved in the study.

To the best of our knowledge, there is no codified palliative care program for Iranian HF patients. In light of these patients' low QOL [30] and palliative care needs, there is an urgent need to design and test a feasible and acceptable standard palliative care intervention for these patients. Our next steps are to examining this intervention's different components through more qualitative studies and a subsequent, fully powered, randomized controlled trial. Our goal is to develop a practical, culturally-responsive intervention that be applicable to patients with HF in Iran and other countries similar to Iran.

Patient consent for publication

Not applicable.

Authors' contributions

AM is the principal investigator of this trial. AM, MB, SG, MK, SMR, JNDO,RW and MZ initiated the study design. MK is the physician in charge of the cardiology clinic of Imam Khomeini Hospital complex (IKHC). MZ is the executive manager of the project. AM, AKK and MK will help with implementation and data collection. AM, MZ, AKK, MB, MK, JNDO and RW prepared the informed consent and data collection forms and the "palliative care in heart failure patients" booklet. AM, AKK and SMR will prepare the data for statistical analysis. SMR will provide statistical expertise in clinical trial design and perform the statistical analysis. All authors contributed to the refinement of the study protocol and are accountable for all aspects of the work.

Funding

There are no funders to report for this submission.

Declaration of competing interest

None declared.

Data availability

No data was used for the research described in the article.

Acknowledgments

This research protocol pertains to AM's MSc thesis in Medical-Surgical Nursing at TUMS. We appreciate the Education, Research and Technology Deputy and the Medical-Surgical Nursing Department at the School of Nursing and Midwifery affiliated with TUMS for the thesis approval. We also thank Hadis Enayati for designing the attractive colored "palliative care in heart failure patients" educational booklet.

References

[1] C.W. Yancy, M. Jessup, B. Bozkurt, J. Butler, D.E. Casey, M.H. Drazner, et al., ACCF/AHA guideline for the management of heart failure: a report of the american college of cardiology foundation/american heart association task force on practice guidelines, Circulation 128 (16) (2013), 2013 Oct.

[2] G. Savarese, L.H. Lund, Global public health burden of heart failure, Card. Fail. Rev. 3 (1) (2017) 7.

[3] N.L. Bragazzi, W. Zhong, J. Shu, A. Abu Much, D. Lotan, A. Grupper, et al., Burden of heart failure and underlying causes in 195 countries and territories from 1990 to 2017, Dec 29 [cited 2022 Jul 28], Eur J Prev Cardiol [Internet] 28 (15) (2021), 1682–90, https://pubmed.ncbi.nlm.nih.gov/33571994/.
[4] S.S. Virani, A. Alonso, H.J. Aparicio, E.J. Benjamin, M.S. Bittencourt, C. W. Callaway, et al., Heart disease and stroke statistics-2021 update: a report from the American heart association, Feb 23 [cited 2022 Sep 14], Circulation [Internet] 143 (8) (2021). E254–743, https://pubmed.ncbi.nlm.nih.gov/33501848/.
[5] M. Givi, D. Shafie, F. Nouri, M. Garakyaraghi, G. Yadegarfar, N. Sarrafzadegan, Survival rate and predictors of mortality in patients hospitalised with heart failure: a cohort study on the data of Persian registry of cardiovascular disease (PROVE), Postgrad. Med. 94 (1112) (2018 Jun 1) 318–324.
[6] S.L. Auener, T.E.P. Remers, S.A. van Dulmen, G.P. Westert, R.B. Kool, P.P. T. Jeurissen, The effect of noninvasive telemonitoring for chronic heart failure on health care utilization: systematic Review, J. Med. Internet Res. (9) (2021 Sep 1) 23.
[7] M. Urbich, G. Globe, K. Pantiri, M. Heisen, C. Bennison, H.S. Wirtz, et al., A systematic Review of medical costs associated with heart failure in the USA (2014–2020), 2020 3811 [Internet], PharmacoEconomics (2020). Aug 19 [cited 2022 Jul 28];38(11):1219–36, https://link.springer.com/article/10.1007/s40273-020-00952-0.
[8] A. Alghamdi, E. Algarni, B. Balkhi, A. Altowaijri, A. Alhossan, Healthcare expenditures associated with heart failure in Saudi arabia: a cost of illness study, Healthcare 9 (8) (2021). Aug 1.
[9] C. Norton, V.V. Georgiopoulou, A.P. Kalogeropoulos, J. Butler, Epidemiology and cost of advanced heart failure, Prog. Cardiovasc. Dis. 54 (2) (2011) 78–85. Sep.
[10] A. Ahmadi, K. Etemad, A. Khaledifar, Risk factors for heart failure in a cohort of patients with newly diagnosed myocardial infarction: a matched, case-control study in Iran, Epidemiol Health 38 (2016), e2016019.
[11] P. Ponikowski, A. Voors, SAE journal of, Undefined. 2016 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure: the Task Force for the Diagnosis and Treatment of Acute and Chronic Heart, Wiley Online Libr, 2016.
[12] H. Walthall, T. Floegel, The lived experience of breathlessness for people diagnosed with heart failure: a qualitative synthesis of the literature, Curr. Opin. Support. Palliat. Care 13 (1) (2019) 18–23. Mar 1.
[13] C. Tziraki, C. Grimes, F. Ventura, R. O'caoimh, S. Santana, V. Zavagli, et al., Rethinking palliative care in a public health context: addressing the needs of persons with non-communicable chronic diseases, Prim. Health Care Res. Dev. (2020) 21.
[14] World Health Organization, WHO Definition of Palliative Care, 2013. Retrieved from, http://www.who.int/cancer/palliative/definition/en/. (Accessed November 2021).
[15] M. Bakitas, J.N. Dionne-Odom, S.V. Pamboukian, J. Tallaj, E. Kvale, K.M. Swetz, et al., Engaging patients and families to create a feasible clinical trial integrating palliative and heart failure care: results of the ENABLE CHF-PC pilot clinical trial, BMC Palliat. Care 16 (1) (2017) 45. Dec 31.
[16] E.L. Aaronson, N. George, K. Ouchi, H. Zheng, J. Bowman, D. Monette, et al., The surprise question can Be used to identify heart failure patients in the emergency department who would benefit from palliative care, J. Pain Symptom Manag. 57 (5) (2019) 944–951. May 1.
[17] L.S. Evangelista, S. Liao, M. Motie, N. De Michelis, D. Lombardo, On-going palliative care enhances perceived control and patient activation and reduces symptom distress in patients with symptomatic heart failure: a pilot study, Eur. J. Cardiovasc. Nurs. 13 (2) (2014) 116–123. Apr.
[18] D.B. Bekelman, C.T. Nowels, L.A. Allen, S. Shakar, J.S. Kutner, D.D. Matlock, Outpatient palliative care for chronic heart failure: a case series, J. Palliat. Med. 14 (7) (2011) 815–821. Jul 1.
[19] K.L. Quinn, T.A. Stukel, E. Campos, C. Graham, D. Kavalieratos, S. Mak, et al., Regional collaborative home-based palliative care and health care outcomes among adults with heart failure, CMAJ [Internet] (2022). Sep 26 [cited 2022 Nov 18];194(37):E1274–82, https://pubmed.ncbi.nlm.nih.gov/36162834/.
[20] Z. Xu, L. Chen, S. Jin, B. Yang, X. Chen, Z. Wu, Effect of palliative care for patients with heart failure, Int. Heart J. [Internet] (2018). May 1 [cited 2022 Nov 18];59 (3):503–9, https://pubmed.ncbi.nlm.nih.gov/29681574/.
[21] A. Yazdanyar, D. Guthier, T. Maitz, S. Singh, D. Parfianowicz, S. Li, et al., Inpatient palliative care encounter and 30-day readmission among hospitalizations for heart failure, Future Cardiol. [Internet] (2022). Sep 1 [cited 2022 Nov 18];18(10): 809–16, https://pubmed.ncbi.nlm.nih.gov/36052818/.
[22] J.G. Rogers, C.B. Patel, R.J. Mentz, B.B. Granger, K.E. Steinhauser, M. Fiuzat, et al., Palliative care in heart failure: the PAL-HF randomized, controlled clinical trial, J. Am. Coll. Cardiol. 70 (3) (2017) 331–341. Jul 18.
[23] D.B. Bekelman, L.A. Allen, C.F. McBryde, B. Hattler, D.L. Fairclough, E. P. Havranek, et al., Effect of a collaborative care intervention vs usual care on health status of patients with chronic heart failure: the CASA randomized clinical trial, JAMA Intern. Med. 178 (4) (2018) 511–519. Apr 1.
[24] R. Wells, M.L. Stockdill, J.N. Dionne-Odom, D. Ejem, K.L. Burgio, R.W. Durant, et al., Educate, nurture, advise, before life ends comprehensive heartcare for patients and caregivers (ENABLE CHF-PC): study protocol for a randomized controlled trial, Trials 19 (1) (2018). Aug 6.
[25] M.A. Bakitas, J.N. Dionne-Odom, D.B. Ejem, R. Wells, A. Azuero, M.L. Stockdill, et al., Effect of an early palliative care telehealth intervention vs usual care on patients with heart failure, JAMA Intern. Med. 180 (9) (2020) 1203. Sep 1.
[26] P.A. Heidenreich, B. Bozkurt, D. Aguilar, L.A. Allen, J.J. Byun, M.M. Colvin, et al., AHA/ACC/HFSA guideline for the management of heart failure: a report of the American college of cardiology/American heart association joint committee on clinical practice guidelines, Circulation (2022) [Internet]. 2022 May 3 [cited 2022 Jul 28];145(18):E895–1032, https://www.ahajournals.org/doi/abs/10.1161/CIR.0000000000001063.
[27] S.L. Feder, T.E. Murphy, E.A. Abel, K.M. Akgün, H.J. Warraich, M. Ersek, et al., Incidence and trends in the use of palliative care among patients with reduced, middle-range, and preserved ejection fraction heart failure, J. Palliat Med. [Internet (2022), https://doi.org/10.1089/jpm.2022.0093. Jun 28.
[28] C.K. McIlvennan, L.A. Allen, Palliative care in patients with heart failure, BMJ [Internet] (2016). Apr 14 [cited 2022 Jan 4];353, https://www.bmj.com/content/353/bmj.i1010.
[29] R. Ghashghaei, R. Yousefzai, E. Adler, Palliative care in heart failure, Prog. Cardiovasc. Dis. 58 (4) (2016) 455–460. Jan 1.
[30] I. Bagheri, N. Hashemi, M. Bahrami, Current state of palliative care in Iran and related issues: a narrative Review, Iran. J. Nurs. Midwifery Res. 26 (5) (2021) 380–391. Sep 1.
[31] N.J. Butcher, A. Monsour, E.J. Mew, A.W. Chan, D. Moher, E. Mayo-Wilson, et al., Guidelines for reporting outcomes in trial protocols: the SPIRIT-outcomes 2022 extension, JAMA [Internet] (2022). Dec 20 [cited 2023 Feb 14];328(23):2345–56, https://jamanetwork.com/journals/jama/fullarticle/2799547.
[32] A.W. Chan, J.M. Tetzlaff, P.C. Gøtzsche, D.G. Altman, H. Mann, J.A. Berlin, et al., SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials, BMJ (2013) 346. Jan 9.
[33] H. Tamartash, B.A. Moghadam, K. Hosseini, S. Musavi, The relationship between disease severity and quality of life in patients with heart failure based on Kansas city questionnaire, Jul 1, J. Mod. Rehabil 11 (3) (2017). SE-Research Article(s)).
[34] J.A. Spertus, P.G. Jones, A.T. Sandhu, S.V. Arnold, Interpreting the Kansas city Cardiomyopathy questionnaire in clinical trials and clinical care: JACC state-of-the-art Review, J. Am. Coll. Cardiol. 76 (20) (2020) 2379–2390. Nov 17.
[35] L. Zeng, G. Bedard, D. Cella, N. Thavarajah, E. Chen, L. Zhang, 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. 16 (5) (2013) 509–515. May 1.
[36] M.C. Shinall, E.W. Ely, M. Karlekar, S.G. Robbins, R. Chandrasekhar, S.F. Martin, Psychometric properties of the FACIT-pal 14 administered in an outpatient palliative care clinic, Am. J. Hospice Palliat. Med. 35 (10) (2018) 1292–1294. Oct 1.
[37] A.E. Bonomi, D.F. Cella, E.A. Hahn, K. Bjordal, B. Sperner-Unterweger, L. Gangeri, et al., Multilingual translation of the Functional Assessment of Cancer Therapy (FACT) quality of life measurement system, Qual. Life Res. 5 (3) (1996) 309–320.
[38] S.L. Eremenco, D. Cella, B.J. Arnold, A comprehensive method for the translation and cross-cultural validation of health status questionnaires, Eval. Health Prof. 28 (2) (2005) 212–232. Jun.
[39] D. Wild, A. Grove, M. Martin, S. Eremenco, S. McElroy, A. Verjee-Lorenz, et al., Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation, Value Health 8 (2) (2005) 94–104.
[40] A. Montazeri, M. Vahdaninia, M. Ebrahimi, S. Jarvandi, The hospital anxiety and depression scale (HADS): translation and validation study of the Iranian version, Health Qual. Life Outcome 1 (2003) 14. Apr 28.
[41] I. Olssøn, A. Mykletun, A.A. Dahl, The Hospital Anxiety and Depression Rating Scale: a cross-sectional study of psychometrics and case finding abilities in general practice, BMC Psychiatry [Internet] (2005). Dec 14 [cited 2022 Jan 6];5, https://pubmed.ncbi.nlm.nih.gov/16351733/.
[42] K.R. Lemay, H.E. Tulloch, A.L. Pipe, J.L. Reed, Establishing the minimal clinically important difference for the hospital anxiety and depression scale in patients with cardiovascular disease, J. Cardiopulm Rehabil Prev. [Internet] (2019 Nov 1) [cited 2022 Jan 6];39(6):E6–11, https://pubmed.ncbi.nlm.nih.gov/30489438/.
[43] World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects, JAMA [Internet] (2013). Nov 27 [cited 2022 Jan 10];310(20):2191–4, https://pubmed.ncbi.nlm.nih.gov/24141714/.
[44] L. Radbruch, L. De Lima, F. Knaul, R. Wenk, Z. Ali, S. Bhatnaghar, et al., Redefining palliative care—a New consensus-based definition, Oct 1, J. Pain Symptom Manag. 60 (4) (2020) 754.