

STUDY PROTOCOL

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Cultural adaptation of ENABLE (Educate, Nurture, Advise, Before Life Ends) an early palliative care model for Iranian patients with heart failure and their caregivers: a qualitative study protocol

Arvin Mirshahi^{1,3*}, Ali Khanipour-Kenchah¹, Marie Bakitas^{2,3}, J. Nicholas Odom^{2,3}, Rachel Wells^{2,3} and Arpi Manookian^{4*}

Abstract

Background ENABLE (Educate, Nurture, Advise, Before Life Ends) is a model of nurse-led, early palliative care that was originally developed for U.S. patients with advanced cancer and their family caregivers and then adapted for patients with heart failure. ENABLE coaching topics include problem-solving, communication, advance care planning, symptom management, and self-care. The purpose of this paper is to detail a qualitative study protocol to assess the cultural acceptability of ENABLE among heart failure patients and their family caregivers in Iran.

Methods This qualitative study employs reflexive thematic analysis (RTA) to guide the cultural adaptation of the ENABLE model. The study is conducted in two phases. In Phase 1, the ENABLE content will be translated and validated into Persian using a forward-backward translation process and expert panel review to ensure linguistic and cultural appropriateness. In Phase 2, semi-structured interviews will be conducted with individuals living with HF, their caregivers, and healthcare providers at Tehran University of Medical Sciences. The one-on-one semi-structured interviews will explore three main areas: (1) the primary needs and challenges faced by individuals with heart failure and their family caregivers, (2) the extent of patients' involvement in healthcare decision-making, and (3) participants' preferences for content and delivery method of ENABLE. Maximum variation sampling will be employed to ensure diverse representation, and data collection will continue until saturation is achieved. Interview audio recordings will be transcribed verbatim and analyzed using Braun and Clarke's reflexive thematic analysis approach. The analysis will involve iterative coding to identify patterns and the development of themes that align with the core components of the ENABLE model while ensuring cultural relevance. Trustworthiness and rigor will be ensured through reflexivity, peer debriefing, and data triangulation, ensuring credible and robust findings to guide the cultural adaptation of the ENABLE model for Iran.

*Correspondence:

Arvin Mirshahi
Mirshaiarvin13750@gmail.com
Arpi Manookian
ar-manookian@sina.tums.ac.ir

Full list of author information is available at the end of the article



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Discussion This study will develop a framework for adapting the ENABLE model to Iran, offering insights into cultural and contextual factors influencing palliative care. The adapted model aims to enhance the quality of life for individuals with HF and their caregivers while addressing gaps in palliative care delivery in Iran.

Keywords Palliative care, Cultural adaptation, ENABLE, Qualitative study, Thematic analysis, Heart failure, Study protocol, Iran

Text box 1. Contributions to the literature

- This study represents the first cultural adaptation of the ENABLE (Educate, Nurture, Advise, Before Life Ends) early palliative care model for heart failure patients and their caregivers in Iran, addressing the lack of culturally tailored palliative care frameworks in the region.
- It provides a methodological approach for adapting complex health interventions, emphasizing cultural, social, and religious considerations, which can serve as a guide for similar adaptations in other diverse contexts.
- Highlights the use of qualitative methods to explore patient, caregiver, and healthcare provider perspectives, enabling the identification of culturally specific needs and preferences for intervention delivery.
- Highlights the potential for the adapted ENABLE model to serve as a foundation for future studies and interventions aimed at improving quality of life for heart failure patients and their caregivers in culturally sensitive ways.

Background

Heart failure (HF) is a prevalent chronic condition associated with complex health challenges and significant morbidity and mortality [1]. As with its high prevalence worldwide [2], HF prevalence in Iran is estimated to be high, at approximately 8% [3], making it a serious concern in the Iranian healthcare system [4]. Individuals living with HF often experience debilitating symptoms and recurrent exacerbations of their condition, leading to a decline functional capability and disruption of their daily activities [5]. Moreover, the effective management of this condition requires a multifaceted approach requiring significant lifestyle modifications, strict adherence to a multiple medication regimen, and regular medical visits [6]. The uncertain and precarious trajectory of heart failure, along with the complexity of its management, affect the physical, psychological, and social aspects of managing their condition, including challenges like depression, mental distress, and reduced quality of life (QoL) in both patients with HF [7, 8], and their caregivers [9]. Additionally, the impact of HF places significant strain on both patients and the healthcare system, leading to frequent hospitalizations, escalating healthcare expenses, and diminished QoL [10]. All of these factors highlight the importance of a holistic approach for these patients.

As an integrated and comprehensive approach, palliative care, focuses on early identification, correct assessment, and treatment of pain and other physical, psychosocial, or spiritual problems [11]. This approach

helps improve the QoL of patients facing serious diseases or life-threatening circumstances [12, 13]. Given the unpredictable trajectory of HF and the challenges in prognostication, it is recommended to integrate palliative care at an early stage when patients are still highly functional [14, 15]. While early palliative care has been explored for its potential benefits in maintaining or enhancing patients' QoL [16], the evidence presents a mixed picture, particularly in heart failure where findings remain equivocal. Previous studies have demonstrated the beneficial outcomes of early palliative care models and interventions in patients with serious conditions such as cancer [17, 18], HF [19] or other severe diseases [16, 19], with only one study focusing on early palliative care in Iranian heart failure patients [20]. On the other hand, Iran currently lacks a well-defined and specific framework for providing palliative and supportive care, especially tailored for heart failure patients [21], highlighting the urgent need for action in this regard. One potential approach to address this gap is through the cultural adaptation of existing early palliative care interventions or models for the Iranian populace. Among these, the ENABLE model emerges as one of the most promising and evidence-based early palliative care interventions.

ENABLE (Educate, Nurture, Advise, Before Life Ends) is a nurse coach-led, telehealth, potentially scalable model to integrate early palliative care for the patients and their caregivers [22, 23]. Nurse-led models of care leverage the expertise of nurses to deliver holistic, patient-centered services that address physical, behavioral, and social health needs. By focusing on prevention, chronic disease management, and care coordination, these models improve access, enhance health equity, and reduce healthcare costs, particularly benefiting under-resourced and under-represented populations [24]. The ENABLE model provides comprehensive guidance and skills training to patients and family caregivers care, on common issues arising across the care continuum for HF including effective symptom management, self-care, crisis prevention, problem-solving, decision-making, coping mechanisms, advance care planning, and approaches to facilitating communication between patients, families, and healthcare providers [25, 26]. Although, a growing body of literature has examined the significant impact of

the ENABLE program on cancer patients and their caregivers [22, 23], this model has had only limited testing on U.S. HF patients demonstrating feasibility [27] and some positive outcomes [19]. Project ENABLE was originally designed for cancer patients living in rural states of the United States [26, 28], and has been adapted for implementation in other geocultural contexts such as African-American communities [29], Turkey [30], and Singapore [31, 32].

Given the Medical Research Council (MRC) guidance, the feasibility, acceptability and effectiveness of complex interventions, such as ENABLE, depends on factors such as the community and cultural context in which the intervention is implemented [33]. Therefore, cultural adaptation is the first critical step in determining the appropriate and effective principles for the implementation of care programs in different communities. Consequently, the ENABLE model has been generating considerable interest in terms of cultural adaptation as a comprehensive early palliative care model in diverse contexts [25]. Although some aspects of ENABLE, such as symptom management, are widely relevant and cross-culturally applicable to individuals with HF, other topics such as advance care planning, spiritual needs, or the way the program would be delivered may differ in countries like Iran which has very different cultural backgrounds and religious beliefs [29, 31, 34]. For example, thinking and planning about end-of-life, can be challenging in Iranian culture, where death is commonly perceived as a dreadful, grim and tragic event that could occur at any moment [35]. Some believe that talking about death and severe conditions will cause these events to occur [36]. In addition, a crucial component of dealing with HF is paying attention to the spirituality and religious beliefs of patients, especially in the highly religious Iranian culture [37]. For example, faith in God's will and divine destiny play a significant role in pursuing religious assistance and hope in Iranian society [34, 38]. Therefore, the perspectives, beliefs, cultural thoughts, and religious values of Iranian patients can influence their preferences about the health care they receive [39]. This point must be taken into account when developing an intervention in this unique context [40].

According to the MRC framework for developing and evaluating complex interventions, there are four perspectives that can be used to guide a complex intervention, including efficacy, effectiveness, theory based, and systems. The theory based perspective can be beneficial in adaptive intervention research, because it focuses on understanding how an intervention works and the interplay between mechanisms and context, thus emphasizing the importance of developing and testing theories that

underpin the intervention and refining them as necessary [41].

Theoretical positioning

ENABLE, informed by Wagner's Chronic Care (CIC) model [27], has also been used successfully to inform care for Iranian patients with chronic diseases [42]. However, it is essential to evaluate whether the theoretical foundations of the CIC model remain applicable in a population of heart failure patients receiving early palliative care. As suggested by the MRC guidance, qualitative designs may be necessary to address questions that go beyond effectiveness, particularly in the context of adaptive intervention research, where interventions are tailored to specific populations and settings [41]. It is generally believed that qualitative methods are valuable tools to explore the way an intervention can be improved because they can provide information on how and why a new method fails or succeeds, as well as how patients and providers perceive a care service [43]. Since qualitative approaches provide in-depth information, perspectives and insights, this method could shed new light on ENABLE model in terms of cultural adaptation in Iranian context especially related to patients' spiritual, social, and cultural perspectives [44]. These insights are of vital importance as they can reveal the intricacies and nuances of human behavior when faced with disease and its treatment [45].

Due to the necessity of examining a suitable early palliative care model in HF patients and their caregivers in the cultural context of Iran and also the importance of investigating the cultural adaptation of care-providing models developed in other countries, this paper describes the study protocol to be used to meet study aims of exploring cultural relevance and modifications for an adapted ENABLE model in Iranian patients living with HF in a two-phase study as below:

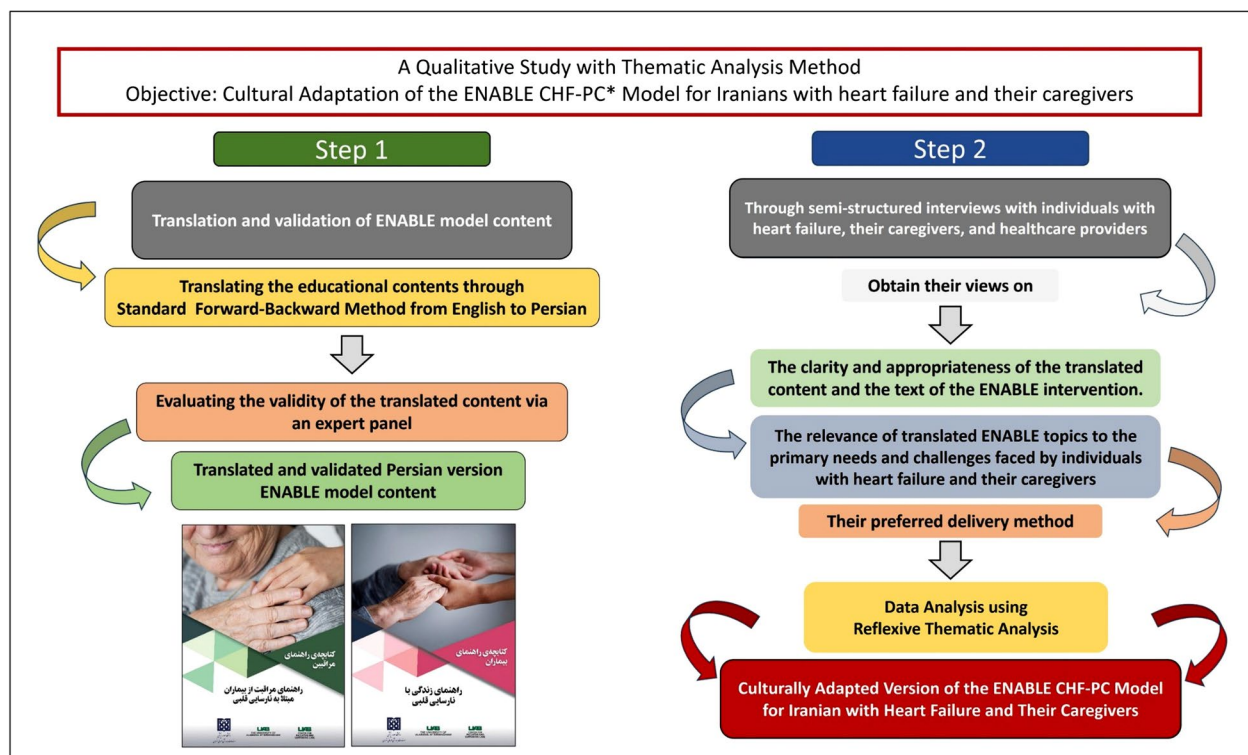
Objectives

The objectives of this study are:

Main objective: To conduct a cultural adaptation of Educate, Nurture, Advise, Before Life Ends-Comprehensive heartcare for patients and caregivers (ENABLE CHF-PC) as an early palliative care model among heart failure patients and caregivers in Iran.

First Phase Objective: To translate and validate the ENABLE model content.

Second Phase Objective: To explore heart failure patients, their caregivers and healthcare providers views on: 1) the clarity and appropriateness of the translated content and the text of the ENABLE intervention, 2) the relevance of translated ENABLE topics to the primary needs and challenges faced by indi-



*Educate, Nurture, Advise, Before Life Ends Comprehensive Heartcare for Patients and Caregivers

Fig. 1 Schematic diagram of the phases of the cultural adaptation study

viduals of patients and their caregivers, 3) and their preferred delivery method.

Methods/design

Study design

This qualitative study employs reflexive thematic analysis (RTA) outlined by Braun and Clarke [46], to explore and describe the cultural adaptation of the ENABLE model for individuals living with heart failure and their caregivers in Iran. ENABLE serves as a conceptual guide for identifying areas of inquiry, such as symptom management and advance care planning, but it is not used as a deductive framework for data analysis. Themes will primarily emerge inductively from participant narratives, allowing the analysis to remain flexible and grounded in the data. The study combines exploratory and descriptive approaches. It aims to explore cultural and contextual factors shaping participants' palliative care needs while also describing their preferences for adapting the ENABLE model to align with Iranian cultural, social, and healthcare contexts.

The 2-phase process of cultural adaptation of the ENABLE CHF-PC intervention, seen in Fig. 1, comprises: Phase 1: Translation and validation of ENABLE content and, Phase 2: Semi-structured interviews with

heart failure patients, their caregivers and healthcare providers to get perspectives on content clarity, relevance, and delivery method. Phase 1 of the study, involving the translation, validation, and finalization of the graphical design for both patient and caregiver booklets based on the ENABLE translated content, was completed by September 25, 2024. Phase 2, consisting of interviews with individuals diagnosed with heart failure, their caregivers, and healthcare providers, began on November 20, 2024. The study is anticipated to conclude with the final report by September 10, 2025. The Institutional Review Board at Tehran University of Medical Sciences (TUMS) approved the study protocol (IR.TUMS.FNM.REC.1401.133). This manuscript complies with the Consolidated criteria for Reporting Qualitative research (COREQ) checklist relevant at the study protocol stage [47].

The adaptation process

Translation and validation of ENABLE program content:

The ENABLE program content, displayed in Fig. 2, was translated into Persian using the standard Forward-Backward method [48]. This methodology required two forward translations into the target language by

	Session	Topic	Contents
Sessions for patients and caregivers	1	Handling problems with a positive attitude	❖ COPE: A positive problem-solving attitude ❖ The seven steps of problem-solving
	2	Taking care of you	❖ Healthy eating, nutrition, medication and exercise ❖ Getting the support you need
	3	Taking control of your symptoms	❖ Common symptoms in heart failure ❖ Spirituality
	4	Talking about what matters most and making choices	❖ Communicating with your family and healthcare providers ❖ Core values: what matters most ❖ Decision aids: making choices that are right for you ❖ Advance care planning
Additional sessions for patients	5	Telling my life story	❖ Encourages participants to frame advanced illness challenges as personal growth opportunities
	6	Looking at today, looking at tomorrow	

Fig. 2 Content outline of educate, nurture, advise, before life ends program sessions

native speakers, a reconciled version of the two forward translations completed by a third independent translator who was a native speaker of the target language, a back-translation of the reconciled version by an English speaker fluent in the target language, harmonization of the translation with other languages, and review/finalization by a native-speaking linguist or health-related quality of life research expert. The validity of the translated content was evaluated by an expert panel consisting of ten faculty members from TUMS with diverse specialties. This panel comprised six nursing faculty members who were experts in palliative care, critical care, and cardiovascular nursing, along with two psychologists and two heart failure specialists.

Semi-structured interviews with heart failure patients, their caregivers and healthcare providers

After obtaining the written informed consent we will use an interview guide to conduct semi-structured interviews on: 1) the clarity and appropriateness of the translated content and the text of the ENABLE intervention, 2) the relevance of translated ENABLE topics to the primary needs and challenges faced by individuals of patients and their caregivers, 3) and their preferred delivery method (such as phone or face-to-face). These interviews will be conducted over two in-person sessions, in which patients and their caregivers will be interviewed separately. During the first session, the study's objectives, needs, and challenges related to palliative care in heart failure will be explored, and an overview of the various aspects of the ENABLE program will be provided. As agreed beforehand, patients, caregivers and healthcare providers will

have 3–7 days to review the content of the ENABLE program, which is provided to them in a booklet designed specifically for them as a patient or caregiver version. In the second interview we will actively seek their perspectives on the content, alignment with their needs, and recommendations for enhancement. To ensure maximum diversity and access to information richness, patient/caregiver participants will be selected with maximum diversity in terms of age, gender, education, and duration of heart failure diagnosis. For health care providers we will seek diversity of age, gender, discipline and work experience. Participants will continue to be interviewed until data saturation, the point at which no new information or themes are present, are attained within all three participant groups [49]. At the end of the second session, as a token of appreciation for the time spent participating in the study, participants will be offered a 100 thousand Toman gift card.

Data collection

Purposive sampling is a commonly employed qualitative research technique aimed at focusing on particular characteristics, knowledge or experience of a population that are of interest in helping to answer the research question. In the present study, maximum variation purposive sampling method is considered to capture the widest and the most relevant perspectives possible [50]. Using this sampling method, all patient, family caregiver, and clinician participants will be selected and their opinions and viewpoints will be collected regarding heart failure patients' needs, ENABLE content, and their preferred delivery method. The interview time and location will

be determined based on the participant's preference and the request for participation, either at the Heart Clinic of Imam Khomeini Hospital Complex (IKHC) or at the Nursing and Midwifery School of Tehran University of Medical Sciences. The interview questions were formulated based on prior research on the cultural adaptation of the ENABLE model in Singapore [31], as well as insights gained from the Iranian research team's previous qualitative studies. The final format of the questions was refined through deliberation among the research team and subsequently approved by all members. See sample interview questions in Fig. 3. Moreover, in the event of any emotional reactions from patients or families during the interviews, the interviewers have been trained to handle emotional distress sensitively and psychological support referrals will be provided if appropriate.

Participants

Patients

All individuals living with HF will be recruited from the heart failure clinic and the cardiovascular department of IKHC which is affiliated with TUMS. Tehran, the capital city of Iran, is the most populous city in the country, with an estimated population of 9.6 million as of 2024. It is a major metropolis with a diverse cultural population, as people from all parts of Iran reside there [51]. The city serves as the nation's economic hub and cultural melting pot, making it an ideal location for studies that aim to

capture the diverse experiences and cultural perspectives of individuals and families living with HF. IKHC is the largest tertiary center in Iran, presently boasting nearly 400 faculty members, 4000 administrative and clinical staff, and more than 1300 active beds across its various specialist centers [52]. Nearly all patients speak Persian as their first language. The inclusion criteria for the patients include: 1) 18 years of age or older, 2) able to communicate in Persian, 3) having a diagnosis of heart failure by a specialized cardiologist, 4) being New York Heart Association (NYHA) class II, III, or IV. The exclusion criteria include individuals with diagnosed and documented untreated psychological disorders in their medical record (e.g., schizophrenia, bipolar disorder, or active substance use disorder) that significantly impairs their functioning and ability to participate in the study.

Caregivers

In this study, a family caregiver is defined as someone who is directly involved with individuals living with heart failure of NYHA class II or III, assisting with daily needs, ensuring care provision, or serving as the decision-maker regarding the patient's care and needs. The inclusion criteria for family caregivers include: 1) 18 years of age or older, 2) able to communicate in Persian, 3) self-endorses providing the majority of support and medical care to the patient due to his or her illness 4) not paid for their support, 5) may or may not live in the same home with

Scopes of questions	Patients	Family Caregivers	Healthcare Providers
Needs and Challenges	What is the most significant challenge for you as a patient with heart failure?	What is the most significant challenge for you as a caregiver of a patient with heart failure?	What is the most significant challenges for both a patient with heart failure and their caregiver?
	What is the most important need of patients with heart failure and/or their caregivers?		
Healthcare Decision-Making	As a patient with heart failure, how and to what extent do you participate in the decision-making process regarding your care? In what areas?	As a caregiver of a patient with heart failure, how and to what extent do you participate in the decision-making process regarding the patient's care? In what areas?	How and to what extent do a patient with heart failure and their caregiver can participate in the decision-making process regarding their care? In what areas?
	-		What information or assistance would be helpful for patients/caregivers in making healthcare decisions?
Views on ENABLE Programme	How appropriate is the content of each session? What topics should be removed or added?		
	A six-week program with one-hour sessions per week has been scheduled for the implementation of this program. What do you think about the number and duration of these sessions?		

Fig. 3 Guiding questions for the interviews

the patient. The exclusion criteria include individuals with diagnosed and documented untreated psychological disorders in their medical record (e.g., schizophrenia, bipolar disorder, or active substance use disorder) that significantly impair their functioning and ability to participate in the study.

Healthcare providers

Among those working as healthcare providers in IKHC, we will recruit HF and palliative care nurses, psychologists, and physicians, working in the cardiology department, and psychologists for at least six months.

Data analysis

To identify common themes among diverse perspectives and experiences of heart failure patients, family caregivers, and clinicians, thematic analysis will be performed according to Braun and Clarke's guide. In Braun and Clarke's seminal work on thematic analysis, they underlined that thematic analysis is theoretically flexible for identifying, describing, and interpreting patterns so that its flexibility and transparency make the analysis more valid [46, 53]. This method employs six stages for identifying and reporting on themes, including: 1) familiarization with the data, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes, and 6) preparing the report / manuscript. All interviews will be digitally-recorded using audio format and transcribed verbatim. The interviews will be transcribed by the first author of the paper, who has completed multiple qualifications in qualitative research methods, demonstrating his expertise for this role. After transcription, the data will be reviewed multiple times to ensure familiarity with participant statements. Qualitative analysis will be aided by using MAXQDA software. Then, using in vivo coding, initial codes will be assigned to the data. After reviewing the initial codes, they will be examined for how they group into themes, sub-themes and patterns. Next, the results, which will be in the form of codes and themes, will be summarized relative to how they guide the intervention adaptation and a final report will be prepared on the participants' views regarding the clarity, appropriateness, relevance of translated ENABLE topics to the needs of patients and caregivers and their preferred delivery method (such as phone or face-to-face) of the ENABLE program.

Rigor and trustworthiness

In this qualitative study, rigor and trustworthiness will be ensured through a series of measures aligned with best practices in qualitative research and RTA, as outlined by Braun and Clarke [46]. To ensure rigor, multiple verification strategies will be employed: (1) ensuring

methodological coherence by aligning the research question with appropriate methods and data analysis procedures to maintain conceptual consistency throughout the study; (2) engaging in reflexivity, with the first (AM) and corresponding author (Arpi.M) critically reflecting on their prior knowledge and experiences with individuals with heart failure and their caregivers. These reflections will be systematically recorded in a reflexive log, enabling transparency about how such insights inform the analysis and ensuring that potential biases are carefully managed; (3) using an iterative process of data familiarization, coding, and theme development, where themes are actively generated through deep engagement with the data and crafted as patterns of shared meaning rather than predefined categories; (4) critically interpreting themes in the context of the research question and existing literature, ensuring that findings provide a nuanced and contextually relevant understanding; and (5) adhering to the Reflexive Thematic Analysis Reporting Guidelines (RTARG) to transparently document analytic decisions, processes, and reflections, enhancing methodological coherence and rigor.

To enhance trustworthiness, the study will focus on three key dimensions: credibility, confirmability, and transferability [54, 55].

Credibility will be ensured through data triangulation and peer debriefing. Data triangulation will involve cross-validating information by integrating multiple sources, such as interview transcripts and relevant literature, to strengthen the accuracy and reliability of the identified codes and themes. Peer debriefing will be conducted with a second team member (AKK), who will independently review the interview transcripts and emergent themes. This collaborative process will challenge assumptions, refine interpretations, and foster a more comprehensive understanding of the findings.

Confirmability will be achieved by maintaining an audit trail, including reflexive logs and analytical memos, to document the processes through which interpretations and decisions are derived. Reflexive logs will enable the research team to critically assess and document their influence on the analysis, ensuring transparency and minimizing potential biases. Triangulation methods will further support confirmability by cross-validating findings across data sources.

Addressing transferability will involve obtaining a "thick description" of the findings, enabling their application to other contexts. This will be accomplished by providing clear descriptions of the research context, participant selection and characteristics, data collection procedures, and data analysis methods. By offering a comprehensive account of these elements, the findings

will become more readily transferable and applicable to other settings.

The study will also incorporate the COREQ checklist to ensure comprehensive reporting [47]. While COREQ will serve as a supplemental framework, the RTARG will be the primary guide for documenting the reflexive thematic analysis process [46]. RTARG emphasizes transparency, methodological coherence, and reflexivity, aligning closely with the study's qualitative approach.

The primary analysis will be done by the first and corresponding author and the opinions of all members of the research team (consisting of different specialties) will be taken into account in relation to the emergent themes. All personal information and interview audio files will be securely stored in locked filing cabinets and password-protected external drives accessible only to the research team. Reflexive and analytical logs will be maintained as part of the audit trail, ensuring adherence to ethical standards. By employing these strategies, the study will uphold methodological rigor, transparency, and alignment with best practices in reflexive thematic analysis, producing findings that contribute meaningfully to the field of palliative care.

Study team

The study team comprises nurses, clinicians, researchers and academics with expertise and specialist training in heart failure and palliative care. Also the principal investigators of the ENABLE program, Dr. Marie Bakitas, Dr. J. Nicholas Odom and Dr. Rachel Wells, will provide consultation on steps of cultural adaptation and study rigor as needed.

Patient and public involvement

There was no patient and public involvement in the development of this protocol.

Discussion

The uncertain course of HF and the complexities of its management affect individuals physically, psychologically, and socially, leading to challenges such as depression and diminished QoL for both people living with HF and their caregivers [7–9]. Additionally, HF results in frequent hospitalizations, increased healthcare costs, and a reduced overall quality of life [10]. While integrating palliative care with standard HF treatment at an early stage is well-documented to improve symptoms, enhance QoL, and reduce hospitalizations [56], limited research exists on palliative care for individuals with HF in Iran [10, 57, 58]. This gap necessitates the development of culturally tailored and well-structured palliative care programs that address the unique needs of individuals with HF and their caregivers [20, 59, 60].

The ENABLE model is a nurse-led early palliative care intervention designed to improve outcomes for people with HF and their caregivers in the U.S [19]. However, adapting this model to Iran requires careful consideration of the geocultural context, healthcare infrastructure, and religious and social norms. In Iran, cultural and religious beliefs significantly influence individuals' perceptions of illness, healthcare preferences, and attitudes toward end-of-life discussions [61, 62]. These factors highlight the importance of a formative qualitative evaluation to adapt the ENABLE model effectively for people with HF and their caregivers in the Iranian context.

This study is expected to yield several significant findings. First, it will identify the cultural and contextual factors that influence the needs and preferences of individuals living with HF and their caregivers in Iran. These factors may include specific challenges in discussing serious illness care, navigating the healthcare system, and managing the emotional and spiritual aspects of illness. Second, the study will provide healthcare providers' insights on integrating early palliative care into the existing healthcare system, addressing barriers, and optimizing the delivery of such interventions. Third, the qualitative findings will inform the cultural adaptation of the ENABLE CHF-PC model, ensuring that it aligns with the values, beliefs, and healthcare infrastructure in Iran. Finally, the adapted ENABLE model will serve as a foundation for future research, offering a culturally relevant framework that can be tested in subsequent studies to assess its feasibility, acceptability, and effectiveness in improving outcomes for people living with HF and their caregivers in Iran.

The ENABLE model has been adapted in various cultural contexts, including United states of America [19], Singapore [32], and Turkey [25], demonstrating its flexibility and global relevance. These adaptations highlight the importance of addressing cultural, social, and healthcare system differences when implementing palliative care interventions. This study builds on these efforts by exploring the unique cultural and contextual factors influencing palliative care delivery in Iran. Insights from this research will contribute to the global knowledge base on adapting palliative care models to diverse settings, enhancing their impact on patient and caregiver outcomes worldwide.

Ethical considerations are crucial in adapting the ENABLE CHF-PC model for use in Iran. The study will address sensitive topics like end-of-life care and advance care planning while respecting cultural and personal beliefs. Informed consent will be obtained, with clear explanations of study objectives and participants' rights. Interviewers will be trained to manage emotional distress and refer participants to psychological support if needed.

Confidentiality and anonymity will be ensured, with secure data storage. The adaptation process will align with cultural and religious values while preserving the intervention's core principles.

By conducting rigorous qualitative research, this study aims to make meaningful contributions to the field of palliative care by providing a replicable process for culturally adapting evidence-based interventions like ENABLE. These findings have the potential to bridge gaps in palliative care provision in Iran and serve as a model for similar adaptations in other cultural contexts.

Strengths and limitations

This study's primary strength is its use of RTA to deeply explore the perspectives of individuals living with heart failure, their caregivers, and healthcare providers regarding palliative care. RTA embraces researcher subjectivity as a resource, enhancing the depth and richness of findings through reflexivity and iterative interpretation. The study adheres to rigorous qualitative principles, including purposive sampling, reflexivity, data triangulation, and peer debriefing, ensuring credibility and trustworthiness. Interdisciplinary collaboration with experts in heart failure and palliative care, as well as guidance from the original ENABLE model investigators, further strengthens the cultural adaptation process.

This study will use purposive and maximum variation sampling to include a diverse group of participants, such as individuals living with heart failure, their caregivers, and healthcare providers. Participants will be selected to reflect different ages, genders, education levels, and roles, such as family caregivers, professional caregivers, cardiologists, and palliative care specialists. To address potential bias from purposive sampling, we will build trust with participants, ask open-ended questions, and document reflections during data collection. These steps will help ensure diverse perspectives and enhance the quality of the findings.

Reliance on self-reported data may pose challenges in capturing entirely candid responses, but trust-building and fostering open dialogue will help mitigate this. The study's findings, focused on Iran's cultural and healthcare setting, may have limited transferability. However, detailed descriptions of the research context and participants will support the applicability of findings to similar settings.

To enhance trustworthiness, multiple researchers will engage in the analysis, employing reflective practices to critically assess how their perspectives influence interpretations. Regular team discussions and documentation of analytic decisions will ensure transparency and rigor throughout the research process.

Abbreviations

HF	Heart Failure
QoL	Quality of Life
ENABLE	Educate, Nurture, Advise, Before Life Ends
MRC	Medical Research Council
CIC	Wagner's Chronic Care model
ENABLE CHF-PC	Educate, Nurture, Advise, Before Life Ends Comprehensive Heartcare for Patients and Caregivers
TUMS	Tehran University of Medical Sciences
COREQ	Consolidated criteria for Reporting Qualitative research
IKHC	Imam Khomeini Hospital Complex
NYHA	New York Heart Association
RTA	Reflexive Thematic Analysis
RTARG	Reflexive Thematic Analysis Reporting Guidelines

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Authors' contributions

AM envisioned the idea and with the support of Dr. AM and Dr. MB. AM took the leadership role in gathering team members to write the research proposal and this protocol manuscript. AM wrote the research proposal with the assistance of AKK. Dr. MB, Dr. JNO and Dr. RW are the principal investigators of the original ENABLE-CHF-PC intervention from the University of Alabama at Birmingham. Their rich experiences informed the study concept and design. All authors - AM, AKK, Dr. MB, Dr. JNO, Dr. RW, and Dr. AM critically reviewed, revised the manuscript, and approved the final manuscript for submission.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Institutional Review Board at Tehran University of Medical Sciences (Code: IR.TUMS.FNM.REC.1401.133). All participants provided written informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

¹Students' Scientific Research Center, Students' Association of Palliative and Supportive Care, School of Nursing and Midwifery, Department of Medical-Surgical Nursing, Tehran University of Medical Sciences, Tehran, Iran. ²School of Nursing, Department of Acute, Chronic, and Continuing Care, University of Alabama at Birmingham, Birmingham, AL, USA. ³Center for Palliative and Supportive Care, University of Alabama at Birmingham, Birmingham, AL, USA. ⁴School of Nursing and Midwifery, Medical-Surgical Nursing Department, Tehran University of Medical Sciences, Tehran, Iran.

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References

1. Malik A, Brito D, Vaqar S, Chhabra L, Doerr C. Congestive Heart Failure (Nursing). In: StatPearls. Treasure Island (FL); 2022.

2. Savarese G, Becher PM, Lund LH, Seferovic P, Rosano G, Coats AJS. Global burden of heart failure: a comprehensive and updated review of epidemiology. *Cardiovasc Res*. 2022;118(17):3272–87.
3. Mahdavi-Roshan M, Vakili-pour A, Mousavi SM, Ashouri A. Dietary diversity and food security status among heart failure patients in the north of Iran. *BMC Nutr*. 2021;7(1):1–9.
4. Esnaasharieh F, Dehghan M, Mangolian Shahrabaki P. The relationship between sleep quality and physical activity among patients with heart failure: a cross-sectional study. *BMC Sports Sci Med Rehabil*. 2022;14(1):20.
5. Snipelisky D, Chaudhry S-P, Stewart GC. The Many Faces of Heart Failure. *Card Electrophysiol Clin*. 2019;11(1):11–20.
6. Heidenreich PA, Bozkurt B, Aguilar D, Allen LA, Byun JJ, Colvin MM, et al. 2022 ACC/AHA/HFSA Guideline for the Management of Heart Failure. *J Card Fail*. 2022;28(5):e1–167.
7. Moshki M, Khajavi A, Hashemizadeh H, Vakilian F, Minaee S, Martin SS. Dark or Bright Half of the Moon: A Qualitative Study Exploring the Experience of Iranian Heart Failure Patients Regarding their Quality of Life. *Open access Maced J Med Sci*. 2019;7(5):824–30.
8. Wingham J, Harding G, Britten N, Dalal H. Heart failure patients' attitudes, beliefs, expectations and experiences of self-management strategies: A qualitative synthesis. *Chronic Illn*. 2013;10(2):135–54.
9. Kim K-A, Park J-S, Seo K-W, Choi E-Y, Ahn J-A. Factors affecting the quality of life of family caregivers of patients with heart failure: A cross-sectional study. *Med (Baltim)*. 2022;101(35):e30042.
10. Mirshahi A, Ghiasvandian S, Khoshavi M, Riahi SM, Khanipour-Kench A, Bakitas M, et al. 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. *Contemp Clin Trials Commun*. 2023;33:101114.
11. World Health Organization. (2013). WHO Definition of Palliative Care. Retrieved from <http://www.who.int/cancer/palliative/definition/en/>. Accessed Nov 2021.
12. Radbruch L, De Lima L, Knaul F, Wenk R, Ali Z, Bhatnagar S, et al. Redefining palliative care—a new consensus-based definition. *J Pain Symptom Manage*. 2020;60(4):754–64.
13. João FP, Paulo RP. Palliative Care in Patients with Advanced Heart Failure: A Systematic Review. *Acta Med Port*. 2022;35(2):111–8.
14. Bakitas M, Dionne-Odom JN, Pamboukian SV, Tallaj J, Kvale E, Swetz KM, 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*. 2017;16(1):45.
15. Diop MS, Rudolph JL, Zimmerman KM, Richter MA, Skarf LM. Palliative care interventions for patients with heart failure: a systematic review and meta-analysis. *J Palliat Med*. 2017;20(1):84–92.
16. Dalggaard KM, Bergenholtz H, Nielsen ME, Timm H. Early integration of palliative care in hospitals: A systematic review on methods, barriers, and outcome. *Palliat Support Care*. 2014;12(6):495–513.
17. Zimmermann C, Swami N, Krzyzanowska M, Hannon B, Leigh N, Oza A, et al. Early palliative care for patients with advanced cancer: a cluster-randomised controlled trial. *Lancet*. 2014;383(9930):1721–30.
18. Haun MW, Estel S, Rücker G, Friederich HC, Villalobos M, Thomas M, et al. Early palliative care for adults with advanced cancer. *Cochrane Database Syst Rev*. 2017;2017:6.
19. Bakitas MA, Dionne-Odom JN, Ejem DB, Wells R, Azuero A, Stockdill ML, et al. Effect of an Early Palliative Care Telehealth Intervention vs Usual Care on Patients With Heart Failure: The ENABLE CHF-PC Randomized Clinical Trial. *JAMA Intern Med*. 2020;180(9):1203–13.
20. Mirshahi A, Bakitas M, Khoshavi M, Khanipour-Kench A, Riahi SM, Wells R, et al. The impact of an integrated early palliative care telehealth intervention on the quality of life of heart failure patients: a randomized controlled feasibility study. *BMC Palliat Care*. 2024;23(1):22.
21. Amroudi M, Raeissi P, Hashemi SM, Reisi N, Ahmadi SA. A comparative study of the status of supportive-palliative care provision in Iran and selected countries: Strengths and weaknesses. *J Educ Health Promot*. 2021;10(1). Available from: <https://pmc/articles/PMC8641730/>. [cited 2023 Jul 26].
22. Bakitas MA, Tosteson TD, Li Z, Lyons KD, Hull JG, Li Z, et al. Early Versus Delayed Initiation of Concurrent Palliative Oncology Care: Patient Outcomes in the ENABLE III Randomized Controlled Trial. *J Clin Oncol*. 2015;33(13):1438.
23. Dionne-Odom JN, Azuero A, Lyons KD, Hull JG, Tosteson T, Li Z, et al. Benefits of Early Versus Delayed Palliative Care to Informal Family Caregivers of Patients With Advanced Cancer: Outcomes From the ENABLE III Randomized Controlled Trial. *J Clin Oncol*. 2015;33(13):1446.
24. Johnson C, Ingraham MK, Stafford SR, Guilamo-Ramos V. Adopting a nurse-led model of care to advance whole-person health and health equity within Medicaid. *Nurs Outlook*. 2024;72(4):102191.
25. Akyar I, Dionne-Odom J, Yang G, Bakitas M. Translating a US Early Palliative Care Model for Turkey and Singapore. *Asia-Pacific J Oncol Nurs*. 2018;5(1):33.
26. Bakitas M, Lyons KD, Hegel MT, Balan S, Brokaw FC, Seville J, et al. Effects of a Palliative Care Intervention on Clinical Outcomes in Patients With Advanced Cancer: The Project ENABLE II Randomized Controlled Trial. *JAMA*. 2009;302(7):741–9.
27. Dionne-Odom JN, Kono A, Frost J, Jackson L, Ellis D, Ahmed A, et al. Translating and Testing the ENABLE: CHF-PC Concurrent Palliative Care Model for Older Adults with Heart Failure and Their Family Caregivers. *J Palliat Med*. 2014;17(9):995.
28. Bakitas M, Stevens M, Ahles T, Kirn M, Skalla K, Kane N, et al. Project ENABLE: a palliative care demonstration project for advanced cancer patients in three settings. *J Palliat Med*. 2004;7(2):363–72.
29. Hendricks BA, Lofton C, Azuero A, Kenny M, Taylor RA, Huang C-HS, et al. The project ENABLE Cornerstone randomized pilot trial: Protocol for lay navigator-led early palliative care for African-American and rural advanced cancer family caregivers. *Contemp Clin Trials Commun*. 2019;16:100485.
30. Akyar I, Dionne-Odom JN, Ozcan M, Bakitas MA. Needs Assessment for Turkish Family Caregivers of Older Persons with Cancer: First-Phase Results of Adapting an Early Palliative Care Model. *J Palliat Med*. 2019;22(9):1065–74.
31. Yang GM, Dionne-Odom JN, Foo YH, Chung AHM, Kamal NHA, Tan L, et al. Adapting ENABLE for patients with advanced cancer and their family caregivers in Singapore: a qualitative formative evaluation. *BMC Palliat Care*. 2021;20(1):86.
32. Ke Y, Cheung YB, Bakitas M, Odom JN, Lum E, Tan DSW, et al. ENABLE-SG (Educate, Nurture, Advise, Before Life Ends for Singapore) as a proactive palliative care model: protocol for a hybrid type 1 effectiveness-implementation randomized wait-list controlled trial. *BMC Palliat Care*. 2024;23(1):29.
33. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008;337:a1655.
34. Farahani MA, Mohammadi E, Ahmadi F, Maleki M, Hajizadeh E. Cultural barriers in the education of cardiovascular disease patients in Iran. *Int Nurs Rev*. 2008;55(3):360–6.
35. Abedi M. Palliative Care within the Iranian Context: Re-Defining Palliative Care, Deploying Spirituality as a Support Measure and Need for Cultural Sensitivity. In Leiden, The Netherlands: Brill; 2013. pp. 249–58.
36. Farahani AS, Rassouli M, Mojen LK, Ansari M, Ebadinejad Z, Tabatabaee A et al. The feasibility of home palliative care for cancer patients: the perspective of Iranian nurses. *Int J Cancer Manag*. 2018;11(8).
37. Mangolian Shahrabaki PP, Nouhi EP, Kazemi MP, Ahmadi FP. Spirituality: A Panacea for Patients Coping with Heart Failure. *Int J community based Nurs midwifery*. 2017;5(1):38–48.
38. Cheraghi MA, Manookian A, Nasrabadi AN. Human dignity in religion-embedded cross-cultural nursing. *Nurs Ethics*. 2014;21(8):916–28.
39. Rassouli M, Farahan AS, Mojen LK, Ashrafizadeh H. The Impact of Culture and Beliefs on Cancer Care. *Global Perspectives in Cancer Care: Religion, Spirituality, and Cultural Diversity in Health and Healing*. Oxford University Press; 2022.
40. Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. *BMJ Open*. 2019;9(8):e029954.
41. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*. 2021;374:n2061.
42. Abolhassani Shahreza F, Hazar N. Implementation of Chronic Care Model for Diabetes Care in Iranian Primary Health Care: Does it work? *Iran J Diabetes Obes*. 2018;10(4):164–71.
43. Hamilton AB, Finley EP. Qualitative Methods in Implementation Research: An Introduction. *Psychiatry Res*. 2019;280:112516.

44. Lee C-W, Wu W, Tan Z-Y, Yang C-F. Qualitative study of the cross-cultural adaptation of Macao students in Mainland China. *Educ Sci*. 2020;10(5):128.
45. Sandelowski M, Barroso J. Writing the proposal for a qualitative research methodology project. *Qual Health Res*. 2003;13(6):781–820.
46. Braun V, Clarke V. Supporting best practice in reflexive thematic analysis reporting in Palliative Medicine: A review of published research and introduction to the Reflexive Thematic Analysis Reporting Guidelines (RTARG). *Palliat Med*. 2024;38(6):608–16.
47. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Heal care J Int Soc Qual Heal Care*. 2007;19(6):349–57.
48. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine (Phila Pa 1976)*. 2000;25(24):3186–91.
49. Francis JJ, Johnston M, Robertson C, Glidewell L, Entwistle V, Eccles MP, et al. What is an adequate sample size? Operationalising data saturation for theory-based interview studies. *Psychol Health*. 2010;25(10):1229–45.
50. Baran ML. Mixed methods research for improved scientific study. IGI Global; 2016.
51. World Population Review. Tehran Population 2024 [Internet]. Available from: <https://worldpopulationreview.com/cities/iran/tehran>.
52. Imam Khomeini Hospital Complex [Internet]. p. 105. Available from: <https://en.tums.ac.ir/en/page/105/imam-khomeini-hospital-complex>.
53. Braun V, Clarke V. Reflecting on reflexive thematic analysis. *Qual Res Sport Exerc Heal*. 2019;11(4):589–97.
54. Braun V, Clarke V, Hayfield N. *Thematic analysis: A reflexive approach*. In SAGE; 2023.
55. Adler RH. Trustworthiness in qualitative research. *J Hum Lact*. 2022;38(4):598–602.
56. Wells R, Stockdill ML, Dionne-Odom JN, Ejem D, Burgio KL, Durant RW 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*. 2018;19(1).
57. Sadat Bahador R, Ghanbarzehi N, Arefi F, Afrazandeh S. The impact of palliative care program on quality of life in patients with chronic heart failure. *Int J Pharm Res Allied Sci*. 2016;5:174–9.
58. Bahador RS, Nouhi E, Jahani Y. The study of palliative care and its relationship with quality of life in patients with chronic heart failure. in 2014–2015. *J Clin Nurs Midwifery*. 2017;5(4):35–46. [persian].
59. Bagheri I, Hashemi N, Bahrami M. Current State of Palliative Care in Iran and Related Issues: A Narrative Review. *Iran J Nurs Midwifery Res*. 2021;26(5):380–91.
60. Bagheri I, Yousefi H, Bahrami M, Shafie D. Adaptation of Interdisciplinary Clinical Practice Guidelines to Palliative Care for Patients with Heart Failure in Iran: Application of AdapteMethod. *Iran J Nurs Midwifery Res*. 2023;28(1):92–8.
61. Hosseini SE, Narabadi AN, Abbasi A, Joolaei S, Sheikhzakaryaei N, Shali M. Exploring the ethical decision-making experience of caregivers of end stage cancer patients in Iran: a phenomenological study. *BMC Med Ethics*. 2024;25(1):130.
62. Jafari N, Loghmani A, Puchalski CM. Spirituality and Health Care in Iran: Time to Reconsider. *J Relig Health*. 2014;53(6):1918–22.

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