A. Title Page

1. Title

Reimagine end of life: An online, personalized coping and decision aid for metastatic breast cancer patients and providers (#22875647)

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2. Abstract

Goal: The goal of the proposed project is to broaden the horizons of the Seven Pillars of Personal Strength™ curriculum and demonstrate that shared decision making (SDM) and end of life (EOL) care knowledge can be improved. Specifically, we aim to: 1) determine the feasibility of metastatic breast cancer (MBC) patient, caregiver, and provider engagement in SDM through participation in *Reimagine's Worries to Wishes Program;* and 2) demonstrate whether *Reimagine* influences patient, caregiver, and provider EOL care knowledge, SDM, and quality of life.

Target population: Patients with MBC, caregivers, and oncology providers.

Methods: Breast cancer patients with metastatic disease will be identified using DEDUCE inquiries of electronic health records (EPIC), recruited from Duke Cancer Center clinics and hospitals, and randomized to treatment or a waitlisted control arm. Consenting participants will meet with a certified Pillar Guide in separate patient/caregiver or provider online group meetings. Short videos are viewed and guided activities completed at leisure so that class time is focused on discussion. Roger's Diffusion of Innovations framework will be used to describe program adoption and dissemination.

Assessment: Electronic assessments at baseline and post-intervention (9 and 18 weeks) with validated instruments are used to determine changes in outcomes. Descriptive analysis will be used to summarize process-related measures such as advance directive completions and program usage (i.e., examine feasibility). Independent sample t-tests will be used to examine changes in outcomes. Multiple regression will be conducted to estimate the relationships between the SDM variable and the outcome measures.

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C. Main Section

1. Overall Goal & Objectives

Breast cancer is the most common cancer in women worldwide. In the United States, one in eight women will be diagnosed with breast cancer in their lifetime and breast cancer is the second leading cause of death among women [1]. Approximately 300,000 cases of breast cancer are diagnosed in the U.S. each year, with an estimated 30% of those cases eventually becoming metastatic [2]. The number of people living with metastatic breast cancer (MBC) in the U.S. is estimated to be over 155,000 and the median survival after MBC diagnosis is a mere three years. There is no cure for MBC and approximately 40,000 women a year die from the disease in the United States [3]. Because there is still no cure for MBC, health care professionals must inevitably address end-of-life (EOL) issues with patients.

The _long-term goal_ of this research program is to test and disseminate educational protocols that can enhance EOL knowledge and coping skills and in so doing, improve outcomes such as shared decision making (SDM) and patient well-being. The _objective of this application_ is to facilitate patient with MBC, caregiver, and provider engagement in SDM around EOL planning. These goals are in alignment with the focus of the RFP, which is to "design and implement programs (i.e., _Reimagine_) that close clinical practice gaps (i.e., lack of SDM and EOL knowledge) and improve the quality of care for patients with MBC through increased competence and performance of health care providers and health care systems." Evidence of effectiveness from this demonstration study will be used to support an R01 application to conduct a larger, multisite dissemination and implementation study to inform best practice.

Aim 1: To assess the feasibility of patient, caregiver, and provider engagement in SDM through participation in _Reimagine_. We will examine the following process measures: 1) the patient with MBC's completion of the _Worries to Wishes Treatment Plan_ and advance directive documents; and 2) patient with MBC, caregiver, and provider program usage (e.g., module viewings and participation in online meetings) and program satisfaction.

Aim 2: To demonstrate whether _Reimagine_ influences patient, caregiver, and provider EOL care knowledge, SDM, and QOL. We will analyze changes in: 1) patient with MBC, caregiver and provider EOL care knowledge and decision making preparedness; 2) patient with MBC decision making self-efficacy and decisional conflict; and 3) patient and caregiver QOL.

The Seven Pillars of Personal Strength™ was tested as a self-management curriculum for cancer survivors to improve QOL and featured during a plenary session at the 7th Biennial Cancer Survivorship Research Conference [4]. In this NIH-funded study of 130 cancer survivors across 17 US hospitals, our team found that participation in this curriculum was associated with statistically and clinically significant improvements in key psychosocial outcome scores (e.g., depression, anxiety, fatigue, QOL) as well as targeted skills (e.g., self-efficacy, spirituality). Also, these improvements were maintained at three months after program cessation (i.e., follow-up), suggesting that the benefits may induce sustained changes [4,5]. The proposed project seeks to broaden the horizons of the Seven Pillars of Personal Strength™ curriculum by demonstrating

that EOL care can be improved through facilitation of MBC patient, caregiver, and provider engagement in SDM thorough participation in *Reimagine's Worries to Wishes Program*.

Also, this project is expected to have a *positive impact* on patients with MBC and caregivers through development of the *Worries to Wishes Treatment Plan* and advance directive documents to share with their providers (improved patient-provider communication). These goals are directly in line with the focus of the NCCN/Pfizer RFP as The Seven Pillars of Personal Strength™ is a standardized, innovative curriculum that was recently awarded the LiveStrong Community Impact Project Award. Similarly, the goals of the project are aligned with the overarching goals of the Duke School of Nursing, *Pillars4Life, Inc.*, and the Duke Cancer Institute, which are to provide psychosocial support and improve the QOL of patients with chronic and/or life-threatening conditions.

2. Current Assessment of Need in Cancer

Gaps in the Quality of End of Life Care

Because there is still no cure for MBC, health care professionals must inevitably address EOL issues with patients. Quality EOL care is increasingly recognized as an ethical obligation of health care providers, both of clinicians and organizations. Domains of quality EOL care include: receiving adequate pain and symptom management; avoiding inappropriate prolongation of dying; achieving a sense of control; relieving burden; and strengthening relationships with loved ones [6]. According to the American Society of Clinical Oncology, goals for EOL care for patients with metastatic cancer should include prioritizing QOL, ensuring that patients are well-informed about prognosis and treatment options including palliative care, having regular discussions with health care providers about options and preferences, and having the opportunity to die with dignity and peace of mind [7]. Certainly, anticipating and making health care decisions about appropriate or preferred treatment around EOL care is intellectually challenging and emotionally distressing for patients, families and friends, oncology clinicians, and other professional caregivers. However, there are many adverse consequences of failing to plan for EOL transition such as increased psychological distress, medical treatments inconsistent with personal preferences, utilization of burdensome and expensive health care resources of little therapeutic benefit, and more difficult bereavement [8].

Yet despite the evident need for quality EOL care and patient-provider discussion regarding EOL, "emerging evidence suggests that, too often, realistic conversations about prognosis, the potential benefits and limitations of disease-directed therapy, and the potential role of palliative care, either in conjunction with or as an alternative to disease-directed therapy, occur late in the course of illness or not at all [7]." Oncology providers often find it difficult to discuss these issues with patients and assume that patients are reluctant to think about the issues involved. For example, one study found that there is a lack of explicit discussion regarding advance directives and patient preferences regarding EOL care, and concluded that facilitation of patient-physician communication is critical in providing quality patient care at EOL [9].

Similarly, another study found that most cancer patients/surrogates sign advance directives on the day of death, indicating delayed EOL palliative care and suboptimal patient-provider

communication. The researchers concluded that their data underscored the importance of communication-training research tailored to improve EOL decision making [10]. Major findings from a systematic review reinforces these points, as it was found that the presence of advance directives was associated with: decreased rate of hospitalization and the chances of dying in the hospital; decreased use of life-sustaining treatment; and increased use of hospice or palliative care [11]. Other studies focus on the risk for late or absent hospice referrals and assert the need to enhance EOL discussions and earlier referral to palliative care and hospice in order to improve care for patients with MBC. One of these studies found that one-third (33%) of metastatic breast cancer patients treated at a cancer center died without a hospice referral, and of those, only 7% had a documented discussion of palliative care as an option by the oncology team [12].

In addition to the effects these gaps in EOL communication and SDM have on patients' QOL, there are also financial consequences for patients and the health care system. As one MBC patient recently explained in an article published in the Washington Post, the current health care system often provides a lot of expensive critical care as people reach the EOL – care that people, if asked and engaged, might say they never wanted. For instance, the author of the article discusses how she chose to forgo more intensive treatments such as chemotherapy and surgery in exchange for a better QOL during the time she had left. She explains how without SDM and effective communication with her doctor, she would not have had the opportunity to make that choice, and purports that EOL discussions with her physician saved her life [13].

Current Evidence-Based Solutions to the Gaps in Quality EOL Care

The evidence-based interventions that currently exist to address gaps in the quality of EOL care revolve largely around improving SDM via decision and communication aids. According to the Agency for Healthcare Research and Quality, "SDM occurs when a health care provider and a patient work together to make a health care decision that is best for the patient. The optimal decision takes into account evidence-based information about available options, the provider's knowledge and experience, and the patient's values and preferences [14]."

Evidence shows that SDM is effective in improving the quality of EOL care. This RFP discusses the importance of SDM and the role of decision aids in helping patients feel more informed about treatment options, reach decisions consistent with their values, and improve communications with their provider. Specifically, research on the impact of SDM interventions has found increased patient satisfaction and better health outcomes, more favorable outcomes such as decreased anxiety, quicker recovery and increased compliance with treatment regimens, and lower demand for health care resources [15]. One study implemented decision and communication aids (such as question lists) among breast cancer patients and found that they positively impacted factors such as knowledge, decisional conflict, preparation for decision-making, satisfaction, and self-efficacy [16]. Another study concluded that decision aids, open communication, and involvement of supportive care specialists may improve emotional and existential distress associated with changing or stopping cancer treatment [17].

However, the research also shows that despite the benefits of SDM, it is still largely

underutilized and suggests that there is a need for interventions directed at improving implementation and quality of SDM [18]. Another study found that question lists may be insufficient to bridge the divide between physicians and patient information needs in the setting of MBC, particularly regarding prognosis. The researchers there concluded that patients may need additional assistance defining question lists, and physicians may benefit from training in communication, particularly regarding discussions of prognosis and EOL [19]. Similarly, the Agency for Healthcare Research and Quality has posited that one key to success in SDM implementation lies in training physicians and other providers to help them understand how to facilitate the process and to "ensure that they appreciate the importance of respecting patient's values, preferences, and expressed needs [15]."

Gaps at the Duke Cancer Center

In terms of a gap analyses, an examination of the Duke Data Warehouse found that among the n=2704 cancer patients who died in 2014 and 2015, only n=406 (15%) individuals had a documented advance directive (i.e., health care power of attorney and/or living will) in place [20]. On closer inspection, among the n=29 patients with MBC, n=5 (17%) had a living will, n=3 (10%) had a health care power of attorney, and none had both documented and in place. This represents a significant gap in practice at the Duke Cancer Center within our target MBC population and across all cancer types.

How Reimagine Can Help Close the Gaps in Quality EOL Care

Reimagine's Seven Pillars of Personal Strength™ is an evidence-based curriculum containing tools that have the ability to improve EOL care for patients with MBC by facilitating SDM and improving QOL. The *Core Program*, which has been tested and proven in multiple clinical settings, teaches individuals with cancer coping in an online group setting to reduce posttraumatic stress, depression, fatigue, and other QOL outcomes [4,5,21,22]. The proposed study will employ these same skill-building exercises through the *Worries to Wishes Program,* an offshoot of the *Core Program.* The *Worries to Wishes Program* has four modules, each of which consists of: 1) a series of interactive videos and workbook activities focusing on EOL reflections and wishes for "how one wants to live and die"; and 2) a live, online, small group session to practice and discuss what was learned in the module under the guidance of specially-trained instructors called Pillar Guides. In addition, participants will have access to *Reimagine's* online, social community that is informed by the curriculum and moderated by Pillar Guides. Participants complete the activities in each module, and then join a Pillar Guide in a live, online, small group session to practice and discuss what they've learned.

3. Target Audience

Duke Oncology providers, patients with MBC disease and their caregivers will be invited to participate in the proposed study. We plan to recruit at least 40 providers among the Duke population (n=58) of 8 oncologists, 15 fellows, 20 nurses, 10 nurse practitioners, and 5 social workers who provide care to patients with MBC. Dr. Kimberly Blackwell, MD and Director of the Duke Breast Oncology program is a strong supporter of the curriculum as documented in the accompanying letter of support and chronicled in *What Love Is: The Duke Pathfinders 50* documentary [23]. In addition, Dr. Kelly Westbrook, MD will serve as the Provider Champion

and will help facilitate the recruitment and training of peer oncologists, fellows, nurses and social workers. Given that provider behavior is a key variable in the sustainable uptake, adoption, and implementation of *Reimagine*, study results should inform other providers who are interested in replicating the implementation in their setting (e.g., community hospitals, large academic health centers).

Patients with MBC will be recruited from the Duke Cancer Center (e.g., Breast Oncology and Treatment Center clinics), Duke Macon Pond Cancer Center, and Duke Regional Hospital. The three oncology settings were recommended by our Provider Champion and selected for inclusion in this project based on having a large number of patients who are not only living with MBC but express a high need for coping strategies. Once identified in EPIC through DEDUCE inquiries or referred by their oncology provider, patients will be approached in one of the three settings during a regularly scheduled appointment and asked to consider their interest in participating in the study and then assessed per eligibility criteria prior to trial enrollment: 1) Diagnosed with MBC or caregiver to patient with MBC; age ≥18 years; patient is actively receiving care at the Duke Cancer Center, Duke Macon Pond, or Duke Regional Hospital; able and willing to participate in online meetings and complete four *Reimagine Worries to Wishes Program* modules; provide informed consent; and able to read/write English. To be able to evaluate a moderate effect we will need to have a sample size of n=100 evaluable participants. Given an estimated dropout rate of 30%, we plan to enroll 140 cancer patients into the study over a period of one year. Oncology providers such as oncologists, nurses, fellows, and social workers who provide care to patients with MBC will also be invited to participate and subsequently enrolled. Participants will receive Amazon gift cards upon completing each survey; $25 at baseline and $75 at post-intervention.

Through an examination of the Duke Tumor Registry, we found that the incidence of diagnosed Stage 4 patients with MBC was n=39 in 2014; the prevalence of MBC patients who are alive and seen within the last year at the Duke Cancer Center, Duke Regional, and Duke Macon Pond is estimated at n=285 (of which the majority have caregivers). Therefore, we are confident in our ability to meet the targeted enrollment of n=140 in one year from the three specified oncology settings. Additional patient recruitment strategies will be pursued in the community (e.g., Research Match, Metavivor), if needed.

Our expectation is that this project would be replicated by other organizations and/or expanded to other cancer populations following a demonstration of effectiveness. For example, the *Pillars4Life* program was expanded to include all cancer types (and replicated across 17 hospitals) following the successful completion of the *Pathfinders* pilot study among women with advanced breast cancer [5,21]. Given the findings from our Data Warehouse query regarding the dearth of advance directive documentation, we would focus our next steps in expanding the *Worries to Wishes Program* to include Duke patients with any metastatic disease and their providers regardless of cancer type (e.g., colorectal, thoracic) [20].

4. Project Design and Methods

DUSON and Pillars4Life Inc. seek to conduct a study that specifically focuses on the impact of *Reimagine's Worries to Wishes Program* on EOL knowledge, SDM, and QOL among patients with MBC, caregivers, and oncology providers. Therefore, the primary aim of the proposed study is to assess the feasibility of patient, caregiver, and provider engagement in SDM through participation in *Reimagine*. The secondary aim is to demonstrate whether *Reimagine* influences participant EOL care knowledge, SDM, and QOL.

Intervention components

In the *Worries to Wishes Program,* participants are guided through four modules containing synchronous and asynchronous content over a period of eight weeks (i.e., one module introduced every two weeks). Each module consists of a live, online meeting and a series of interactive videos and workbook activities focusing on EOL care knowledge, reflections and wishes for "how one wants to live and die" (see Table 1). While patients and caregivers will join together in the online meetings, providers will participate separately in an effort to protect patient confidentiality. The *Foundation* module addresses palliative care by teaching skills to control symptoms, such as improving response to physical pain and even potentially reducing pain. *Reflections, Worries to Wishes, and Sharing* provides a safe, structured process for patients and caregivers to identify fears, wishes surrounding those fears, and create a plan for communicating wishes to supporters, including providers. In the *Worries to Wishes* module, participants complete the "My Wishes" activity, which includes education on hospice and palliative care. Additionally, participants complete an advance directive that is legally binding in most states, including North Carolina [24]. While completion of the advance directive is of paramount importance to the patients and their caregivers, providers will also be encouraged to complete one so that he/she will have a deeper understanding in how to communicate with patients and families around these issues. In *Sharing*, patients create a *Worries to Wishes Treatment Plan* in which they decide what to share and communicate with their loved ones and provider. Here, providers will learn how to discuss the plan with the patient. Our intention is that *Reimagine's Worries to Wishes Program* will improve participant QOL through facilitation of improved SDM and EOL care that revolves around patient preferences and values.

Table 1. The *Reimagine Worries to Wishes Program* Module Content

Foundation	Reflections	Worries to Wishes	Sharing
Intro to Foundation	Intro to Reflections	Intro to Worries to Wishes	Intro to Sharing
Emotion Journey/Sentence	Emotion Journey/Sentence	Emotion Journey/Sentence	Emotion Journey/Sentence
Personal Compass	Mini	Mini	Mini
Think, Shift, Release	Personal Compass	Personal Compass	Personal Compass
Meditation	Common Stressors/Fears	Worries to Wishes part 2	Support/Share Treatment Plan
The Raft & Mini	Worries to Wishes part 1	My Wishes/5 Wishes AD	The Campfire
Journal	Reflections	Perfect Last Day / Safe Place	Self-Care Plan
Self-Care Plan	Movie of your Life	Self-Care Plan	
	Self-Care Plan		

Similarly to *Reimagine's Core Program*, the *Worries to Wishes Program* teaches patients, caregivers, and providers two major skill sets as they move through each module. The first is Solution-Focused Thinking, which is a way of restructuring people's thinking about stressors and fears that shifts them out of the story of the problem and into a proactive process of identifying and attaining what they need to feel better. Solution-focused thinking starts with clarifying thoughts and feelings and how they impact physical well-being and behavior. Then it focuses on identifying what's in someone's control in regard to finding a concrete, attainable solution for feeling better. However, insight alone is not enough to change behavior or make someone feel better. That's where Mind-Body Skills, the second skill set that is taught in *Reimagine*, come in. Mind-Body Skills include activities such as guided visualization, stream-of-consciousness writing, and drawing that drop people beneath the chatter or their thinking minds into a pool of inner peace and wisdom where they have access to their truest truths about what is best for them. Activities like guided imagery and mindfulness meditation provide direct access to our inner wisdom and are also proven tools for elevating mood and alleviating symptoms of stress. *Reimagine's Worries to Wishes Program* offers a much-needed tool for clarifying wishes for EOL by combining solution-focused thinking skills and mind-body skills in a curriculum that allows people to explore their needs for QOL and their fears around death and dying in a safe, supportive, structured, anonymous environment.

Project infrastructure

Figure 1 presents the architecture that will be established for studying the *Reimagine* intervention. It combines three elements: (1) *Worries to Wishes Program* modules that are administered online and live sessions via Adobe Connect; (2) an online social community; and (3) a web-based application, REDCap, that administers surveys at three time-points and generates a *Worries to Wishes Treatment Plan* and advance directive documents that are emailed directly to the participants and uploaded to EPIC for viewing by their providers.
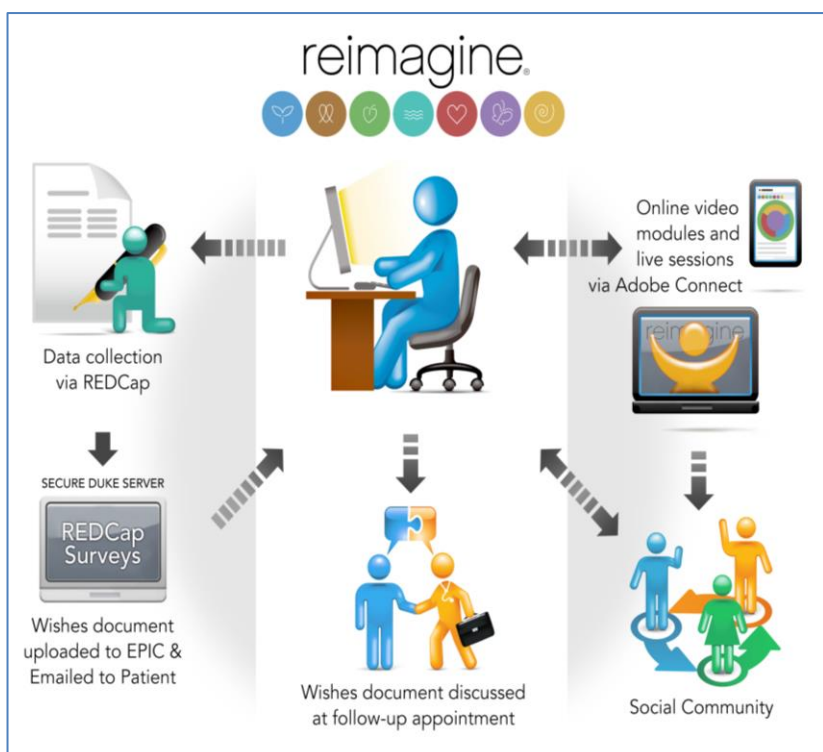

Figure 1. Architecture for studying *Reimagine*

Patient and caregiver participants will be given access to the *Reimagine Worries to Wishes Program* website; providers will also be invited to participate in the same. While patients and

caregivers will participate together in the live, online meetings, separate meetings will be held for the providers as a means of respecting confidentiality between the groups.

Study Design

All study participants will be asked to complete a baseline assessment at the time of consent.

Patients and caregivers. This study will employ the use of a staggered enrollment trial in which patients (n=140) are randomized into the *Reimagine* intervention or waitlisted control arm for a period of 8 weeks [25]. As discussed earlier, we plan to recruit 140 patients to reach our goal of n=100 (i.e., account for an estimated dropout rate of 30%). Caregivers will be placed into the same arm as the patient (if applicable) so that they may receive the intervention together. At the end of 8 weeks, both treatment and control arms will be asked to complete another assessment, and the initial control participants are started on *Reimagine* so that all participants may receive the intervention. As shown in Figure 2, the waitlisted group will receive a final assessment at Week 18.

	Baseline	Weeks 1-8	Week 9	Weeks 10-17	Week 18
R_1	O	X	O		
R_1	O		O	X	O

Figure 2. Staggered enrollment trial for patients and caregivers

Providers. Oncology providers will receive the intervention immediately and will not be randomized as the projected number of participants (n=40) does not warrant the application of a comparison group (i.e., a pre/post design is more appropriate).

The effectiveness of *Reimagine* will be measured using validated instruments including the Preparation for Decision Making Scale (i.e., primary outcome variable) at baseline and post-intervention [26]. Other outcome measures will be administered to assess decision self-efficacy and conflict, EOL knowledge, QOL, and program satisfaction; measures were chosen carefully to minimize participant burden. Tables 3 and 4 in the Evaluation section provide details regarding the instruments and assessment schedule.

Audience engagement

Roger's Diffusion of Innovations will be used as a theoretical lens to influence the adoption of the *Reimagine* intervention by the Duke Oncology providers, patients with MBC, and caregivers. This theory is used extensively for studying adoption and dissemination of innovations including information technology-assisted interventions such as *Reimagine* [27,28]. According to Rogers, there are four factors that influence adoption: the innovation itself, the communication channels used to spread info about the innovation, time, and the nature of the society to whom it is introduced. As described in the next section, the Seven Pillars of Personal Strength™ curriculum has been used since 2003 and the delivery mode adapted through the years to enhance program reach, adoption, and implementation (e.g., changing from an individual to a group format to decrease costs, moving the delivery from in-person to online to increase reach). In terms of communication channels, several strategies were employed in the past and

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present. The documentary film, *What Love Is: The Duke Pathfinders 50*, was instrumental in communicating the impact of the program across the Duke community and nation given its screening on public television [23]. In addition*, Pillars4Life Inc.* has a large Internet presence including a website and Facebook page that are comprehensive, visually pleasing, updated frequently, and easy to navigate [29,30]. As for "time," the curriculum has been in place since 2003 or 12 years and counting; it has been vigorously studied and patients consistently find the curriculum to be helpful, including the original Duke *Pathfinders* pilot study among 50 women with advanced breast cancer [21,22]. Therefore, several provider "adopters" are already in place at Duke. Finally, the social system of which the proposed study will take place (i.e., Duke Cancer Center and hospitals) has benefited from previous studies such as the Duke *Pathfinders* pilot, the LiveStrong funded *Pillars4Life* implementation, and the Pfizer *Pillars4Life* pain trial. In addition, Dr. Blackwell and Dr. Westbrook are strong opinion leaders within the Breast Oncology team and will be integrally involved in study preparation and execution. Program usage will be monitored and recorded in the *Reimagine* web platform (i.e., clickstream data will be collected and stored).

Importantly, our proposed study design is guided by Roger's Diffusion of Innovations key individual attributes of innovations that influence rate and extent of adoption and thereby reduce uncertainty. In terms of attributes, the EOL-focused content will be meaningful to the targeted audience. To highlight the relative advantage, potential study participants will be provided with a recruitment brochure and FAQ document that highlights previous study results and a web link to view the documentary film [23]. In addition, the flipped classroom experience is compatible with patients' preference for flexibility (i.e., learn at their convenience). A project-specific location will be developed to facilitate participant navigation within the *Reimagine* website and their staff will be available to assist with any IT-related issues as a means to minimize complexity. The *Worries to Wishes Program* modules will be accessible to the participants to trial and complete as often as they wish. Role modeling (i.e., observability) by the Provider Champion will be used to facilitate provider uptake. Participation in the online meetings is another strategy used to facilitate observations of benefit (i.e., peer learning). Finally, continuous improvement through reinvention has been a mainstay of this intervention; it will continue in this study and beyond.

Project originality
This project is innovative in that it addresses a critical need for quality EOL care by leveraging an existing curriculum, the Seven Pillars of Personal Strength™*,* for patients with MBC, caregivers, and providers. Recently GOOD/Corps, a market research company hired by *Pillars4Life, Inc.*, conducted qualitative interviews and extensive contextual research that aimed to understand where the cancer community was being served, with a focus on online tools. GOOD/Corp determined that the Seven Pillars of Personal Strength™ is the only standardized curriculum that teaches cancer survivors coping skills such as solution-focused thinking, relaxation and breathing exercises, and guided imagery in a real-time, online setting (i.e., scripted and timed classes with live teachers or "Pillar Guides")[31].

How this project builds on existing work

The Seven Pillars of Personal Strength™ curriculum teaches individuals with cancer coping skills in an online group setting to reduce posttraumatic stress, depression, fatigue, and other QOL outcomes. The delivery of the curriculum has evolved over the years; hence the change in names (i.e., *Pathfinders* to *Pillars4Life* to *Reimagine*) to reflect platform improvements (see Figure 3). Originally delivered with an in-person, one-on-one, counseling model in the clinical setting, the *Pathfinders* program was associated with improvements in QOL among patients with advanced breast cancer in a Duke pilot study [21,22]. Realizing that the in-person counseling model was not scalable or affordable led its founders to modify the platform (i.e., *Pillars4Life*) for curriculum distribution via small online groups led by specially-trained guides with live video conferencing technology. In a Livestrong and NIH-funded study of 130 cancer survivors in 17 hospitals, *Pillars4Life* participation was associated with statistically and clinically significant improvements in key psychosocial outcomes and targeted resources [4,5].
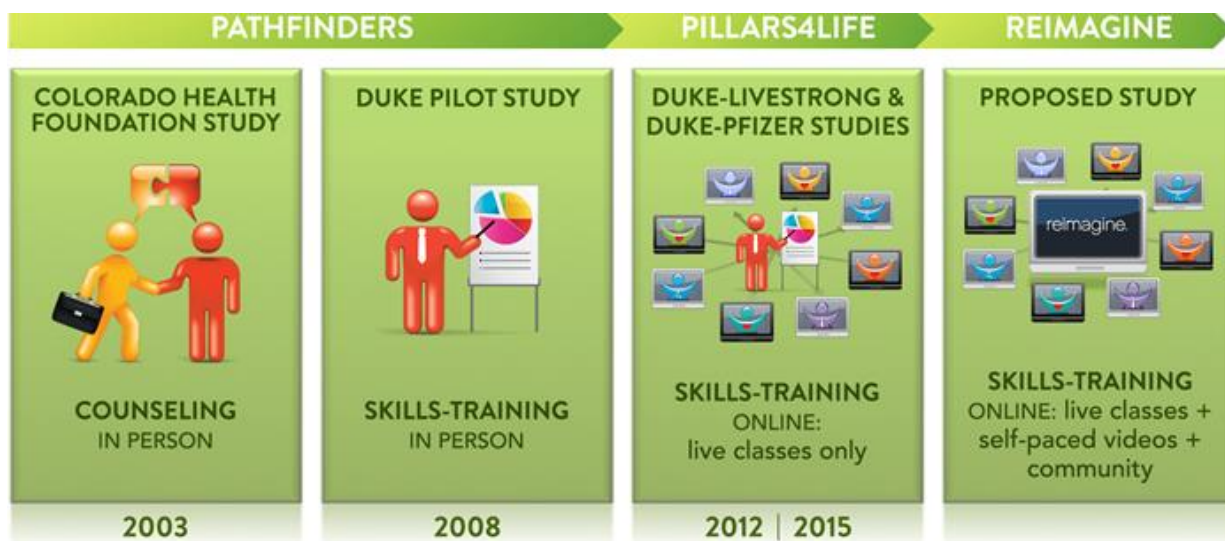

Figure 3. Continuous improvement of Seven Pillars of Personal Strength™ delivery platform

The newly released *Reimagine* platform is comprised of the *Core Program* and companion *Worries to Wishes Program*. *Reimagine* represents a significant evolution of the program in response to participant desire for two things: 1) a more flexible, self-paced schedule; and 2) more time during the live sessions for discussion, which is now possible because everyone completes the activities before the sessions (i.e., flipped classroom). The live online sessions allow participants to engage with Pillar Guides (who are certified by *Pillars4Life Inc*. and have at minimum a master's degree in counseling, psychology, or social work) and other learners in a highly structured/manualized format via Adobe Connect. Therefore, the proposed study would benefit from this new classroom experience and employ the *Worries to Wishes Program,* thereby leveraging the same skills taught in the *Core Program* with an EOL focus.

5. Evaluation Design

Data Collection Measures and Procedures

A REDCap baseline survey will be used to collect self-reported demographic (e.g., gender, race, age, income) from all study participants. Clinical characteristics (e.g., cancer diagnosis, treatment status, medications) will be collected from patients. Standardized instruments administered via REDCap surveys will be used to collect outcome data at baseline and post-intervention among the treatment (Week 9) and control (Week 18) groups (see Table 2). As shown in Table 3, each of the surveys is estimated to take less than 30 minutes to complete; efforts were made to limit the number of administered instruments to minimize survey burden.

Outcomes. The 10-item Preparation for Decision Making Scale will be used as the primary outcome to assess an individual's perception of how useful a decision support intervention is in preparing the respondent to communicate with others in making a health decision (i.e., SDM; see Table 3) [26]. This scale also has a practitioner version and will be administered to provider participants. The 11-item Decision Self-Efficacy and 16-item Decisional Conflict scales will also be used to assess for the patient's self-confidence and uncertainty in making a health decision [32,33]. The City of Hope EOL Knowledge Assessment will be revised slightly to reflect content within the *Reimagine Worries to Wishes Program* [34]. The 10-item PROMIS Global scale will be used to assess for patient and caregiver QOL [35].

Table 2. Assessment schedule

Data collected	Baseline	Week 9 Control	Week 9 or 18: Post-Intervention
Participant Characteristics			
Demographics	X		
Clinical Status	X		
Outcomes			
Decision Making Instruments [26,32,33]	X	X	X
End of Life Knowledge [34]	X	X	X
PROMIS Global QOL [35]	X	X	X
Process Measures			
Program Satisfaction			X
Program Usage			X
Document Completions			
-*Worries to Wishes Treatment Plan*			X
-Advance Directive			X

Process Measures. Documentation of the *Worries to Wishes Treatment Plan* and advance directive will be examined for completion within the *Reimagine* application. Clickstream data associated with viewing videos and other web content (e.g., social community) will be collected and analyzed through a web analytics software package. Session attendance will be collected by the Pillar Guides and sent to the study team for analysis following each of the online meetings. Questions regarding the participants' experience with *Reimagine* such as user satisfaction are included in the post-intervention survey; recommendations will be solicited for informing program improvement. To help control for confounding factors, a question will be included to assess for participation in other programs (e.g., counseling, support groups).

Table 3. Instruments

Instrument	Who	Instrument Summary	Scoring	# of Items	# of Minutes
Preparation for Decision Making Scale [26]	ALL	Reliable and validated self-reported measure of the patient or provider's perception of how useful a decision support intervention is in preparing the respondent to communicate with others to make a health decision.	Items are summed and scored, then divided by 10; scores can be converted to a 0-100 scale. Higher scores indicate higher perceived level of preparation for decision making.	10	3-5
Decision Self-Efficacy Scale [32]	Patients	Reliable and validated instrument measures self-confidence or belief in one's abilities in decision making, including SDM.	Items are summed, divided by 11, and multiplied by 25. Scores range from 0 to 100 (very confident).	11	3-5
Decisional Conflict Scale [33]	Patients	Reliable and validated measure of the state of uncertainty about a course of action.	Items are summed, divided by 16, and multiplied by 25. Scores range from 0 to 100 (high decisional conflict).	16	5-7
End of Life Knowledge	ALL	The content of the City of Hope End of Life Knowledge Assessment [34] will be revised to reflect the Reimagine curriculum.	Correctly answered questions will be awarded one point, summed, and a total score generated.	24	8-10
PROMIS Global [35]	Patients & Caregivers	Reliable and validated measure of general perceptions of health. Items are predictive of health care utilization and mortality.	This scale produces two health scores – physical and mental. Items are summed and can be converted into t-scores.	10	3-5
Program Satisfaction & Evaluation	ALL	Study team-developed questions to assess perceived helpfulness of the program in terms of outcomes and patient-provider communication	Points are totaled and summed	12	5-7

Data Analyses and Statistical Considerations

Aim 1: To assess the feasibility of patient, caregiver, and provider engagement in SDM through participation in *Reimagine*. We hypothesize that, as compared to usual care, this intervention will lead to more frequent completions of advance directive documents. Descriptive analyses will be used to examine the following process measures: 1) the patient's completion of the *Worries to Wishes Treatment Plan* and advance directive documents; and 2) patient, caregiver, and provider program usage (e.g., module viewings and participation in online meetings) and satisfaction. Binomial tests will examine the proportion of advance directives completed against the expected proportion.

Aim 2: To demonstrate whether *Reimagine* influences the metastatic breast cancer patient, caregiver, and provider EOL care knowledge, SDM, and QOL. We hypothesize that, as compared to usual care, *Reimagine's Worries to Wishes* intervention will effectively improve EOL knowledge, SDM, and QOL among the patients, caregiver, and providers. We will analyze changes in: 1) patient, caregiver and provider EOL care knowledge and decision making

preparedness; 2) patient decision making self-efficacy and decisional conflict; and 3) patient and caregiver QOL. To assess SDM, the primary response variable will be a continuously scaled measure of patient, caregiver and provider decision making preparedness, obtained from summing the 10 items of the Preparation for Decision Making scale, dividing by 10, and converting to a 0-100 point scale [26]. This outcome variable is measured at baseline and post-intervention. The most straightforward analysis is an independent samples t-test. Second, multiple regression will be conducted to estimate the relationships between the SDM variable and the outcome measures. Analyses of other outcome variables will proceed similarly. All outcome variables are measured at baseline and post-intervention.

To be conservative, a power analysis was conducted for the most complex statistical model (i.e., multiple regression of each outcome on all three SDM variables: preparedness, self-efficacy, and conflict), using G*Power [36]. The power analysis shows that for n = 100 patients, the multiple regression will be able to detect a small to medium effect size (f^2 = 0.11) and, for n = 40 providers, the multiple regression will be able to detect a medium to large effect size (f^2 = 0.30), both with a power of .80 at the significance level of .05.
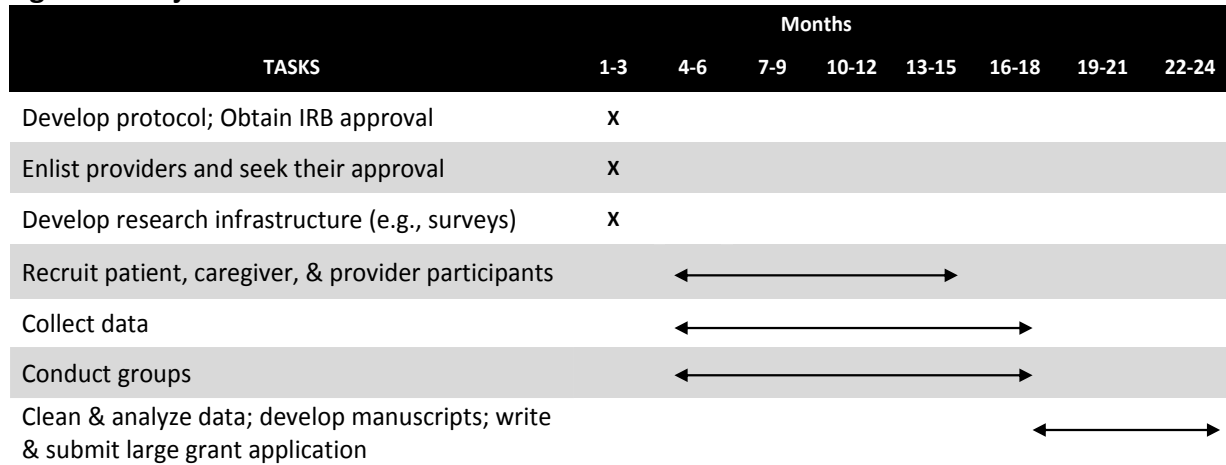
6. Detailed Work Plan and Deliverables Schedule

A major advantage of this proposal is that much of the research infrastructure such as the intervention materials, REDCap surveys, and enrollment and tracking application were developed to support the *Pillars4Life* RCT and should only require minor revisions (e.g., adding the decision making instruments) for the proposed project. This will allow us to "hit the ground running" and execute the project within a two-year period. The first step will be to develop the protocol and submit to the Duke Institutional Review Board (IRB) for approval as shown in Figure 4. Following IRB approval, we will seek physician approval to contact patients in one of the three specified oncology settings. In parallel, the project infrastructure will be developed, tested and implemented by the project team. This includes revisions to the REDCap surveys, enrollment and tracking database, and development of the *Worries to Wishes Treatment Plan* and advance directive document transmission function. Training of the clinical research coordinator (CRC) will also occur during this period. Following IRB and physician approval and development of the project infrastructure, patient/caregiver and provider recruitment is planned to begin in Month 4 and continue for one year; it is anticipated that all participants will have moved through the intervention by Month 15. Data collection is scheduled to start at Month 4 as well, and consented patients will be emailed a REDCap baseline survey link by the CRC; repeat survey links will be emailed at post-intervention (9 and 18 weeks). Links to access Amazon gift cards (i.e., incentives) will be emailed by the CRC to participants following each survey submission. Data cleaning and analysis, manuscript development, and grant proposal preparation and submission are planned during the final six months of the study period.

At the end of this study, we expect to have demonstrated the effectiveness of a facilitated, synchronous and asynchronous online curriculum to improve the quality of EOL care for patients with MBC through increased competence and performance of health care providers. At least one manuscript and several conference (e.g., ASCO, APOS, AOSW) abstracts will be developed and submitted for publication. The next logical step in our program of research

would be to conduct a dissemination and implementation study that examines the delivery of *Reimagine* at a large academic institution, a major managed care consortium, and community cancer programs.

Figure 4. Project Timeline

	Months							
TASKS	1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24
Develop protocol; Obtain IRB approval	x							
Enlist providers and seek their approval	x							
Develop research infrastructure (e.g., surveys)	x							
Recruit patient, caregiver, & provider participants		←————————————→						
Collect data		←——————————————→						
Conduct groups		←——————————————→						
Clean & analyze data; develop manuscripts; write & submit large grant application							←————→	

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