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ORIGINAL ARTICLE

Reimagine: a randomized controlled trial of an online, symptom self-management curriculum among breast cancer survivors

S. K. Smith [1,2] · K. MacDermott [3] · S. Amarasekara [1] · W. Pan [1] · D. Mayer [4] · M. Hockenberry [1,2]

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Abstract

Purpose Chronic pain, depression, and fatigue are common effects resulting from the cancer experience; new interventions are needed. This study examined the effect of *Reimagine*, an online symptom self-management curriculum that teaches coping skills, on key outcomes.

Methods Adult breast cancer survivors with chronic pain were recruited from the Army of Women volunteer registry for this randomized controlled trial and randomized 1:1 to *Reimagine* or usual care conditions. Electronic surveys collected demographic, clinical, and outcome data at baseline and 18 weeks post-intervention.

Results Participants ($N = 89$) were mean age 56.7 ± 8.7 years; 67% married; 58% employed; mean years since diagnosis 8.2 ± 6.6; and 89% were in remission or cured of their breast cancer. There was a significant difference in the change in depression scores for treatment ($M = -1.7$, $SD = 4.5$) and usual care ($M = 0.3$, $SD = 3.8$) conditions; $t(85) = -2.3$, $p = .03$. Difference in the change in fatigue scores was significant for treatment ($M = 4.8$, $SD = 9.0$) and usual care ($M = 1.2$, $SD = 6.6$) conditions; $t(87) = 2.2$, $p = .03$. Most *Reimagine* users (94%) would recommend the curriculum to others.

Conclusions These results suggest that *Reimagine* has an effect on depression and fatigue symptoms for breast cancer survivors. Online programs can be a feasible and effective alternative to in-person support. Additional research is recommended with larger and more diverse samples.

Keywords Breast cancer survivors · Cancer survivorship · Chronic pain · Fatigue · Depression · Self care · Randomized controlled trial · Symptom management

Introduction

Approximately 15.5 million Americans with a history of cancer are alive; this year, there will be an estimated 1,688,780 new cancer cases diagnosed and 600,920 cancer deaths in the USA [1]. Unfortunately, pain is a common and devastating symptom of cancer; 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 [2]. These prevalence statistics are especially high in breast cancer survivors, and estimated at 30% of patients reporting above average pain 10 years after treatment. 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].

Pain impacts patients' physical functioning, psychological wellbeing, and social interactions and it increases both direct and indirect medical expenses [4]. In addition, chronic pain

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Depression and fatigue are common effects resulting from the breast cancer experience. Results indicate that an online symptom self-management curriculum, *Reimagine*, has an effect on these key outcomes, but future research with larger and more diverse samples is needed.

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✉ S. K. Smith
sophia.smith@duke.edu

[1] Duke University School of Nursing, Box 3322, Durham, NC 27710, USA

[2] Duke Cancer Institute, Durham, NC 27710, USA

[3] The MacDermott Method, Inc., 345 N. Maple Drive, Suite 208, Beverly Hills, CA 90210, USA

[4] University of North Carolina at Chapel Hill School of Nursing, Chapel Hill, NC, USA

experienced by cancer survivors is associated with other problematic symptoms such as depression and fatigue [5, 6]. Pain can cause these symptoms and likewise these symptoms can cause and worsen pain. For example, one in four survivors from an American Cancer Society study fell into the high symptom category where pain, depression, and fatigue had the greatest impact on quality of life [3].

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 established treatment guidelines [7–9]. 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. This gap has led to a growing body of research and resulting evidence suggesting that a variety of psychological and cognitive behavioral treatments can reduce pain severity and interference with function [6]. Coping skills training and mind-body therapies such as relaxation, meditation, imagery, hypnosis, and cognitive-behavioral therapy (CBT) are shown to be effective in the treatment of pain-related medical conditions [6, 10–13]. 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 has resulted in reduced pain [6]. Additionally, while these researchers noted that there is still a large gap in the evidence validating these techniques in the patients with canceri, 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.

The objective of this randomized control trial is, therefore, to test the efficacy of a standardized, online coping skills curriculum for managing pain and associated symptoms among cancer survivors [14]. More specifically, we aim to determine the impact of *Reimagine* on (1) pain, depression, and fatigue symptoms; and, (2) evaluate user satisfaction with the web-based, coping skills curriculum among breast cancer survivors who are living with chronic pain.

Methods

This study employed a randomized controlled design where adult breast cancer survivors with chronic pain were randomized 1:1 to *Reimagine* or usual care condition. The Dr. Susan Love Research Foundation Army of Women volunteer registry served as the recruitment site. Treatment arm participants viewed online videos and completed cognitive reframing exercises. Links to electronic surveys were emailed to participants at baseline and 18 weeks post-intervention to assess for pain severity and interference, depression, fatigue, and satisfaction. Independent samples *t* tests compared changes in outcomes in treatment and usual care conditions.

Participants and procedures

The Duke University Health System Institutional Review Board approved this study (Pro00061381). Participants were recruited from the Dr. Susan Love Research Foundation's Army of Women volunteer registry via an email blast that included a link to an electronic Qualtrics survey to confirm eligibility: age ≥ 18 years; breast cancer diagnosis; pain level ≥ 3/10 currently and on average over the last 4 weeks [15]; informed consent; reliable Internet access; and, ability to read/write English. Then, participants were randomized 1:1 to the treatment or usual care condition in this trial using a dataset provided by our statistician.

To address the chronic pain burden experienced by breast cancer survivors, we applied a manualized coping skills curriculum intervention that has gone through an evolution of content and delivery the past decade. The *Pathfinders* program began as a one-on-one in-person model and was formalized and studied at Duke in 2008 [16]. Given significant improvements in quality of life (QOL) among patients with advanced breast cancer, it was implemented across 17 hospitals in 2012 where the *Pillars4Life* curriculum was administered online each week via 10 live Adobe Connect sessions. Significant improvements in QOL outcomes including post-traumatic stress disorder and depression symptoms and self-efficacy were found. In preparation for this trial, most of the curriculum was placed offline such that participants could access content at their leisure (i.e., "flipped classroom") and renamed *Reimagine* (Fig. 1).

The *Reimagine* curriculum consists of web-based content and required activities included attending one online introductory group meeting, viewing videos, and completing cognitive reframing and mind-body exercises over an 18-week period. The curriculum teaches two major skill sets: solution-focused thinking about stressors (first identifying their needs and what is in their control to get their needs met); and cognitive reframing (identifying the reasons for their choices and then choosing better-feeling thoughts). The program also teaches

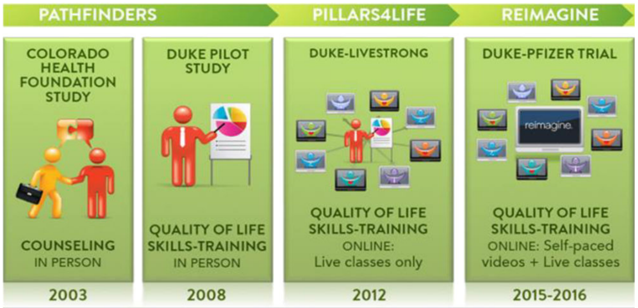

Fig. 1 Progression of the original Pathfinders intervention

mind-body exercises such as guided imagery and meditation. The one online group meeting (i.e., Adobe Connect synchronous session) was led by a masters-prepared and certified Pillar Guide (i.e., LMFT) using a manualized script. The web-based videos and exercises were available to the participants to access at any time (i.e., asynchronous). Usual care participants were offered *Reimagine* free of charge at study completion. Participant characteristics and outcome data were collected electronically via REDCap following informed consent at baseline and 18 weeks (post-intervention) using validated measures.

Measures

Demographic (e.g., age, race, education) and clinical (e.g., remission status, time since diagnosis, treatment status) information were self-reported at baseline. The nine item Brief Pain Inventory (BPI) was used to assess pain severity (PS) and pain interference (PI) in this study (Cronbach's $\alpha = .92$ and .91, respectively) [17]. The Patient Health Questionnaire (PHQ-8) was used to capture symptoms of depression (Cronbach's $\alpha = .87$) [18]. The 13-item FACIT-Fatigue scale has been validated in cancer samples [19]; note that it is scored such that less fatigue is represented by a higher score (Cronbach's $\alpha = .85$). The six-item Self-efficacy for Managing Chronic Disease scale had excellent reliability in this study (Cronbach's $\alpha = .92$) [20]. Finally, our team developed 21 items to assess user satisfaction with *Reimagine*.

Statistical analysis

Participants who completed baseline and Week18 assessments were included in these analyses (see Fig. 2). To ensure that study instruments were reliable and performing as expected, Cronbach's alpha coefficients were computed using the baseline data. Descriptive analyses were used to report the baseline sample characteristics and examine user satisfaction among the treatment arm participants. Independent samples *t* test and generalized linear model (GLM) procedures were conducted to compare change in pain, depression, and fatigue outcomes in treatment and usual care conditions. Effect size was calculated using Cohen's *d* formula.

Results

Participants

A total of 197 breast cancer survivors responded to the invitational email blast, of which 50 were not interested in participating and 25 did not meet inclusion criteria; 122 consented to participate (71% of those eligible; see Fig. 2). Attrition over the 18-week intervention period was 27%. Reasons cited for withdrawal from the program and/or study ($n = 33$) included lost contact, feeling too sick, and lack of time. Participants in the final sample ($N = 89$) were mostly white, married, employed, and in remission or cured. On average, participants were 56.7 ± 8.7 years old and 8.2 ± 6.6 years post-diagnosis (Table 1). Participants in the treatment arm were more likely to

Fig. 2 Consort diagram

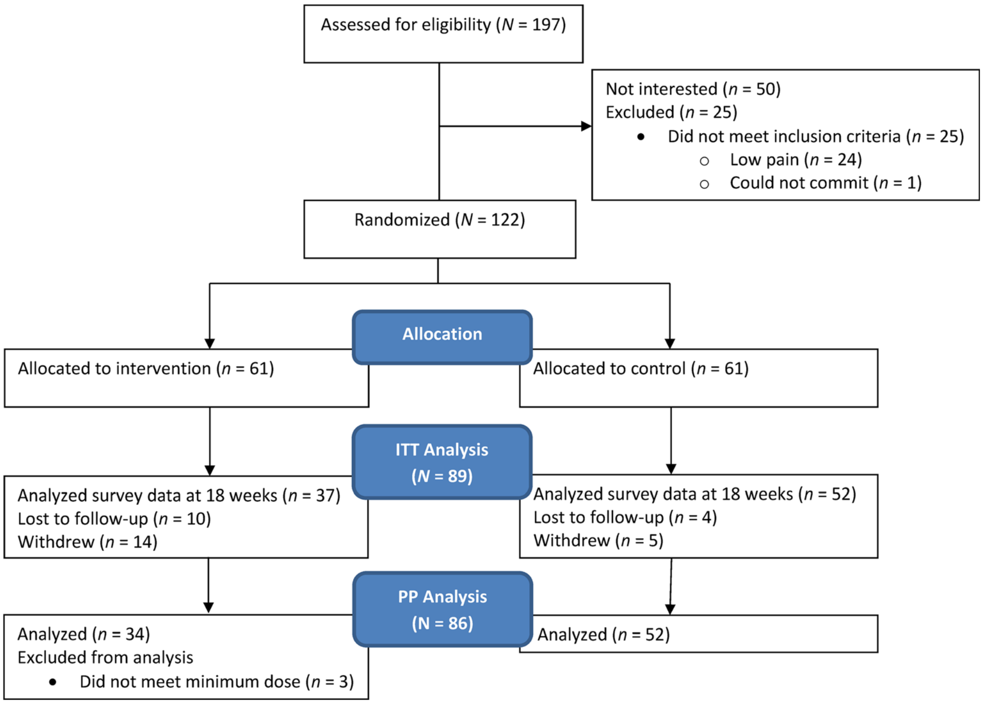

Table 1 Participant characteristics

	All ($N = 89$)		Treatment ($n = 37$)		Control ($n = 52$)		
Demographics	N	% or mean ± *SD*	*n*	% or mean ± *SD*	*n*	% or mean ± *SD*	*p**
Female sex	88	98.9	37	100.0	51	98.1	.39
College degree or higher	65	73.0	27	72.9	38	73.1	.70
Married or living with partner	60	67.4	19	51.4	41	78.8	.06
White race	83	94.3	32	88.9	51	98.1	.08
Employed full or part time	52	58.4	21	56.8	31	59.6	.19
Income < $30,000	12	13.5	9	24.3	3	5.8	*.02*
Private health insurance	62	69.7	22	59.5	40	76.9	*.03*
Mean age	89	56.7 ± 8.7	37	56.1 ± 8.9	52	57.1 ± 8.6	.60
Clinical characteristics							
In remission or cured	79	88.8	35	94.6	44	84.6	.24
Currently receiving treatment	28	31.5	12	32.4	16	30.8	.87
Mean years since diagnosis	89	8.2 ± 6.6	37	7.7 ± 6.5	52	8.6 ± 6.6	.50
Mean baseline scores							
BPI-Pain Severity	87	4.2 ± 1.9	37	4.1 ± 1.8	50	4.3 ± 1.9	.53
BPI-Pain Interference	88	4.7 ± 2.2	37	4.6 ± 2.2	51	4.8 ± 2.2	.67
PHQ-8 Depression	87	10.3 ± 5.9	35	10.3 ± 5.6	52	10.3 ± 6.1	.96
FACIT-Fatigue	89	26.7 ± 8.8	37	26.8 ± 9.3	52	26.6 ± 8.6	.93
Self-efficacy	89	31.2 ± 13.0	37	31.6 ± 13.5	52	30.9 ± 12.8	.83

*Chi-square and *t* test used

BPI brief pain inventory, *PHQ-8* Patient Health Questionnaire, *FACIT-Fatigue* Functional Assessment of Chronic Illness Therapy-Fatigue scale, *Self-efficacy* Self-efficacy for Managing Chronic Disease scale

report low income and less likely to have private health insurance (all $p < .05$).

Change in mean scores

As shown in Table 2 and Fig. 3, mean depression change scores from baseline to week18 were significant for treatment and usual care conditions ($p = .026$). In addition, fatigue change scores were significant for treatment and usual care conditions ($p = .034$). *Reimagine* had a moderate effect on depression and fatigue outcomes, with effect sizes of .49 and .46, respectively. There were no significant differences in pain severity and pain interference between the treatment and usual care conditions. The difference in improvements in self-efficacy between the treatment and usual care conditions was not significant (all $p > .05$).

Relationship between self-efficacy and outcomes

Results from the linear regression conducted to identify predictors of change in depression and fatigue symptoms indicate that the demographic and clinical variables were not predictive of program outcomes. Multiple linear regression models were also generated to examine the relationships between the change from baseline to Week18 for self-efficacy (i.e., a targeted mediator) and significant outcomes (i.e., depression and fatigue) among the treatment arm after adjustment for participant characteristics (age, race, marital status, education and income levels, and years since diagnosis). After adjustment, changes in self-efficacy were found to have an independent association with depression and fatigue symptoms among the treatment arm participants (both $p < .001$).

User satisfaction

A large majority (94%) of treatment arm participants would recommend *Reimagine* to others. In addition, 81% felt more resilient at study completion. Furthermore, 89% indicated that they would continue to use the tools such as guided imageries and cognitive reframing exercises on their own.

Discussion

This study examined the efficacy of an online symptom self-management curriculum among a sample of breast cancer survivors with chronic pain who were randomized to receive *Reimagine* or usual care. *Reimagine* had an effect on two of the three targeted symptoms as demonstrated by significant reductions in depression and fatigue symptoms among the

Table 2 *t* test results on the mean differences of Week18 and baseline scores

		Treatment ($n = 37$)		Usual care ($n = 52$)				
	α	Mean Diff	*SD*	Mean Diff	*SD*	*t* value	*p*	Effect Size*
Measures								
BPI Pain Severity	.92	− .83	1.4	− .63	1.5	− .65	.52	.14
BPI Pain Intensity	.91	− .95	2.5	− .65	1.5	− .65	.52	.15
PHQ-8	.87	− 1.7	4.5	.34	3.8	− 2.3	.026	.49
FACIT-Fatigue	.85	4.8	9.0	1.2	6.6	2.2	.034	.46
Self-efficacy	.92	5.6	12.0	2.2	10.7	1.4	.17	.30

*Cohen's *d*

BPI brief pain inventory, *PHQ-8* Patient Health Questionnaire, *FACIT-Fatigue* Functional Assessment of Chronic Illness Therapy-Fatigue scale, *Self-efficacy* Self-efficacy for Managing Chronic Disease scale

treatment condition participants. Self-efficacy was found to be independently associated with improvements in depression and fatigue among our sample of breast cancer survivors. Importantly, self-efficacy is a key psychosocial resource that *Reimagine* is intended to impact and these findings are consistent with our conceptual model of how the curriculum could improve personal outcomes by enhancing targeted personal resources as first published in 2010 [16].

While *Reimagine* did not effect pain severity and intensity, findings are consistent with the prior Pillars4Life study among cancer survivors. For example, improvements in self-efficacy were independently associated with improvements in at least one key outcome (i.e., depression and anxiety). Participation in *Reimagine* and Pillars4Life was associated with reductions in depression and fatigue symptoms. These findings are consistent with results from a growing portfolio of effective virtual-based psycho-educational interventions [21–23]. As a means to potentially enhance efficacy for pain management, *Reimagine* is being updated to provide mindfulness exercises and daily "prompts" that encourage program use.

Interestingly, education level did not have a bearing in program outcomes in the linear regression, yet most participants had a college degree ($p > .05$). In addition, nonwhite participants reported less improvement in symptoms than white participants, but these differences were not statistically significant ($p > .05$). Furthermore, time since diagnosis had no bearing on depression or fatigue ($p > .05$). Of all the variables examined, self-efficacy was most predictive of program outcomes.

How do these *Reimagine* trial results compare to the live (i.e., synchronous) administered Pillars4Life study results [14]? While the Pillars4Life study employed a larger cadre of instruments than the *Reimagine* study, significant improvements were

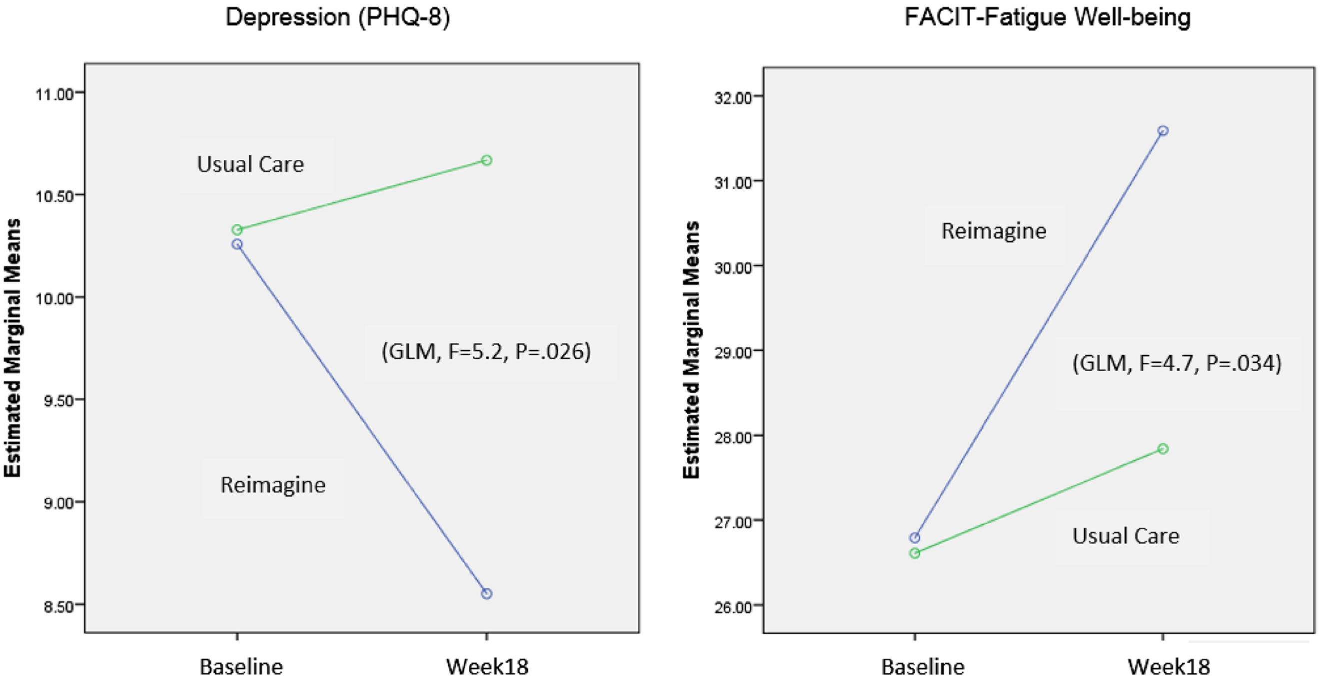

Fig. 3 Generalized linear model of changes in depression and fatigue symptoms over time

reported in both studies at post-intervention for these instruments: PHQ8 and FACIT-Fatigue. These findings provide evidence that moving to a more cost-effective, scalable, and accessible *Reimagine* model was not detrimental to the outcomes reported by program participants.

Study limitations include the differential attrition rate between the treatment and usual care group, thereby raising the possibility of bias (i.e., imbalance between the groups). However, the baseline symptom scores did not differ significantly between the groups. Second, a majority of college graduates were enrolled, thereby limiting generalizability among survivors who had less education. However, education level was not found to be predictive of changes in symptom outcomes. Third, there was limited power to detect differences given the sample size, yet a significant difference was detected in depression and fatigue change scores between groups. Fourth, several patients were lost to follow-up despite multiple attempts to contact them, which could bias the findings. Despite these limitations, these data provide compelling support that the *Reimagine* participants derive important improvements in symptom outcomes. The next step is to disseminate this curriculum among a broader cancer population and study its effectiveness in not only improving symptom management but also in reducing health care utilization costs.

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Author contributions Sophia Smith: Conceptualization, funding acquisition, software, project administration, data analysis, and writing—original draft, and writing—review and editing. Kristin MacDermott: Conceptualization, funding acquisition, software, and writing—review and editing. Wei Pan: Data analysis and writing—review and editing. Sathya Amarasekara: Data analysis and writing—review and editing. Marilyn Hockenberry: writing—review and editing.

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Compliance with ethical standards

Conflict of interest All authors received support from money paid to Duke University as part of the Pfizer Independent Grants for Learning and Change award. The authors whose names are listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Author names: S.K. Smith, PhD MSW; S. Amarasekara, MS; W. Pan, PhD; D. Mayer, PhD; M. Hockenberry, PhD

Ms. Kristin MacDermott, LMFT reports the following details of affiliation or involvement in an organization or entity with a financial or non-financial interest in the subject matter or materials discussed in this manuscript: Board membership and Employment by Pillars4Life, Inc.

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