



Integrating palliative care into self-management of breast cancer: Protocol for a pilot randomized controlled trial



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ARTICLE INFO

Article history:

Received 16 February 2016

Received in revised form 9 April 2016

Accepted 17 April 2016

Available online 20 April 2016

Keywords:

Breast cancer
Self-management
Palliative care

ABSTRACT

Background: Despite evidence that palliative care increases quality and length of life, many patients and families remain uninformed about its nature and benefits. The purpose of this study is to test a psycho-educational intervention, *Managing Cancer Care: A Personal Guide (MCC)*, intended to improve breast cancer patients' knowledge of palliative care and to facilitate its timely integration into cancer self-management.

Methods: Aims are to: 1) evaluate the effects of MCC on patients' knowledge of palliative care; 2) examine preliminary effects of MCC on patients' behaviors (role in self-management, engagement in goals of care conversations, medical communication, management of transitions, health care utilization), and feelings (self-efficacy, anxiety, depression, uncertainty); and 3) evaluate protocol feasibility and acceptability. An exploratory aim is to investigate how demographic and clinical factors may moderate intervention effects, with emphasis on differences in use and outcomes among minority participants. We plan to enroll 60 patients and their family caregivers with 50% minority participation. The intervention group receives MCC; the attention-control group receives a Symptom Management Toolkit. We collect data at baseline, one, and three months.

Discussion: This study will inform a large scale trial of MCC. It is challenging for patients with breast cancer, their family caregivers, and providers to make choices that include palliation alone or in combination with potentially curative treatment. MCC may help address this challenge by giving patients the information, skills, and confidence to better self-manage breast cancer. Results may help to establish palliative care as a mainstay of self-management interventions targeting serious illness.

Trial registration: ClinicalTrials.gov Identifier NCT02148575 (date registered: 5.21.14; date first patient enrolled: 7.15.14)

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1. Introduction

Palliative care is specialized medical care for patients with progressive, advanced disease, offering relief from the pain, symptoms, and stress of serious illness. Palliative care can be offered concurrently with curative care and is embedded in hospice care. As such, palliative care is a care option for seriously ill patients at all points on the care trajectory. Although the number of hospital-based palliative care programs in the United States has more than doubled in the past decade [1], palliative care is underutilized [2]. Patients are referred to these programs late, if at all, because health care providers may not be fully informed about the scope of palliative care and may fear taking away patients'

hope [3–6]. Consequently, patients often receive only a fraction of the services offered by palliative care, and there is a missed opportunity to address a spectrum of needs beginning early in the care trajectory [7]. Thus, care provided to seriously ill patients is inadequate and may have a negative impact on the physical, personal, and social situations of patients and their families [8].

Use of palliative care interventions and services may increase if incorporated into self-management. Self-management refers to the activities in which patients engage to manage their symptoms, treatments, lifestyle changes, and psychosocial, cultural, and spiritual consequences of their health condition(s) [9]. Self-management skills include building knowledge about one's health condition, communicating effectively, developing self-efficacy, and using health care resources appropriately [10]. Women with breast cancer want to self-manage with their family caregivers and health care providers [11–13]; however, these parties are often uninformed or uncomfortable discussing palliative care [14] because it is frequently mistaken as being only for patients at the end of life. An intervention that teaches about palliative care among the

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range of care options that also includes curative and hospice care may help patients to integrate palliative care into their self-management plans in a more timely way.

Our purpose is to test a psycho-educational intervention, *Managing Cancer Care: A Personal Guide*, which is intended to improve breast cancer patients' knowledge of palliative care and to facilitate its timely integration into cancer self-management. This intervention focuses on knowledge of palliative care, key self-management behaviors (role in self-management, engagement in goals of care conversations, communication skills, management of transitions, health care utilization), and related feelings (self-efficacy, anxiety, depression, uncertainty) to improve overall self-management and mitigate the challenges of living with breast cancer.

2. Background

There is a critical need to improve knowledge of palliative care among patients with breast cancer. Breast cancer is the second most common cause of cancer deaths in women; however, due to earlier detection and improved treatment, survivorship rates have increased [15]. The physical and emotional intensity and chronicity of breast cancer and its treatment, as well as a preference among these patients to self-manage [12,14,16], makes studying palliative care and self-management in this population very useful to learn how cancer self-management may be improved through integration of palliative care. Although there are other self-management interventions for patients with breast cancer [12,17–20], most do not incorporate palliative care and are designed for patients who have completed treatment and are reintegrating into life after cancer. *Managing Cancer Care* can be used among this group of survivors, but also addresses the needs of patients for whom breast cancer is a chronic and/or life-limiting illness.

3. Methods

3.1. Design

This is a single-center, single-blind pilot randomized controlled trial of 60 patients with breast cancer and their family caregivers. The Institutional Review Board at Yale University approved the study (Protocol #1307012400). All participants to date have provided written informed consent.

3.2. Setting

Smilow Cancer Hospital is housed within Yale–New Haven Hospital, a 1541-bed private, nonprofit teaching hospital located in New Haven, Connecticut. Yale–New Haven Hospital is the largest acute care provider in southern Connecticut. We recruit participants from the Breast Center at Smilow Cancer Hospital where patient participation in clinical trials within the past year is approximately 68% White, 13% Black, 12% Hispanic, 3% Asian, and 4% Other.

3.3. Participants

Eligible patients are females with Stage I–IV breast cancer who have a ≥ 6 month prognosis (per their health care provider), are age 21+, are English-speaking, and live in Connecticut. Participants can be receiving any type of treatment (e.g., surgery, chemotherapy, radiation). To supplement patients' self-reported data, each participant is asked to nominate a family caregiver (or friend) who must be aged 18+ and English-speaking to assess the patient's communication skills and other aspects of self-management. It is not required that a patient have a family caregiver to participate in the study because some patients do not have a family caregiver. We exclude patients if their health care provider advises us that they are inappropriate for the study, for example, due to

psychiatric instability. We plan to enroll 60 patients and their family caregivers with a goal of 50% minority participation.

3.4. Procedures

We identify potential participants in the outpatient setting through nurses at the Breast Center, breast surgeons, and the palliative care service. Patients are approached by their surgeon or regular infusion nurse to determine interest in the study. If interested, a research assistant (RA) details the purpose and procedures of the study. Consented participants complete baseline data collection with the RA during their infusion, after their appointment with their surgeon, or at another convenient time. Participants work with the same RA throughout the study for consistency. We randomize participants to their group assignment immediately following baseline data collection. We schedule one- and three-month data collection contacts by phone. These contacts, about 30–45 min, usually take place at the Breast Center, but may be at participants' homes or another preferred location. RAs may pause or reschedule data collection should a patient not feel well enough to complete this activity. We make every effort to schedule data collection at a convenient time and place for all participants and are very flexible with last minute changes. All data collection instruments, identified only by participant ID number, are in a format (TELEform software, Cardiff TELEform, Vista, CA) that is easy to read and complete. TELEform allows us to scan instruments directly into an encrypted, password-protected computer database. Protected health information is also stored in this secure database.

Following randomization, the RA asks participants which family member (or friend) most helps them with self-management. This is often the person who accompanies them to appointments at the infusion clinic. If the family caregiver is present at the time, the RA will explain the family caregiver's role in the study, obtain written consent, and complete data collection. If the nominated caregiver is not present, the RA obtains consent and collects data at home or at another convenient location. If a family caregiver refuses participation, the RA asks the patient to nominate an alternate family member or friend.

We compensate all participants for their time with a gift card when they exit the study. We inform all participants that they may exit the study at any time at their discretion and without consequence. This protocol presents minimal risks to participants; however, any serious and unanticipated adverse events, problems, or potential changes are reported in writing within 48 h to the Yale University Human Investigation Committee.

3.5. Randomization

We use the standard allocation concealment method of SNOSE [21] (sequentially numbered, opaque, sealed envelopes) to randomize participants. In order to balance the number of minority participants in the intervention and attention-control groups, we use two sets of envelopes: one for those who self-identify as minorities on the demographic information form and another for white patients. For each set of envelopes, the statistician randomized in blocks of six, labeled and inserted cards into the envelopes, and sequentially numbered and sealed the envelopes. Following baseline data collection, the RA, who is blinded, opens the next envelope in the sequence to randomize the new participant. We present the participant flow scheme in Fig. 1.

3.6. Intervention group

We summarize the protocol for each group in Table 1. The RA gives participants in the intervention group (“Self-Management Group”) *Managing Cancer Care* immediately following randomization. The RA briefly (1 min) explains the purpose of *Managing Cancer Care*, reviews the contents, and answers questions. The RA calls participants by phone approximately two weeks before the one- and three-month

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