Palliative care in the treatment of women with breast cancer: a scoping review protocol

Romel Jonathan Velasco Yanez,1 Ana Fátima Carvalho Fernandes,1 Samuel Miranda Mattos,2 Thereza Maria Magalhães Moreira,1,2 Régia Christina Moura Barbosa Castro,1 Erlaine de Freitas Corpes,1 Luís Carlos Lopes-Júnior3

ABSTRACT

Introduction Currently, breast cancer ranks first among female malignancies; hence, there are strong recommendations for the early inclusion of these patients in palliative care. Palliative care aims to alleviate symptoms improving the quality of life of dying patients, an essential component of breast cancer care. This study aimed to map and synthesise the available evidence on palliative care for women with breast cancer and to discuss the review results with stakeholders.

Methods A scoping review protocol is presented in this article, consisting of two phases. In the first phase, a scoping review study will be conducted adhering to the Preferred Reporting Items for Systematic Reviews and Meta- Analyses Extension for Scoping Reviews (PRISMA-ScR) guidelines and guided by the Joanna Briggs Institute Manual for Evidence Synthesis. Nine databases, an electronic repository, a trial register website, grey literature and additional sources will be searched. A focus group discussion with six stakeholders will occur in the second phase. The analysis will be performed through inductive and manifest content analysis using the IRaMuTeQ V.0.7 alpha software.

Ethics and dissemination The scoping review protocol did not require ethical approval. However, the study’s second phase has been approved by the institutional review board of Maternidade Escola Assis Chateaubriand/MEAC/UFC. The findings will be disseminated through professional networks, conference presentations and publications.

INTRODUCTION

Palliative care (PC) is complex because it encompasses medical, psychological, spiritual and cultural dimensions. However, the concept of PC is not new. Saunders,1 the forerunner of modern hospice philosophy, emphasised in 1978 the importance of PC for patients with serious illnesses. This premise has gained importance over time when life expectancy increases due to scientific advances. The increasing incidence of chronic degenerative diseases and associated treatments have resulted in a prolonged dying process, reinforcing the importance of integrating PC and end-of-life care.

Despite the importance of PC, only 14% of patients who need PC receive it. It is estimated that 40 million individuals worldwide require PC annually. Around 78% live in low-income and middle-income countries,2 which lack training, professional awareness, public and government policies aimed at PC at different healthcare levels.3

PC aims to improve the quality of life, well-being and comfort of patients with life-threatening illnesses and their families,4 which is especially important for patients with chronic diseases.3–7 Global cancer statistics are increasingly alarming, and there

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ To the best of our knowledge, this study will be the first scoping review to systematically map and synthesise the available evidence on palliative care for women with breast cancer. A consultation step will also be conducted to discuss the review results with stakeholders.

⇒ Scoping reviews with a consultation phase are scarce. This study will provide a comprehensive methodological outline of palliative care with the recent recommendations of the Joanna Briggs Institute.

⇒ In this scoping review, we will adopt a rigorous approach by adhering to the PRISMA Extension for Scoping Reviews guidelines and conducting a systematic search strategy covering all study designs, grey literature and preprints, with no period or language restrictions.

⇒ The study’s results will provide an up-to-date understanding of palliative care for women with breast cancer and a future direction for new study designs in the field.

⇒ A possible limitation of the study is the chance of including a limited number of articles, even though a broad and systematic search strategy will be employed.
were about 20 million new cases of cancer and 10 million deaths in 2022. In addition, the International Agency for Research on Cancer (IARC) estimates that, by 2040, the incidence of breast cancer will increase by more than one-third to more than 3 million new cases per year, and breast cancer mortality will increase by more than one-half, to more than 1 million deaths per year. Although breast cancer is one of the most treatable cancers when discovered early, treatment modalities with curative purposes can trigger undesirable side effects that compromise the quality of life, reinforcing the importance of PC.2 10

From a biopsychosocial perspective, breast cancer diagnosis negatively affects women, who often experience anxiety and distress during the diagnosis, treatment and survival phases.11 12 PC aims to improve the quality of life of these patients and their families by alleviating the symptoms and controlling them, balancing the progression of the disease with the discomfort caused by medical treatments.13

A study carried out by Kokkone et al.44 and the Clinical Practice Guidelines of the American Society of Clinical Oncology15 recommend that hospitalised or outpatient patients with advanced cancer receive specific PC from the beginning of the treatment. However, recent studies address the importance of including early PC at the same time as the diagnosis and the curative treatment.16 17 Furthermore, the literature shows that these recommendations are not always met, leading to referrals to PC services only in the last weeks of life,17 untreated symptoms, patient distress and unnecessary aggressive treatments at the end of life,18 especially in countries where there is an unmet need for PC.19 20

Despite the strong recommendation to begin PC from diagnosis, a high prevalence of symptom clusters (pain, anxiety, fear, fatigue, insomnia, dyspnoea and sexual dysfunction) has been reported in recent studies assessing the quality of life of women with breast cancer,11 21–26 leading us to reflect on the current role and how PC has been delivered. Although review studies on the topic have been conducted,13 27 no study has been identified with an objective similar to ours. Both systematic reviews13 27 addressed the theme differently regarding the scope of available evidence and the consultation exercise. One study15 reviewed published studies (1992–2019) that examined the quality of life of women receiving PC, while the other17 addressed current knowledge on the efficacy of palliative single-agent chemotherapy drugs, including capcitabine, vinorelbine, gemcitabine and lipo-somal doxorubicin, which are commonly used in daily clinical practice.27

Hence, the literature has not addressed a broad scoping review that integrates stakeholder consultation exercises. In addition, this study emphasises the importance of understanding the role of PC in the healthcare of vulnerable populations per Sustainable Development Goal 3,28 which aims to ensure healthy lives and promote well-being for all ages.

**Research aim**

This study aims to answer two objectives linked to each phase of the study:

1. To map and synthesise the available evidence on PC for women with breast cancer.
2. To discuss the main results emerging from the scoping review with stakeholders through a consultation exercise.

**METHODS**

**Study design**

This scoping review protocol includes a stakeholder consultation exercise and will be divided into two phases. The first phase, the selection of articles and synthesis of findings, will follow the Joanna Briggs Institute (JBI) methodological recommendations29 and adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) (online supplemental material 1) reporting guidelines.30 In the second phase, a stakeholder consultation will be conducted to discuss and validate the results of the review, following recent JBI recommendations31 (figure 1). The study protocol was registered to the Open Science Framework (osf.io/yqubp).

**Phase 1: scoping review**

**Literature review question**

The population, concept and context strategy proposed by the Jonna Briggs Institute (JBI) will be used to formulate the research question.29 In this review, the population will be ‘young to older women’, the concept will be ‘PC’ and the context will be ‘breast cancer’. The following question was formulated: What is known about the impact of PC in the treatment of women with breast cancer?

**Eligibility**

**Inclusion criteria**

All studies designs will be included (eg, experimental, quasi-experimental, prospective, retrospective cohort, case–control, cross-sectional, case series, single-case, and case–control studies) that examine the quality of life of women with breast cancer. Although review studies on the topic have been conducted,13 27 no study has been identified with an objective similar to ours. Both systematic reviews13 27 addressed the theme differently regarding the scope of available evidence and the consultation exercise. One study15 reviewed published studies (1992–2019) that examined the quality of life of women receiving PC, while the other17 addressed current knowledge on the efficacy of palliative single-agent chemotherapy drugs, including capcitabine, vinorelbine, gemcitabine and lipo-somal doxorubicin, which are commonly used in daily clinical practice.27

**Figure 1** Flow chart of the scoping review methodology. Adapted from: Arksey and O’Malley.46 JBI, Joanna Briggs Institute; PCC, population, concept and context.
Population conducted with young women will be included, considering the age classification of the WHO: young, 25–44 years; middle age, 44–60 years; advanced age, 60–75 years; senile age, 75–90 years; and long-lived, 90 years and over. This distinction was made because the highest incidence of breast cancer occurs in women aged ≥40 years. Studies with women with breast cancer concomitant with other pathologies will be excluded. Studies with survivors in remission will also be excluded as these patients no longer receive treatment.

Exclusion criteria Studies with women with breast cancer concomitant with other pathologies or those with patients in PC secondary to other pathologies will be excluded. Studies with survivors in remission will also be excluded as these patients no longer receive treatment.

Search strategy The search will be conducted systematically in nine databases: MEDLINE (via PubMed), Embase (Excerpta Medica Database), LILACS (Latin American and Caribbean Health Sciences Literature), Cochrane Library, Web of Science, Scopus, Epistemonikos, CINAHL/Cumulative Index to Nursing and Allied Health Literature (via EBSCO), JBI Evidence Synthesis and the electronic repository SciELO (Scientific Electronic Library Online). The final search will be reviewed by a librarian. There will be no date or language restrictions, and an individual strategy will be designed for each database.

The grey literature will be searched due to the flexibility of including grey literature in scoping reviews and the importance of understanding the role of PC in breast cancer treatment. Secondary searches will be conducted in a variety of other sources, including the British Library, Google Scholar, Preprints for Health Sciences (medRXiv), Open Grey, Institutional Repository for Information Sharing, ProQuest Global Dissertations & Theses and ClinicalTrials.gov trial register website, in addition to clinical practice guidelines, protocols and information available on the websites of recognised scientific societies.

The final reference list of the included primary studies will be manually analysed to identify relevant studies. The search strategy will be performed independently by two researchers according to the recommendations of the JBI guidelines. First, the presence of an index of subject-specific titles (with MeSH terms, Emtree, DeCS and CINAHL headings) and their synonyms (keywords) will be identified in each database. The search terms will then be combined with the Boolean operators “AND” and “OR”. The search strategy combines controlled descriptors with specific keywords in each database, as shown in online supplemental material 2.

Selection of the sources of evidence The Rayyan Systems software will be used during the title and abstract analysis. First, all articles from the general search will be deposited in the software. Duplicate studies will then be removed, and the percentage of agreement between the two blinded reviewers will be obtained. A sample of 25 articles will be drawn for analysis, and the review will not begin until a percentage of agreement of >70% is reached, according to the JBI recommendations.

In the next stage, titles and abstracts of potentially relevant studies will be reviewed to determine whether they meet the criteria for inclusion. A third reviewer will clarify any uncertainty regarding the inclusion of studies. Once the title and abstract screening has been completed, full articles will be retrieved and screened through a full-text reading, and a third reviewer will resolve any conflicting decisions to obtain a final list of studies. The search and review processes will be illustrated using the PRISMA-ScR flow chart.

Data extraction The data extraction will be done using a chart designed by one of the research team members. The chart will be adapted from the data extraction template proposed by
the JBI and based on previously published tools. A pilot test will determine whether the chart enables the extraction of all relevant study data. In this pilot test, two reviewers will separately extract relevant data from two of the included studies, and finally, a third reviewer will make a final decision.

The information to be extracted includes the following: (A) study identification and objectives, (B) study population and baseline characteristics, (C) study design, (D) sample size, (E) results, (F) main findings, (G) clinical and epidemiological significance, (H) conclusions, (I) implications and (J) limitations.

Data analysis and presentation
A narrative synthesis of the evidence will be conducted, and the primary quantitative data from the studies will be tabulated. The results will be grouped and presented in tables, graphical models and text categories depending on the information found in the review. In addition, similarity analysis will be performed using IRaMuTeQ software V.0.7 alpha 2, leading to textual categories and themes of relevant meaning identified through word association.

Phase 2: consultation exercise
The consultation exercise is the sixth additional step for scoping reviews proposed by Arksey and O’Malley, and Levac et al. Although this phase was not included in the JBI Manuals released in 2015 and 2020, a recent JBI publication provides methodological guidance for consultation exercises based on the ACTIVE (Authors and Consumers Together Impacting on eVidencE) framework used in systematic reviews to define stakeholder engagement. In our study, the consultation exercise will be conducted longitudinally during the two phases of the scoping review. Therefore, the JBI recommendations will be adapted to the expertise of the stakeholder group. A description of the ACTIVE framework is presented in figure 3.

ACTIVE framework
Stakeholders
Stakeholders are persons who use the research knowledge but are not directly involved in the research. In other words, stakeholders are individuals whose characteristics or attributes may provide relevant information to discuss the review results. We will use the term ‘specialists’ to refer to the professionals who will lead the study and ‘stakeholders’ to refer to those who will participate in the second phase of the study (the consultation), following the ACTIVE framework.

It should be noted that The ACTIVE framework does not offer a specific recommendation on the number of stakeholders needed for the consultation but mentions the importance of including at least three categories (in our study, the following categories will be included: patients, health professionals and researchers). The number of stakeholders for this study was chosen based on a previous study. The sample of specialists will include a breast cancer specialist, a PC specialist and a scoping review expert. The sample of stakeholders will be heterogeneous, comprising six individuals who will meet the following characteristics: two patients diagnosed with metastatic breast cancer and receiving PC in any modality, a representative of a breast cancer non-governmental organisation, a nurse practitioner involved in breast cancer care, a physician specialised in PC, and a Ph.D. professor involved in research on these topics. The heterogeneous sample will be used because each stakeholder can contribute with their knowledge and experience, complementing each other’s discourse and being directly benefited from the scoping review findings.

Figure 3 Development of the stakeholder consultation exercise through the ACTIVE framework. Adapted from: Pollock et al. ACTIVE, Authors and Consumers Together Impacting on eVidencE; NGO, non-governmental organisation.
Recruitment
A group of specialists and stakeholders will be invited to participate in the study through closed recruitment, considering a purposive sample.31 Closed recruitment involves inviting only specific individuals to participate in the study based on research interests.49

Mode and stages of participation
The mode of participation refers to how specialists and stakeholders are involved in a study.49 The group of specialists will participate continuously throughout the study non-interactively, from the conception of the protocol to the final report. Stakeholders will participate only once and interact through focus group discussions in the discussion phase of the scoping review.

Level of participation
The ACTIVE framework comprises five levels of participation: leading, controlling, influencing, participating and receiving.49 The specialists’ level of participation will be at the levels of controlling, influencing and contributing, whereas those of the stakeholders will be at the levels of controlling and receiving.

Methodical structure of the consultation exercise
The stakeholder consultation will follow a qualitative research design as follows:52

Data collection technique and instruments
The consultation exercise will occur through focus group discussions.53 The number of focus group sessions will be determined based on the criterion of data saturation, the point when no more new and relevant data are obtained.54 55 The sessions will last 1–2 hours56 57 to minimise participant fatigue that can interfere with the discussion goals.58 The focus groups will be held in accessible, free-of-noise and acoustically isolated rooms without no disturbances so that participants can listen and discuss freely.59 Each focus group will be moderated by the principal investigator using a list of questions obtained from the scoping review and reviewed by a group of experts. The session will be recorded with two mobile devices owned by the researcher, which will be hidden from the group’s view to prevent them from feeling intimidated, but with prior consent from the participants.

Data analysis
Information obtained from the focus groups will be analysed qualitatively using Elo and Kyngäs’ inductive and manifest content analysis approach, divided into three phases: preparation, organisation and report. The audio recordings will be transcribed into a word processor, and familiarisation will be achieved by reading and rereading the transcripts in the preparation step. Open coding and categorisation will then be conducted to identify meaningful text and code them under high-level headings. Then, a general description of the research topic will be generated by creating summarised categories and subcategories. This phase will be supported by the constant comparison method.62 Finally, the analysis process and results will be presented using categories, conceptual models and lines of reasoning used to develop the final analysis.

Scientific rigour
The consultation will meet the criteria of scientific rigour for qualitative research proposed by Lincoln and Guba:53 credibility, transferability, reliability and confirmability.

Credibility: It refers to the accurate and truthful description of the experience lived by a participant.64 In this study, this criterion will be achieved through the immersion of the researcher in the context of the phenomenon, knowing the PC service and interacting with people similar to the focus group, in order to minimise the distortions that could infiltrate the data.

Transferability: It consists of transferring research results to other contexts using an intentional sampling method. We will provide a wide range of information through detailed and accurate descriptions of stakeholders, their speeches and their contributions.64

Reliability: This criterion refers to the stability of the data. In qualitative research, due to its complexity, the stability of the data is not guaranteed, nor is the exact replicability possible due to the great diversity of situations analysed.65 In our study, reliability will be achieved by triangulating the results with other researchers. Researchers with a doctorate degree and experience in qualitative research will be requested to review some transcribed documents and identify new codes or categories. The suggestions will be triangulated with the principal investigator and the tutor.64

Confirmability: In this criterion, the research results must guarantee the veracity of the descriptions made by the participants. In our study, this criterion will be met through content analysis,60 that is, only the speeches will be analysed without considering the non-verbal expressions of the subjects, as they will not provide information to respond to the consultation objectives.

The methodological appraisal of the stakeholder consultation will be ensured by responding to the items in the ACTIVE framework to ensure transparency and rigour. The final report’s presentation will align with the GRIPP2 checklist for reporting patient and public involvement in health and social care research.66

Patient and public involvement
The first phase of this research will not include patients. However, in the second phase, stakeholders (patients and professionals) will be consulted through a focus group, and the most relevant results emerging from the scoping review will be discussed. It should be noted that this participation will be direct and occur only once during the entire consultation period.

Ethics and dissemination
Since the consultation step requires the participation of interested parties, the protocol was approved by the Institutional Review Board (IRB) of Maternidade Escola

REFERENCES


17 Zimmermann C, Mathews J. Palliative care is the umbrella, not the rain—a metaphor to guide conversations in advanced cancer. JAMA Palliat Med 2022;8:681–2.


