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

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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

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Authors' contributions

All authors made significant contributions to the conception and design of this study. DSG and SL drafted the first version of this article, and all other authors revised it critically.

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Competing interests

The authors have no competing interests to declare.

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.

Keywords

breast cancer; self-management; palliative care

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 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.

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.

METHODS

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.

Setting

Smilow Cancer Hospital is housed within Yale-New Haven Hospital, a 1,541-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.

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.

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 minutes, 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 hours to the Yale University Human Investigation Committee

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 Figure 1.

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 minute) 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 data collection contacts to inquire about their use of *Managing Cancer Care*, and to answer any questions, set appointment times, and monitor adherence. At the three-month contact, the RA asks participants for detailed feedback on *Managing Cancer Care* as part of a structured interview. Questions include ratings for each module, frequency of use, and open-ended questions on the effects of *Managing Cancer Care* on self-management.

Managing Cancer Care (Table 2) is a set of seven printed modules that includes information about core self-management topics, worksheets and other means of personalizing content, “conversation starters” to facilitate communication with family caregivers and providers, and targeted links to local and internet resources. A main feature of *Managing Cancer Care* is that unlike most self-management interventions, it is self-guided to facilitate accessibility and ease of use, and requires minimal resources. In pilot tests, our participants have preferred printed to web-based materials; however, we will likely offer a web- or app-based *Managing Cancer Care* in the future [22]. *Managing Cancer Care* is a ground-level approach to explain basics of palliative care and self-management and serves as a clearinghouse to related information. We describe development of *Managing Cancer Care* in detail elsewhere [22].

Attention-Control Group

The RA gives participants in the attention-control group (“Symptom Management Group”) the Symptom Management Toolkit [23] (© Michigan State University Board of Trustees) directly after randomization. The Toolkit provides information on commonly experienced cancer symptoms and side effects, such as fatigue, nausea, and sleep problems. Each chapter uses a question and answer format that covers who is most likely to experience the symptom, when and why the symptom may occur, how the symptom can be managed, and when to call a provider. The RA briefly (1 minute) explains the purpose of the Toolkit, reviews the contents, and answers any questions. The RA contacts participants by phone approximately two weeks before the one- and three- month data collection contacts to inquire about their use of the Toolkit, answer any questions, set appointment times, and monitor adherence. At the three-month contact, the RA asks participants for feedback on the Toolkit as part of a structured interview. Questions solicit ratings for overall usefulness of the Toolkit and additional information participants would have liked to receive.

Specific aims and hypotheses

The specific aims of this study are to: 1) evaluate the effects of *Managing Cancer Care* on breast cancer patients’ knowledge of palliative care; 2) examine preliminary effects of

Managing Cancer Care on breast cancer patients' 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), and; 3) evaluate the feasibility and acceptability of the protocol in preparation for a large randomized controlled trial. An exploratory aim is to investigate the extent to which demographic and clinical factors moderate the effects of *Managing Cancer Care*, with emphasis on differences in use of *Managing Cancer Care* and outcomes among various minority participants.

We hypothesize that users of *Managing Cancer Care*, compared to attention-control participants, will demonstrate: 1) improved knowledge of palliative care among the range of care options that also includes curative and hospice care; 2) achievement of their preferred role in self-management, engagement in goals of care conversations, improved communication skills and management of transitions, and appropriate health care utilization (e.g., use/non-use of services, not costs); and 3) improved self-efficacy and reduced anxiety, depression, and uncertainty.

Patient outcomes

Our primary outcomes are knowledge of care options (Knowledge of Care Options Test-KOCO) [24], role in self-management (Control Preferences Scale- CPS) [25], engagement in goals of care conversations (Goals of Care Form) [26], communication skills (Medical Communication Competence Scale- MCCS) [27], and management of transitions (Measurement of Cancer Transitions Scale- MOT-C) [28]. Our secondary outcomes are self-efficacy (Chronic Disease Self-Efficacy Scale- CDSE) [29], anxiety and depression (Hospital Anxiety and Depression Scale- HADS) [30], and uncertainty (Mishel Uncertainty in Illness Scale- MUIS-C) [31]. We also collect demographic and clinical data. We have previously used all of the outcome measures, which have established reliability and validity. Three months after participants exit the study, we assess health care utilization by abstracting data from participants' medical records, including use of the emergency room, unscheduled hospital admissions, admission to ICU, use of chemotherapy and radiation in the last two weeks of life, and referral to hospice, among other indicators of disease burden as specified by the Center to Advance Palliative Care [32].

Family caregiver data

The RA asks family caregivers to complete a demographic information form at baseline, as well as a caregiver version of the Medical Communication Competence Scale (MCCS) at baseline and three months to evaluate patients' communication skills. Family caregivers also complete structured interviews about either *Managing Cancer Care* or the Toolkit at three months to assess other aspects of patients' self-management. The number of participating caregivers will be an important result to inform our future work.

Sample size

A power analysis based on our feasibility study of *Managing Cancer Care* [33] indicated significant change in our primary outcome of knowledge of care options as measured by the Knowledge of Care Options Test (KOCO) (Cohen's Effect Size=0.74). For this pilot

randomized controlled trial, a sample size of 60 (30 per group) will have 81% power to detect intervention effects on KOCO at a 5% significance level and will allow us to estimate effect sizes for the other outcomes.

Statistical methods

Using SAS version 9.2 (SAS Institute, Cary, NC), we will calculate descriptive statistics for demographic and clinical characteristics and all outcome measures at baseline. We will assess baseline equivalence between the intervention and attention-control groups using t-test/Wilcoxon Rank sum (nonparametric) tests for continuous variables and chi-squares for categorical variables. We will compare patient and family caregiver scores on the MCCS by paired t-test. We will use descriptive statistics to analyze participants' ratings of *Managing Cancer Care* and will use content analysis to examine open-ended data. While we hope to minimize missing data through immediate auditing of data collection forms and routine database cleaning, we will handle any missing data through multiple imputation. We will use qualitative and fidelity data to revise *Managing Cancer Care* and study procedures for the larger trial.

DISCUSSION

We have described the protocol of a pilot randomized controlled trial to determine the impact of a psycho-educational self-management intervention for breast cancer patients on their knowledge of palliative care, key self-management behaviors, and related feelings. We believe that improved knowledge of palliative care, self-management behaviors, and management of feelings will lead to better health outcomes. Results will guide our revision of *Managing Cancer Care* and planning of a large randomized controlled trial.

Self-management interventions evolved out of research with chronic conditions such as arthritis and diabetes. Due to improved treatment options and increased survivorship, breast and some other cancers have come to be regarded as chronic conditions. Many aspects of cancer care now occur in outpatient settings, including the home, where patients and their family caregivers have more responsibility than ever in managing cancer care [34]. In addition, many patients and their family caregivers are interested in taking an active role in their health care. Active involvement is associated with better decisions, greater adherence to treatment regimens, higher patient satisfaction, and better health outcomes [35]. As more patients and their family caregivers take on the demands of cancer self-management, it is critical that self-management science expands to discover the best ways of providing cancer self-management education and support. Our previous tests of the *Managing Cancer Care* intervention have shown great promise [33, 36]. Testing *Managing Cancer Care* more robustly in pilot randomized controlled trial will further inform this effort.

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Abbreviations

RA	Research Assistant
KOCO	Knowledge of Care Options Test
MCCS	Medical Communication Competence Survey

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Figure 1.
Participant Flow Diagram

Table 1

Schedule of Study Activities for Intervention and Attention-Control Groups

	Week 0 (baseline)	Week 2	Week 4 (1 month)	Week 10	Week 12 (3 months)
Intervention Group	Consent; Complete outcome measures; Give <i>Managing Cancer Care: A Personal Guide</i>	Check-in phone call; Schedule 1 month appointment	Complete outcome measures	Check in phone call; Schedule 3 month appointment	Complete outcome measures and Use of <i>Managing Cancer Care: A Personal Guide</i> form
Attention-Control Group	Consent; Complete outcome measures; Give <i>Symptom Management Toolkit</i>	Check-in phone call; Schedule 1 month appointment	Complete outcome measures	Check-in phone call; Schedule 3 month appointment	Complete outcome measures and Use of <i>Symptom Management Toolkit</i> form

Table 2

Intervention Content, Relation to Study Model, and Outcome Measures

SM Domain	Module	Selected Content	Instrument
KNOWLEDGE	<i>Care Options</i>	Definitions of curative, palliative and hospice care; When it is time to ask about each	-Knowledge of Care Options Test (KOCO)
FEELINGS	<i>Acting Confidently During Uncertainty</i>	Situations that cause uncertainty; How to become empowered	-Chronic Disease Self-Efficacy Scale (CDSE) -Uncertainty in Illness Scale (MUIS-C)
	<i>Managing Symptoms</i>	Common symptoms; Reporting symptoms	-Clinical Information Form -Hospital Anxiety & Depression Scale (HADS)
BEHAVIORS	<i>Managing Care and Setting Goals</i>	Who/what is involved in self-management; "good"/possible goals	-Control Preferences Scale (CPS) -Goals of Care Form -Health Care Use Form
	<i>Talking with Health Care Providers</i>	Why it is important to communicate; How to communicate well	-Medical Communication Competence Scale (MCCS) -Caregiver version of MCCS
	<i>Talking with Family and Friends</i>	What to talk about; Decision-making	
	<i>Managing Transitions</i>	What transitions are and when they happen; Successful transitioning	-Measurement of Transitions Scale (MOT)