A.1. Title

Pillars4Life: An online, self-management curriculum for cancer survivors (#16218019)

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A.2. ABSTRACT

Goal: The *Pillars4Life* curriculum teaches coping skills to cancer patients in a virtual group setting; it was recently implemented and studied at 17 hospitals. *Pillars4Life* participation (n=130) was associated with statistically and clinically significant improvements in targeted outcomes (e.g., depression, fatigue, quality of life) and skills (e.g., self-efficacy, coping). The goal of the proposed project is to broaden the horizons of the program and demonstrate that chronic pain management can be improved through *Pillars4Life*. More specifically, we aim to demonstrate the impact of *Pillars4Life,* distributed via live video conferencing technology, on: 1) a reduction in cancer-related pain and associated outcomes; and 2) optimized health care utilization and patient-provider communication.

Target population: Patients with chronic cancer-related pain.

Project: Cancer patients who report multiple pain scores >=4 will be identified using DEDUCE inquiries of electronic health records (EPIC) and recruited from four outpatient clinics within the Duke Cancer Center. Consenting participants in the treatment group (n=150) will meet with a certified Pillar Guide (i.e., facilitator) weekly for nine weeks in a virtual group environment. The control group (n=150) will receive usual care.

Evaluation: Electronic assessments at baseline, 9 weeks (post-intervention), and 18 weeks (follow-up) using validated instruments to determine changes in *Pillars4Life* targeted skills and outcomes. Repeated-measures MANOVA will be used to assess the effects of the *Pillars4Life* intervention on the outcomes. A mediation analysis using multiple regression will also be conducted for testing the mediation effects of the targeted skill changes on the relationships between the *Pillars4Life* intervention and the outcomes.

C. Main Section

1. Overall Goal & Objectives

It is well documented that many cancer survivors suffer from chronic pain; an estimated two-thirds of patients with advanced cancer and up to one-third of patients who received curative therapy following cancer treatment experience pain [1,2]. Factors associated with the development of chronic cancer-related pain include chemotherapy (e.g., painful peripheral neuropathy), radiation (e.g., brachial plexopathy), and surgery (e.g., mastectomy pain) [3]. In addition, chronic pain experienced by cancer survivors is associated with other problematic symptoms such as depression and fatigue [4]. Pain can cause these symptoms and likewise, these symptoms can cause and worsen pain. There is a growing body of evidence suggesting that psychosocial therapies, such as guided imagery, breathing, and other coping skills are effective treatments for pain and can improve quality of life (QOL) [5-8]. The *long-term goal* of this research program is to develop behavioral treatment protocols that can reduce pain and associated symptoms in cancer survivors and in doing so, improve outcomes such as patient well-being and reduced health care utilization. The *objective of this application* is to pilot test the efficacy of a standardized, online coping skills curriculum for managing pain and associated symptoms among cancer survivors [9,10]. More specifically, we aim to demonstrate the impact of *Pillars4Life* on: 1) the reduction in pain, depression, and fatigue and enhanced quality of life (QOL); and 2) optimized health care utilization and patient-provider communication among cancer survivors who are living with chronic pain. Evidence of preliminary efficacy from this randomized control trial will be used to support an R01 application to conduct a larger, multisite study to inform best practice.

Aim 1: To evaluate the impact of an online, coping skills curriculum (i.e., *Pillars4Life*) on cancer-related pain, depression, fatigue, and QOL. We hypothesize that, as compared to usual care, this intervention will effectively improve patient well-being including pain relief.

Aim 2: **To evaluate the impact of the *Pillars4Life* intervention on health care utilization resources (unplanned hospitalizations and emergency room visits) and patient-provider communications.** We hypothesize that, as compared to usual care, this intervention will optimize health care utilization and improve patient-provider communication.

This project is *innovative* in that it addresses a critical need in oncology by leveraging an existing curriculum, *Pillars4Life* (originally marketed as *Pathfinders),* that was shown to be associated with reductions in depression, anxiety and fatigue [9-12]. Recently GOOD/Corps, a market research company hired by Reimagine (the owner and marketer of *Pillars4Life*), 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 *Pillars4Life* is the only standardized curriculum that teaches cancer survivors psychosocial coping skills such as solution-focused thinking, relaxation and breathing exercises, and guided imagery in a real-time, virtual setting (i.e., scripted and timed classes with live teachers) [13].

Pillars4Life was recently tested as a self-management tool for cancer survivors to improve QOL and featured during a plenary session at the 7th Biennial Cancer Survivorship Research Conference [9]. In this NIH-funded study (CA156687) of 130 cancer survivors across 17 US

hospitals, our team found that participation in *Pillars4Life* 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 [9,10]. The proposed project seeks to broaden the horizons of the program to: 1) show that chronic pain management can be improved through *Pillars4Life;* and 2) begin to examine causality via a randomized control trial (i.e., previous related studies were correlational). Also, this project is expected to have a *positive impact* on cancer survivors through participation in the program and development of a symptom report to share with their providers (improved patient-provider communication). These goals are directly in line with the focus of the RFP as *Pillars4Life* is a standardized, innovative program 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 (DUSON), Reimagine, and Duke Cancer Institute (DCI), which are to provide psychosocial support and improve the QOL of patients with chronic and/or life-threatening conditions.

2. Technical Approach

a. Current Assessment of Need in Cancer

Approximately 14.5 million Americans with a history of cancer are alive; this year, there will be an estimated 1,665,540 new cancer cases diagnosed and 585,720 cancer deaths in the US [14]. Cancer remains the second most common cause of death in the US, accounting for nearly 1 of every 4 deaths. In terms of the proposed study population, the Duke Cancer Center provides care to 6,000 new patients and more than 50,000 survivors with all forms of cancer annually [15].

Unfortunately, pain is a common and devastating symptom of cancer [16]. It impacts patients' physical functioning, psychological wellbeing, and social interactions and it increases both direct and indirect medical expenses [17]. According to one review, the prevalence of pain averages 53% across the cancer continuum from diagnosis through survivorship or end of life [5]. Another systematic review on the prevalence of pain in cancer patients yielded results suggesting that 64% of patients with metastatic, advanced or terminal disease, 59% of patients in active anticancer treatment and 33% in patients who had been "cured" of cancer experience pain [2]. Of these patients, more than one-third third rated their pain as moderate to severe. The researchers concluded that this may have serious effects on health care costs and resource utilization. These prevalence statistics suggest that millions of Americans are currently suffering from cancer-related pain that is severe enough to require attention.

In 1986, the World Health Organization (WHO) developed a 3-step analgesic ladder to guide cancer pain management worldwide [18]. Other guidelines based on this have been developed at the national and international level [16]. However, the degree to which WHO guidelines have been effective in changing practice and improving patient care remains contentious. Despite the high prevalence of cancer-related pain and the growing interest in pain and pain relief over the past decade, many patients frequently receive inadequate pain treatment despite the

established treatment guidelines [2,19]. This suggests that current palliative care efforts (including the use of opioids and other drug therapies) have not solved the significant issue of cancer-related pain [2]. Indeed, cancer-related pain prevalence in the US has not decreased in the past 20 years, even though opioid prescribing in the US has increased more than 10-fold since 1990 [19].

In addition to drug therapies, there is a growing body of evidence suggesting that a variety of psychological and cognitive behavioral treatments can reduce pain severity and interference with function [5]. Pain, especially chronic pain, is associated with psychological factors such as emotional distress, depression, anxiety, uncertainty and hopelessness, even sometimes leading to an increased desire for hastened death. Also, these psychological factors influence both the experience of pain and the response to pain treatment for patients with cancer. Furthermore, the Institute of Medicine [20] reports that unmet psychosocial needs can lead to increased morbidity and mortality, and reduced health care use and behaviors necessary to self-manage illness and promote health.

Mind-body therapies such as relaxation, meditation, imagery, and cognitive-behavioral therapy (CBT), have been shown to be effective in the treatment of pain-related medical conditions [21]. Effective methods include education (with coping skills training), hypnosis, cognitive behavioral approaches, and relaxation with imagery, among others [5-8]. For instance, there is evidence that the enhancement of self-efficacy as well as educational methods that address barriers to pain treatment and teach patients to understand and communicate their pain and medication needs have resulted in reduced pain [5]. Additionally, while these researchers noted that there is still a large gap in the evidence validating these techniques in the end-of-life stage, education-oriented interventions that included CBT components and relaxation with imagery were successfully used to teach patients skills for managing pain at end of life.

Unfortunately, when it comes to psychosocial needs and treatments, patients do not feel their physician adequately addresses these problems. For example, one study found that 50% of a group of cancer patients believed that their health care professional did not consider their QOL as an important aspect of the overall care plan [16]. The same study found that substantial minorities of patients felt that their clinician would rather treat their cancer than the accompanying pain, that their clinician did not have time to discuss pain within a consultation, and that their treating clinician did not know how to treat moderate-to-severe cancer pain.

Clearly, mind-body therapies are being increasingly validated and integrated as additional treatments for chronic cancer-related pain. However, there still remain some gaps in the research as well as a large gap in the ability of physicians and the health care system to implement such programs in a cost-effective way. *Pillars4Life* aims to do just that. Building on existing research, we aim to test a psychosocial intervention that has already been show to be associated with factors related to pain (e.g., depression, fatigue, QOL) among cancer survivors. The program includes many of the components found to be effective in reducing pain, including mind/body exercises such as relaxation with imagery, coping skills and self-efficacy training, and spirituality. Because it is affordable, scalable and easily distributed, the *Pillars4Life* program has the potential to dramatically impact cancer-related pain, improve the primary care providers' ability to better manage treatment for pain, and ultimately impact health care utilization.

b. Project Design and Methods

Theoretical Basis

The *Pillars4Life* curriculum is based on established theory and empirical evidence from social work and psychology, clinical observations, and a comprehensive review of the literature on adjustment to chronic disease [22-27]. The overarching goal is to facilitate "personal recovery," defined as the ability to live fully and meaningfully despite the presence of cancer in one's life. Research and clinical experience suggested the need for an intervention that offered a multimodal approach (because cancer patients must adjust in a variety of domains in their lives) that was longitudinal and flexible enough to adjust for the uniqueness of each patient.

In order to develop a scalable and generalizable model, the *Pillars4Life* founders drew upon the theories of Positive Psychology, Resiliency Theory, and various stress and coping theories, including the importance of self-efficacy and meaning-making coping strategies. Positive Psychology focuses on positive subjective experiences or emotions (e.g., love, gratitude), positive traits or inner strengths (e.g., courage, persistence), positive "institutions" or external influences (e.g., social support) and examines characteristics such as hope, wisdom, courage, spirituality, and perseverance under stress in order to help individuals flourish [22,23]. Resilience, or features that allow an individual to thrive despite adverse circumstances, has been shown to be a major factor in the ability of cancer patients to cope with their disease [24,25]. In addition, research demonstrates that coping is a process rather than a trait and that it can be learned (such as the Positive Psychology concept of "learned optimism") [26,27]. Therefore, a major aspect of the *Pillars4Life* intervention is in teaching coping skills to facilitate personal recovery.

Thus was born the Seven Pillars of Personal Strength (see Figure 1), a set of seven overarching concepts that shape a patient's cancer journey, forging a positive statement for each concept. The Pillars serve as a systematic framework for self-assessing personal needs, activating inner strengths and building self-care plans to address specific stressors that are impacting QOL. The founders believe that each of these Pillars exists within every individual, but that certain pillars may be weakened by cancer, others may become stronger or dominant while others may be unrecognized or underutilized – and that patterns will be unique for each individual.

Figure 1. The Seven Pillars of Personal Strength™

The goal of *Pillars4Life* is to strengthen each Pillar within each survivor. Over the course of the past decade, the founders developed and revised a set of educational materials that form a coherent curriculum for personal recovery, based on observation of patients, results, and suggestions from workshops such as the Benson-Henry Institute for Mind-Body Medicine at Massachusetts General Hospital [28]. Working iteratively from Pillar to intervention tool to patients' experiences, the toolset was honed into a standardized curriculum organized under the framework of the Seven Pillars.

Intervention Components

In the *Pillars4Life* curriculum, patients are guided through nine synchronous, online courses by a trained mental health provider (e.g., social worker, therapist, psychologist) called a Pillar Guide who follows a standardized, scripted curriculum of personal exploration and skills training. The curriculum helps the patient identify needs, activate inner strengths, learn adaptive coping skills, mobilize resources and support, and define a self-care plan that promotes healing and a sense of wellbeing despite the multiple challenges (including chronic pain) posed by cancer. Kristin MacDermott, a licensed professional counselor and marriage and family therapist, and Tina Staley, a licensed clinical social worker, developed the *Pillars4Life* curriculum. Originally delivered as an in-person, primarily one-on-one, counseling model in the clinical setting, the current curriculum was developed for distribution via small online groups led by expert facilitators with live video conferencing technology after realizing that the in-person counseling model was not scalable or affordable.

The *Pillars4Life* curriculum teaches patients two major skill sets as they move through the Seven Pillar themes. The first is Solution-Focused Thinking, which is a way of restructuring people's thinking about stressors 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 feelings and then jumps right to finding a solution for feeling better. This is not "positive thinking," but rather, is about taking an honest look at thoughts and beliefs around particular issues and clearly identifying what someone needs to feel better about them.

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 at *Pillars4Life*, comes 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. Things 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. By combining solution-focused thinking skills and mind-body skills in a curriculum that explores seven dimensions of resiliency, *Pillars4Life* teaches a comprehensive skillset for self-assessing personal needs and building self-care plans to meet those needs. The fundamental believe on which this program is built on is, "You can choose what to focus on at any given moment, and what you focus on will determine how you feel."

As depicted in Figure 2, study participants will be given tools that are presented in a curriculum workbook with supplemental Pillar booklets for use throughout his/her participation and thereafter. Courses are standardized, scripted and timed, and led by Pillar Guides. Each course always begins with a verbal agreement to keep everything that is shared in the session private. After the pledge there is an opening check-in by which everyone is invited to share around a few specific questions. Participation is encouraged but not required. Listening to others share is a powerful part of the learning process, and the shares in the program are specifically structured to benefit everyone who is listening (i.e., not only the person who is sharing).

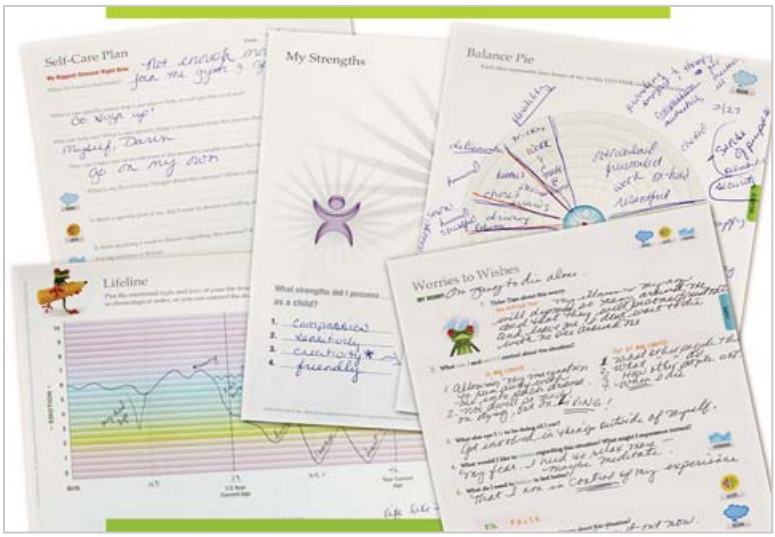

Figure 2. *Pillars4Life* Tools

Figure 3. The Nine Classes of *Pillars4Life* Training

As mentioned above, there are nine classes in total – an Introduction course followed by a full course on each of the seven Pillars, and finally a Closing session (see Figure 3). In each weekly 75-minute class, the Pillar Guides lead patients through a series of activities, visualizations, dialogues, surveys and shares. Everyone does the exercises together and then has an

opportunity to process what they learned with the Pillar Guide. For example, in the Balance course, patients get very specific about how they spend their time and energy in daily life and making sure the things they are spending time on are in alignment with their true priorities. In this session, patients create a visual perspective of how they spend their time and how they feel in each aspect of their lives. They learn to set boundaries that help them keep stressors from taking up too much time and energy and allowing more time for the things that feel good.

Project infrastructure

Figure 4 presents the architecture that will be established for studying the *Pillars4Life* intervention in the cancer environment. It combines two elements: (1) A curriculum that is administered online via Adobe Connect to patient devices (e.g., laptop, desktop computer, tablet); and (2) A web-based application, Qualtrics, that administers surveys at three time-points and generates customized reports that are emailed directly to the patients. Upon receipt, the patient may choose to share and/or email each report directly to a provider of his or her choice (e.g., primary care provider, oncologist, nurse practitioner). Often, it is the oncologist or oncology nurse practitioner who serves as the primary care provider (or "quarterback") while the patient is in active treatment; hence, the decision was made to empower the patient to select which provider or providers would benefit most from examining the symptom report.

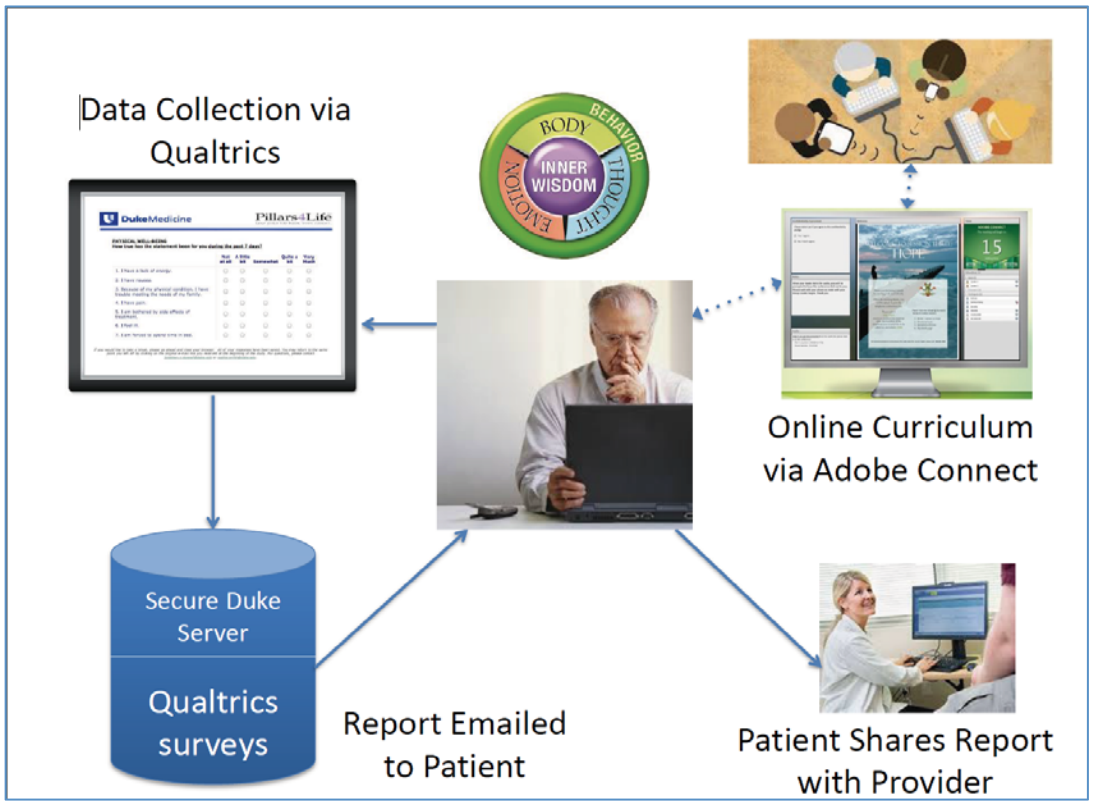

Figure 4. Architecture for studying *Pillars4Life*

Recruitment and Participant Selection

Cancer patients who reported a most recent and at least one additional score of moderate to severe pain as documented in the electronic health record (EPIC) will be recruited from the Duke Cancer Center Breast, Gastrointestinal (GI), Genitourinary (GU), and Thoracic Clinics. The four oncology clinics were recommended by Duke Cancer Center oncology providers and selected for inclusion in this project based on having a large number of patients who are not only living with chronic pain but express a high need for coping strategies [29].

Once identified in EPIC through DEDUCE inquiries, patients will be approached in one of the four clinics 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) Current pain level ≥4 and at least one prior score ≥4 on a scale of 0-10 as reported in EPIC; age ≥18 years; diagnosed with Breast, GI, GU, or Thoracic cancer and actively receiving care at the Duke Cancer Center; able and willing to have an online interaction with a *Pillars4Life* group every week; providing informed consent; and able to read/write English. The pain cutoff used in the eligibility criteria was informed by the National Comprehensive Guidelines that define moderate (4-6) and severe (7-10) pain on a 0-10 scale [30]. To be able to evaluate a moderate effect we will need to have a sample size of n=200 evaluable participants. Given an estimated dropout rate of 30%, we plan to enroll 300 cancer patients into the trial over a period of five months, or 60 patients per month. Study participants will receive Amazon gift cards upon completing each survey; $25 at baseline, $35 at post-intervention, and $40 at follow-up.

Through an examination of our electronic health records system (i.e., DEDUCE query), we found that 365 Breast, 764 GI, 318 GU, and 557 Thoracic oncology clinic patients and 298 patients with encounters in two or more of the clinics mentioned above (total N= 2302) met our pain eligibility criteria this past year, representing a total of 15,527 patient visits. Therefore, we are confident in our ability to meet our targeted enrollment of 300 patients in five months from the four specified cancer center clinics.

Trial Design

This study will employ the use of a randomized control trial of *Pillars4Life* vs. standard or usual care. Study participants will be randomly allocated to the *Pillars4Life* intervention or usual care control group. Patients in the intervention group (n=150) will be asked to complete the baseline assessment and then begin *Pillars4Life* within one month of enrollment, while those in the usual care group (n=150) will only be asked to follow a data collection schedule that is identical to the intervention group. The effectiveness of *Pillars4Life* will be measured using validated instruments including the Brief Pain Inventory (BPI) [31] pre-intervention (baseline), at 9 weeks (post-intervention), and 18 weeks (follow-up). Other outcome measures will be administered to assess symptoms, QOL, and health care utilization; measures were chosen carefully (i.e., associated with pain). Tables 1 & 2 provide details re the instruments and assessment schedule.

c. Evaluation Design

Data Collection Measures and Procedures

A Qualtrics baseline survey will be used to collect self-reported demographic (e.g., gender, race, age, income) and clinical (e.g., cancer diagnosis, stage, treatment and status, medications)

characteristics from all study participants. In addition, the Self-administered Comorbidity Questionnaire [32] will be used at baseline to collect non-cancer related disease information. Standardized instruments administered via the Qualtrics surveys will be used to collect targeted outcome and skill data at baseline, post-intervention (Week 9), and follow-up (Week 18) among the treatment and control groups as shown in Figure 5. Each of the three surveys is estimated to take 30-40 minutes to complete. Importantly, efforts were made to limit the number of administered instruments to minimize survey burden, as findings from the correlational study informed a more targeted selection of evaluative measures in the proposed project [9,10].

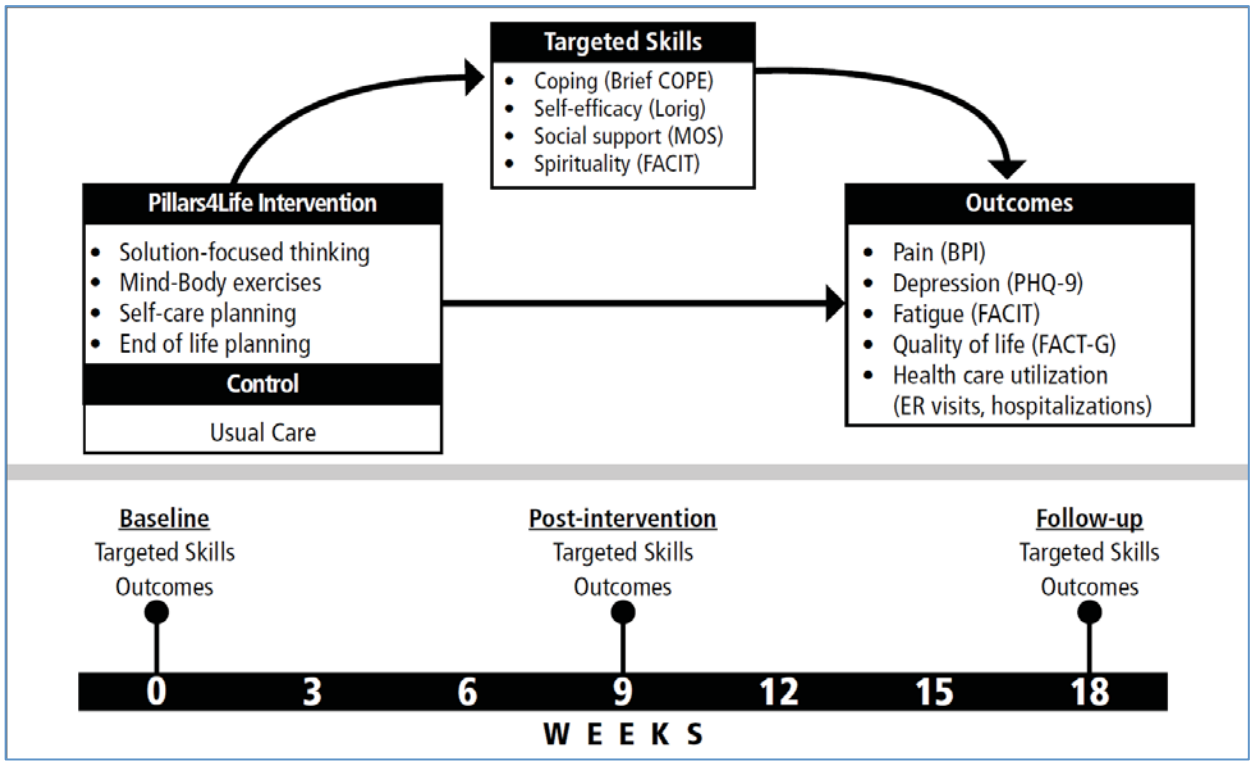

Figure 5. *Pillars4Life* Conceptual Model and Data Collection Timeline

Outcomes. The Brief Pain Inventory (BPI) is a validated measure of chronic pain in cancer and other clinical populations and will be used in the proposed study [31]. The 4-item severity scale assesses current and past week intensity, and the 7-item interference scale assesses pain-related functional interference (see Table 1). Each scale's total score is the average of all items; a higher score is indicative of worse pain or interference. The Patient Health Questionnaire (PHQ-9) will be used to capture symptoms of depression [33]. The 13-item FACIT-Fatigue scale will be used to measure fatigue and has been validated in cancer samples [34]. The 27-item Functional Assessment of Cancer Therapy (FACT-G) will be used to measure QOL [35]. The four subscales sum to a total score; a higher score is indicative of better QOL. Questions regarding the patients' use of health care utilization (i.e., emergency room visits, unplanned hospitalizations) will be included to assess for utilization among the intervention and control groups.

Table 1. Study Instruments

Construct	Instrument	Instrument Summary	Scoring	# of Items	Min. to complete
Pain symptoms (Outcome)	Brief Pain Inventory (BPI) [31]	Reliable and validated self-reported measure used in cancer and other clinical populations	4-item BPI severity scale assesses current & past week intensity (0-10). 7-item BPI interference scale assesses pain-related functional interference. Each scale's total score is average of all items; higher score= worse pain	11	5-7
Depression (Outcome)	PHQ-9 [33]	Reliable and validated measure for assessing and monitoring depression severity	Points are totaled and summed to a severity score	9	2-4
Fatigue (Outcome)	FACIT-Fatigue [34]	Reliable and validated measure of fatigue in cancer patients	Items are summed; less fatigue is represented by a higher score	13	5-7
Quality of life (Outcome)	FACT-General [35]	Reliable and validated measure of four QOL dimensions: Physical, Social, Emotional, and Functional	Individual domains are scored as described in the reference; scores are summarized to give a total score	27	8-12
Coping (Mediator)	Brief COPE [36]	Reliable, validated inventory of maladaptive, adaptive coping strategies	Scored using 14 subscales and overall score	28	8-12
Self-efficacy (Mediator)	Self-efficacy for Managing Chronic Disease [37]	Reliable and validated measure of self-efficacy ("doing for one's self") and confidence in managing disease	Scored as a mean of six items	6	2-4
Social Support (Mediator)	MOS Social Support Survey [38]	Reliable and validated measure of four social support subscales and overall index	Scores on each subscale are averaged; a formula is used to generate a summary score	19	7-10
Spirituality (Mediator)	FACIT-SP [39]	Reliable, validated measure of spiritual well-being	Total score is a sum of all items	12	5-7
Patient Satisfaction & Program Evaluation	N/A	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

Table 2. Assessment schedule

Data collected	Baseline	9 Weeks	18 Weeks
Demographics	X		
Disease & comorbidity data	X		
Outcomes			
Brief Pain Inventory (BPI) [31]	X	X	X
Depression (PHQ-9) [33]	X	X	X
FACIT-Fatigue [34]	X	X	X
Quality of life (FACT-G) [35]	X	X	X
Health care utilization	X	X	X
Skills			
Brief COPE [36]	X	X	X
Self-Efficacy [37]	X	X	X
Medical Outcomes Social Support [38]	X	X	X
FACIT-Spirituality [39]	X	X	X
Patient Satisfaction & Program Evaluation*		X	
Attendance log*		X	X

**Intervention group only*

Skills. The skills targeted by *Pillars4Life* will be assessed using validated instruments that employ Likert-type scoring (see Table 1). The Brief COPE is a 28-item coping inventory designed to assess adaptive and maladaptive coping strategies [36]. The Self-efficacy for Managing Chronic Disease Scale is a 6-item measure of self-efficacy for coping with chronic disease [37]. The Medical Outcomes Study – Social Support Survey is a 19-item measure used to assess the perceived availability of social support and has been used extensively in various populations, including breast cancer survivors [38]. The Functional Assessment of Chronic Illness Therapy – Spiritual Well-being (FACIT-SP-12) is a 12-item scale that assesses spiritual well-being [39].

Patient Satisfaction and Program Usage. Questions regarding the intervention group participants' experience with *Pillars4Life* (i.e., user satisfaction, patient-provider communication) will be added to the post-intervention and follow-up surveys to solicit recommendations for future improvements to the program. Session attendance will be collected weekly by the Pillar Guides and sent to the study team for analysis. Also, a question will be used in the surveys to assess for participation in other programs (e.g., yoga) to control for confounding factors.

Data Analyses and Statistical Considerations

Aim 1: To evaluate the impact of an online, coping skills curriculum (i.e., *Pillars4Life*) on cancer-related pain, depression, fatigue, and QOL. We hypothesize that, as compared to usual care, this intervention will effectively improve patient wellbeing including pain relief.

To assess patient outcomes, the primary response variable will be a continuously scaled measure of pain symptoms, obtained from taking the 4 items of the BPI and averaging them. This outcome variable is measured at baseline, 9, and 18 weeks. The most straightforward analyses are repeated-measures MANOVA and multiple regression. First, we will use repeated-measures MANOVA to estimate the effects (denoted as E1) of the *Pillars4Life* intervention on the patient well-being outcomes and the effects (denoted as E2) of the *Pillars4Life* intervention on the targeted skills. Second, multiple regression will be conducted to estimate the relationships (denoted as E3) between the targeted skills and the patient well-being outcomes. We expect that E1, E2, and E3 are significant at $p < .05$ and the product of E2xE3 is also significant at $p < .05$ which will test the mediation effect [40].

Aim 2: **To evaluate the impact of the *Pillars4Life* intervention on health care utilization resources (unplanned hospitalizations and emergency room visits) and patient-provider communications.** We hypothesize that, as compared to usual care, this intervention will optimize health care resource utilization and improve patient-provider communication and such impact will also be mediated by targeted skills.

To assess patient health care resource utilization, the primary response variable will be the summed number of visits to the emergency room and unplanned hospitalizations during the intervention and follow-up period. While this outcome variable is measured at baseline, 9, and 18 weeks, the baseline value will only be used for comparison purposes between the intervention and control groups (i.e., assess for potential bias). The patient-provider outcome variable will be assessed by questions in the patient satisfaction and program evaluation survey. The analytic approach to Aim 2 is similar to that in Aim 1 with only the outcomes changed to health care resource utilization and patient-provider communication.

A power analysis is conducted using G*Power for determining an adequate sample size for both Aims 1 and 2 [41]. The G*Power results revealed that our sample size of 200 (100 for each group) will provide a power of .80 to detect a medium effect size ($f = 0.31$ for repeated-measures and $f^2 = 0.06$ for multiple regression) at a significance level of $\alpha = .05$.

3. Detailed Workplan and Deliverables Schedule

A major advantage of this proposal is that much of the research infrastructure such as the intervention materials, Qualtrics surveys, and enrollment and tracking application were developed to support the LiveStrong study and should only require minor revisions (e.g., adding a pain component) for the proposed project. This will allow us to “hit the ground running” and execute the project within a one-year period. The first step will be to develop the protocol and submit to the Duke IRB for approval as shown in Table 3. Following IRB approval, we will seek physician approval to contact their patients in one of the four specified cancer center clinics. In parallel, the project infrastructure will be developed, tested and implemented by the entire project team. This includes revisions to the *Pillars4Life* curriculum (i.e., addition of pain-related

content), Qualtrics surveys, enrollment and tracking database, and development of the personalized reports. Training of the clinical research coordinator (CRC) will also occur during this period. Clinic recruitment is planned to begin in Month 3 and will continue for 5 months, following IRB and physician approval and development of the project infrastructure. Data collection is scheduled to commence at this time, and consented patients will be emailed a link to the Qualtrics baseline survey by the CRC; repeat survey links will be emailed at post-intervention (9 weeks) and follow-up (18 weeks). Links to access Amazon gift cards (i.e., incentives) will be emailed by the CRC to participants following each survey submission.

At the end of this study, we expect to have demonstrated the effectiveness of a facilitated, synchronous online curriculum to manage symptoms of pain in cancer survivors. In addition, this project would provide valuable efficacy data on the impact of *Pillars4Life* on pain and associated symptoms (i.e., examine causality), as previous related studies were correlational. 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 *Pillars4Life* at a large academic institution, a major managed care consortium, and cancer programs.

Table 3. Project Timeline

TASKS	Months					
	1-2	3-4	5-6	7-8	9-10	11-12
Develop protocol; Obtain IRB Approval	X					
Enlist Providers	X					
Develop infrastructure (e.g., surveys, reports)	←	→				
Recruit participants		←	—	→		
Collect data		←	—	—	—	→
Conduct groups		←	—	—	→	
Analyze data and develop manuscripts					←	→

D. Organizational Detail

1. Leadership and Organizational Capability

Duke School of Nursing (DUSON)

The School of Nursing has a strong reputation and is a key fixture at Duke University. Founded in 1931, the DUSON remains on the forefront of nursing education, practice and research. The mission of the school is to create a center of excellence for the advancement of nursing science; the promotion of clinical scholarship; and the education of clinical leaders, advanced practitioners, and researchers. Through nursing research, education, and practice, students and faculty seek to enhance the quality of life for people of all cultures, economic levels and geographic locations. The philosophy of the School of Nursing is consistent with the purposes of Duke University and Duke University Medical Center, which include undergraduate, graduate, and professional education, research, and service.

More than 850 students are now enrolled across DUSON's four degreed programs (ABSN, MSN, DNP, and PhD), the largest number of students in the school's 80-year history. Many programs are now available online and are meeting the needs of students in remote geographic locations in the U.S. and in sites around the world. DUSON rose to 7th place in the 2012 US News and World Report rankings of graduate schools of nursing in the United States. DUSON's pediatric nursing program is ranked 5th nationally; the adult nurse practitioner program, 10th; gerontology, 10th; the anesthesiology program ranked 11th. For the 2013 fiscal year, faculty members at DUSON received $1.2 million in training grants and $7.5 million in research and other grants, for a total of $8.7 million in external sponsored funding. As a result, the School is eleventh among schools of nursing in NIH funding.

As faculty members of DUSON, Dr. Smith, Dr. Hockenberry, and Dr. Pan are well-poised to provide the general oversight of all activities in support of this proposed study. Dr. Smith is serving as lead investigator of the NIH-funded *Pillars4Life* study (CA156687) and LiveStrong-funded program implementation at 17 hospitals across the United State. In addition, she is leading a DCI-funded pilot study of the Cancer Distress Coach mobile application among breast, prostate and lymphoma survivors. As the Bessie Baker Professor of Nursing, Dr. Hockenberry brings many years of experience as a cancer researcher to this project, with an in-depth knowledge of project management and protocol issues related to running clinical trials. Dr. Pan has supported many research grants that were funded by federal agencies such as the National Institutes of Health, the National Science Foundation, and the US Department of Education. He brings a wealth of experience to the project in quantitative methods and applied statistics. Proposed study-related activities include: obtaining medical records and approval for patient contact from the physicians; design and execution of the study, development of the patient survey and provider reports; coordination of the recruitment process; analyzing the data; writing manuscripts and preparing reports for the funding agency.

Reimagine: The *Pillars4Life* curriculum, The Seven Pillars of Personal Strength™, was developed by Kristin MacDermott, a licensed professional counselor and marriage and family therapist, and Tina Staley, a licensed clinical social worker. Originally delivered with an in-person, primarily one-on-one, counseling model in the clinical setting, the curriculum was found to

improve the quality of life of cancer patients in a study completed in 2008 at the Duke Comprehensive Cancer Center. Realizing that the in-person counseling model was not scalable or affordable led MacDermott and Staley to develop a new curriculum for distribution via small online groups with live video conferencing technology. Led by Dr. Sophia Smith, the online curriculum was recently shown to be even more effective in improving QOL and is greatly preferred by participants for the convenience and anonymity it offers. In the beginning of 2012, Staley and MacDermott established a for-profit corporation, *Pillars4Life*, Inc., now doing business as "Reimagine" in Los Angeles, California, to facilitate distribution of the *Pillars4Life* course (and other courses in development) to the general public via an online portal (www.reimagine.me). Reimagine has graduated close to 2000 people in the course, trained approximately 40 instructors (i.e., Pillar Guides), and has the capacity to serve over 2000 participants at a time. Reimagine received funding from the LiveStrong Foundation, Susan G. Komen Foundation, Pancreatic Cancer Action Network, Women's Cancer Research Fund, and Painted Turtle Camp. Ms. MacDermott will oversee the conduct of *Pillars4Life* sessions and distribution of program materials to study participants in the treatment group.

The Duke Cancer Institute (DCI) was launched in the fall of 2010 as a single entity – the first of its kind at Duke – with the goal of uniting hundreds of physicians, researchers, educators, and staff across the Duke University Medical Center, Duke University School of Medicine, and the Duke University Health System under a shared administrative structure to offer unprecedented opportunities for teamwork among scientists and caregivers.

The vision of the new DCI is to accelerate research advances related to cancer and to translate these discoveries into the most advanced cancer care to patients. The DCI is a National Cancer Institute-designated cancer center and is ranked as the top cancer hospital in the South by U.S. News & World Report. Duke has made a $400 million investment in the DCI by opening, in 2012, the new 267,000-square foot Duke Cancer Center to expand clinical services with a substantive investment in state-of-the-art technologies dedicated to patient-focused cancer care and include more spacious treatment rooms, a rooftop terrace and gardens, quiet spaces for conversation or reflection, and a cafe. **Each year, the DCI provides care to nearly 6,000 new patients and more than 50,000 patients with all forms of cancer.** Patients who come to Duke represent every county in North Carolina and virtually every state in the nation. More than 60 percent of new Duke patients are referred to Duke for their initial treatment.

The DCI includes more than 300 researchers and physicians and 500 clinical staff. It offers hundreds of clinical trials for the treatment and prevention of many forms of cancer. The DCI supports numerous shared resources that provide access to technologies, services, and scientific consultation that enhance scientific interaction and productivity. **DCI oncologists as well as their staff have agreed to help us recruit patients and work closely with the study team to facilitate recruitment. In addition, our CRC has allocated space at the cancer center to use during the recruitment process. As outlined in our main proposal, a DEDUCE query identified 365 breast, 764 GI, 318 GU, and 557 Thoracic clinic cancer patients and 298 patients with encounters in two or more of the clinics mentioned above (total N= 2302) that met our pain eligibility criteria this past year, representing a total of 15,527 patient visits.**

2. Staff Capacity

Dr. Smith will serve as PI and brings a unique blend of multidisciplinary experience and expertise to the project, with a PhD in social work, training in health services research and cancer care quality, and a personal history as a two-time cancer survivor (which provides a unique perspective of the complexities of care from the patient and healthcare provider perspectives). As PI on a NIH-funded grant to study QOL among NHL survivors while a doctoral student, Dr. Smith successfully administered the project, collaborated with researchers, and produced several peer-reviewed publications. In the postdoctoral fellowship at UNC-Chapel Hill, she was PI on a funded NC Translational and Clinical Sciences grant that broadened her dissertation project that focused on defining the longitudinal QOL and patient experience of survivors of non-Hodgkin lymphoma, with particular focus on posttraumatic stress disorder, the impact of cancer, and implementation of evidence-based supportive care services. At Duke, Dr. Smith is leading an evaluation study of the *Pillars4Life* online program implementation across 17 hospitals that received funding through a LiveStrong Community Impact Project award; Dr. Smith's effort was funded through an NIH KM1 award. In addition, Dr. Smith is PI of several mobile health related studies, instructs and mentors MSN and DNP students in research methods and statistics, and is the faculty coordinator for a new DUSON course offering. In summary, Dr. Smith has a demonstrated record of successful and productive research projects in an area of high relevance for our cancer population, and is well poised to lead this project.

Dr. Pan will serve as the study statistician, and is well versed in methodological methods including propensity score analysis, structural equation modeling, and longitudinal growth curve analysis. In addition, Dr. Pan has been a major advisor for several PhD students and has served on 30 doctoral dissertation committees. In sum, based on his research, teaching, and mentoring experiences, Dr. Pan is competent in serving this proposed work as a statistician.

The Application Specialist resides in the Duke Clinical Research Institute's Center for Learning Health Care (CLHC) and will serve as the programmer on this project. The CLHC development team is supporting the *Pillars4Life* NIH-funded study; therefore, this programmer is well suited to reformat and revise the surveys and enrollment database and implement minor modifications to fit the proposed study. In addition, he/she will be responsible for developing the symptom and project status reports and controlling and issuing data sets. Of note, the CLHC is well versed in developing patient-reported outcome surveys and symptom reports, as evidenced by a previous Pfizer grant that supported the e-Tablet project. The programmer will work closely with Dr. Smith and Dr. Pan to ensure that the database is designed to collect data in the formats necessary to ensure the planned analysis at project end. The proposed effort for the Programmer is sufficient to carry out this work at 20%.

The Clinical Research Associate (CRC) will be responsible for coordination and implementation of study procedures such as recruitment, consent, data collection (survey administration), and tracking of study participants. In addition, the CRC will assist with maintaining project records including the preparation of amendments to protocols as appropriate. The CRC will, in part, be supervised by the DUSON Research Practice Manager and participate in university wide professional development opportunities and ongoing training in addition to working closely with the project team. Their full (100%) effort will be devoted to this project.

G. Letters of Commitment

Sophia Smith, PhD, MSW
Associate Professor
Duke School of Nursing
307 Trent Dr., DUMC 3322
Durham, NC 27710

October 2, 2014

Dear Sophia,

I am very pleased to offer my consulting services to you and your team for your study and look forward to another opportunity to collaborate together. Cancer survivors need more programs to address their unmet needs and the Pillars4Life program will be valuable addition to existing servicers. Therefore, I am happy to commit myself to devoting 40 hours to the Pfizer submission entitled, *Pillars4Life: An online, self-management curriculum for cancer survivors (#16218019)* and will receive $5,000 as compensation. I believe that this coping skills curriculum has great potential in helping cancer patients manage symptoms of pain, depression, and fatigue along the survivorship trajectory, during treatment and post-treatment. This is particularly important given the new Commission on Cancer Standard requiring distress screening as more cases of distress can be expected to be diagnosed. As more cases are identified, there will be a concomitant need to provide support services to address these problems. Pillars4Life will be invaluable as one of those services, especially for survivors who may have trouble attending face-to-face programs.

I am an advanced practice oncology nurse who has consulted with organizations on issues to improve cancer care and have over 40 years of cancer nursing practice, education, research, and management experience. My program of research focuses on the issues facing cancer survivors (including pain and fatigue management) and improving cancer care through the development and implementation of behavioral ehealth interventions.

I will bring my experience with designing interventions and symptom reports/care plans for cancer survivors to this project and thereby ensuring successful study execution through development and execution of the trial.

I look forward to further collaborations working with you and your team on this important and significant project.

Sincerely,

Deborah K. Mayer, PhD, RN, AOCN, FAAN

The UNIVERSITY of NORTH CAROLINA at CHAPEL HILL
Deborah K. Mayer, PhD, RN, AOCN, FAAN, Professor
Director of Cancer Survivorship UNC Lineberger Comprehensive Cancer Center
Adult/Gero Health ▯ CB#7460, Carrington Hall ▯ Chapel Hill, NC 27599-7460
email: dmayer@unc.edu ▯ phone: 919-843-9467 ▯ fax: 919-966-7298

October 7, 2014

Sophia Smith, PhD, MSW
Associate Professor, Duke University School of Nursing
Duke Clinical Research Institute / Center for Learning Health Care
307 Trent Dr., DUMC 3322
Durham, NC 27710

Dear Dr. Smith,

This letter will serve to confirm our plans to collaborate on the study entitled, "Pillars4Life: An online, self-management curriculum for cancer survivors." Our company, Reimagine, is well-staffed with certified Pillar Guides who are licensed, masters-level counselors (e.g., social work, family therapy) to conduct the online classes. In addition, we will provide the necessary course materials to each study participant that will be included in the $399 cost per person.

My understanding is that your application is aimed to demonstrate that participation in our Pillars4Life curriculum is associated with symptom reductions (e.g., pain, fatigue, depression) and improvements in quality of life. The focus is well matched to our goal of making "the other half of care" - care for the social and emotional effects of cancer - affordable and accessible for everyone touched by cancer.

We truly look forward to working with you on this very important project.

Sincerely,

Kristin

Kristin MacDermott, LPC, MFT
Founder and President, Reimagine

LIVESTRONG
FOUNDATION

September 25, 2014

Sophia Smith, PhD, MSW
Associate Professor, Duke University School of Nursing
Duke Clinical Research Institute / Center for Learning Health Care
307 Trent Dr., DUMC 3322
Durham, NC 27710

Dear Dr. Smith,

I am writing to provide my full support and enthusiasm to your application entitled, "Pillars4Life: An online, self-management curriculum for cancer survivors." As you know, Pillars4Life was awarded one of our Community Impact Project awards, which ran from 2012-2014 at 20 sites across the United States. Feedback from all stakeholders confirms that the Pillars4Life team was highly organized and successful in implementing their program.

My understanding is that your application proposes to determine if the Pillars4Life curriculum is effective at reducing pain and related symptoms, thereby improving quality of life. These aims are consistent with LIVE**STRONG**'s goal of improving the lives of people affected by cancer and pushing forward patient centered care models.

We are excited at the possibility of seeing your work move forward!

Sincerely,

Jordan Parks
Community Program Manager
LIVE**STRONG** Foundation

2201 E. Sixth Street, Austin, Texas 78702 TEL 512.236.8820 FAX 512.236.8482 LIVESTRONG.org

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I. Appendix

1. Manuscript under review

Evaluation of Pillars4Life: A Virtual Coping Skills Program for Cancer Survivors

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Affiliations: [1]Duke School of Nursing; [2]Duke Clinical Research Institute; [3]Duke Cancer Institute; [4]Duke University School of Medicine; [5]Duke Department of Medicine, Division of Medical Oncology; [6]Re-imagine, Inc.; [7]Duke Department of Biostatistics and Bioinformatics

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ABSTRACT

Objective: Pillars4Life is an educational program that teaches coping skills to cancer patients in a virtual group setting; it was recently implemented at 17 hospitals across the US. The Pillars4Life curriculum targets psychosocial resources (e.g., self-efficacy, coping skills) as a means to reduce symptoms (e.g., depression, anxiety, posttraumatic stress) and enhance quality of life (QOL).

Methods: Cancer patients were recruited from hospitals that received the LiveStrong Community Impact Project Award to enroll in a pilot study of Pillars4Life. Consenting participants met with a certified instructor weekly for ten weeks in a virtual environment; the manualized intervention trained participants in personal coping skills. Longitudinal assessments over 6 months were assessed using validated instruments to determine changes in Pillars4Life targeted resources and outcomes. Multiple linear regression models examined the relationship between changes in targeted resources and changes in outcome from Baseline to three months post intervention.

Results: Participants (n=130) were: mean age 56±11, 87% female, 11% non-Caucasian, 77% college degree. At three and six month follow-up, mean scores improved on all key outcome measures such as depression (PHQ-9), anxiety (GAD-7), posttraumatic stress (PCL-C), fatigue (FACIT-Fatigue), and well-being (FACT-G) from Baseline (all $P<.01$); results were most pronounced among participants who reported $\geq$4/10 on the Distress Thermometer at Baseline (all $P<.001$). Changes in each targeted resource were associated with 3-month improvements in at least one outcome.

Conclusions: Participation in the Pillars4Life program was associated with statistically and clinically significant improvements in scores on pre-specified outcomes and targeted resources.

Keywords: cancer survivor, psycho-education, quality of life, psychosocial intervention, coping skills, symptom management

BACKGROUND

Accumulating evidence documents the substantial unmet psychosocial needs of cancer patients, as summarized in the 2007 release of an Institute of Medicine (IOM) report entitled "Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs [1]." Many cancer patients indicate that they feel dissatisfied with their providers' attentions to their psychosocial concerns [2-4]. Unmet psychosocial needs lead to increased morbidity and mortality and reduced health care behaviors necessary to manage illness and promote health during survivorship [5-7].

In response to the IOM report and needs of patients, quality of life (QOL) focused programs have proliferated; widespread implementation without evaluation of the interventions' feasibility and efficacy is common. Available studies have been limited to a narrow participant population or have assessed the natural history of QOL itself rather than studying the impact of an intervention on the course of QOL. Evidence-based programs that demonstrably improve cancer patient outcomes are needed.

In alignment with the IOM's proposed strategy, the Pillars4Life (formerly, "Pathfinders") educational program was designed as a strengths-based coping skills model. It integrates psychosocial assessment and care for cancer patients through the guidance of a program manual. A pilot study of Pathfinders at Duke University's cancer center demonstrated the program's feasibility and acceptability in the academic medical center setting; participation was significantly associated with improvements in distress, despair and QOL among women with advanced breast cancer [8]. The findings of the Duke pilot study coupled with the face validity of the Pathfinders model led to the development of a more cost-effective, scalable, and accessible version named Pillars4Life. The online and virtual group format was fundamental for wide-scale implementation at multiple clinical sites in the United States (US), catalyzed by funding from the LiveStrong Foundation.

This manuscript presents the initial outcomes and efficacy results of an evaluation study of Pillars4Life disseminated to 17 different sites among cancer patients. We hypothesized that participation in the Pillars4Life intervention would be associated with reduction in symptoms and improved QOL outcomes as shown in Figure 1. Although this evaluation program was uncontrolled, we hypothesized that positive changes in the personal coping resources targeted

by Pillars4Life would correlate with improvements in the clinical outcomes of interest, thereby providing credible support for the hypothesis that observed improvements in patient outcomes were due to participation in the Pillars4Life program.

METHODS

Participants and procedures

This was a multi-site single-arm study. Eligible patients were: age ≥18 years; diagnosed with cancer of any type; actively receiving cancer care at one of 17 Institutional Review Board approved sites in the US that offered the Pillars4Life program to their patients; able and willing to have telephone or video interaction with a Pillars4Life group every week; providing informed consent; and able to read/write English.

The Pillars4Life intervention consisted of weekly 75-minute virtual training groups of up to 15 participants over a ten-week period. A masters-prepared and certified Pillar Guide who was trained in the model led the group via Adobe Connect (Adobe Systems Incorporated) using a manualized script. Participants without Internet access joined the group sessions by phone. The standardized curriculum included a set of intervention "tools" (i.e., solution focused thinking and mind body skills) that were developed to foster inner strengths and facilitate coping [8]. Participant resources and outcome data were collected at Baseline, three and six months using validated measures. Data were collected electronically using the web-based Qualtrics v2012 (Provo, UT) survey interface or by paper. Planned data collection time-points were Baseline, Month3 (post-intervention), and Month6 (follow-up).

Measures

Participant characteristics. Demographic (e.g., gender, age, race, education) and clinical (e.g., cancer type, date of diagnosis, treatment status) information were collected via self-report prior to the start of the intervention. Comorbidities were reported via the Self-administered Comorbidity Questionnaire [9]. The Australia-modified Karnofsky Performance Scale (AKPS) was used to assess functional performance status [10].

Resources. The resources targeted by the Pillars4Life intervention were assessed using validated instruments that employed Likert-type scoring. The Brief COPE is a 28-item coping

inventory designed to assess adaptive and maladaptive coping strategies [11]. A higher score indicates increased frequency of coping style usage. The Medical Outcomes Study – Social Support Survey is a 19-item measure used to assess the perceived availability of social support and has been used extensively in various populations, including breast cancer survivors [12,13]. Greater perceived availability of social support is indicated by a higher score. The Self-efficacy for Managing Chronic Disease Scale is a 6-item measure of self-efficacy for coping with chronic disease [14]. A higher score is indicative of expectancies in achieving an outcome. The Functional Assessment of Chronic Illness Therapy – Spiritual Well-being (FACIT-SP-12) is a 12-item scale that assesses spiritual well-being [15]. A higher score represents better spirituality-related QOL. The 10-item Life Orientation Test - Revised (LOT-R) was used to assess optimism and can discriminate between generalized optimism versus pessimism; greater optimism is indicated by a higher score [16]. All psychosocial resource instruments had excellent internal consistency in our sample ($\alpha>0.80$) with the exception of the Brief COPE ($\alpha>0.71$).

Symptoms. The Generalized Anxiety Disorder (GAD-7) [17] and Patient Health Questionnaire (PHQ-9) [18] were used to capture symptoms of anxiety and depression. The Patient Care Monitor (PCM v2) was used to assess for despair and distress [19]. The 1-item Distress Thermometer (DT) was also used to assess for distress [20]. The 17-item Posttraumatic Stress Disorder Checklist (PCL-C) was modified so that symptoms were aligned to the specific traumatic stressor of interest (i.e., cancer diagnosis and treatment). Higher scores on all measures are indicative of more symptoms [21]. Strong reliability was found in all symptom measures ($\alpha>0.80$).

Quality of life. The 27-item Functional Assessment of Cancer Therapy - General (FACT-G) was used to measure QOL [22]. Its four sub-scales sum to a total score in which a higher score is indicative of better QOL. The 13-item FACIT-Fatigue scale is scored such that less fatigue is represented by a higher score. Also, the PCM v2 QOL subscale was used to assess QOL; a higher score is representative of better QOL. All QOL measures showed strong reliability in this study ($\alpha>0.80$).

Statistical analysis

Participants who completed Baseline and Month3 assessments were included in these analyses. To ensure that study instruments were reliable and performing as expected, Cronbach's alpha coefficients were computed using the Baseline data. The paired-samples t-test procedure was used to compute the differences between the values of two variables (i.e., Baseline and Month3; Baseline and Month6) for each participant and test whether the average differed from 0. T-tests were performed for the entire sample as well as for the distressed subsamples (i.e., participants who scored ≥ 4 on the Distress Thermometer at Baseline) and non-distressed subsamples. For each targeted resource, multiple linear regression models were used to examine the independent associations between changes in resources and select changes in outcomes between Baseline and Month3, adjusted for patient characteristics (age, education, and treatment and performance status).

A two-sided significance level of 0.05 was used for all statistical tests. Clinical significance was defined as moderate to strong effect sizes ranging from 0.5 to 1.0 standard deviation units. Analyses were conducted using SAS V9.1 (SAS Institute, Cary, NC).

RESULTS

Participants

A total of 241 patients were referred for study screening, of whom 237 patients were eligible, and 191 consented to participate (81% of those eligible). Attrition over the three month intervention period was 32%. Reasons cited for withdrawal from the program and/or study (n=55) included lack of time or being overwhelmed, feeling sick, and too fatigued. Participants (n=130) were: mean age 55.7±10.5 years; 87% female; 89% white; 61% married; and 48% employed (Table 1). Most participants were breast cancer survivors (51%), diagnosed with an early stage disease (52%), and currently receiving treatment (63%). The mean time since diagnosis was 2.8±3.6 years.

Change in Mean Scores

Outcomes. As shown in Table 2, all mean psychosocial symptom scores (i.e., anxiety, depression, despair, distress, posttraumatic stress) improved from Baseline to Month3 (all

P<.001). Similarly, mean QOL scores (i.e., cancer-related Wellbeing, Fatigue, QOL t-score) improved from Baseline to Month3 (all *P*<.001), except for Social/Family Well-being subscale. Month3 results were more pronounced among patients with higher Baseline levels of distress. Among participants who reported distress (DT≥4) at Baseline, clinically significant improvements (i.e., moderate to strong effect sizes) in all psychosocial symptoms were detected at Month3 (all *P*<.001). Clinically significant changes in cancer-related Well-being and QOL t-scores were also reported by distressed participants at Month3 (all *P*<.001).

Per Table 2, significant improvements in all mean psychosocial symptom scores were retained at Month6 (all *P*<.001). Also, mean QOL scores improved from Baseline to Month6 (all *P*<.01) except for the Social/Family Wellbeing subscale. Among distressed participants, clinically significant improvements were reported at Month6 in all psychosocial symptoms (all *P*<.001), cancer-related Well-being, fatigue, and QOL t-score (all *P*<.001).

Resources. Table 2 displays improved mean scores from Baseline to Month3 on targeted resources (i.e., coping skills, self-efficacy, spirituality; all *P*<.001). Significant improvements were reported for learned optimism, self-efficacy, and spirituality at Month6 (all *P*<.01). Among participants who were distressed at Baseline, clinically and statistically significant improvements in self-efficacy and spirituality were reported at Month3 and Month6 (all *P*<.001).

Relationship between Targeted Resources and Outcomes

Multiple linear regression models were generated to examine the relationships between the change from Baseline to Month3 for targeted resources and key outcomes after adjustment for patient characteristics (age, education, and treatment and performance status). As per the conceptual model (Figure 1), we focused on Baseline to Month3 for the changes in targeted resources, since it was theorized that changes in targeted resources would precede changes in outcomes. After adjustment, the following resources were found to have an independent association with at least one outcome: coping with anxiety (*P*=.002); optimism with posttraumatic stress, despair, and QOL t-score (all *P*<.05); self-efficacy with depression, posttraumatic stress, despair, distress, cancer-related well-being, QOL t-score, and fatigue (all *P*<.01); social support with anxiety, despair, distress, cancer-related well-being, and QOL t-score

(all *P*<.05); and spirituality with anxiety, depression, despair, distress, cancer-related well-being, and QOL t-score (all *P*<.01). Findings are summarized in Figure 2.

DISCUSSION

This study examined longitudinal changes in symptoms of psychosocial distress and QOL among a sample of cancer patients participating in the Pillars4Life program. Over 6 months, all outcomes improved. As there was not a comparator group, we cannot confidently attribute the improvements to the Pillars4Life intervention. However, several important findings increase the likelihood that the study findings are related to the intervention. First of all, there was clinically and statistically significant improvement in the psychosocial resources that Pillars4Life is intended to impact, namely self-efficacy and spirituality; this aligns with our conceptual model of how the program could improve personal outcomes by enhancing targeted personal resources as first published in 2010 [8] (Figure 1). Second, change in these personal resources correlates with longitudinal symptom and QOL outcomes, including depression, despair, distress, cancer-related well-being, and QOL. Third, study participants with the highest levels of distress at Baseline received the most benefit. In addition, improvements in resources and outcomes were maintained at three months following intervention cessation (i.e., Month6). These findings are consistent with results from a growing portfolio of effective virtual-based psycho-educational interventions [23-25].

Improvements in each targeted resource were independently associated with improvements in at least one key outcome. The conceptual model presented in Figure 1 was supported by the results in Figure 2, in which changes in psychosocial resources targeted by the intervention were associated with improved symptom and QOL outcomes. Improvement in spirituality and self-efficacy scores were associated with improvements in six and seven of the eight outcome scores reported, respectively (all *P*<.01). It is curious that the targeted resource with the most face validity and alignment with the goals of Pillars4Life showed the lowest relationship to outcomes –i.e., personal coping as measured on the Brief-COPE. This may be an indicator that Pillars4Life is not very effective at supporting coping; or it may be a signal that the Brief-COPE is a poor measure of personal coping. Psychometrically-valid short coping assessment instruments have been very difficult to develop, and available instruments are often suspect; in

fact, the Brief-COPE's published psychometrics are lower than that of the rest of the measures in our evaluation framework [11] and, in this study, the Cronbach's alpha of 0.71 was lower than the rest of our instruments (otherwise >0.8).

How do these Pillars4Life study results compare to the one-on-one, in-person administered Pathfinders study results [8]? While the Pillars4Life study employed a larger cadre of instruments than the Pathfinders study, significant improvements were reported in both studies at Month3 for these common instruments: PCM Distress, Despair, and QOL t-scores; and FACT-G Emotional subscale. However, the Pillars4Life study also reported improvements in these shared instruments: FACIT-SP; FACIT-Fatigue; and FACT-G, -Physical, and –Functional. These findings are encouraging and provide an early indication that moving to a more cost-effective, scalable, and accessible Pillars4Life model was not detrimental to the outcomes reported by program participants.

Study limitations include the lack of a control group, thereby preventing any determinations regarding causality (i.e., if the improvements in resources and outcomes were caused by participation in the program). However, the use of longitudinal data collection and deliberate timing of assessments and related analyses assisted in the establishment of sustained improvements in resources and outcomes. Second, a majority of women with breast cancer were enrolled, thereby limiting generalizability among men and survivors who were diagnosed with a different type of cancer. Third, sub-scales within the MOS-SSS and FACT-G overlap, which could account for observed correlations.

Despite these limitations, these data provide compelling support that the Pillars4Life participants derive important improvements in targeted resources and outcomes. A future study that employs a more definitive experimental study design is needed to determine whether the Pillars4Life intervention is superior to regular standard for care for reducing psychosocial symptoms and improving QOL in cancer survivors.

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Table 1: Characteristics of the Study Sample at Baseline (n=130)

Characteristic	No. of Participants N	%	Mean ± SD
Demographics			
Female sex	113	87	
Income < $30,000	19	15	
College or Postgraduate degree	100	77	
Married or living with partner	79	61	
White race	116	89	
Non-Hispanic	124	96	
Employed full- or part-time	62	48	
Veteran status	10	8	
Private health insurance	89	69	
Age, years			55.7 ± 10.5
Clinical			
Breast cancer	66	51	
Stage I or II at diagnosis	67	52	
In remission or cured of disease	54	42	
Had received cancer surgery	99	76	
Had received radiation therapy	60	46	
Had received chemotherapy	89	68	
Currently receiving treatment	82	63	
Co-morbidities, number			3.2 ± 1.9
Time since diagnosis, years			2.8 ± 3.6
Performance status			82.7 ± 13.3
Symptoms			
Anxiety			6.3± 5.3
Depression			7.6 ± 5.5
Despair T-score			57.4 ± 10.0
Distress Thermometer			4.5 ± 2.7
Distress T-score			57.6 ± 10.2
Posttraumatic stress			32.6 ± 12.8
Quality of Life			
Cancer-related Well-being			70.4 ± 20.4
Physical Well-being			20.3 ± 6.0
Emotional Well-being			16.0 ± 5.2
Social/Family Well-being			18.1 ± 7.1
Functional Well-being			15.9 ± 6.4
Fatigue			30.7 ± 11.8
Quality of Life T-score			46.6 ± 9.5
Targeted resources			
Coping skills			68.3 ± 8.3
Learned Optimism			16.1 ± 6.4
Self-efficacy			37.7 ± 12.4
Social support			76.0 ± 18.0
Spirituality			30.8 ± 11.4

Table 2: Paired *t*-Test Results

Domain	α	At Month3 (n=130) Mean Diff*	SD	*t* value	*P*	At Month6 (n=116) Mean Diff†	SD	*t* value	*P*
Symptoms									
Anxiety	.90	-2.3	4.7	-5.6	<.001	-2.6	4.0	-6.8	<.001
Depression	.86	-2.3	4.5	-5.8	<.001	-2.7	4.6	-6.3	<.001
Despair T-score	.90	-2.9	8.4	-3.9	<.001	-2.8	7.8	-3.9	<.001
Distress Thermometer	--	-0.9	2.7	-3.7	<.001	-1.0	2.5	-4.3	<.001
Distress T-score	.88	-3.0	8.7	-3.9	<.001	-3.8	8.6	-4.8	<.001
Posttraumatic stress	.94	-4.3	9.1	-5.4	<.001	-5.2	8.6	-6.5	<.001
Quality of Life									
Cancer-related Well-being	.94	4.7	14.0	3.8	<.001	6.0	13.7	4.7	<.001
Physical	.86	1.2	5.3	2.7	.009	1.5	5.3	3.0	.003
Emotional	.83	2.0	3.9	5.7	<.001	2.1	3.7	6.1	<.001
Social/Family	.89	-0.1	5.5	-0.1	.97	0.7	4.5	1.7	.08
Functional	.88	1.7	5.2	3.6	<.001	1.8	6.0	3.2	.002
Fatigue	.94	3.3	11.3	3.4	.001	4.9	10.0	5.3	<.001
Quality of Life T-score	.89	3.1	7.7	4.4	<.001	3.2	7.1	4.8	<.001
Targeted Resources									
Coping	.71	2.3	7.5	3.5	<.001	0.2	8.6	0.3	.80
Learned Optimism	.89	0.8	4.6	1.9	.06	1.1	4.4	2.7	.009
Self-efficacy	.91	3.6	9.9	4.1	<.001	5.3	11.1	5.2	<.001
Social Support	.96	0.9	11.4	0.9	.37	1.7	11.6	1.6	.12
Spirituality	.93	3.2	7.8	4.7	<.001	3.0	8.5	3.8	<.001

* Mean difference is calculated using the following formula: [Month 3 - Baseline Score]

† Mean difference is calculated using the following formula: [Month 6 - Baseline Score]

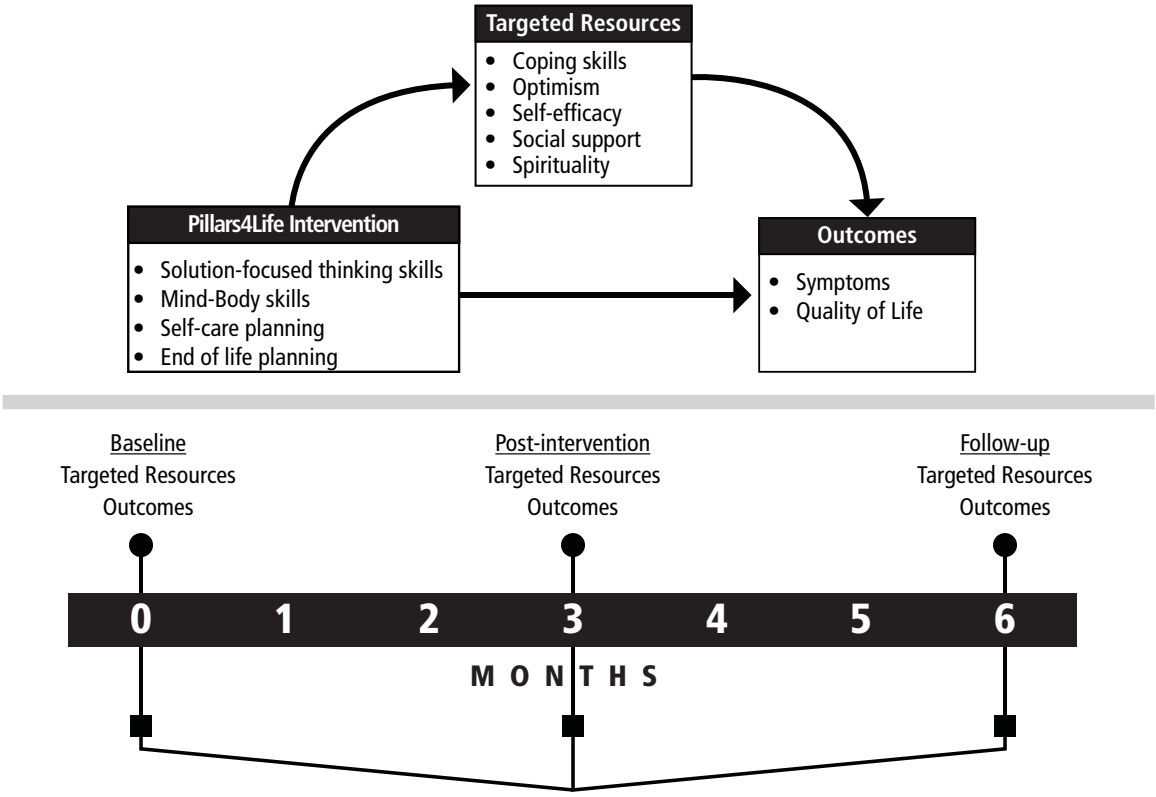

Figure 1. Pillars4Life Conceptual Model and Data Collection Timeline

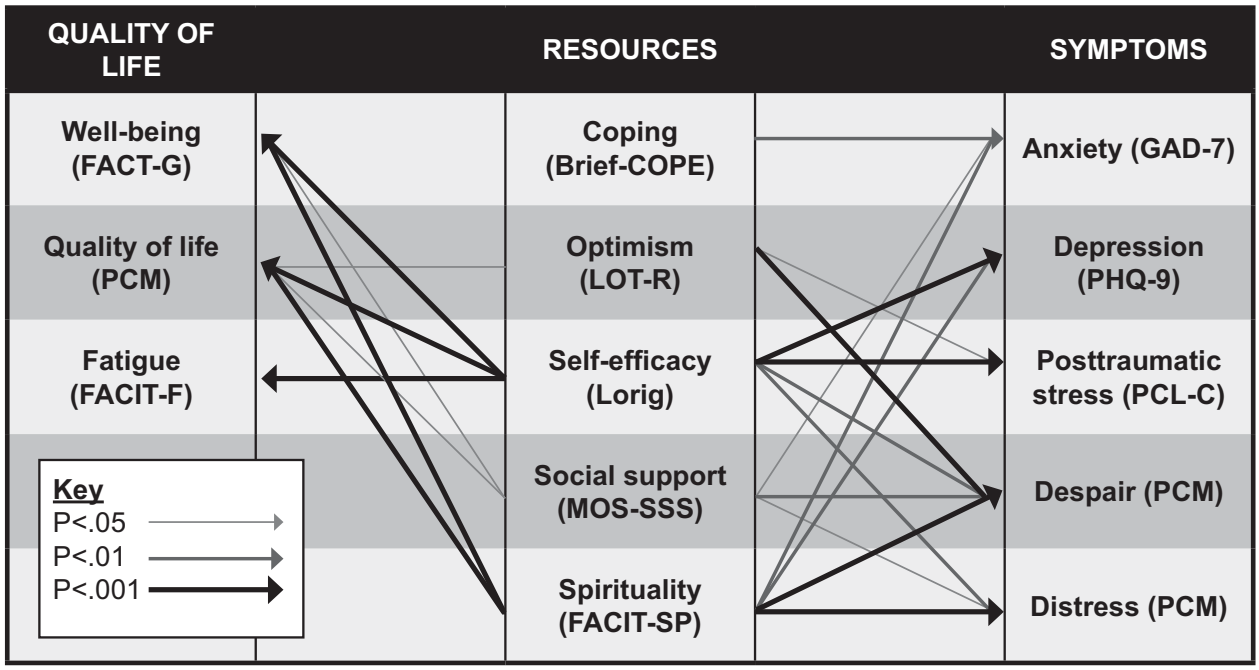

Figure 2. Independent associations between changes in resources and symptom and QOL outcomes at Month3.

Note: All models adjusted for age, education, and treatment and performance status. Abbreviations: FACTG, Functional Assessment of Cancer Therapy–General Version; PCM (Patient Care Monitor); LOT-R, Life Orientation Test; MOS-SSS, Medical Outcomes Study Social Support Survey; FACIT-SP, Functional Assessment of Chronic Illness Therapy – Spirituality; GAD-7, Generalized Anxiety Disorder; PHQ-9, Patient Health Questionnaire; PCLC, PTSD Checklist.