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Contents

I. Structured Abstract

Purpose: Chronic pain, depression, and fatigue are common effects resulting from the cancer experience. The study objective is to pilot test the efficacy of Reimagine, a standardized, online coping skills curriculum among cancer survivors with chronic pain.

Scope: To evaluate the impact of Reimagine on cancer and healthcare outcomes.

Methods: Adult cancer survivors with chronic pain were recruited from the Duke Oncology Clinic and Army of Women (AOW) Registry. Consenting participants were randomized 1:1 to receive Reimagine versus usual care and completed REDCap surveys at Baseline and 18 weeks (post-intervention). Treatment arm participants accessed content online; required online activities included viewing videos, attending group meetings, and completing cognitive reframing exercises. An independent-samples t-test was conducted to compare changes in pain, depression, and fatigue outcomes in treatment and usual care conditions.

Results: Participants (n=179) were: mean age 55.1$\pm$11.1 years; 90% female; 85% white; 68% breast cancer; and mean time since diagnosis 5.2$\pm$5.8 years. Among the AOW sample (n=91) there was a significant difference in the reduction in depression and improvement in fatigue scores for treatment (M=-1.7, SD=4.7; M=4.8, SD=9.1) versus usual care (M=0.3, SD=3.8; M=1.2, SD=6.6) conditions, respectively (all p<.05). Significant differences in missed provider appointments were found for treatment vs. usual care conditions among the AOW sample (n=86; p<.05). Differences in pain severity and interference scores were not significant for treatment vs. usual care conditions. Most treatment arm participants (94%) would recommend Reimagine to others.

Key Words: Cancer pain, survivorship, fatigue, depression, coping, eHealth intervention

II. Purpose

The objective of this study is to pilot test the efficacy of a standardized, online coping skills curriculum for managing pain and associated symptoms among cancer survivors.[1,2] More specifically, we aim to demonstrate the impact of Reimagine on: 1) the reduction in pain, depression, and fatigue and enhanced quality of life (QOL); and 2) optimized health care utilization 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., Reimagine) 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 Reimagine intervention on health care utilization resources (i.e., unplanned hospitalizations, emergency room visits, missed clinic appointments). We hypothesize that, as compared to usual care, this intervention will optimize health care utilization.

III. Scope

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.[3] 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.[4]

Unfortunately, pain is a common and devastating symptom of cancer.[5] It impacts patients' physical functioning, psychological wellbeing, and social interactions and it increases both direct and indirect medical expenses.[6] According to one review, the prevalence of pain averages 53% across the cancer continuum from diagnosis through survivorship or end of life.[7] 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.[8] Of these patients, more than one-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.[9] Other guidelines based on this have been developed at the national and international level.[5] 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.[5,8] 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. 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.[8]

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.[7] 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 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.[10]

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.[11] Effective methods include education (with coping skills training), hypnosis, cognitive behavioral approaches, and relaxation with imagery, among others.[7,12-14] 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.[7] 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.[5] 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. Reimagine aims to do just that. Building on existing research, we aim to test a psychosocial intervention that has already been shown 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 Reimagine 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.

The Reimagine 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.[15-20] 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, Inc. 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. [15,16] 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.[17,18] 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").[19,20] Therefore, a major aspect of the Reimagine intervention is in teaching coping skills to facilitate personal recovery.

Figure 1. The Seven Pillars of Personal Strength™

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.

The goal of Reimagine 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.[21] 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.

IV. Methods

Design & Procedures

This study employed the use of a randomized control trial of Reimagine vs. standard or usual care. Study participants were randomly allocated to the Reimagine intervention or usual care control group. Patients in the intervention group were asked to complete the baseline assessment and then begin Reimagine, while those in the usual care group were only asked to

follow a data collection schedule that is identical to the intervention group. The effectiveness of Reimagine is measured using validated instruments including the Brief Pain Inventory (BPI)[22] pre-intervention (baseline) and 18 weeks (post-intervention). Other outcome measures were administered to assess symptoms and health care utilization; measures were chosen carefully (i.e., associated with pain).

Reimagine is delivered by Pillar Guides who are employed by Pillars4Life Inc. in Los Angeles, CA. The Reimagine psychosocial intervention is a manualized curriculum as described below; all Pillar Guide therapists conducting the intervention are masters-prepared counselors specifically trained in the Reimagine intervention.

There were two recruitment sites used in this study: Duke Cancer Center and the Susan Love Army of Women (AOW) volunteer registry. At Duke, the principal investigator secured physician approvals in targeted clinics at the Cancer Center to grant permission to approach his/her patients in the clinics, treatment, and waiting rooms. The study team used DEDUCE to identify patients and then: 1) mailed a signed physician letter and followed up with a phone call prior to their next visit; or 2) presented the patient's name to the unit and asked either a provider to introduce them to the patient. Eligible patients provided informed consent by paper or via a secure, web-based electronic survey (i.e., REDCap). In terms of the AOW recruitment, email blasts introducing the study were sent to the registry and volunteers were invited to register. Interested volunteers were emailed a link to a Qualtrics eligibility form; and, if eligible, were emailed a link to the REDCap consent form.

Eligibility criteria were as follows: Current pain level ≥3 and at least one prior score ≥3 on a scale of 0-10 as reported in EPIC; age ≥18 years; diagnosed with Breast, GYN, GI, GU, or Thoracic cancer and actively receiving care at the Duke Cancer Center; able and willing to have an online interaction with a Reimagine group every week; life expectancy ≥ 6 months; 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 defines a 3 (on a 0-10 scale) as mild-moderate.[23]

Following informed consent, participants were randomized to the treatment or control group. Data collection surveys were administered to all study participants electronically at baseline and 18 (post-intervention) weeks using REDCap. No alternatives to electronic data collection such as paper surveys were needed since patients required online access as part of the study

eligibility criteria. Participants remained in the study for 18 weeks. Individuals in the treatment group participated in 75-minute group online meetings for up to 18 weeks. Study participants received Amazon gift cards as compensation. Participants in the treatment arm were included in the data analysis only if they met the minimum dose requirement

Reimagine Intervention

In the Reimagine curriculum, patients are guided through 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. 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. In addition, online educational videos and workbooks are provided to the participants.

The Reimagine 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, 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. Tools like guided imagery and mindfulness meditation provide direct access to our inner wisdom and were also shown to elevate mood and alleviate symptoms of stress among cancer survivors.[1,2] By combining solution-focused thinking skills and mind-body skills in a curriculum that explores seven dimensions of resiliency, Reimagine 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 were 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 class 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).
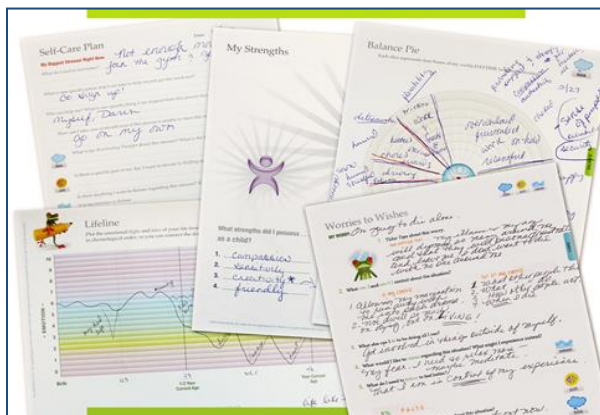

Figure 2. *Reimagine* Tools

Figure 3. The Nine Training Classes

As mentioned above, there are nine modules in total – an Introduction followed by a full course on each of the seven Pillars, and finally a Closing session (see Figure 3). In each module, the participant may view the online videos at their leisure, and then join the Pillar Guide who leads patients through a series of activities, visualizations, dialogues, and shares in online groups.

Data Analysis & Statistical Considerations

Aim 1: To evaluate the impact of an online, coping skills curriculum (i.e., Reimagine) 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.

To assess patient outcomes, the primary response variables are continuously scaled measures of pain severity and interference, obtained for each from four distinct items of the BPI and

averaging them. Depression was measured with the 8-item Patient Health Questionnaire (PHQ8).[24] Fatigue was measured with the x-item FACIT-Fatigue instrument. [25] Self-efficacy (mediator) was assessed using the Lorig Self-efficacy instrument. [26] These outcome and mediator variables are measured at baseline and 18 weeks. The most straightforward analyses are independent t-tests of the mean difference in change scores. Subsequently, we will conduct a multiple regression analysis to estimate the relationships between participant characteristics including the targeted skill (self-efficacy) and the patient well-being outcomes.

Aim 2: To evaluate the impact of the Reimagine intervention on health care utilization resources (i.e., unplanned hospitalizations, emergency room visits, missed clinic appointments). We hypothesize that, as compared to usual care, this intervention will optimize health care utilization.

To assess patient health care resource utilization, the response variables are the number of visits to the emergency room, unplanned hospitalizations, and missed appointments during the intervention period. The analytic approach to Aim 2 is similar to that in Aim 1 with only the outcomes changed to health care resource utilization.

A power analysis was conducted using G*Power for determining an adequate sample size for both Aims 1 and 2.[27] The G*Power results revealed that our sample size of 126 (63 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 α = .05. To be able to evaluate a moderate effect we will need to have a sample size of n=126 evaluable participants. Given an estimated dropout rate of 30%, we planned to enroll 180 cancer patients into the trial over a period of seven months, or ~25 patients per month.

V. Results

Main Findings

A total of 279 adults consented to participate in this study. There were 89 participants who withdrew (32%) following completion of the baseline survey; reasons included death, illness, not enough time, and lost to contact. Among the 190 active study participants, 179 met the inclusion requirements. As shown in Table 1, participants were: mean age 55.1±11.1 years; 90% female; 84% white; 68% breast cancer; and mean time since diagnosis 5.2±5.8 years. AOW participants (n=91) were more likely to report: female; white race, breast cancer; in remission or

cured; post-treatment; and a greater mean years since diagnosis than Duke participants (all at p<.01; n=88).

Among the AOW sample there was a significant difference in the reduction in depression and improvement in fatigue scores for treatment (M=-1.7, SD=4.7; M=4.8, SD=9.1) versus usual care (M=0.3, SD=3.8; M=1.2, SD=6.6) conditions, respectively (all p<.05). Significant differences in missed provider appointments were found for treatment vs. usual care conditions among the AOW sample (p<.05). Differences in pain severity and interference and self-efficacy scores were not significant for treatment vs. usual care conditions.

Table 1. Sample Characteristics

Demographics	All Participants N=179		Duke N=88		Army of Women N=91		P value
	N	% or Mean ± SD	N	% or Mean ± SD	N	% or Mean ± SD	
Female sex	161	90.0	71	80.7	90	98.9	<.0001
College degree or higher	132	73.7	66	75.0	66	72.6	.71
Married or living with partner	122	68.2	61	69.3	61	67.0	.74
White race	151	84.4	66	75.0	85	93.4	.001
Employed full or part time	99	55.3	44	50.0	55	60.5	.16
Private health insurance	125	69.8	61	69.3	64	70.3	.88
Mean age at study	179	55.1 ± 11.1	88	53.8 ± 13.0	91	56.4 ± 8.8	.13
Clinical characteristics							
Breast cancer	121	67.6	30	34.1	91	100.0	<.0001
In remission/cured of cancer	122	68.2	41	46.6	81	89.0	<.0001
Currently receiving treatment	107	59.8	78	88.6	29	31.9	<.0001
Mean years since diagnosis	179	5.2 ± 5.8	88	2.4 ± 3.2	91	7.9 ± 6.5	<.0001

A large majority (94%) of treatment arm participants would recommend Reimagine to others. Also, 88% endorsed that Reimagine was beneficial or helpful. And, a large proportion (69%) reported feeling more resilient and able to handle challenges following participation in the Reimagine program. All participants (100%) reported that they learned at least one new skill and will continue using it in their lives.

Discussion

This study examined the efficacy of the Reimagine program in addressing symptoms of pain, depression, and fatigue and healthcare utilization among a sample of cancer patients with chronic pain. Over the 18-week study period, there were significant differences in the reduction of depression and improvement in fatigue scores among the AOW sample. Importantly, the AOW participants differed from the Duke participants in several important ways (e.g., longer-term survivorship, post-treatment). Regardless of these differences, participants in both samples

reported significant differences in the number of missed appointments between the treatment and usual care arms. However, there were no significant differences in the reduction of pain severity and pain interference between the treatment and usual care conditions.

Study limitations include the high drop-out rate in the treatment arms, particularly in the Duke sample. This resulted in a lack of statistical power to detect differences in symptom reduction between the treatment and usual care conditions in the Duke sample (all p>.05). However, the lower drop-out rate in the AOW sample contributed to more power to detect differences in symptom reduction between the treatment and usual care groups. It is likely that the Duke sample was sicker given that they were more likely to be receiving active treatment and less likely to be in remission or cured. Second, a majority of women with breast cancer were enrolled, thereby limiting generalizability among men and patients who were diagnosed with a different type of cancer. Third, the heterogeneity of the Duke sample in terms of cancer type, gender, race, and treatment status limits power in examining predictors of outcomes. However, the sample's diversity may enhance the generalizability of these findings to the greater population.

Implications and Future Directions

Despite these limitations, these data provide support that the Reimagine participants derive important improvements in depression and fatigue symptoms and reductions in missed clinic appointments. A future study that employs a more homogeneous sample population (i.e., post-treatment survivors) and employing a similar experimental study design is needed to determine whether the Reimagine intervention is superior to regular standard for care for reducing psychosocial symptoms and improving quality of life in cancer survivors.

The findings from this study will be documented in two manuscripts. Given the significant differences between the Duke and AOW participant characteristics and high Duke drop-out rate, the first manuscript will report on the results obtained from the AOW sample.[28] In addition, an abstract was recently submitted to the ASCO Survivorship Conference to be held in January, 2017.[29] The second manuscript will compare the Duke and AOW outcomes, and focus on identifying the characteristics associated with reductions in symptoms and improvement in healthcare utilization (i.e., profile of patients for whom this intervention works for).[30]

VI. List of Publications

1. Smith SK. Pillars4Life: Activating cancer survivors through self-management. Plenary Presentation, 7th Biennial Cancer Survivorship Research Conference, Atlanta, GA, June 19, 2014.

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30. Smith SK, MacDermott K, Amarasekara S, Van Sant C, Patterson L, Pan W, Hockenberry M. An examination of an online coping skills curriculum among two distinct samples: What works for whom? Manuscript under development.